CInMED
Institute for Medicines and
Medical Devices of Montenegro

RULEBOOK
ON INTERNAL ORGANISATION AND JOB SCHEME IN THE INSTITUTE FOR MEDICINES AND MEDICAL DEVICES

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Pursuant to Article 323, paragraph 1, item 2) of the Law on Medicinal Products (Official Gazette of Montenegro, No. 14/26), Article 17 and 29 of the Statute of the Institute for Medicines and Medical Devices (No. 3020/26/136/5-2856 the Management Board of the Institute for Medicines and Medical Devices, at its sitting held on, has issued

RULEBOOK
ON INTERNAL ORGANISATION AND JOB SCHEME IN THE INSTITUTE FOR MEDICINES AND MEDICAL DEVICES

1. LEGAL GROUNDS

1.1 RELATED INTERNAL DOCUMENTS

(1) Statute
(2) Collective agreement

1.2 RELATED EXTERNAL DOCUMENTS

(1) Labour Law („Official Gazette of Montenegro“ No. 74/19, 8/21, 59/21, 68/21,145/21, 77/24, 84/24, 86/24, 122/25, 165/25 and 51/26)
(2) Law on the national qualifications framework („Official Gazette of Montenegro” No 80/10 and 53/25)
(3) Law on medicinal products („Official Gazette of Montenegro” No 14/26)
(4) Law medical devices („Official Gazette of Montenegro“, No. 24/19 and 84/24)

2. GENERAL PROVISIONS

Article 1

This Rulebook shall establish internal organization and job scheme of the Institute for Medicines and Medical Devices (hereinafter: Institute).

Internal organization and job scheme of the Institute is being developed continuously, in accordance with duties undertaken to strengthen administrative capacities of the Institute in the process of accession to the European Union, concluded agreements and obligations arising from membership in international organizations, as well as in accordance with the Strategy of the Institute.

Internal organisation shall be regulated by the Rulebook on internal organization and job scheme of the Institute for Medicines and Medical Devices (hereinafters: the Rulebook in such a manner as to:

1) establish organizational units with a description of responsibilities and structure;
2) provide grounds of job scheme;
3) set principles of coordination of work and management in the Institute.

Internal organization and job scheme shall ensure the following:

1) technological unity of the work process in the Institute as a whole;
2) separation of responsibilities within business processes in which multiple organizational units participate;
3) rational and cost-effective business operation in accordance with technological development and the needs of interested parties;
4) achieving efficiency, cost-effectiveness, functionality, uniformity and interrelatedness of activities.

Article 2

The job scheme shall further develop internal organization by determining names of jobs, conditions for their performance,

responsibilities, authorizations, skills and work experience, the number of employees, the type and level of qualifications, levels of education and occupations in the Institute.
Tasks of the job are grouped according to their similarity, complexity and the conditions that employees need to meet to perform them.
All jobs have their own name, which, as a rule, is determined by the activity and type of work.

Article 3

Terms used in this Rulebook in masculine gender shall include the same terms in feminine gender.

3. DEFINITIONS AND ABBREVIATIONS

Article 4

3.1. DEFINITIONS

Terms used in this Rulebook shall shave the following meaning:

Job – a set of related tasks performed by one or more employees in the course of regular working hours.

Job requirements – general and special job requirements, or conditions that need to be met, and relate to the level and sub-level of qualification, level of education and professional qualification, work experience, internship, probation period, prior work ability test, special health ability and other special conditions required for performing the tasks of a specific job.

Qualification of the level of education is acquired by completing a publicly valid educational program and achieving required scope of qualification, after a prescribed test and obtaining evidence of the acquired level of education, or one or more professional qualifications.

Diploma, or exceptionally a certificate, is the evidence of acquired qualification of the level of education.

Professional qualification is acquired by completing part of a publicly valid educational program (module, course) or a special educational program, or by recognizing a foreign certificate.

Certificate, or confirmation or attestation shall serve as a proof of acquired professional qualification, part of a qualification or other qualification.

Levels of professional education acquired under previous regulations shall be considered equivalent to the education levels prescribed in Article 27 of the Law on the National Qualifications Framework (Official Gazette of Montenegro 80/10).

Work experience shall mean the period spent in employment at a specific level of professional qualification, or education level and occupation. Work experience acquired through professional training under the Programme of the Government of Montenegro lasting 9 months shall be considered as 12 months of work experience in accordance with the Law on professional training.

Probation period shall constitute a special condition for establishing employment in certain jobs.

Article 5

3.2. ABBREVIATIONS

The following abbreviations are used in this Rulebook:

Full name	Abbreviation
Institute for medicines and medical devices	Institute
Management Board	MB
General act	GA
Information-communication technologies	ICT
Good manufacturing practice	GMP
Good distribution practice	GDP
Good pharmacovigilance practice	GVP
Good clinical practice	GCP
Coefficient of job complexity and professional qualifications	C1
World Health Organisation	WHO
European Medicines Agency	EMA
Contract Research Organisation	CRO
Periodic Safety Update Report	PSUR
International Council for Harmonisation	ICH
Active Substance Master File	ASMF

4. GENERAL JOB REQUIREMENTS

Article 6

General job requirements:

1) that the person is at least 15 years of age;
2) that he/she has general health capacity.

5. OTHER JOB REQUIREMENTS

Article 7

Other job requirements may be:

1) level and sub-level of qualification
2) level of education and professional qualification
3) work experience
4) treineeship
5) probation period
6) previous work ability test
7) other special requirements for performing tasks of a specific job (professional exam, licenses, knowledge of a foreign language, computer skills, etc.).

The annexes to this Rulebook set out the job titles, job descriptions, as well as the requirements that an employee must fulfil to be employed or assigned to a job.

Article 8

The internship period may be determined to last:

1) 9 months - for positions with a high level of education (VII and VI);
2) 6 months - for positions with a secondary level of education (III or IV1).

Article 9

A probation period shall apply exclusively upon recruitment (and not in the case of internal reassignment) and shall be determined by the Employment contract as follows:

1) 6 months – for positions requiring a high level of education (VII and VI);
2) 3 months – for positions requiring other levels of educations.

Article 10

Depending on the qualification level of education or professional qualification and responsibilities, the required work experience may be determined as follows:

1) for managing director and assistant managing director – at least 5 years of work experience in the areas within the Institute's competence;
2) for managerial positions – at least 5 years of work experience in the area within the competence of the organizational unit;
3) for expert associates/pharmaceutical inspectors level I – at least 5 years of work experience in the area within the competence of the organizational unit;
4) for expert associates/coordinators/pharmaceutical inspectors level II – at least 3 years of work experience in the area within the competence of the organizational unit;
5) for expert associates/pharmaceutical inspectors level III – at least 1 year of work experience in the area within the competence of the organizational unit;
6) for senior associates - at least 1 year of work experience in the area within the competence of the organizational unit;
7) for associates – at least 1 year of professional work experience;
8) for administrative officers – at least 1 year of work experience.

6. ORGANISATIONAL STRUCTURE

Article 11

The organisational structure of the Institute shall consist of the governing and management bodies and organisational units.

A schematic presentation of the Institute’s organisational structure is provided in Annex I to this Rulebook.

7. GOVERNING BODIES OF THE INSTITUTE

Article 12

The governing bodies and their scope of responsibilities shall be determined by the Law and the Statute of the Institute.

8. INTERNAL AUDIT

Article 13

Internal audit activities – the review of financial and operational statements, information and other related matters – shall be performed through the allocation of staff to established positions within the Internal Audit Department.

In the performance of their duties, the Internal Auditor shall be accountable to the Managing Director of the Institute.

9. ORGANISATIONAL UNITS

9.1. TYPES AND NAMES OF ORGANISATIONAL UNITS

Article 14

The Institute shall be organised into following organisational forms: the Managing Director’s Office, centres, departments, the Inspectorate and the Laboratory.

For the performance of the activities and tasks of the Institute, as laid down in this Rulebook, Managing Director of the Institute and a total of 120 job holders shall be determined.

Article 15

Organisational units of the Institute are listed as follows:

1) Managing Director's Office;
2) Internal Audit Department
3) Centre for Medicines Authorisation;

- Department for Regulatory Affairs;
- Department for Variations;
- Department for Veterinary Medicines;
- Department for Clinical Trials and Medicines Safety and Efficacy Assessment;
- Department for Medicines Quality Assessment;

4) Centre for Market Affairs and Safe Use of Medicines;
   - Department for Pharmacovigilance;
   - Department for Medicines Consumption Monitoring and Setting Maximum Prices;
   - Department for Medicines Import/Export Authorisation;
5) Inspectorate;
6) Laboratory;
7) Centre for Medical Devices;
8) Centre for Science, International Cooperation and Projects;
9) Centre for Support;
   - Department for Legal, Personnel and General Affairs;
   - Department for Financial Affairs;
   - Registry Office
10) Centre for Information and Communication systems

9.2. STRUCTURE AND DESCRIPTION OF ORGANISATIONAL UNITS

9.2.1. MANAGING DIRECTOR'S OFFICE

Number of job holders: 8

Article 16

The Managing Director's Office shall perform activities related to the organisation and management of the Institute's operations, ensurance of the legality, efficiency and cost-effectiveness of the Institute's operations, development and monitoring the implementation of the Institute's strategies, work programmes and plans, adoption of decisions and other administrative acts falling within the competence of the Institute which do not fall within the competence of the Management Board, implementation of decisions of the Management Board, decision-making concerning employees' rights, duties and responsibilities, quality management activities, development and updating of the Risk Register, activities related to regulatory harmonisation with the acquis of the European Union and international cooperation, activities related to public relations, providing information to and communication with the media and interested stakeholders and general public on matters of importance to public health, protocol-related activities, organization of meetings, and management of the managing director's official correspondence, as well as other activities in accordance with the Law, the Statute, this Rulebook and other general acts of the Institute.

The Managing Director's Office shall be organised as follows:
1) Managing Director
2) Head of the Centre for Medicines Authorisation – Assistant Director
3) Advisor to the Managing Director for Legal Affairs and EU Integrations
4) Advisor to the Managing Director for Medical Affairs
5) Head of the Office
6) Quality Manager
7) Human Resources Manager
8) Business secretary.

9.2.2. INTERNAL AUDIT DEPARTMENT

Number of job holders: 3

Article 17

The Internal Audit Department:
- monitors, organises and controls the implementation of legislative requirements within the Institute's

operations;
- monitors, organises and controls the implementation of international auditing standards;
- monitors, organises and controls business processes within the Institute, in accordance with the law and the international framework of professional internal audit practice;
- reviews, examines and evaluates the adequacy and effectiveness of financial management and control systems, aimed at ensuring lawful and adequate risk management;
- examines the reliability and completeness of financial and operational information;
- evaluates the comprehensive application of organisational, managerial, accounting, financial, human resources and other operational internal controls;
- ensures compliance with policies, plans, procedures, decisions and legislation relevant to the Institute's operations;
- examines and evaluates the extent to which all internal controls are aligned with the Institute's business strategy established by management, as well as the adequacy and effectiveness of their implementation;
- examines and assesses the adequacy and efficiency of the internal control system that falls under accounting internal control;
- assesses the efficiency, effectiveness and cost-effectiveness of operations;
- ensures the protection of property and other resources and makes recommendations in the field of prevention of possible losses due to abuse, mismanagement, errors, fraud and irregularities;
- provides and monitors the implementation of recommendations for improving the internal control system and the processes themselves and ensures that business risks are reduced to an acceptable level for the Management Board, Managing Director and managers of organizational units;
- cooperates with all competent authorities for audit affairs (internal and external).

9.2.3. CENTRE FOR MEDICINES AUTHORISATION
Number of job holders: 50

Article 18

Within the Centre for medicines authorisation, the following expert, scientific, regulatory and administrative activities shall be performed in order to fulfil the competences of the Institute in the field of human and veterinary medicinal products prescribed by the Law:
- activities relating to marketing authorisations for medicinal products (granting of marketing authorisations, renewal of marketing authorisations, variations to marketing authorisations, termination of the procedures, transfer of marketing authorisations and suspension and cessation of validity of marketing authorisations, notifications);
- activities relating to the registration of traditional herbal medicinal products and homeopathic medicinal products under simplified procedure (registration, renewal of registration, variations to registrations, transfer of the decision on registration and suspension and revocation of the decision on registration);
- activities relating to the issuance of approvals for clinical trials of medicinal products, amendments to clinical trials, as well as administrative and technical support provided to the Ethics Committee in accordance with the Law;
- recording non-interventional studies of medicinal products for human use;
- activities relating to the expert assessment of documentation concerning quality, safety and efficacy of medicinal products within marketing authorisation and variation procedures;
- participation in international standardisation activities in the field of medicinal products, including preparation, organisation and participation in the work of commissions for medicinal products and other commissions of the Institute;
- issuance of expert opinions within the competence of the Centre;
- activities related to import/export of veterinary medicinal products and veterinary medicinal products containing drugs/precursors, clinical trials of veterinary medicinal products;
- pharmacovigilance activities in the field of veterinary medicinal products;
- establishment and implementation of risk management processes at the level of the Centre;
- other activities in accordance with the law and this Rulebook.

The activities of the Centre for Medicines Authorisation shall be organised within:
1. Department for Regulatory Affairs;
2. Department for Variations;

3. Department for Veterinary Medicines;
4. Department for Clinical Trials and Assessment of Safety and Efficacy of Medicinal Products and
5. Department for Medicines Quality Assessment.

9.2.3.1. Department for Regulatory Affairs

Within the Department for Regulatory Affairs the following expert, scientific, regulatory and administrative activities shall be carried out in procedures for granting marketing authorisations for human medicinal products, renewal, transfer and suspension and cessation of validity of marketing authorisations and termination of the procedure for granting/renewal of a marketing authorisation for a medicinal product for human use, as well as activities relating to the registration of homeopathic medicinal products and traditional herbal medicinal products:

- recording and verification of data relating to submitted applications;
- processing of applications within the competence of the Department;
- performance of assessment of completeness of the documentation;
- notifying applicants of the need to supplement documentation and of completeness of applications;
- monitoring timelines for the assessment of completeness of the documentation;
- coordinating the acceptance of assessment reports issued by other regulatory authorities (e.g. within centralised, decentralised and mutual recognition procedures);
- monitoring timelines following completion of the assessment of the documentation on quality, safety and efficacy;
- entry of master data relating to medicinal products into the Institute's information system;
- preparation, organisation and participation in the work of commissions for medicinal products;
- preparation of notifications to applicants from the Institute's commissions;
- preparation and issuance of expert opinions within the scope of the Department's competence;
- processing notifications and informing the marketing authorisation holders of their acceptability;
- verification of consistency between administrative and pharmaceutical data on the medicinal product in the Summary of Product Characteristics (SmPC), Package Leaflet and labelling of the medicinal product with the data contained in the medicinal product dossier;
- preparation and issuance of output documents and documents in procedures relating to transfer and cessation of validity/revocation/suspension of the marketing authorisations for human medicinal products and discontinuation of marketing authorisation procedures for human medicinal products;
- preparation and issuance of output documents and documents in procedures for granting and renewal of marketing authorisations for human medicinal products, as well as procedures relating to the registration of homeopathic medicinal products and traditional herbal medicinal products;
- preparation and publication of data on granted marketing authorisations for human medicinal products, approved Summaries of Product Characteristics, Package Leaflets and specific obligations, or conditions attached to conditional marketing authorisations, including the deadlines for the fulfilment of such obligations and/or conditions, as well as information on marketing authorisations that have ceased to be valid, on the website of the Institute;
- other activities falling within the competence of the Centre.

9.2.3.2. Department for Variations

Within the Department for Variations, the following expert, scientific, regulatory and administrative activities shall be carried out in procedures for amendments (variations) to marketing authorisations for medicinal products for human use, as well as activities relating to the amendments to the registration of homeopathic medicinal products and traditional herbal medicinal products:

- recording/verification of data relating to submitted applications and receipt of applications not submitted via e-service in the Institute's information system;
- processing of applications within the competence of the Department;
- conducting assessment of documentation for variations;
- notifying applicants of the need to supplement documentation;
- verification of consistency between administrative and pharmaceutical data in the Summary of Product Characteristics, Package Leaflet and labelling of a medicinal product with the data contained in the medicinal product dossier;

- updating master data relating to medicinal products in the Institute's information system, in accordance with approved variations;
- preparation, organisation and participation in the work of commissions for medicinal products;
- participation in the preparation of notifications to applicants from the Institute's commissions;
- preparation and issuance of output documents and documents in procedures for variations of marketing authorisations for human medicinal products, including *extension line* applications;
- preparation and issuance of expert opinions within the scope of the Department's competence;
- other activities falling within the competence of the Centre.

9.2.3.3. Department for veterinary medicines

Within the Department for veterinary medicines, the following expert, scientific, regulatory and administrative activities shall be performed in exercising the competences of the Institute prescribed by law in the field of veterinary medicinal products:

- activities relating to marketing authorisations for veterinary medicinal products (granting of marketing authorisations, renewal/extension of the validity of marketing authorisations, amendments to marketing authorisations (variations), assessment of safety and efficacy of veterinary medicinal products, suspension of marketing authorisation procedures, transfer of marketing authorisations, suspension and cessation of validity of marketing authorisations for veterinary medicinal products);
- activities related to the registration of homeopathic veterinary medicinal products;
- entry of master data relating to veterinary medicinal products into the Institute's information system;
- verification of the applicability of assessment reports issued by other regulatory authorities (e.g. under the centralised, decentralised and mutual recognition procedures) to procedures conducted in Montenegro;
- preparation, organisation and participation in the work of Commission for medicinal products and other commissions of the Institute;
- preparation of notifications to applicants regarding the decisions of the Institute's Commission;
- preparation and issuance of expert opinions within the scope of the Department's competence;
- preparation and publication of data on granted marketing authorisations for veterinary medicinal products, approved Summaries of Product Characteristics, Package Leaflets and conditions attached to granted approvals, including timelines for fulfilment of such conditions, on the Institute's internet portal;
- processing applications and issuing approvals for the procurement i.e. import of veterinary medicinal products for which no marketing authorisation has been granted, as well as veterinary medicinal products containing narcotic drugs and/or precursors;
- assessment of documentation relating to clinical trials of veterinary medicinal products;
- pharmacovigilance activities in the field of veterinary medicinal products;
- other activities falling within the competence of the Centre.

9.2.3.4. Department for clinical trials and assessment of safety and efficacy of medicines

Within the Department for Clinical Trials and Assessment of the Safety and Efficacy of Medicinal Products, the following expert, scientific, regulatory and administrative activities shall be performed:

- verification of data relating to submitted applications and processing of applications falling within the competence of the Department;
- conducting assessment of documentation relating to clinical trials and non-interventional studies;
- administrative and technical support provided to the Ethics Committee in accordance with the Law;
- notifying applicants of the need to supplement documentation and of the completeness of applications;
- monitoring timelines for assessment of documentation, defining, processing and entering master data relating to clinical trial/non-interventional study into the Institute's information system;
- preparation, organisation and participation in the work of the Commission for clinical trials;
- preparation and issuance of final acts and documents in procedures for granting approvals for clinical trials, substantial amendments to clinical trials and recording of non-interventional studies;
- participation in monitoring the safety of medicinal products undergoing clinical investigation;
- assessment of Postauthorisation Safety Study (PASS)
- preparation for publication on the Institute's internet portal of data on approved clinical trials and registered non-interventional studies;

- performing expert assessment of pre-clinical and clinical documentation on medicinal products and documentation relating to bioavailability (BA) and bioequivalence (BE) studies within procedures for issuance, renewal of marketing authorisations and variations;
- Environmental Risk Assessment (ERA) of medicinal products;
- assessment of the justification of requests for exemption of conducting BE (bioequivalence) studies ("biowaiver");
- comparison of data stated in the Assessment Report with the documentation submitted to the Institute for the purpose of concluding on the applicability of the Assessment Report;
- verification of consistency of data on the safety and efficacy of medicinal products in the Summary of Product Characteristics, Package Leaflet and labelling of a medicinal product with the data contained in the pre-clinical and clinical documentation on the medicinal product within procedures for issuance, renewal of marketing authorisations and variations;
- participation in the preparation of documentation and in the work of commissions for medicinal products and other commissions of the Institute;
- participation in decision-making regarding justification of import of an unauthorised medicine;
- participation in the conduct of inspections of clinical trials approved by the Institute;
- other activities falling within the competence of the Centre.

9.2.3.5. Department for quality assessment

Within the Department for quality assessment, the following expert, scientific, regulatory and administrative activities shall be performed:

- expert assessment of documentation relating to the quality of medicinal products in procedures for granting and renewal of marketing authorisations and variations of a medicinal product for human use and veterinary medicinal product;
- monitoring timelines following determination of the completeness of applications;
- notifying applicants of the need to supplement documentation and monitoring compliance with set deadlines;
- assessment of the texts of the Summary of Product Characteristics, Package Leaflet and labelling in sections relating to the quality of medicinal products within procedures for issuance, renewal of marketing authorisations and variations;
- preparation, organisation and participation in the work of commissions for medicinal products and other commissions of the Institute;
- participation in planning of activities relating to quality control of medicinal products placed on the market;
- participation in planning, coordination, management and supervision of the performance of expert-operational activities relating to the assessment of quality defects/falsified medicinal products;
- participation in international standardisation activities in the field of medicinal products;
- other activities falling within the competence of the Centre.

9.2.4. CENTRE FOR MARKET AFFAIRS AND SAFE USE OF MEDICINES
Number of job holders: 11

Article 20

Within the Centre for market affairs and safe use of medicines, the following expert, scientific, regulatory and administrative activities shall be performed:

- activities relating to the assessment of pharmacovigilance documentation in procedures for granting, varying and renewing marketing authorisations;
- activities relating to pharmacovigilance for the purpose of monitoring the safety of medicinal products on the market and detecting any changes in the benefit-risk ratio during their use;
- organisation and participation in the work of the Commission for safety;
- participation, in the capacity of expert assessor, in pharmacovigilance inspections;
- pharmacoepidemiological activities;
- collection and processing of data on marketing and consumption of medicinal products and promotion of their rational use;
- setting maximum prices for human medicinal products;
- issuance of approvals for the importation of medicinal products without a marketing authorisation;
- issuance of approvals for the import and export of immunological medicinal products and medicinal products

derived from human blood and plasma;
- issuance of expert opinions within the competence of the Centre;
- issuance of certificates for export purposes in accordance with WHO recommendations;
- issuance of authorisations for the import/export of narcotic drugs and precursors;
- implementation and fulfilment of obligations arising from ratified international conventions of the United Nations: the Single Convention on Narcotic Drugs of 1961, the Convention on Psychotropic Substances of 1971 and the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988;
- participation in international standardisation activities in the field of medicinal products;
- establishment and implementation of risk management processes at the level of the Centre;
- other activities in accordance with the law and this Rulebook.

The activities of the Centre for Market Affairs and Safe Use of Medicines shall be organised within:
1. Department for Pharmacovigilance;
2. Department for Medicines Consumption Monitoring and Setting Maximum Prices;
3. Department for Medicines Import/Export Authorisation.

9.2.4.1. Department for Pharmacovigilance

Within the Department for Pharmacovigilance, the following expert, scientific, regulatory and administrative activities shall be performed:
- activities relating to the assessment of pharmacovigilance documentation in procedures for granting, varying and renewing marketing authorisations;
- activities relating to pharmacovigilance for the purpose of monitoring safety of medicinal products on the market and detecting any changes in the benefit-risk ratio during their use;
- participation, in the capacity of expert assessor, in pharmacovigilance inspections (GVP inspections);
- collection and processing of data on adverse reactions to medicinal products and preparation of annual reports on adverse medicine reactions;
- entry of adverse reactions reports into the VigiFlow/EudraVigilance database;
- processing Direct Healthcare Professional Communications (DHPCs);
- signal detection;
- assessment of PSUR, RMP and additional risk minimisation measures;
- monitoring safety of medicinal products undergoing clinical investigation (through reports submitted by applicants/sponsors and individual reports from clinical trials conducted in Montenegro);
- informing and educating stakeholders on medicinal products with the aim of ensuring their safe and rational use;
- participation in the preparation of documentation for, and in the work of the Commission for medicinal products, the Commission for safety and other Institute commissions;
- cooperation with EMA and WHO in the area of safe use of medicinal products;
- cooperation with the Institute for Public Health in the monitoring vaccine use;
- other activities falling within the competence of the Centre.

9.2.4.2. Department for Medicines Consumption Monitoring and Setting Maximum Prices

Within the Department for Medicines Consumption Monitoring and Setting Maximum Prices, the following expert, scientific, regulatory and administrative activities shall be performed:
- activities relating to the collection and processing of data on the consumption of medicinal products;
- analysis of processed data, including comparison with previous years and monitoring of trends;
- issuance of reports on medicinal product consumption at the request of clients through expert opinions;
- detection of problems related to excessive consumption of a particular group of medicinal products or an individual medicinal product, including initiation of measures aimed at promoting rational use of medicinal products;
- cooperation with the WHO in the field of rational use of medicinal products;
- preparation of publications (brochures) in the field of medicinal product consumption;
- cooperation with reference countries designated by subordinate legislation governing the criteria for setting maximum prices of medicinal products, as well as with the competent authorities of those countries;
- activities relating to the esteblishing (setting) and harmonisation of maximum prices of medicinal products;

- publication of reports on set, approved and harmonised maximum prices of medicinal products;
- monitoring medicinal product price trends for the preparation of pharmacoeconomic analyses;
- other activities falling within the competence of the Centre.

9.2.4.3. Department for Medicines Import/Export Authorisation

Within the Department for Medicines Import/Export Authorisation, the following expert, scientific, regulatory and administrative activities shall be performed:

- verification of data relating to submitted applications and processing of applications falling within the competence of the Department;
- processing of applications for procurement approvals, i.e. importation of unauthorised medicines;
- participation in decision-making regarding justification of importation of unauthorised medicines;
- processing of applications for issuance of approvals for the import and export of immunological medicinal products and medicinal products derived from blood and plasma;
- processing of applications for issuance of certificates for export purposes in accordance with WHO recommendations (CPP certificates);
- notifying applicants of the need to supplement documentation and monitoring deadlines;
- defining, processing and entry of data on medicinal products for import/export into the Institute's information system;
- defining and entry of master data into the Institute's information system;
- preparation and issuance of output documents in procedures for granting approvals and authorisations for import and export of medicinal products;
- preparation and issuance of output documents and documents in procedures for issuing CPP certificates;
- issuance of expert opinions relating to import/export of medicinal products, exemptions from approved packaging of medicinal products and similar matters;
- processing of applications and issuance of authorisations for import/export/transit of narcotic drugs and import/export of precursors;
- processing of applications and issuance of approvals for individual narcotic drugs on national ships and aircraft in international traffic;
- monitoring the implementation of import controls for controlled substances;
- analysis and preparation of reports submitted by wholesale distributors on annual requirements and reports on consumption, import/export of narcotic drugs, as well as annual requirements for import/export of precursors;
- preparation and submission to the ministry responsible for health matters of quarterly reports on import/export of narcotic drugs and psychotropic substances and annual reports on import, export, consumption and annual requirements for narcotic drugs, psychotropic substances and precursors;
- returning export authorisations to the competent authority of the importing country;
- participation in drafting the list of drugs (narcotic drugs and psychotropic substances) and precursors;
- participation in the work of a multisectoral working group for alerting to the emergence of new psychoactive substances (Early Warning System on NPS), as well as regular submission of data to the ministry responsible for health matters regarding new psychoactive substances reported to the Institute by the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA);
- implementation and fulfilment of obligations arising from ratified United Nations conventions: the Single Convention on Narcotic Drugs of 1961, the Convention on Psychotropic Substances of 1971 and the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988;
- conducting activities related to international cooperation with the International Narcotics Control Board (INCB), the United Nations Office on Drugs and Crime (UNODC) and the EMCDDA;
- cooperation at national level with the ministry responsible for health matters and administrative authorities competent for customs affairs.
- cooperation with the Administration for Food Safety, Veterinary and Phytosanitary Affairs and the Customs Administration;
- other activities falling within the competence of the Centre.

9.2.5. INSPECTORATE

Number of job holders: 11

Within the Inspectorate, the following expert, scientific, regulatory, administrative activities and inspection activities in the fields of the manufacture of medicinal products for human use and veterinary medicinal products, wholesale distribution of medicinal products for human use, as well as compliance with the principles and guidelines of Good Manufacturing Practice (GMP), Good Distribution Practice (GDP), Good Pharmacovigilance Practice (GVP), and Good Clinical Practice (GCP) shall be carried out. The Inspectorate is also responsible for the oversight of the manufacture and distribution of active substances used as starting materials in the manufacture of medicinal products for human use and veterinary medicinal products, including compliance with GMP and GDP guidelines applicable to active substances:

- activities related to issuing manufacturing authorisations for medicinal products, medicinal products containing narcotic drugs and psychotropic substances, and precursors (Category 1 precursors used in the manufacture of medicinal products and Category 4 precursors);;
- activities related to the issuance of wholesale distribution authorisations for medicinal products for human use, medicinal products for human use containing narcotic drugs and psychotropic substances, precursors (Category 1 precursors used in the manufacture of medicinal products and Category 4 precursors), and poppy and/or cannabis derivatives intended for medical or pharmaceutical purposes;
- entering manufacturers, importers and distributors of active substances used as starting materials for medicinal products for human use and veterinary medicinal products into the Register;
- GMP inspections of manufacturers of medicinal products, active substances and excipients and issuance of GMP Certificates;
- GDP inspections of wholesale distributors and issuance of GDP compliance certificates;
- GDP inspections of importers and distributors of active substances and issuance of GDP compliance certificates for active substances;
- GVP inspections of marketing authorisation holders and issuance of GVP inspection report;
- GCP inspections of clinical trial sites, clinical trial sponsors and/or Contract Research Organisations (CROs), laboratories, and issuing GCP inspection reports;
- participation in procedures for quality control of medicinal products on the market;
- participation in procedures for control and investigation of suspected falsified and substandard medicinal products;
- sampling of medicinal products and active substances during manufacturing and wholesale distribution activities for the purpose of quality verification;
- activities related to entry into the Register of manufacturers, importers and wholesale distributors of active substances;
- ordering the withdrawal of medicinal products/batch of a medicinal product from the market and suspension of distribution of medicinal products/batch of a medicinal product;
- participation in the assessment of reported quality defects and the submission of Rapid Alert (RA) notifications through the Rapid Alert Network (RAN);
- participation in the work of commissions established to determine fulfilment of conditions for registration in the register of manufacturers and legal persons performing wholesale distribution of medicinal products and wholesale distribution of medical devices;
- undertaking administrative measures and actions in accordance with the Law;
- other activities falling within the competence of the Centre.

9.2.6. LABORATORY
Number of job holders: 5

Within the Laboratory, the following expert, scientific, regulatory and administrative activities shall be performed in the field of medicinal product quality control:

- activities relating to quality control testing of medicinal products and other product samples in accordance with available laboratory techniques, as well as to documentation-based quality control;
- activities relating to quality control aimed at detecting substandard and falsified medicinal products;
- preparation of reports on performed medicinal product quality control testing and maintenance of records;
- issuance of certificates of analysis based on laboratory testing reports;
- preparation of programmes, work plans and reports relating to the activities of the Laboratory and maintenance of records;
- management and participation in projects within the scope of the Laboratory's activities;

- implementation of EU, ICH and other international scientific and expert guidelines and standards;
- cooperation with the Network of Official Medicines Control Laboratories (OMCL), EDQM, WHO and other competent bodies within the scope of the Laboratory's activities;
- control of the implementation of requirements arising from the Laboratory quality system documentation;
- verification of compliance of the Laboratory quality system documentation with the requirements of relevant national legislation;
- management of non-conformities within the Laboratory quality system;
- initiation and monitoring of implementation of corrective actions;
- management of reference standards and standard substances (receipt of standards, entry of data into the information system, labelling, storage, handling and issuance, return, disposal/destruction) required for the operation of the Laboratory;
- maintenance and continuous improvement of the Laboratory's occupational health and safety management system;
- preparation of technical specifications/characteristics for procurement of laboratory equipment;
- verification and validation of equipment performance in accordance with manufacturer documentation, EU standards and other international standards;
- preparation and development of revalidation programmes (validation plans) for laboratory equipment and instruments;
- receipt, record-keeping and storage of laboratory samples;
- other activities in accordance with the Law and this Rulebook.

9.2.7. CENTRE FOR MEDICAL DEVICES
Number of job holders: 10

Article 22

Within the Centre for Medical Devices, the following expert, scientific, regulatory and administrative activities shall be performed:

- activities relating to verification of fulfilment of conditions for entering manufacturers and legal persons performing wholesale distribution of medical device into the registers, as well as legal persons operating specialised retail stores;
- activities relating to the registration, renewal, amendment/supplementation of registration and deletion of medical devices from the register;
- classification of medical devices in accordance with submitted documentation and assessment of prescribed documentation within relevant procedures;
- activities relating to approval of clinical trials and control of clinical trials;
- participation in educational activities relating to medical devices;
- issuance of expert opinions within the competence of the Centre;
- establishment of the medical device vigilance system (collection and analysis of data obtained after placing medical devices on the market);
- informing healthcare professionals and, where necessary, general public about medical devices – regulatory matters, information relevant to use, prevention of incidents and similar matters;
- implementation of and participation in educational activities relating to medical devices and organisation of workshops for healthcare professionals and industry representatives;
- preparation of reports on medical device vigilance systems and publication thereof on the Institute's portal;
- establishment and implementation of risk management processes at the level of the Centre;
- other activities in accordance with the Law and this Rulebook.

9.2.8. CENTRE FOR SCIENCE, INTERNATIONAL COOPERATION AND PROJECTS
Number of job holders: 5

Article 23

Within the Centre for Science, International Cooperation and Projects, the following expert, scientific, regulatory and administrative activities shall be performed:

- monitoring the implementation and achievement of the objectives set out in the Institute's strategic documents;
- coordination of the strategic development of innovations in the field of medicinal products and medical devices, as well as the development of the Institute in the process of integration into the European regulatory and scientific research area;

- management and implementation of tasks assigned to the Institute within the framework of Montenegro's European integration process;
- promoting and implementing cooperation and coordinating dialogue with the pharmaceutical industry;
- participation in drafting strategic and general documents, as well as legislation relevant to the Institute's activities;
- coordination of training, expert and scientific development activities for employees of the Institute and maintenance of relevant records (registers);
- cooperation in educational and scientific research activities with faculties in the field of health sciences and other higher education and scientific institutions in the country and abroad;
- conducting inventory, cataloguing and storage of books, doctoral dissertations, master's theses, specialist papers, publications, brochures and journals;
- participation in the preparation of publications issued by the Institute, as well as scientific papers of employees published in professional and scientific journals;
- initiation, preparation, management and implementation of projects funded by European Union funds, international programmes and other funding sources (e.g. IPA, Horizon Europe, COST, Twinning, etc.);
- maintenance of records (registers) of development and scientific research projects;
- coordination and monitoring of implementation of objectives and results of development and scientific research projects;
- establishing and maintaining cooperation with professional, regulatory and scientific institutions at the national and international levels;
- initiation and coordination of activities relating to maintenance of licences for scientific research and innovation activities;
- provision of translation and proofreading support for the needs of Managing Director and organisational units of the Institute;
- coordination and implementation of activities relating to organisation of Institute conferences, as well as preparation and quality control of expert materials and presentations for educational activities organised by the Institute;
- initiation, coordination and implementation of educational activities organised by the Institute for the pharmaceutical industry, healthcare professionals, students and others;
- coordination of activities aimed at strengthening the Institute's institutional and administrative capacities in line with European Union standards;
- management and coordination of activities related to the Institute's preparation process for full membership in European regulatory networks and other relevant EU bodies;
- cooperation with European Union institutions, European regulatory agencies, international organisations and networks in the field of medicinal products and medical devices;
- managing and coordinating activities related to the Institute's participation in European regulatory, professional and scientific networks, as well as enhancing the Institute's international visibility through participation in European and international initiatives, projects and professional forums;
- other activities in accordance with the Law and this Rulebook.

9.2.9. CENTRE FOR SUPPORT
Number of job holders: 12

Article 24

Within the Centre for Support, the following legal, economic, human resources, general administrative and information-communication support activities shall be performed:

- preparation of general and individual acts of the Institute;
- performance of administrative and technical support activities for the needs of the Institute's Management Board, the Managing Director's Office and other organisational units of the Institute;
- ensuring necessary financial and technical conditions for the operation of the Institute;
- performance of accounting and financial activities;
- preparation and consolidation of work programmes, work plans and reports on the activities of organisational units, including preparation of drafts of such documents;
- preparation of draft annual financial reports on the Institute's operations;
- preparation of proposals and monitoring implementation of the Institute's financial plan;
- preparation of general acts and documents regulating matters relating to the Institute's general and human resources organisation;

- management of the Institute's assets;
- monitoring activities relating to the management and internal control system;
- implementation of public procurement procedures;
- provision of support to other centres and the Managing Director's Office in resolving legal matters and performing activities within their scope of work from the perspective of application of regulations and legality of operations;
- participating in the drafting of legislation within the Institute's area of competence;
- maintenance of technical systems necessary for the operation and improvement of the Institute's activities.
- establishment and implementation of risk management processes at the level of the Centre;
- other activities in accordance with the Law and this Rulebook.

The activities of the Centre for Support shall be organised within:

1) Department for Legal, Personnel and General Affairs;
2) Department for Financial Affairs;
3) Registry Office.

9.2.9.1. Department for Legal, Personnel and General Affairs

Within the Department for Legal, Personnel and General Affairs, the following legal and administrative activities shall be performed:

- preparation of the Institute's general acts;
- participation in drafting laws and subordinate legislation in the field of medicinal products and medical devices;
- performance of administrative activities supporting the Institute's Management Board, the Managing Director's Office and organisational units of the Institute;
- provision of legal opinions regarding the application of laws and other regulations within the competence of the Centre;
- participation in resolving legal matters arising in procedures for issuance of administrative acts within the competence of the Institute;
- drafting decisions, conclusions and other acts in administrative procedures;
- drafting responses to lawsuits in administrative and other disputes;
- management of the Institute's assets;
- monitoring activities related to the management and internal control system;
- implementation of public procurement procedures;
- implementation of procedures for exercising the right of free access to information held by the Institute;
- monitoring implementation and initiating amendments to general acts for the purpose of their improvement, as well as preparation of proposals for new acts or amendments to existing general acts;
- preparation of draft proposals and draft internal normative acts in compliance with applicable legislation for the needs of the Centre and the Institute, including harmonisation of internal acts with healthcare and international standards;
- monitoring mutual consistency of normative acts and their compliance with the Constitution, laws, subordinate legislation and other regulations;
- monitoring implementation and observance of internal general acts, laws and other regulations;
- legal activities relating to determination, registration, transfer and termination of proprietary rights over the Institute's assets and registration of changes in the property cadaster;
- alignment of data on the Institute's assets with data from accounting records;
- preparation of submissions and representation in administrative procedures and disputes arising from identified tax liabilities of the Institute;
- administrative and technical support activities within the Department;
- cooperation with law firms representing the Institution;
- expert and administrative-technical activities related to maintaining all types of records and reporting on matters within the competence of the Department;
- preparation and harmonisation of standard and non-standard contracts for procurement of goods, works and/or services;
- preparation of reports within the competence of the Department;
- receipt of all incoming mail, maintenance of the registry protocol and delivery books;

- distribution of mail to organisational units and external recipients;
- maintenance of records relating to archival materials in accordance with general acts and the law;
- archiving and monitoring retention periods for individual documentation;
- submission of consignments, parcels and valuable letters to postal services;
- performing courier and technical support tasks;
- storage of registry material and archival records, and implementation of procedures for disposal and destruction of valueless registry material;
- planning, monitoring and control of the human resources situation and participation in the development of the human resources strategy;
- participation in negotiations with trade union organizations;
- defining, organizing and performing tasks related to the establishment of employment, employee deployment, termination of employment, other rights and obligations arising from employment, and maintaining personnel and personal records, and controlling the implementation of tasks;
- providing advice and opinions in the field of labor relations;
- participation in the development of general and individual acts in the field of and labor relations;
- expert processing of requests in the field of labor relations;
- tasks related to disciplinary procedures and procedures for resolving housing issues of employees;
- communication with competent institutions and insurance institutions (tax administration, pension fund, health fund, etc.);
- participating in the work of commissions;
- keeping records of licenses of institutes and individuals;
- maintenance of hygiene in business premises;
- occupational health and safety activities for employees;
- tasks related to catering services during meetings in the Managing Director's Office, sessions of the Institute's Management Board, as well as other meetings and gatherings held in the Institute's premises;
- janitorial tasks for the purpose of maintenance and necessary repairs in the Institute's official premises;
- managing all processes in the area of labor relations and human resources administration;
- and other tasks within the competence of the Center.

9.2.9.2. Department for economic affairs

- The following accounting and financial tasks are performed in the Department of Economic Affairs:
- ensuring financial conditions necessary for the work of the Institute;
- preparing proposals for the Institute's financial plans and proposals for financial performance reports;
- proposing measures to maintain the Institute's solvency and eliminate the causes of indebtedness;
- recording accounting changes and maintaining business records, providing records, monitoring and analysis of
- revenues and expenditures;
- preparing accounting and financial statements in accordance with applicable legislation and international
- accounting standards;
- preparing and presenting necessary information for the purposes of auditing the Institute's financial statements;
- monitoring, performing and recording payments and disbursements, debts and receivables and other tasks of a financial and accounting nature;
- determining economic and financial parameters for defining the amount of fees;
- tasks related to the management and control of the Institute's operations;
- monitoring tasks related to the system of internal financial control system;
- tasks of calculating salaries and other employee compensation, and control and processing of financial documentation related to the calculation of salaries and other employee compensation;
- control and harmonisation of records, individual calculations and recapitulations;
- internal and external reporting related to salaries and other compensation;
- monitoring of employee loans and other deductions and monitoring credit indebtedness of employees;
- tasks of processing of employees' requests for exercising rights from work and employment;
- monitoring and implementation of legal and subordinate legislation in the field of salaries and personal income,

taxes and contributions;
- preparation, control and verification and reconciliation of documentation (contract, delivery note, receipt, invoice, warranty) related to the procurement of goods, works and services;
- proposing a development strategy in the field of strategic planning and strategic procurement,
- and other tasks within the competence of the Center.

9.2.9.3. Registry office

The following administrative activities shall be performed within the Registry office:
- receipt and dispatch of mail, and timely forwarding of necessary information to Managing Director, centres and other organisational units;
- maintenance of primary records relating to the receipt of submissions, documents and other consignments, as well as outgoing mail;
- classification, distribution, recording and delivery of documents by subject/file within the Institute's information system;
- recording of incoming and outgoing correspondence, including its archiving and retention;
- management of the storage of documentation and records on files and other registry materials by organisational units;
- provision of administrative support to other employees and Centres in activities related to scanning, copying, organisation and packaging of documents for distribution;
- other activities falling within the competence of the Centre.

9.2.10. CENTRE FOR INFORMATION AND COMMUNICATION SYSTEMS

Number of job holders: 5

Within the Centre for Information and Communication Systems, the activities shall be performed:
- development and implementation of security policies in compliance with applicable legislation and adopted standards;
- planning and implementing the digital transformation and digitalisation of the Institute's business processes;
- developing, implementing and maintaining electronic services (e-services) for the pharmaceutical industry, healthcare institutions, healthcare professionals and the general public;
- developing and maintaining information systems supporting regulatory processes in the field of medicinal products and medical devices, as well as the European integration process and data exchange with European Union databases;
- establishing and maintaining interoperability between the Institute's information systems and the information systems of other public authorities and institutions, particularly in the healthcare sector;
- integrating the Institute's information systems with national data exchange platforms, e-government services, and other national and European services;
- establishing technical and organisational solutions for data exchange with European Union bodies, international institutions and other regulatory authorities in the field of medicinal products;
- aligning the Institute's information systems with the requirements of European regulatory authorities and international standards in the field of medicinal products and medical devices;
- establishing and implementing information security and cybersecurity management systems;
- implementing standards and best practices in the fields of information security and data protection;
- managing digital identities, system access rights and the protection of sensitive regulatory data;
- developing and maintaining electronic document exchange and document management systems;
- planning and developing the Institute's ICT architecture in accordance with the principles of interoperability and digital transformation;
- participating in EU and international projects and initiatives related to digitalisation, regulatory information systems and data exchange;
- monitoring and implementing recommendations and technical requirements issued by European regulatory authorities in the field of information systems supporting the regulation of medicinal products;
- activities related to the analysis, planning, design and implementation of information and communication technologies (ICT) and other technical solutions required for the Institute's operations;

- identification of deficiencies and their continuous elimination, as well as enhancement of existing ICT solutions applied within the Institute's operations;
- activities related to troubleshooting, maintenance, administration and upgrading of existing ICT systems and other technical solutions necessary for the uninterrupted operation and improvement of the Institute's activities;
- activities related to the management and maintenance of network and computer infrastructure;
- establishment of a logical organisation of business processes, documents and data through software solutions and IT infrastructure, in order to ensure uninterrupted operation and improvement of the Institute's activities;
- management, analysis and routine maintenance of network and computer infrastructure;
- establishment of clear procedures, continuous monitoring of technical developments and innovations in the ICT field, as well as regular personnel training on new technologies and tools;
- provision of technical support to employees and external users of the Institute's information systems, including assistance and guidance regarding the proper application of ICT within the Institute's operations;
- activities related to the preparation of ICT equipment for conferences, meetings and other gatherings organised by the Institute;
- activities related to the maintenance and administration of server and network infrastructure (configuration, maintenance and monitoring of server and network equipment);
- provision of support in relation to applications and systems; maintenance, administration and enhancement of ICT systems at both software and hardware level, including application solutions, databases, document management systems (DMS), active directory, e-mail systems, systems for data exchange with experts, web portals, web services, network equipment, file-sharing systems, storage systems, user workstations, operating systems, hardware and other system components;
- development and regular updating of backup copies of data and configurations in order to ensure the security of the Institute's data;
- management of licences for the use of software and software solutions;
- maintenance of a high level of information system security in order to protect sensitive Institute data and ensure system reliability;
- maintenance of other technical systems necessary for uninterrupted operation and enhancement of the Institute's activities, including telecommunications infrastructure and equipment, power supply systems, alarm and video surveillance systems, access control and working time recording systems, conference systems, fire protection systems, air-conditioning systems and similar;
- planning, coordination of activities and monitoring of the implementation of contracts and other activities with service providers for the maintenance and enhancement of ICT and other technical systems necessary for the Institute's operations, in order to ensure efficiency and compliance with technical standards aimed at maintaining ICT systems within the Institute;
- preparation of analyses and information relating to the activities of the Centre and the development and implementation of new technologies;
- ensuring and updating necessary documentation in accordance with the requirements of ISO standards implemented within the Institute, relating to ICT systems and processes, in cooperation with the quality manager;
- other activities falling within the competence of the Centre.

10. COORDINATION OF WORK OF ORGANISATIONAL UNITS

Article 25

The coordination of activities and tasks among organisational units within the Institute shall be carried out through:

1. direct management;
2. system of operational planning and control;
3. adopted rulebooks, procedures and other acts governing operations;
4. the work of the management meeting.

The Managing Director shall be responsible for coordinating the work of the Institute.

Through direct instructions, the Managing Director shall direct, monitor and coordinate the activities of the Centres and Departments, as well as the Inspectorate and Laboratory, with the aim of ensuring their harmonised functioning in the interest of the Institute as a whole.

Operational planning within the Institute shall be carried out through the adoption of strategies, plans and work programmes/business plans, including their monitoring and control.

Within the Institute, rulebooks, procedures and instructions shall be applied in order to further define the workflow and manner of conducting business processes.

Each organisational unit of the Institute shall develop adequate procedures and instructions governing the key business processes performed within that unit.

The implementation of procedures and instructions shall be monitored and carried out by the Managing Director, Assistant to Managing Director, Heads of Centres, Departments, Inspectorate and Laboratory, at the level of their respective organisational units.

The Managing Director shall coordinate the work of organisational units within the Institute also through the work of the Management meeting, composed of:

1) Managing Director;
2) Advisor to the Managing Director for Legal affairs and EU integrations;
3) Advisor to the Managing Director for Medical Affairs;
4) Human Resources Manager;
5) Quality Manager;
6) Head of the Internal Audit Department;
7) Head of the Centre for Medicines Authorisation – Assistant director;
8) Head of the Centre for Market Affairs and Safe Use of Medicines;
9) Head of the Inspectorate;
10) Head of the Laboratory;
11) Head of the Centre for medical devices;
12) Head of the Centre for Science, International Cooperation and Projects;
13) Head of the Centre for Information and Communication Systems
14) Head of the Centre for Support;
15) Head of the Office.

11. MANAGEMENT AND LEADERSHIP

Article 26

The Managing Director shall manage and lead the operations and assets of the Institute in accordance with the powers prescribed by the Law, the Statute and the Agreement concluded with the Management Board defining rights, obligations and responsibilities of the Managing Director.

The activities referred to in paragraph 1 of this Article shall be performed by the Managing Director directly or through organisational units.

Article 27

Heads of organisational units shall organise the work and manage the respective organisational unit.

The Head of an organisational unit shall be directly accountable to their immediate superior for the work of the organisational unit and for their own performance.

Article 28

All organisational units of the Institute, as well as all employees, shall be required to cooperate mutually within the scope of responsibilities prescribed by this Rulebook.

All employees of the Institute shall, in the performance of their duties, apply the implemented quality management system standards, the Institute's general acts relating to the protection of confidential data and business secrets, occupational health and safety, as well as other general acts of the Institute and standard operating procedures.

All organisational units, i.e. their Heads, shall be responsible for risk management and maintaining a risk register within the scope of their activities.

All employees of the Institute shall observe the principles of professional conduct, business and professional ethics, and ethics of interpersonal communication in business communication.

The Institute's spatial capacities shall be organised in a manner that enables optimal monitoring of work processes.

Article 29

Within the scope of their responsibilities, and in accordance with this Rulebook and employment contracts, employees shall participate in the performance of the following activities:

- cooperation with faculties in the fields of health sciences, natural sciences and technical-technological disciplines, as well as development and exchange of expert knowledge aimed at improving quality and education;
- cooperation with competent inspection authorities and organisations at national and international level;
- participation in national and international projects;
- participation in the implementation of scientific research in the fields of pharmaceutical sciences, medical sciences and interdisciplinary research, as well as in scientific activities within the Institute's scope of work;
- preparation and amendment of Quality Management System (QMS) documentation in accordance with established procedures;
- participation in QMS reviews;
- risk analysis and implementation of appropriate measures;
- identification of opportunities for improvement and implementation of appropriate measures;
- participation in internal and external audits of the system;
- preparation and issuance of expert opinions within the Institute's scope of activities;
- cooperating with experts from the list of experts established by the Institute, where applicable;
- participation in the Institute's publishing activities;
- preparation/review of documents, information and instructions for clients for publication on the Institute's internet portal;
- participation in the preparation of responses to enquiries from stakeholders and the general public, and participating in public engagements intended to inform the media and the public about activities within the Institute's remit, in agreement with the immediate supervisor and subject to the managing director's instruction and approval;
- participation in the preparation of notifications of expert or general public interest relating to the Institute's activities;
- analysis of the work of Centres/Departments/Inspectorate/Laboratory, preparation of work plans and reports relating to the activities of Centres/Departments/Inspectorate/Laboratory;
- monitoring and improvement of the Institute's information system, submission of requests for correction of errors in the functioning of the information system, participation in the preparation of requests for upgrades of the information system, monitoring the status of requests and verification of their resolution;
- preparation of quality management system documentation and participation in quality management activities in relation to the requirements of ISO standards for which certification has been obtained, within the Institute's scope of activities;
- participating in the preparation of expert background materials for the drafting of legislation and regulations within the Institute's area of competence;
- participation in the organisation, planning and implementation of professional gatherings and educational events within the Institute's scope of activities;
- participating in working bodies, working groups and commissions related to the activities of the organisational unit or the Institute;
- participating in the implementation of projects arising from inter-institutional and/or international cooperation;
- planning of employee training, organisation of its implementation and related reporting;
- implementation of continuous training of employees by Heads and expert associates of higher level;
- providing comments/opinions on quality management system documentation;
- participation in supervisory assessments of the Institute upon the instruction of the Managing Director of the Institute.

Article 30

Prior to adopting a decision on the employment of new personnel members, an assessment of the candidates' professional and psychological capabilities may be conducted, in accordance with the legislation governing labour relations and the Institute's procedures.

Article 31

Persons may be employed in trainee positions for associate/officer level jobs, in accordance with the Law.

12. FINAL PROVISIONS

Article 31

This Rulebook shall enter into force on the date of its adoption.

The assignment of employees within the Institute in accordance with this Rulebook shall be carried out within a period not exceeding 60 days from the date of entry into force of this Rulebook.

Upon the entry into force of this Rulebook, the Rulebook on Internal Organisation and Job Scheme No. 3020/23/406/3-7684 of 1 November 2023, 3020/24/553/6-9132 of 8 October 2024 and 3020/25/324/4-5642 of 18 June 2025 shall cease to apply.

13. ANNEXES AND OTHER APPENDICES

Article 32

The following annexes shall form an integral part of this Rulebook:

1) Organisation chart of the Institute;
2) Job descriptions.

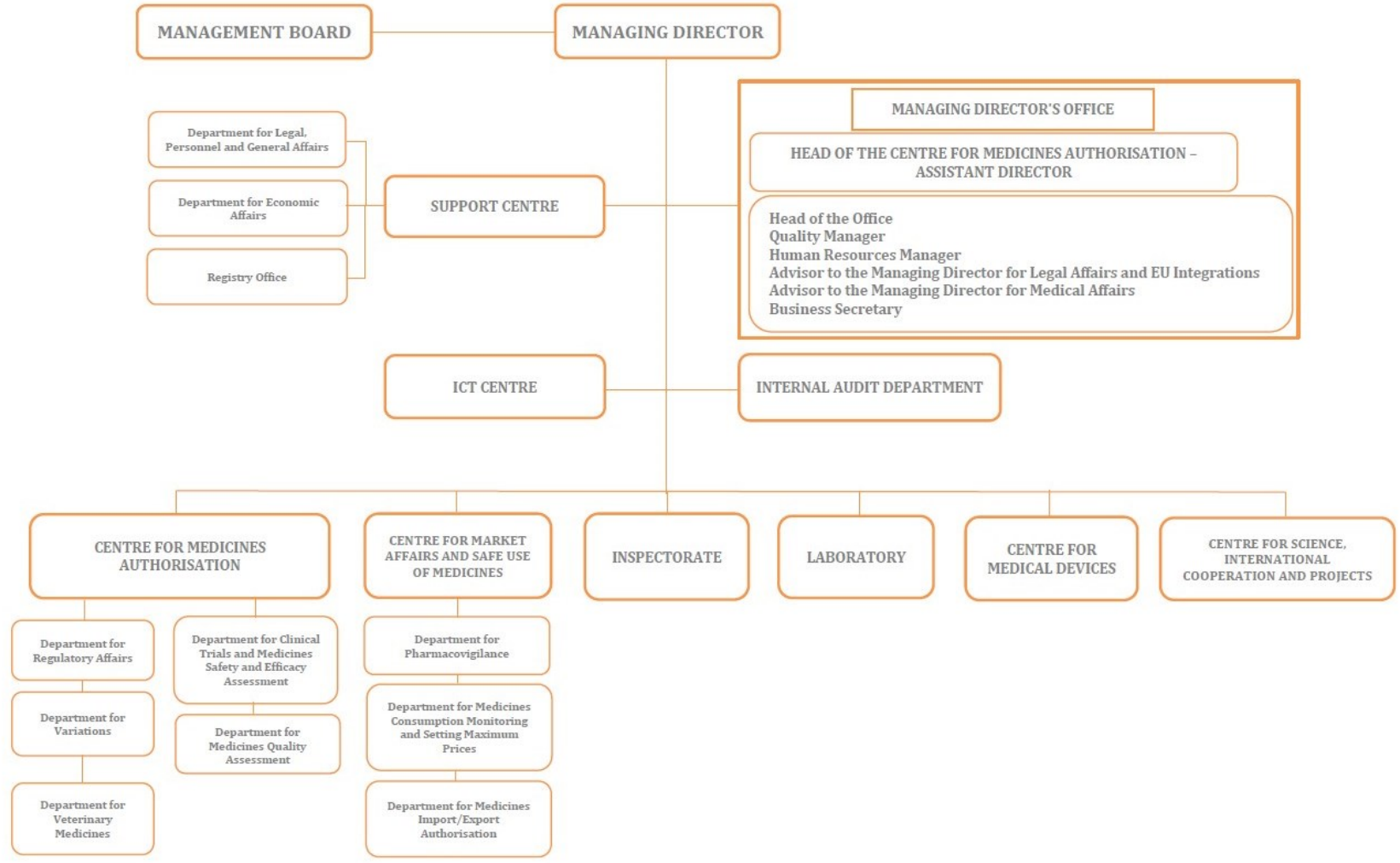
Chair of the Management Board
Dr spec. Jovan Milić

ANNEX 1 – Organisation chart of the Institute

CInMED

Institute for Medicines and Medical Devices of Montenegro

ORGANISATIONAL STRUCTURE



CInMED
Institute for Medicines and
Medical Devices of Montenegro

ANNEX 2 – Job descriptions

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No.	1
MANAGING DIRECTOR'S OFFICE		
(name of the organisational unit)		
MANAGING DIRECTOR		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years)	
Work experience	5 years in expert and managerial positions in the field of regulation of medicines and/or medical devices	
Special health requirements	NO	
Working hours	Full time - 40 hours per week	
Competencies	Organisational and communication skills	
Other requirements	Successful completion of the professional examination for work in state administration bodies, advanced knowledge of English language (written and spoken) computer literacy (especially Microsoft Office package).	
POSITION COEFFICIENT		
C1		
DUTIES OF THE POSITION		

- Organizes and manages the work of the Institute;
- Responsible for ensuring the legality, efficiency and cost-effectiveness of the Institute's operations;
- Responsible for the implementation and achievement of the Institute's strategies, programmes and work plans;
- Adopts decisions, or administrative acts within the competence of the Institute that are not within the competence of the Management Board;
- Executes decisions of the Management Board;
- Decides on the rights of employees, in accordance with the law;
- Acts in accordance with the Institute's integrity principles and ethical standards;
- Uses work resources and materials in a purposeful, efficient and economical manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while safeguarding his/her own life and health as well as the life and health of others;
- Informs the Management Board of any significant circumstances that affect or may affect the performance of duties and the operation of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	2
MANAGING DIRECTOR'S OFFICE		
(name of the organisational unit)		
ADVISOR TO THE MANAGING DIRECTOR FOR LEGAL AFFAIRS AND EU INTEGRATIONS		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in law, pharmacy, or medicine.	
Work experience	5 years of experience in regulatory affairs in the area of medicines and/or medical devices	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Organisational and communication skills	
Other requirements	Successful completion of the professional examination for work in state administration bodies, advanced knowledge of English language (written and spoken) computer literacy (especially Microsoft Office package).	
POSITION COEFFICIENT		
C1		
DUTIES OF THE POSITION		

- Executes the orders of the Managing director;
- Coordinates regulatory affairs activities and is responsible for the organisation and monitoring of the implementation of activities;
- Monitors and contributes to the execution of tasks entrusted to the Institute within Montenegro's European integration process;
- Responsible for ensuring the alignment of activities falling within the Institute's competences with European Union legislation, standards, principles, and guidance documents;
- Oversees the implementation of European Union legislation and the activities of European institutions in the areas of medicinal products, medical devices, narcotic drugs, and psychotropic substances, and proposes measures for regulatory alignment;
- Responsible for preparing assessments of the degree of conformity of national legislation with European Union legislation and relevant guidelines of Member States;
- Responsible for the approximation of regulations within the Institute's scope of competence with European Union legislation and guidance;
- Responsible for cooperation with and support to the relevant organisational units of the Institute in the preparation of expert bases for drafting legislation, guidelines, and templates within the Institute's competences, as well as for the review and alignment of draft primary and secondary legislation;
- Participates in the implementation of European regulatory standards and best practices within the Institute;
- Responsible for organising and delivering continuous professional training and presentations related to the regulatory framework;
- Responsible for providing expert opinions and advisory support concerning the implementation of regulations within the Institute's competence;
- Responsible for ensuring collaboration with other institutions and civil society organisations at both national and international level;
- Responsible for organising and contributing to the Institute's publishing and educational activities and for participating in the administration of the Institute's website;
- Ensures the publication and regular updating of adopted legislation, secondary legislation, guidelines, and templates on the Institute's website;
- Responsible for providing guidance to Institute employees regarding the application of regulations within the Institute's competence;
- Participates in working groups, commissions, and working bodies;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute;
- Uses work equipment and materials in a purposeful and cost-effective manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	3
MANAGING DIRECTOR'S OFFICE		
(name of the organisational unit)		
ADVISOR TO THE MANAGING DIRECTOR FOR MEDICAL AFFAIRS		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed medical studies.	
Work experience	5 years of experience in the area of medicines and/or medical devices	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Organisational and communication skills	
Other requirements	Successful completion of the professional examination for work in state administration bodies, advanced knowledge of English language (written and spoken) computer literacy (especially Microsoft Office package).	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- executes orders issued by the Director;
- coordinates the Institute's cooperation with the Ministry of Health, patient associations, healthcare institutions, the Health Insurance Fund, the Institute of Public Health, and other stakeholders within the healthcare system;
- participates in the assessment of the benefit-risk ratio of medicinal products from the perspective of public health protection;
- provides expert support to employees on medical matters;
- participates in educational campaigns and activities organised by the Institute;
- participates in projects implemented by the Institute;
- participates in working groups, committees and other working bodies;
- prepares expert opinions and responses to enquiries from healthcare professionals and the general public regarding the use of medicinal products;
- participates in the preparation of expert background materials for the development of regulations, strategies and the Institute's work plans;
- acts in accordance with the Institute's integrity principles and ethical standards;
- uses work resources and materials in a purposeful, efficient and economical manner;
- ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while safeguarding his/her own life and health as well as the life and health of others;
- informs the immediate supervisor of any significant circumstances that affect or may affect the performance of duties, result in material damage, or impact his/her own safety and health, the safety and health of other employees, or the environment;
- performs other duties commensurate with his/her qualifications and competencies, in accordance with the law, the Statute, and the general and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	4
MANAGING DIRECTOR'S OFFICE		
(name of the organisational unit)		
HEAD OF THE OFFICE		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, social, or humanities studies	
Work experience	3 years of professional experience	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Organisational and communication skills	
Other requirements	Successful completion of the professional examination for work in state administration bodies, advanced knowledge of English language (written and spoken) computer literacy (especially Microsoft Office package).	
POSITION COEFFICIENT		
C1		
DUTIES OF THE POSITION		

- Carries tasks assigned by the Managing director;
- Coordinates and carries out activities related to events organised by the Institute;
- Responsible for the planning, organisation, and promotion of expert meetings and educational programmes delivered by the Institute;
- Organises and coordinates the activities of the Managing Director's Office and provides operational guidance regarding the execution of tasks within the Office;
- Actively supports the establishment and maintenance of effective internal communication between the Managing Director's Office and Institute employees;
- Responsible for communication and coordination of activities with national, European, and international organisations, institutions, and working groups;
- Responsible for the editorial management and oversight of information published on the Institute's web portal;
- Responsible for publishing information on, and monitoring the visibility of, the Institute's activities in traditional media and on social media channels;
- Provides support for organisational change management through communication and dissemination of information to employees;
- Coordinates the provision of information to employees regarding significant events, initiatives, and projects;
- Performs protocol-related duties within the Managing Director's Office;
- Prepares and coordinates the Managing Director's correspondence, as well as participation in activities and events at national and international level;
- Maintains records of the Managing Director's planned commitments and monitors their timely fulfilment;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute;
- Uses work equipment and materials in a purposeful and cost-effective manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	5
MANAGING DIRECTOR'S OFFICE		
(name of the organisational unit)		
QUALITY MANAGER		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in health, natural, social or technical field.	
Work experience	3 years of professional experience	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies		
Other requirements	Successful completion of the professional examination for work in state administration bodies, advanced knowledge of English language (written and spoken) computer literacy (especially Microsoft Office package). Completed course for internal and/or external auditor according to ISO 9001	
POSITION COEFFICIENT		
C1		
DUTIES OF THE POSITION		

- Executes the orders ofthe Managing director;
- Coordinates and manages activities related to the establishment and improvement of the quality management system;
- Coordinates and manages activities related to the quality system, information security management system, and other systems aimed at improving the quality of services;
- Promotes a quality culture within the Institute;
- Ensures the establishment, implementation, and maintenance of the quality system in accordance with the requirements of implemented standards;
- Plans the resources necessary for the functioning of the quality system;
- Reports to the Managing Director of the Institute and the heads of organisational units on the performance and effectiveness of the quality management system for the purposes of management review and the identification of improvement opportunities;
- Performs activities related to identifying deficiencies and proposing improvements to the quality system;
- Performs activities related to organising and documenting management reviews of the quality system and monitoring the implementation of adopted decisions;
- Performs activities related to risk and opportunity management, reviewing the Risk Register and risk treatment plan;
- Performs activities related to the management of quality system documentation (preparation, review, distribution, and archiving of documentation);
- Responsible for preparing the quality policy, quality manual, and other quality-related acts of the Institute, as well as quality procedures and instructions in accordance with implemented standards;
- Participates in drafting other acts governing the operation and organisation of the Institute;
- Participates in the development and implementation of policies and plans relating to integrity and impartiality;
- Performs activities related to preparing objective plans and training and professional development plans, monitoring their implementation, and maintaining related documentation;
- Responsible for identifying training needs, planning, organising, and delivering employee training in the area of quality system management, and promoting understanding and effective implementation of the quality management system.;
- Communicates with certification and accreditation bodies;
- Performs activities related to planning and organising internal audits, participating in and supervising the conduct of internal audits, and reporting on them;
- Performs activities related to planning and organising audits of service providers and reporting thereon;
- Carries out the necessary activities for conformity assessment procedures with the requirements of implemented standards by certification, accreditation other external bodies ;
- Responsible for coordinating the implementation of corrective and preventive actions within the quality management system, monitoring their execution, efficiency, and effectiveness, and ensuring appropriate reporting and documentation of such activities;
- Performs activities related to organising effective control (inspection) and testing of products/services;
- Responsible for suspending the service provision process in cases of non-conformity of services, processes, or the quality system;
- Responsible for establishing and implementing the quality information system;
- Participates in the preparation and consolidation of the Institute’s work programmes and plans, activity reports, financial plan, and financial report;
- Responsible for monitoring legislation, scientific and expert literature, technical documentation, standards, and other documentation in the fields of quality management and quality assurance;
- Participates in the evaluation and selection of suppliers and external collaborators of the Institute;
- Performs activities related to the preparation, implementation, and analysis of stakeholder surveys;
- Responsible for monitoring and ensuring the timely fulfilment of obligations arising from the Institute’s work programme;
- Participates in the preparation of Institute publications;
- Participates in contract review activities;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute;
- Uses work equipment and materials in a purposeful and cost-effective manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	6
MANAGING DIRECTOR'S OFFICE		
(name of the organisational unit)		
HUMAN RESOURCES MANAGER		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in law, management, psychology,economy, or similar social fields.	
Work experience	3 years of professional experience	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Organisational, advisory, and communication skills;	
Other requirements	Successful completion of the professional examination for work in state administration bodies, advanced knowledge of English language (written and spoken) computer literacy (especially Microsoft Office package).	
POSITION COEFFICIENT		
C1		
DUTIES OF THE POSITION		

- Executes the orders ofthe Managing director of the Institute;
- Coordinates and supervises the preparation of the Institute's Strategic and Business Plans in the field of human resources;
- Participates in the preparation of reports on the implementation of strategic and business plans in the area relating to human resources;
- Prepares and organises materials for Management Board sessions related to human resources and monitors the implementation of conclusions and decisions;
- Participates in the preparation and revision of acts on internal organisation and job classification;
- Participates in the selection and evaluation of candidates in recruitment procedures;
- Defines workforce requirements and associated staffing costs, as well as the professional development and training needs of employees;
- Organises and conducts the orientation of new employees and evaluates their probationary work;
- Prepares the Employee Training Plan and monitors the implementation of professional development activities;
- Coordinates employee development activities (trainings, workshops, courses), team development, and talent management;
- Initiates and implements measures aimed at enhancing interpersonal relationships, fostering a positive working environment, and strengthening employee engagement and motivation;
- Develops and implements a system for monitoring and evaluating work performance, career advancement, and rewarding employees;
- Monitors and analyses key HR indicators (KPIs), including staff turnover, absences, employee satisfaction, and performance by organisational units;
- Organises employee satisfaction and engagement surveys and analyses findings for the purpose of proposing improvement measures;
- Develops and implements employee retention strategies and talent management policies;
- Monitors the implementation of labour law regulations, occupational health and safety requirements, and internal HR acts;
- Ensures compliance with ethical standards and equal opportunity principles within the Institute (DEI principles);
- Participates in the preparation and amendment of internal rules and acts related to human resources;
- Conducts activities related to resolving workplace issues, disciplinary procedures, and conflict situations;
- Handles reports and situations indicating risks in interpersonal relations and proposes measures for risk reduction, prevention, and mitigation;
- Implements measures for ensuring quality of work and employee protection at work;
- Exchanges and analyses data relevant to human resources management and the improvement of organisational climate;
- Coordinates communication between management and employees and applies the principles of effective internal communication;
- Performs other duties as assigned by the Managing director, in accordance with the law and the general acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	7
MANAGING DIRECTOR'S OFFICE		
(name of the organisational unit)		
BUSINESS SECRETARY		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VI/VII	
Level of educational and professional qualifications	University degree, qualification comprising 180 or 240 (180+60), 300 or 360 (ECTS) credits (study programme lasting 3, 4 or 3+1 or 3+2 years).	
Work experience	1 year or professional experience	
Special health requirements	NO	
Required daily working hours	Full time – 40 hours per week	
Competencies	Organisational and communication skills	
Other requirements	Successful completion of the professional examination for work in state administration bodies, advanced knowledge of English language (written and spoken) computer literacy (especially Microsoft Office package).	
POSITION COEFFICIENT		
C1		
DUTIES OF THE POSITION		

- Executes the orders ofthe Managing director;
- Organises and coordinates the work of the Managing director's Office and provides detailed instructions regarding the performance of tasks within the Office;
- Organises and prepares meetings and meeting materials, and prepares minutes from meetings of the Managing director's Office and the Institute's Management meetings;
- Actively contributes to establishing and maintaining clear and effective internal communication between the Managing director's Office and employees;
- Coordinates informing employees about significant events, initiatives, and projects;
- Provides support for change management processes through effective communication and dissemination of information to employees regarding organisational changes;
- Conducts protocol-related activities within the Managing director's Office;
- Participates in activities related to events organised by the Institute;
- Prepares and coordinates the Managing director's correspondence and participation in activities and events at national and international level;
- Maintains records of the Managing director's scheduled obligations and monitors their timely implementation;
- Responsible for preparing press clippings for the needs of the Managing director and heads of organisational units of the Institute;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute;
- Uses work equipment and materials in a purposeful and cost-effective manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	8
INTERNAL AUDIT DEPARTMENT		
(name of the organisational unit)		
HEAD OF THE INTERNAL AUDIT DEPARTMENT		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Compeletd studies in economy or law.	
Work experience	5 years of professional experience, including 2 years of experience in audit-related activities.	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Other requirements	Successful completion of professional examination for work in state administration bodies; Successful completion of professional examination for audit activities (Certified Internal Auditor in the Public Sector); knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		
DUTIES OF THE POSITION		

- Organises, coordinates, monitors, and supervises the work of internal auditors;
- Monitors and coordinates the oversight of compliance with legislation, applicable international regulations, standards, and procedures in the areas of accounting, external audit, and internal audit within the Institute's operations;
- Responsible for ensuring the resources necessary for audit engagements;
- Plans the financial budget for internal audit activities;
- Connects members of the audit team with managers of the organisational units of the Institute covered by the internal audit plan;
- Identifies and analyses key risk areas within the Institute where risks may occur, evaluates such risks, and, in cooperation with management, implements measures to prevent them or mitigate them to an acceptable level;
- Prepares comprehensive strategic and annual internal audit plans based on risk assessment and controls;
- Establishes internal audit policies and procedures;
- Coordinates activities with external audit;
- Defines the methodology for preparing audit reports;
- Establishes the plan for each individual audit and, based on a prior assessment of the significance of risks, determines the priority audit procedures and tests;
- Prepares standardised working papers for internal audit;
- Reviews the final audit report submitted to the Managing Director of the Institute and to the heads of the organisational units subject to audit, including recommendations for strengthening internal controls and reducing risks to an acceptable level;
- Organises the monitoring of the implementation of action plans for improving internal controls and risk management;
- Submits a report on the work of internal audit to the Management Board and the ministry responsible for finance at least once a year;
- Establishes performance standards and evaluates team members' performance against those standards;
- Interprets internal audit standards, professional ethics standards, and the contents of the Guidelines on the Method and Procedure for Conducting Audits, and provides internal training to team members accordingly;
- Participates in and performs other special audits as assigned by the Managing director;
- Prepares and submits for adoption to the head of the entity the annual plan for the continuous professional development of internal auditors;
- Acts in accordance with other obligations established by law, collective agreements, employment contracts, and other internal acts governing the Institute's operations;
- Uses work equipment and materials in a purposeful and cost-effective manner;
- Complies with occupational health and safety regulations and performs duties carefully in a manner that protects his/her own life and health, as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment.
- Is accountable for their work to the Managing Director and the Management Board.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	9
INTERNAL AUDIT DEPARTMENT		
(name of the organisational unit)		
SENIOR INTERNAL AUDITOR		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in economy or law.	
Work experience	3 years of professional experience, including 1 year of experience in audit-related activities.	
Completed traineeship		
Working hours	Full time – 40 hours per week	
Other requirements	Successful completion of professional examination for work in state administration bodies; Successful completion of professional examination for audit activities (Certified Internal Auditor in the Public Sector); knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package).	
POSITION COEFFICIENT		
C1		
DUTIES OF THE POSITION		

- Monitors and controls the implementation of legislative regulations in the Institute's operations;
- Monitors and controls the implementation of the Law on Accounting and Auditing and the International Standards on Auditing;
- Monitors and controls business processes within the Institute in accordance with the International Professional Practices Framework for Internal Auditing;
- Participates in the preparation of the strategic and annual internal audit plan and prepares plans for individual internal audits;
- In accordance with the adopted work programme, conducts audits individually or as part of a team, under the coordination of the Head of Department or together with him/her;
- Independently or together with the Head of Department prepares process descriptions/designs of internal controls;
- Independently or together with the Head of Department conducts the agreed methods and types of internal control testing;
- Independently, together with the Head of Department, or with the audit team prepares draft audit reports;
- Together with members of the audit team participates in identifying risk areas, analysing and assessing risks within the Institute, and developing the risk matrix;
- Examines, evaluates, and monitors the adequacy and effectiveness of the accounting system, accounting controls, and all other non-accounting and financial internal controls, and provides recommendations for their improvement;
- Examines the accuracy, timeliness, and reliability of accounting, financial, and non-accounting and financial information, documents, and records;
- Monitors and examines the legality and regularity of completed financial and commercial transactions;
- Examines the economy, efficiency, and effectiveness of operations;
- Examines legality in administrative functions and decision-making systems;
- Controls compliance of operations with legislative and internal regulations;
- Identifies business risks and proposes measures for their elimination or reduction to an acceptable level;
- Monitors the implementation of recommendations arising from operational audits and corrective measures for reducing risks to an acceptable level, in accordance with defined action plans, and prepares reports on performed controls;
- Undertakes activities aimed at preventing and detecting criminal acts, fraud, and abuse;
- Prepares reports on conducted audits;
- Participates, as necessary, in other individual or team internal audit activities;
- Participates in the work of commissions and working groups;
- Performs other duties as assigned by superiors, within the scope of his/her qualifications and competencies;
- Acts in accordance with other obligations established by law, collective agreements, employment contracts, and other internal acts governing the Institute's operations;
- Uses work equipment and materials in a purposeful and cost-effective manner;
- Complies with occupational health and safety regulations and environmental protection requirements and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Accountable for his/her work to the Head of the Internal Audit Department.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	10
INTERNAL AUDIT DEPARTMENT		
(name of the organisational unit)		
JUNIOR INTERNAL AUDITOR		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in economy or law	
Work experience	2 years of professional experience, including 1 year of experience in audit-related activities.	
Special health requirements	NO	
Working hours	Full time - 40 hours per week	
Other requirements	Successful completion of professional examination for work in state administration bodies; Successful completion of professional examination for audit activities (Certified Internal Auditor in the Public Sector); Advanced knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office).	
POSITION COEFFICIENT		
C1		
DUTIES OF THE POSITION		

- Monitors and controls the implementation of legislative regulations in the Institute's operations;
- Monitors and controls the implementation of the Law on Accounting and Auditing and the International Standards on Auditing;
- Monitors and controls business processes within the Institute in accordance with the International Professional Practices Framework for Internal Auditing;
- Participates in the preparation of the annual work programme of the Internal Audit Department;
- In accordance with the adopted work programme, conducts audits individually or as part of a team, under the coordination of a Senior Auditor or together with him/her;
- Independently or together with the audit team prepares process descriptions/designs of internal controls;
- Independently or together with the audit team conducts the agreed methods and types of internal control testing;
- Independently, together with the Senior Auditor, or with the audit team prepares draft audit reports;
- Together with members of the audit team participates in identifying risk areas, analysing and assessing risks within the Institute, and developing the risk matrix;
- Examines, evaluates, and monitors the adequacy and effectiveness of the accounting system, accounting controls, and all other non-accounting and financial internal controls, and provides recommendations for their improvement;
- Examines the accuracy, timeliness, and reliability of accounting, financial, and non-accounting and financial information, documents, and records;
- Monitors and examines the legality and regularity of completed financial and commercial transactions;
- Examines the economy, efficiency, and effectiveness of operations;
- Examines legality in administrative functions and decision-making systems;
- Controls compliance of operations with legislative and internal regulations;
- Identifies business risks and proposes measures for their elimination or reduction to an acceptable level;
- Monitors the implementation of recommendations arising from operational audits and corrective measures for reducing risks to an acceptable level, in accordance with defined action plans, and prepares reports on performed controls;
- Undertakes activities aimed at preventing and detecting criminal acts, fraud, and abuse;
- Prepares reports on conducted audits;
- Participates, as necessary, in other individual or team internal audit activities;
- Performs other duties as assigned by superiors, within the scope of his/her qualifications and competencies;
- Acts in accordance with other obligations established by law, collective agreements, employment contracts, and other internal acts governing the Institute's operations;
- Uses work equipment and materials in a purposeful and cost-effective manner;
- Complies with occupational health and safety regulations and environmental protection requirements and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Accountable for his/her work to the Head of the Internal Audit Department.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	11
CENTRE FOR MEDICINES AUTHORISATION		
(name of the organisational unit)		
HEAD OF THE CENTRE FOR MEDICINES AUTHORISATION – ASSISTANT DIRECTOR		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in pharmacy or medicine	
Work experience	5 years of experience in activities within the competence of the Centre	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Organisational and communication skills	
Other requirements	Successful completion of professional examination for work in state administration bodies; Advanced knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office).	
POSITION COEFFICIENT		
C1		
DUTIES OF THE POSITION		

- Executes the orders ofthe Managing director;
- Participates in strategic planning and defining the development directions of the Institute, in accordance with the Institute's mission and vision;
- Proposes initiatives and measures for improving the regulatory framework, operational efficiency, and quality of the Institute's services;
- Participates in coordinating the work of the organisational units of the Institute and ensures their mutual cooperation for the efficient implementation of regulatory and expert activities;
- Participates in representing the Institute before competent national and international bodies, organisations, and partners;
- Provides expert opinions to the Managing director of the Institute regarding strategic issues in the field of the medicinal products regulatory system;
- Participates in the preparation and implementation of initiatives and activities related to international cooperation and harmonisation with European Union legislation and practice;
- Manages the work of the Centre and is responsible for planning, organising, implementing, and controlling business processes within the competence of the Centre, and supervises their implementation;
- Responsible for performing the most complex tasks and activities within the competence of the Centre;
- Responsible for assigning tasks to associates within the Centre and ensuring coordination and cooperation in their execution;
- Chairs the Commission for Marketing Authorisation of Medicinal Products and is responsible for the minutes of meetings of commissions within the competence of the Centre;
- Responsible for issuing official acts and documents in procedures within the competence of the Centre;
- Responsible for organising and participating in the continuous education of employees within the Centre;
- Responsible for preparing/controlling information and documents published on the Institute's web portal within the competence of the Centre;
- Responsible for entering parameters necessary for the entry of master data on medicinal products into the Institute's information system, as well as other related parameters;
- Ensures that activities within the competence of the Centre are carried out in the manner and within the deadlines prescribed by law;
- Ensures the accuracy and completeness of records related to received applications within the competence of the Centre;
- Supervises the processing of applications within the competence of the Centre;
- Supervises activities related to informing applicants about the need to supplement documentation and the status of files processed within the Centre;
- Participates in activities related to harmonising medicinal products legislation with the legislation and guidelines of the European Union and international institutions;
- Responsible for preparing and drafting reports related to activities within the competence of the Centre;
- Responsible for supervising standard operating procedures within the competence of the Centre;
- Participates in preparing professional bases for drafting correspondence, responses to inquiries, public announcements, media statements, and other informational content within the competence of the Centre;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute, and for ensuring compliance with and implementation of such principles and standards within the organisational unit under his/her management.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	12
CENTRE FOR MEDICINES AUTHORISATION		
(name of the organisational unit)		
TECHNICAL AFFAIRS OFFICER		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	III/IV1	
Level of educational and professional qualifications	Secondary education, qualification comprising 180 (ECTS) credits (study programme lasting 3 years), or 240 (ECTS) credits (study programme lasting 4 years)	
Work experience	1 year of experience in technical and administrative affairs	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies		
Other requirements	Successful completion of professional examination for work in state administration bodies; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes the orders ofthe Managing director and the Head of the Centre;
- Responsible for administrative and technical activities within the Centre (scanning, copying, archiving, and distributingpatching documentation);
- Required to have knowledge of the basic regulatory requirements in the field of medicinal products in order to adequately receive and classify files;
- Ensures that each document, submission, or file is directed to the appropriate Centre or Department in accordance with its content and the regulatory framework governing medicinal products;
- Performs activities related to the classification, allocation, recording, and distribution of documents according to the specificities of the medicinal products field through file management in the Institute's information system;
- Performs activities related to maintaining the Institute's basic records concerning the receipt of submissions, acts, and other consignments, as well as the dispatch of mail;
- Performs activities related to the classification, allocation, recording, and distribution of documents according to the specificities of the fields of medicinal products and medical devices through file management in the Institute's information system;
- Responsible for the classification, allocation, and maintenance of records relating to documentation in procedures within the competence of the Centre;
- Provides support regarding documentation within the competence of the Centre, makes documentation available for review, and monitors retention and archiving deadlines;
- Provides support and participates in the organisation of events organised by the Centre;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute;
- Uses work equipment and materials in a purposeful and cost-effective manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	13
CENTRE FOR MEDICINES AUTHORISATION		
(name of the organisational unit)		
ADMINISTRATIVE OFFICER		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	III/IV1	
Level of educational and professional qualifications	Secondary education, qualification comprising 180 (ECTS) credits (study programme lasting 3 years), or 240 (ECTS) credits (study programme lasting 4 years)	
Work experience	1 year of experience in administrative affairs	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies		
Other requirements		
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- executes orders issued by the Managing Director, the Head of the Centre and Heads of Departments;
- provides administrative support to all organisational units (departments) within the Centre;
- receives applications in the Information System (IS) and performs the initial administrative processing of variation applications that have not been submitted through e-services;
- performs the administrative processing of applications and issues outgoing documents in procedures concerning the suspension of proceedings, suspension of marketing authorisations, termination of marketing authorisations and transfer of marketing authorisations for medicinal products, in accordance with the applicable procedures of the Centre;
- ensures the administrative preparation of files for further processing by expert staff;
- prints outgoing documents related to procedures within the Centre's remit upon completion of the scientific/regulatory assessment and maintains records thereof in the Centre's internal records;
- participates in the classification and allocation of files among departments in accordance with the type of procedure and regulatory requirements;
- enters master data on medicinal products into the Institute's Information System for procedures within the Centre's remit;
- enters parameters into the Institute's Information System for procedures within the Centre's remit;
- updates file-related information in the Information System and the Centre's internal records, including monitoring the status of procedures;
- provides support in maintaining records and databases related to procedures within the Centre's remit;
- cooperates with other organisational units of the Institute to ensure the efficient flow of documentation and information;
- archives documentation within the Centre's remit in accordance with applicable regulations and internal acts;
- participates in improving administrative procedures and enhancing the operational efficiency of the Centre;
- provides support and participates in the organisation of events organised by the Centre;
- acts in accordance with the Institute's integrity principles and ethical standards;
- uses work resources and materials in a purposeful, efficient and economical manner;
- ensures compliance with occupational health and safety regulations and environmental protection requirements and performs duties in a manner that does not endanger or adversely affect the environment, while safeguarding his/her own life and health as well as the life and health of others;
- informs the immediate supervisor of any significant circumstances that affect or may affect the performance of duties, result in material damage, or impact his/her own safety and health, the safety and health of other employees, or the environment;
- performs other duties commensurate with his/her qualifications and competencies, in accordance with the law, the Statute, and the general and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	14
CENTRE FOR MEDICINES AUTHORISATION **DEPARTMENT FOR REGULATORY AFFAIRS**		
(name of the organisational unit)		
HEAD OF THE DEPARTMENT FOR REGULATORY AFFAIRS		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural or technical-technological field	
Work experience	5 years of work experience in activities within the competence of the Department	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Organisational and communication skills	
Other requirements	Successful completion of professional examination for work in state administration bodies; Advanced knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		
DUTIES OF THE POSITION		

- Executes the orders ofthe Managing director and the Head of the Centre;
- Manages the work of the Department and is responsible for planning, organising, implementing, and controlling business processes within the competence of the Department, and supervises their implementation;
- Responsible for performing the most complex tasks and activities within the competence of the Department;
- Responsible for assigning tasks to associates within the Department and ensuring coordination and cooperation in their execution;
- Ensures that activities within the competence of the Department are carried out in the manner and within the deadlines prescribed by law;
- Responsible for preparing/controlling minutes from meetings of commissions within the competence of the Department;
- Responsible for issuing official acts and documents in procedures within the competence of the Department;
- Responsible for the timely forwarding of complete applications to the organisational units of the Institute according to the type of application;
- Proposes and participates in the continuous education of employees within the Department;
- Responsible for preparing/controlling information and documents published on the Institute's web portal within the competence of the Department;
- Responsible for entering parameters necessary for the entry of master data on medicinal products into the Institute's information system, as well as other related parameters;
- Provides guidance for maintaining records of received applications within the competence of the Department;
- Supervises the processing of applications within the competence of the Department;
- Ensures timely informing of applicants regarding the need to supplement documentation, as well as the status of files processed within the Department;
- Responsible for preparing and drafting reports related to activities within the competence of the Department;
- Responsible for preparing standard operating procedures within the competence of the Department;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute, and for ensuring compliance with and implementation of such principles and standards within the organisational unit under his/her management;
- Uses work equipment and materials in a purposeful and cost-effective manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	15
CENTRE FOR MEDICINES AUTHORISATION **DEPARTMENT FOR REGULATORY AFFAIRS**		
(name of the organisational unit)		
COORDINATOR IN THE DEPARTMENT FOR REGULATORY AFFAIRS		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural or technical-technological field	
Work experience	3 years of experience in activities within the competence of the Department	
Special health requirements	NO	
Working hours	Full time- 40 hours per week	
Competencies	Organisational and communication skills	
Other requirements	Successful completion of professional examination for work in state administration bodies; Advanced knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		
DUTIES OF THE POSITION		

- Executes the orders ofthe Managing director, the Head of the Centre, and the Head of the Department;
- In agreement with the Head of the Department, coordinates the implementation of business processes within the competence of the Department and participates in their planning, organisation, and supervision;
- Responsible for assigning tasks to associates within the Department and ensuring coordination and cooperation in their execution;
- Responsible for independently performing the most complex tasks and activities within the competence of the Department;
- Ensures that activities within the competence of the Department are carried out in the manner and within the deadlines prescribed by law;
- Responsible for preparing/controlling minutes from meetings of commissions within the competence of the Department;
- Responsible for issuing official acts and documents in procedures within the competence of the Department;
- Proposes and participates in the continuous education of employees within the Department;
- Responsible for preparing/controlling information and documents published on the Institute's web portal within the competence of the Department;
- Responsible for entering parameters necessary for the entry of master data on medicinal products into the Institute's information system, as well as other related parameters;
- Provides guidance for maintaining records of received applications within the competence of the Department;
- Supervises the processing of applications within the competence of the Department;
- Ensures the timely informing of applicants regarding the need to supplement documentation, as well as the status of files processed within the Department;
- Responsible for preparing and drafting reports related to activities within the competence of the Department;
- Responsible for the preparation and revision of standard operating procedures within the competence of the Department;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute;
- Uses work equipment and materials in a purposeful and cost-effective manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	16
CENTRE FOR MEDICINES AUTHORISATION **DEPARTMENT FOR REGULATORY AFFAIRS**		
(name of the organisational unit)		
EXPERT ASSOCIATE I FOR REGULATORY AFFAIRS		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural or technical-technological field	
Work experience	5 years of work experience in activities within the competences of the Department	
Special health requirements	NO	
Working hours	Full time - 40 hours per week	
Competencies	Specialised expertise and independence in work	
Other requirements	Successful completion of professional examination for work in state administration bodies; Advanced knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office).	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes the orders ofthe Managing director, the Head of the Centre, and the Head of the Department;
- Responsible for independently performing the most complex activities in procedures within the competence of the Department, including assessment of documentation and monitoring of deadlines, as well as supervising the work of other employees within the Department;
- Responsible for preparing notifications to applicants regarding the need to supplement documentation, for the purpose of determining completeness of applications;
- Responsible for entering parameters into the Institute's information system, as well as entering master data on medicinal products into the Institute's information system for procedures within the competence of the Department;
- Responsible for preparing and issuing official acts and documents in procedures within the competence of the Department;
- Prepares minutes from meetings of commissions for activities within the competence of the Department;
- Prepares notifications for applicants following meetings of commissions within the competence of the Department;
- Coordinates the assessment of the acceptability of documentation assessment reports issued by other regulatory authorities (e.g. from centralised, decentralised, and mutual recognition procedures);
- Cooperates with experts from the list of experts established by the Institute;
- Proposes continuous training activities for employees within the Department and participates in the training of lower-level employees;
- Proposes improvements and revisions to standard operating procedures within the competence of the Department;
- Participates in the work of working groups, commissions, and working bodies;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute;
- Uses work equipment and materials in a purposeful and cost-effective manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	17
CENTRE FOR MEDICINES AUTHORISATION **DEPARTMENT FOR REGULATORY AFFAIRS**		
(name of the organisational unit)		
EXPERT ASSOCIATE II FOR REGULATORY AFFAIRS		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural or technical-technological field	
Work experience	3 years of work experience in activities within the competences of the Department	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Specialised expertise and independence in work	
Other requirements	Successful completion of professional examination for work in state administration bodies; knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes the orders ofthe Managing director, the Head of the Centre, and the Head of the Department;
- Responsible for independently performing complex activities in procedures within the competence of the Department, including assessment of documentation and monitoring of deadlines;
- Responsible for preparing notifications to applicants regarding the need to supplement documentation for the purpose of determinig completeness of applications;
- Responsible for entering master data on medicinal products into the Institute's information system for procedures within the competence of the Department;
- Responsible for preparing and issuing official acts and documents in procedures within the competence of the Department, under the supervision and control of the Head of the Department and the Head of the Centre;
- Prepares minutes from meetings of commissions for activities within the competence of the Department;
- Proposes improvements and revisions to standard operating procedures within the competence of the Department;
- Proposes continuous training activities for employees within the Department and participates in the training of lower-level employees;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute;
- Uses work equipment and materials in a purposeful and cost-effective manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	18
CENTRE FOR MEDICINES AUTHORISATION DEPARTMENT FOR REGULATORY AFFAIRS		
(name of the organisational unit)		
EXPERT ASSOCIATE III FOR REGULATORY AFFAIRS		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural or technical-technological field	
Work experience	1 year of experience in activities within the competences of the Department	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies		
Other requirements	Successful completion of professional examination for work in state administration bodies; knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes the orders of the Managing director, the Head of the Centre, and the Head of the Department;
- Responsible for performing simple tasks in procedures within the competence of the Department, including assessment of documentation and monitoring of deadlines, under the continuous supervision and control of Expert Associates I and II, the Head of the Department, and the Head of the Centre;
- Responsible for preparing notifications to applicants regarding the need to supplement documentation for the purpose of determining completeness of applications;
- Responsible for entering master data on medicinal products into the Institute's information system for procedures within the competence of the Department, under the supervision and control of Expert Associate I and the Head of the Department;
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- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute;
- Uses work equipment and materials in a purposeful and cost-effective manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	19
CENTRE FOR MEDICINES AUTHORISATION DEPARTMENT FOR REGULATORY AFFAIRS		
(name of the organisational unit)		
ASSOCIATE FOR REGULATORY AFFAIRS		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural or technical-technological field	
Work experience	1 year of experience in the relevant field	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies		
Other requirements	Successful completion of professional examination for work in state administration bodies; knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Carries tasks assigned by the Managing director, the Head of the Centre, and the Head of the Department;
- Responsible for performing the simplest tasks in procedures within the competence of the Department, including assessment of documentation and monitoring of deadlines, under the continuous supervision and control of Expert Associates I and II, the Head of the Department, and the Head of the Centre;
- Participates in the preparation of notifications to applicants regarding the need to supplement documentation, for the purpose of determining completeness of applications;
- Participates in the preparation of official acts and documents in procedures related to the transfer and termination of marketing authorisations for medicinal products and the suspension of procedures for granting/renewing marketing authorisations, under control of Expert Associates I and II, the Head of the Department, and the Head of the Centre;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute;
- Uses work equipment and materials in a purposeful and cost-effective manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	20
CENTRE FOR MEDICINES AUTHORISATION **DEPARTMENT FOR VARIATIONS**		
(name of the organisational unit)		
HEAD OF THE DEPARTMENT FOR VARIATIONS		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural or technical-technological field	
Work experience	5 years of experience in activities within the competence of the Department	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Organisational and communication skills	
Other requirements	Successful completion of professional examination for work in state administration bodies; Advanced knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes the orders of the Managing director and the Head of the Centre;
- Manages the work of the Department and is responsible for planning, organising, implementing, and controlling business processes within the competence of the Department, and supervises their implementation;
- Responsible for performing the most complex tasks and activities within the competence of the Department;
- Responsible for assigning tasks to associates within the Department and ensuring coordination and cooperation in their execution;
- Ensures that activities within the competence of the Department are carried out in the manner and within the deadlines prescribed by law;
- Responsible for issuing official acts and documents in procedures within the competence of the Department;
- Proposes and participates in the continuous education of employees within the Department;
- Responsible for preparing/controlling information and documents published on the Institute's web portal within the competence of the Department;
- Responsible for entering parameters necessary for the entry of master data on medicinal products into the Institute's information system, as well as other related parameters;
- Provides guidance for maintaining records of received applications within the competence of the Department;
- Supervises the processing of applications within the competence of the Department;
- Ensures the timely informing of applicants regarding the need to supplement documentation, as well as the status of files processed within the Department;
- Responsible for preparing and drafting reports related to activities within the competence of the Department;
- Responsible for preparing standard operating procedures within the competence of the Department;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute, and for ensuring compliance with and implementation of such principles and standards within the organisational unit under his/her management;
- Uses work equipment and materials in a purposeful and cost-effective manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;

- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	21
CENTRE FOR MEDICINES AUTHORISATION **DEPARTMENT FOR VARIATIONS**		
(name of the organisational unit)		
EXPERT ASSOCIATE I FOR VARIATIONS		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural or technical-technological field	
Work experience	5 years of experience in activities within the competence of the Department	
Completed traineeship	NO	
Prior knowledge assessment	YES	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Specialised expertise and independence in work	
Other requirements	Successful completion of professional examination for work in state administration bodies; Advanced knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes tasks assigned by the Managing director, the Head of the Centre, and the Head of the Department;
- Responsible for independently performing the most complex activities in procedures within the competence of the Department, including assessment of documentation and monitoring of deadlines, as well as supervising the work of other employees within the Department;
- Responsible for preparing notifications to applicants regarding the need to supplement documentation;
- Responsible for entering parameters into the Institute's information system, as well as updating master data on medicinal products in the Institute's information system in accordance with the approved variation;
- Responsible for preparing and issuing official acts and documents in procedures within the competence of the Department;
- Prepares minutes from meetings of commissions for activities within the competence of the Centre;
- Prepares notifications for applicants following meetings of commissions within the competence of the Centre;
- Proposes continuous training activities for employees within the Department and participates in the training of lower-level employees;
- Proposes improvements and revisions to standard operating procedures within the competence of the Department;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute;
- Uses work equipment and materials in a purposeful and cost-effective manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	22
CENTRE FOR MEDICINES AUTHORISATION **DEPARTMENT FOR VARIATIONS**		
(name of the organisational unit)		
EXPERT ASSOCIATE II FOR VARIATIONS		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural or technical-technological field	
Work experience	3 years of experience in activities within the competence of the Department	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Specialised expertise and independence in work	
Other requirements	Successful completion of professional examination for work in state administration bodies; knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes the orders ofthe Managing director, the Head of the Centre, and the Head of the Department;
- Responsible for independently performing complex activities in procedures within the competence of the Department, including assessment of documentation and monitoring of deadlines;
- Responsible for preparing notifications to applicants regarding the need to supplement documentation;
- Responsible for entering master data on medicinal products into the Institute's information system, as well as updating master data on medicinal products in the Institute's information system in accordance with the approved variation;
- Responsible for preparing and issuing official acts and documents in procedures within the competence of the Department, under the supervision and control of the Head of the Department and the Head of the Centre;
- Prepares minutes from meetings of commissions for activities within the competence of the Centre;
- Proposes improvements and revisions to standard operating procedures within the competence of the Department;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute;
- Uses work equipment and materials in a purposeful and cost-effective manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	23
CENTRE FOR MEDICINES AUTHORISATION **DEPARTMENT FOR VARIATIONS**		
(name of the organisational unit)		
EXPERT ASSOCIATE III FOR VARIATIONS		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural or technical-technological field	
Work experience	1 year of experience within the competence of the Department	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies		
Other requirements	Successful completion of professional examination for work in state administration bodies; knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes the orders ofthe Managing director, the Head of the Centre, and the Head of the Department;
- Responsible for performing simple tasks in procedures within the competence of the Department, including assessment of documentation and monitoring of deadlines, under the continuous supervision and control of Expert Associates I and II, the Head of the Department, and the Head of the Centre;
- Responsible for preparing notifications to applicants regarding the need to supplement documentation;
- Responsible for updating master data on medicinal products in the Institute's information system for procedures within the competence of the Department, under the supervision and control of Expert Associate I and the Head of the Department;
- Participates in the preparation and issuance of official acts and documents in procedures within the competence of the Department, under the supervision and control of Expert Associate I, the Head of the Department, and the Head of the Centre;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute;
- Uses work equipment and materials in a purposeful and cost-effective manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	24
CENTRE FOR MEDICINES AUTHORISATION **DEPARTMENT FOR VARIATIONS**		
(name of the organisational unit)		
ASSOCIATE FOR VARIATIONS		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural or technical-technological field	
Work experience	1 year of experience in the relevant field	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies		
Other requirements	Successful completion of professional examination for work in state administration bodies; knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Carries out tasks assigned by the Managing director, the Head of the Centre, and the Head of the Department;
- Responsible for performing the simplest tasks in procedures within the competence of the Department, including assessment of documentation and monitoring of deadlines, under the continuous supervision and control of Expert Associates I and II, the Head of the Department, and the Head of the Centre;
- Participates in the preparation of notifications to applicants regarding the need to supplement documentation;
- Participates in the preparation of official acts and documents in procedures within the competence of the Department, under the supervision and control of Expert Associate I, the Head of the Department, and the Head of the Centre;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute;
- Uses work equipment and materials in a purposeful and cost-effective manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	25
CENTRE FOR MEDICINES AUTHORISATION **DEPARTMENT FOR VETERINARY MEDICINAL PRODUCTS**		
(name of the organisational unit)		
HEAD OF THE DEPARTMENT FOR VETERINARY MEDICINAL PRODUCTS		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural or technical-technological field	
Work experience	5 years of experience in activities within the competence of the Department	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Organisational and communication skills	
Other requirements	Successful completion of professional examination for work in state administration bodies; Advanced knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes the orders ofthe Managing director and the Head of the Centre;
- Manages the work of the Department and is responsible for planning, organising, implementing, and controlling business processes within the competence of the Department, and supervises their implementation;
- Responsible for performing the most complex tasks and activities within the competence of the Department;
- Responsible for assigning tasks to associates within the Department and ensuring coordination and cooperation in their execution;
- Ensures that activities within the competence of the Department are carried out in the manner and within the deadlines prescribed by law;
- Responsible for preparing/controlling minutes from meetings of commissions within the competence of the Department;
- Responsible for issuing official acts and documents in procedures within the competence of the Department;
- Proposes and participates in the continuous education of employees within the Department;
- Responsible for preparing/controlling information and documents published on the Institute's web portal within the competence of the Department;
- Responsible for entering parameters necessary for the entry of master data on medicinal products into the Institute's information system, as well as other related parameters;
- Provides guidance for maintaining records of received applications within the competence of the Department;
- Performs/supervises the processing of applications within the competence of the Department;
- Ensures timely informing of applicants regarding the need to supplement documentation, as well as the status of files processed within the Department;
- Responsible for preparing and drafting reports related to activities within the competence of the Department;
- Responsible for preparing standard operating procedures within the competence of the Department;
- Responsible for analysing and processing reports submitted by wholesale distributors on annual requirements, as well as reports on the consumption and import of narcotic drugs and reports on annual requirements for and imports of precursors; preparing quarterly reports on the import/export of narcotic drugs and psychotropic substances and annual reports on the import, export, consumption and annual requirements for narcotic drugs and psychotropic substances; and monitoring the implementation of imports of controlled substances;

- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute, and for ensuring compliance with and implementation of such principles and standards within the organisational unit under his/her management;
- Uses work equipment and materials in a purposeful and cost-effective manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	26
CENTRE FOR MEDICINES AUTHORISATION **DEPARTMENT FOR VETERINARY MEDICINAL PRODUCTS**		
(name of the organisational unit)		
EXPERT ASSOCIATE I FOR REGULATORY AFFAIRS		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural or technical-technological field	
Work experience	5 years of experience in activities within the competence of the Department	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Specialised expertise and independence in work	
Other requirements	Successful completion of professional examination for work in state administration bodies; Advanced knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes the orders ofthe Managing director, the Head of the Centre, and the Head of the Department;
- Responsible for independently performing the most complex activities in procedures within the competence of the Department, including assessment of completeness of the application and the documentation and monitoring of deadlines, as well as supervising the work of other employees within the Department;
- Responsible for preparing notifications to applicants regarding the need to supplement documentation, as well as notifications on the completeness of applications;
- Responsible for entering parameters into the Institute's information system, as well as entering master data on medicinal products into the Institute's information system for procedures within the competence of the Department;
- Responsible for preparing and issuing official acts and documents in procedures within the competence of the Department;
- Prepares minutes from meetings of commissions for activities within the competence of the Department;
- Prepares notifications for applicants following meetings of commissions within the competence of the Department;
- Coordinates the assessment of the acceptability of documentation assessment reports issued by other regulatory authorities (e.g. from centralised, decentralised, and mutual recognition procedures);
- Responsible for the independent assessment and processing of the most complex applications for approvals for the procurement or import of medicinal products that do not have a marketing authorisation;
- Responsible for the independent processing of applications and the issuance of authorisations for the import, export and transit of narcotic drugs and precursors;
- Responsible for analysing and processing reports submitted by wholesale distributors on annual requirements, the consumption and import of narcotic drugs, and the annual requirements for and import of precursors;
- Responsible for processing applications for the issuance of authorisations for the import and export of immunological medicinal products and medicinal products derived from blood and plasma;
- Ensures the issuance of outgoing documents in procedures for issuing certificates required for the export of medicinal products in accordance with WHO recommendations (Certificate of a Pharmaceutical Product - CPP);
- Participates in the preparation of quarterly reports on the import and export of narcotic drugs and psychotropic substances, and annual reports on the import, export, consumption and annual requirements for narcotic drugs, psychotropic substances and precursors;
- Monitors the implementation of imports of controlled substances intended for use in veterinary medicine;

- Proposes continuous training activities for employees within the Department and participates in the training of lower-level employees;
- Proposes improvements and revisions to standard operating procedures within the competence of the Department;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute;
- Uses work equipment and materials in a purposeful and cost-effective manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	27
CENTRE FOR MEDICINES AUTHORISATION **DEPARTMENT FOR VETERINARY MEDICINAL PRODUCTS**		
(name of the organisational unit)		
EXPERT ASSOCIATE II FOR REGULATORY AFFAIRS		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural or technical-technological field	
Work experience	3 years of experience in activities within the competence of the Department	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Specialised expertise and independence in work	
Other requirements	Successful completion of professional examination for work in state administration bodies; knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes the orders ofthe Managing director, the Head of the Centre, and the Head of the Department;
- Responsible for independently performing complex activities in procedures within the competence of the Department, including assessment of completeness of documentation and monitoring of deadlines;
- Responsible for preparing notifications to applicants regarding the need to supplement documentation, for the purpose of determining completeness of applications;
- Responsible for entering master data on medicinal products into the Institute's information system for procedures within the competence of the Department;
- Responsible for preparing and issuing official acts and documents in procedures within the competence of the Department, under the supervision and control of the Head of the Department and the Head of the Centre;
- Prepares minutes from meetings of commissions for activities within the competence of the Department;
- Responsible for the independent assessment and processing of complex applications for approvals for the procurement or import of medicinal products that do not have a marketing authorisation;
- Responsible for the independent processing of applications and the issuance of authorisations for the import, export and transit of narcotic drugs and precursors;
- Responsible for analysing and processing reports submitted by wholesale distributors on annual requirements, the consumption and import of narcotic drugs, and the annual requirements for and import of precursors;
- Responsible for processing applications for the issuance of authorisations for the import and export of immunological medicinal products and medicinal products derived from blood and plasma;
- Ensures the issuance of outgoing documents in procedures for issuing Certificates of a Pharmaceutical Product (CPPs) for the export of medicinal products in accordance with the recommendations of the World Health Organization (WHO);
- Participates in the preparation of quarterly reports on the import and export of narcotic drugs and psychotropic substances, and annual reports on the import, export, consumption, and annual requirements for narcotic drugs, psychotropic substances and precursors;
- Monitors the implementation of imports of controlled substances intended for use in veterinary medicine.
- Proposes improvements and revisions to standard operating procedures within the competence of the Department;
- Proposes continuous training activities for employees within the Department and participates in the training of lower-level employees;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute;

- Uses work equipment and materials in a purposeful and cost-effective manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	28
CENTRE FOR MEDICINES AUTHORISATION **DEPARTMENT FOR VETERINARY MEDICINAL PRODUCTS**		
(name of the organisational unit)		
EXPERT ASSOCIATE III FOR REGULATORY AFFAIRS		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural or technical-technological field	
Work experience	1 year of experience in activities within the competence of the Department	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies		
Other requirements	Successful completion of professional examination for work in state administration bodies; knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office).	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes the orders ofthe Managing director, the Head of the Centre, and the Head of the Department;
- Responsible for performing simple tasks in procedures within the competence of the Department, including assessment of completeness of the documentation and monitoring of deadlines, under the continuous supervision and control of Expert Associates I and II, the Head of the Department, and the Head of the Centre;
- Responsible for preparing notifications to applicants regarding the need to supplement documentation, as well as notifications on completeness of applications;
- Responsible for entering master data on medicinal products into the Institute's information system for procedures within the competence of the Department, under the supervision and control of Expert Associate I and the Head of the Department;
- Processes less complex applications for approvals for the procurement or import of medicinal products that do not have a marketing authorisation, under the supervision of superiors;
- Processes less complex applications for the issuance of authorisations for the import and export of immunological medicinal products and medicinal products derived from blood and plasma, under the supervision of superiors;
- Participates in the issuance of outgoing documents in procedures for issuing Certificates of a Pharmaceutical Product (CPPs) for the export of medicinal products in accordance with the recommendations of the World Health Organization (WHO);
- Participates in entering data on medicinal products for import and export into the application processing system for procedures within his/her area of responsibility;
- Processes less complex applications for authorisations for the import, export and transit of narcotic drugs and precursors under the continuous supervision of superiors;
- Monitors the implementation of imports of controlled substances under the supervision of superiors;
- Participates in analysing and processing reports submitted by wholesale distributors on annual requirements, the consumption and import of narcotic drugs, and the annual requirements for and import of precursors;
- Participates in collecting data for and preparing quarterly reports on the import and export of narcotic drugs and psychotropic substances, and annual reports on the import, export, consumption, and annual requirements for narcotic drugs, psychotropic substances and precursors;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute;
- Uses work equipment and materials in a purposeful and cost-effective manner;

- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	29
CENTRE FOR MEDICINES AUTHORISATION **DEPARTMENT FOR VETERINARY MEDICINAL PRODUCTS**		
(name of the organisational unit)		
ASSOCIATE FOR REGULATORY AFFAIRS		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural or technical-technological field	
Work experience	1 year of experience in the relevant field	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies		
Other requirements	Successful completion of professional examination for work in state administration bodies; knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes the orders ofthe Managing director, the Head of the Centre, and the Head of the Department;
- Responsible for performing the simplest tasks in procedures within the competence of the Department, including assessment of completeness of documentation and monitoring of deadlines, under the continuous supervision and control of Expert Associate I, the Head of the Department, and the Head of the Centre;
- Participates in the preparation of notifications to applicants regarding the need to supplement documentation, for the purpose of determining completeness of applications;
- Participates in the preparation of outgoing acts and documents in procedures related to the transfer and termination of marketing authorisations for medicinal products and the suspension of procedures for granting/renewing marketing authorisations, under control of Expert Associate I, the Head of the Department, and the Head of the Centre;
- Processes less complex applications for approvals for the procurement or import of medicinal products that do not have a marketing authorisation, under training and supervision;
- Processes less complex applications for the issuance of authorisations for the import and export of immunological medicinal products and medicinal products derived from blood and plasma, under training and supervision;
- Participates in the issuance of outgoing documents in procedures for issuing Certificates of a Pharmaceutical Product (CPPs) for the export of medicinal products in accordance with the recommendations of the World Health Organization (WHO);
- Participates in entering master data on medicinal products into the database for compassionate-use import/export, under training and supervision;
- Processes applications for authorisations for the import, export and transit of narcotic drugs and precursors, under training and supervision;
- Monitors the implementation of imports of controlled substances under the supervision of superiors;
- Participates in analysing and processing reports submitted by wholesale distributors on annual requirements, the consumption and import of narcotic drugs, and the annual requirements for and import of precursors;
- Participates in collecting data for and preparing quarterly reports on the import and export of narcotic drugs and psychotropic substances, and annual reports on the import, export, consumption, and annual requirements for narcotic drugs, psychotropic substances and precursors
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute;

- Uses work equipment and materials in a purposeful and cost-effective manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	30
CENTRE FOR MEDICINES AUTHORISATION **DEPARTMENT FOR VETERINARY MEDICINAL PRODUCTS**		
(name of the organisational unit)		
EXPERT ASSOCIATE I FOR SAFETY AND EFFICACY ASSESSMENT		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural or technical-technological field	
Work experience	5 years of experience in activities within the competence of the Department	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Specialised expertise and independence in work	
Other requirements	Successful completion of professional examination for work in state administration bodies; Advanced knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office).	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes orders issued by the Managing Director, the Head of the Centre and the Head of the Department;
- Responsible for independently performing the most complex assessments of documentation on the safety and efficacy of veterinary medicinal products in procedures for the granting, extension/renewal of marketing authorisations and variation, including the preparation of assessment reports, monitoring of deadlines, and supervision of the work of other employees within the Department;
- Responsible for preparing notifications to applicants requesting the submission of supplementary documentation;
- Participates in the preparation of documentation for, and in the work of, committees responsible for matters within the Department's remit;
- Participates in the preparation of minutes of commission meetings relating to matters within the Department's remit;
- Participates in the preparation of notifications to applicants regarding the decisions of commissions within the Department's remit;
- Responsible for assessing the applicability of assessment reports issued by other regulatory authorities (e.g. under the centralised, decentralised and mutual recognition procedures);
- Responsible for assessing and verifying the compliance of the Summary of Product Characteristics (SmPC), Package Leaflet (PL) and labelling with regulatory requirements concerning the safety and efficacy of veterinary medicinal products in procedures for the granting, exteension/renewal of marketing authorisations and variations;
- Prepares and sends documentation to external experts for assessment;
- Proposes continuing professional development activities for Department staff and participates in the training of junior employees;
- Proposes improvements to and revisions of the Department's standard operating procedures;
- Acts in accordance with the Institute's integrity principles and ethical standards;
- Uses work resources and materials in a purposeful, efficient and economical manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements and performs duties in a manner that does not endanger or adversely affect the environment, while safeguarding his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of any significant circumstances that affect or may affect the performance of duties, result in material damage, or impact his/her own safety and health, the safety and health of other employees, or the environment;
- Performs other duties commensurate with his/her qualifications and competencies, in accordance with the law, the Statute, and the general and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	31
CENTRE FOR MEDICINES AUTHORISATION **DEPARTMENT FOR VETERINARY MEDICINAL PRODUCTS**		
(name of the organisational unit)		
EXPERT ASSOCIATE II FOR SAFETY AND EFFICACY ASSESSMENT		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural or technical-technological field	
Work experience	3 years of experience in activities within the competence of the Department	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Specialised expertise and independence in work	
Other requirements	Successful completion of professional examination for work in state administration bodies; Advanced knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes orders issued by the Managing Director, the Head of the Centre and the Head of the Department;
- Responsible for independently performing complex assessments of documentation on the safety and efficacy of veterinary medicinal products in procedures for the granting, extension/renewal of marketing authorisations and variations, including the preparation of assessment reports and monitoring of deadlines;
- Responsible for preparing notifications to applicants requesting the submission of supplementary documentation;
- Participates in the preparation of documentation for, and in the work of, commissions responsible for matters within the Department's remit;
- Participates in the preparation of minutes of commissions meetings relating to matters within the Department's remit;
- Participates in the preparation of notifications to applicants regarding the decisions of commissions within the Department's remit;
- Responsible for assessing the applicability of assessment reports issued by other regulatory authorities (e.g. under the centralised, decentralised and mutual recognition procedures);
- Responsible for assessing and verifying the compliance of the Summary of Product Characteristics (SmPC), Package Leaflet (PIL) and labelling with regulatory requirements concerning the safety and efficacy of veterinary medicinal products in procedures for the granting, extension/renewal of marketing authorisations and variations;
- Prepares and submits documentation to external experts for assessment;
- Proposes training and professional development activities for Department staff;
- Proposes improvements to and revisions of the Department's Standard Operating Procedures (SOPs);
- Acts in accordance with the Institute's integrity principles and ethical standards;
- Uses work resources and materials in a purposeful, efficient and economical manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements and performs duties in a manner that does not endanger or adversely affect the environment, while safeguarding his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of any significant circumstances that affect or may affect the performance of duties, result in material damage, or impact his/her own safety and health, the safety and health of other employees, or the environment;
- Performs other duties commensurate with his/her qualifications and competencies, in accordance with the law, the Statute, and the general and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	32
CENTRE FOR MEDICINES AUTHORISATION **DEPARTMENT FOR VETERINARY MEDICINAL PRODUCTS**		
(name of the organisational unit)		
EXPERT ASSOCIATE III FOR SAFETY AND EFFICACY ASSESSMENT		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural or technical-technological field	
Work experience	1 year of experience in activities within the competence of the Department	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Specialised expertise and independence in work	
Other requirements	Successful completion of professional examination for work in state administration bodies; knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes orders issued by the Managing Director, the Head of the Centre and the Head of the Department;
- Responsible for performing less complex assessments of documentation on the safety and efficacy of veterinary medicinal products in procedures for the granting, extension/renewal of marketing authorisations and variations, including the preparation of assessment reports and monitoring of deadlines, under the continuous supervision and review of Expert Associate I, the Head of the Department and the Head of the Centre;
- Participates in the preparation of notifications to applicants requesting the submission of supplementary documentation;
- Responsible for assessing and verifying the compliance of the Summary of Product Characteristics (SmPC), Package Leaflet (PIL) and labelling with regulatory requirements concerning the safety and efficacy of veterinary medicinal products in procedures for the granting, extension/renewal of marketing authorisations and variations;
- Prepares and submits documentation for assessment to experts from the list of experts established by the Institute;
- Acts in accordance with the Institute's integrity principles and ethical standards;
- Uses work resources and materials in a purposeful, efficient and economical manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements and performs duties in a manner that does not endanger or adversely affect the environment, while safeguarding his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of any significant circumstances that affect or may affect the performance of duties, result in material damage, or impact his/her own safety and health, the safety and health of other employees, or the environment;
- Performs other duties commensurate with his/her qualifications and competencies, in accordance with the law, the Statute, and the general and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	33
CENTRE FOR MEDICINES AUTHORISATION **DEPARTMENT FOR VETERINARY MEDICINAL PRODUCTS**		
(name of the organisational unit)		
ASSOCIATE FOR SAFETY AND EFFICACY ASSESSMENT		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural or technical-technological field	
Work experience	1 year of professional experience	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies		
Other requirements	Successful completion of professional examination for work in state administration bodies; knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office).	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes orders issued by the Managing Director, the Head of the Centre and the Head of the Department;
- Responsible for performing the least complex assessments of documentation on the safety and efficacy of veterinary medicinal products in procedures for the granting, extension/renewal of marketing authorisations and variations, under the continuous supervision and review of Expert Associate I, the Head of the Department and the Head of the Centre;
- Participates in the assessment and verification of the compliance of the Summary of Product Characteristics (SmPC), Package Leaflet (PIL) and labelling with regulatory requirements concerning the safety and efficacy of veterinary medicinal products in procedures for the granting, extension/renewal of marketing authorisations and variations;
- Participates in the preparation of documentation for assessment by experts from the list of experts established by the Institute;
- Acts in accordance with the Institute's integrity principles and ethical standards;
- Uses work resources and materials in a purposeful, efficient and economical manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements and performs duties in a manner that does not endanger or adversely affect the environment, while safeguarding his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of any significant circumstances that affect or may affect the performance of duties, result in material damage, or impact his/her own safety and health, the safety and health of other employees, or the environment;
- Performs other duties commensurate with his/her qualifications and competencies, in accordance with the law, the Statute, and the general and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	34
CENTRE FOR MEDICINES AUTHORISATION DEPARTMENT FOR CLINICAL TRIALS AND MEDICINES SAFETY AND EFFICACY ASSESSMENT		
(name of the organisational unit)		
HEAD OF THE DEPARTMENT FOR CLINICAL TRIALS AND MEDICINES SAFETY AND EFFICACY ASSESSMENT		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural or technical-technological field	
Work experience	5 years of experience in activities within the competence of the Department	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Organisational and communication skills	
Other requirements	Successful completion of professional examination for work in state administration bodies; Advanced knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes the orders ofthe Managing director and the Head of the Centre;
- Manages the work of the Department and is responsible for planning, organising, implementing, and controlling business processes within the competence of the Department, and supervises their implementation;
- Responsible for performing the most complex tasks and activities within the competence of the Department;
- Performs statistical processing, analysis and interpretation of data related to the activities and processes within the Department's remit;
- Responsible for assigning tasks to associates within the Department and ensuring coordination and cooperation in their execution;
- Ensures that activities within the competence of the Department are carried out in the manner and within the deadlines prescribed by law;
- Responsible for controlling minutes from meetings of commissions within the competence of the Department;
- Responsible for issuing official acts and documents in procedures within the competence of the Department;
- Proposes and participates in the continuous education of employees within the Department;
- Responsible for preparing/controlling information and documents published on the Institute's web portal within the competence of the Department;
- Controls entering master data on clinical trials/non-interventional studies/import authorisations for investigational medicinal products into the Institute's information system;
- Provides guidance for maintaining records of received applications within the competence of the Department;
- Supervises the processing of applications within the competence of the Department;
- Ensures timely informing of applicants regarding the need to supplement documentation, as well as the status of files processed within the Department;
- Responsible for preparing and drafting reports related to activities within the competence of the Department;
- Responsible for preparing and reviewing standard operating procedures within the competence of the Department;
- Participates in the conduct of inspections of clinical trials approved by the Institute in accordance with the Law, the Rulebook on Clinical Trials, and the Good Clinical Practice Guidelines;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute, and for ensuring compliance with and implementation of such principles and standards within the organisational unit under his/her management;

- Uses work equipment and materials in a purposeful and cost-effective manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	35
CENTRE FOR MEDICINES AUTHORISATION DEPARTMENT FOR CLINICAL TRIALS AND MEDICINES, SAFETY AND EFFICACY ASSESSMENT		
(name of the organisational unit)		
COORDINATOR IN THE DEPARTMENT FOR CLINICAL TRIALS AND MEDICINES SAFETY AND EFFICACY ASSESSMENT		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural or technical-technological field	
Work experience	3 years of work experience in activities within the competence of the Department	
Completed traineeship	NO	
Prior knowledge assessment	YES	
Special health requirements	NO	
Required daily working hours	8 hours	
Competencies	Organisational and communication skills	
Other requirements	Successful completion of professional examination for work in state administration bodies; Advanced knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes the orders ofthe Managing director, the Head of the Centre, and the Head of the Department;
- In agreement with the Head of the Department, coordinates the implementation of business processes within the competence of the Department and participates in their planning, organisation, and supervision;
- Responsible for assigning tasks to associates within the Department and ensuring coordination and cooperation in their execution;
- Performs statistical processing, analysis and interpretation of data related to the activities and processes within the Department's remit;
- Responsible for controlling minutes from meetings of commissions within the competence of the Department;
- Responsible for issuing official acts and documents in procedures within the competence of the Department;
- Proposes and participates in the education of employees within the Department;
- Responsible for entering master data on clinical trials/non-interventional studies/import authorisations for investigational medicinal products into the Institute's information system;
- Responsible for the assessment of the documentation for clinical trials;
- Carries out administrative-technical tasks for the need of Ethics committee in accordance with the law;
- Provides guidance for maintaining records of received applications within the competence of the Department;
- Supervises the processing of applications within the competence of the Department;
- Ensures the timely informing of applicants regarding the need to supplement documentation, as well as the status of files processed within the Department;
- Responsible for the assessment and verification of compliance of the Summary of Product Characteristics, Package Leaflet, and outer and inner packaging text of medicinal products (SmPC, PIL, labelling) with regard to data on the safety and efficacy of medicinal products in procedures for granting and renewing marketing authorisations;
- Responsible for preparing and drafting reports related to activities within the competence of the Department;
- Participates in the preparation and revision of standard operating procedures within the Department's remit;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute;
- Uses work equipment and materials in a purposeful and cost-effective manner;

- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	36
CENTRE FOR MEDICINES AUTHORISATION DEPARTMENT FOR CLINICAL TRIALS AND MEDICINES SAFETY AND EFFICACY ASSESSMENT		
(name of the organisational unit)		
EXPERT ASSOCIATE I FOR CLINICAL TRIALS AND MEDICINES SAFETY AND EFFICACY ASSESSMENT		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural or technical-technological field	
Work experience	5 years of experience in activities within the competence of the Department	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Specialised expertise and independence in work	
Other requirements	Successful completion of professional examination for work in state administration bodies; Advanced knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes the orders ofthe Managing director, the Head of the Centre, and the Head of the Department;
- Responsible for independently performing the most complex activities related to the assessment of pre-clinical and clinical documentation for the granting, renewal of marketing authorisations and variation, including preparation of assessment reports and monitoring of deadlines, as well as supervising the work of other employees within the Department;
- Performs statistical processing, analysis and interpretation of data related to the activities and processes within the Department's remit;
- Responsible for preparing notifications to applicants regarding the need to supplement documentation as an outcome of the assessment of documentation;
- Responsible for preparing data and documentation for the work of the Commission for placing medicinal product on the market;
- Responsible for preparing and issuing official acts and documents in procedures within the competence of the Department;
- Responsible for entering master data on clinical trials/non-interventional studies/import authorisations for investigational medicinal products into the Institute's information system;
- Responsible for the assessment of documentation submitted for clinical trials;
- Performs administrative and technical tasks in support of the Ethics Committee, in accordance with the law;
- Participates in the oversight of clinical trials authorised by the Institute, in accordance with the Law, the Rulebook on Clinical Trials and the Good Clinical Practice (GCP) Guidelines;
- Responsible for the assessment of the Environmental Risk Assessment (ERA);
- Participates in the preparation of notifications for applicants following meetings of commissions within the competence of the Department;
- Responsible for assessing the acceptability of assessment reports on the safety and efficacy documentation issued by other regulatory authorities;
- Responsible for the assessment and verification of compliance of the Summary of Product Characteristics, Package Leaflet, and outer and inner packaging text of medicinal products (SmPC, PIL, labelling) with regard to data on the safety and efficacy of medicinal products in procedures for granting and renewing marketing authorisations and variations;
- Prepares and sends the documentation to external experts for assessment• Proposes continuous training activities for employees within the Department and participates in the training of lower-level employees;
- Proposes improvements and revisions to standard operating procedures within the competence of the Department;

- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute;
- Uses work equipment and materials in a purposeful and cost-effective manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	37
CENTRE FOR MEDICINES AUTHORISATION DEPARTMENT FOR CLINICAL TRIALS AND MEDICINES SAFETY AND EFFICACY ASSESSMENT		
(name of the organisational unit)		
EXPERT ASSOCIATE II FOR CLINICAL TRIALS AND MEDICINES SAFETY AND EFFICACY ASSESSMENT		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural or technical-technological field	
Work experience	3 years of experience in activities within the competence of the Department	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Specialised expertise and independence in work	
Other requirements	Successful completion of professional examination for work in state administration bodies; knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes the orders ofthe Managing director, the Head of the Centre, and the Head of the Department;
- Responsible for independently performing complex activities related to the assessment of pre-clinical and clinical documentation for the granting and renewal of marketing authorisations and variations, including preparation of assessment reports and monitoring of deadlines;
- Performs statistical processing, analysis and interpretation of data related to the activities and processes within the Department's remit;
- Responsible for preparing data and documentation for the work of the Commission for placing medicinal product on the market;
- Responsible for preparing notifications to applicants regarding the need to supplement documentation as an outcome of the substantive assessment of documentation;
- Responsible for preparing and issuing official acts and documents in procedures within the competence of the Department, under the supervision and control of the Head of the Department and the Head of the Centre;
- Responsible for entering master data on clinical trials/non-interventional studies/import authorisations for investigational medicinal products into the Institute's information system;
- Responsible for the assessment of documentation for clinical trials;
- Performs administrative and technical tasks in support of the Ethics Committee, in accordance with the law;
- Responsible for the assessment of the Environmental Risk Assessment (ERA);
- Responsible for the assessment and verification of compliance of the Summary of Product Characteristics, Package Leaflet, and outer and inner packaging text of medicinal products (SmPC, PIL, labelling) with regard to data on the safety and efficacy of medicinal products in procedures for granting and renewing marketing authorisations and variations;
- prepares ation and sends the documentation to external experts in the field within the competence of the Department;
- Proposes continuous training activities for employees within the Department;
- Proposes improvements and revisions to standard operating procedures within the competence of the Department;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute;
- Uses work equipment and materials in a purposeful and cost-effective manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;

- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	38
CENTRE FOR MEDICINES AUTHORISATION DEPARTMENT FOR CLINICAL TRIALS MEDICINES SAFETY AND EFFICACY ASSESSMENT		
(name of the organisational unit)		
EXPERT ASSOCIATE III FOR CLINICAL TRIALS AND MEDICINES SAFETY AND EFFICACY ASSESSMENT		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural or technical-technological field	
Work experience	1 year of experience in activities within the competence of the Department	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies		
Other requirements	Successful completion of professional examination for work in state administration bodies; knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes the orders ofthe Managing director, the Head of the Centre, and the Head of the Department;
- Responsible for performing simple tasks related to the assessment of pre-clinical and clinical documentation for renewal of marketing authorisations and variation, including preparation of assessment reports and monitoring of deadlines, under the continuous supervision and control of Expert Associate I, the Coordinator, the Head of the Department, and the Head of the Centre;
- Participates in the assessment of pre-clinical and clinical documentation in procedures for the granting of marketing authorisations for medicinal products;
- Participates in the statistical processing and analysis of data relating to the activities and processes within the Department's remit;
- Participates in the preparation of data and documentation for the work of the Commission for placing medicinal products onto the market;
- Participates in the preparation of notifications to applicants regarding the need to supplement documentation as an outcome of the substantive assessment of documentation;
- Responsible for entering master data on clinical trials/non-interventional studies/import authorisations for investigational medicinal products into the Institute's information system, under the supervision and control of Expert Associate I and the Head of the Department;
- Participates in the assessment of documentation for clinical trials;
- Performs administrative and technical tasks in support of the Ethics Committee, in accordance with the law;
- Responsible for the assessment of the Environmental Risk Assessment (ERA);
- Responsible for the assessment and verification of compliance of the Summary of Product Characteristics, Package Leaflet, and outer and inner packaging text of medicinal products (SmPC, PIL, labelling) with regard to data on the safety and efficacy of medicinal products in procedures for granting and renewing marketing authorisations and variations;
- Participates in the preparation and submission of documentation to external experts in the field within the competence of the Department;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute;
- Uses work equipment and materials in a purposeful and cost-effective manner;

- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	39
CENTRE FOR MEDICINES AUTHORISATION DEPARTMENT FOR CLINICAL TRIALS AND MEDICINES SAFETY AND EFFICACY ASSESSMENT		
(name of the organisational unit)		
ASSOCIATE FOR CLINICAL TRIALS AND MEDICINES SAFETY AND EFFICACY ASSESSMENT		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural or technical-technological field	
Work experience	1 year of experience in the relevant field	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies		
Other requirements	Successful completion of professional examination for work in state administration bodies; knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes the orders ofthe Managing director, the Head of the Centre, and the Head of the Department;
- Responsible for performing the simplest tasks in the assessment of pre-clinical and clinical documentation in procedures for the renewal of marketing authorisations and variation, under the control of Expertl Associate I , the Coordinator, the Head of the Department, and the Head of the Centre;
- Enters master data on clinical trials/non-interventional studies/import authorisations for investigational medicinal products into the Institute's information system, under the supervision and control of the Coordinator and the Head of the Department;
- Responsible for the verification of compliance of the Summary of Product Characteristics, Package Leaflet, and outer and inner packaging text of medicinal products (SmPC, PIL, labelling) with regard to data on the safety and efficacy of medicinal products in procedures for granting and renewing marketing authorisations and variations;
- Participates in the preparation of documentation for external experts and members of the Institute's commissions;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute;
- Uses work equipment and materials in a purposeful and cost-effective manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	40
CENTRE FOR MEDICINES AUTHORISATION DEPARTMENT FOR CLINICAL TRIALS AND MEDICINES, SAFETY AND EFFICACY ASSESSMENT		
(name of the organisational unit)		
ASSOCIATE FOR UPDATING INFORMATION ON SAFETY AND EFFICACY OF MEDICINES		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural or technical-technological field	
Work experience	1 year of professional experience	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies		
Other requirements	Successful completion of professional examination for work in state administration bodies; knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes orders issued by the Managing Director, the Head of the Centre and the Head of the Department;
- Responsible for performing the least complex tasks within the Department's remit, under the supervision and review of Expert Associates, the Coordinator, the Head of the Department and the Head of the Centre;
- Responsible for verifying the compliance of the Summary of Product Characteristics (SmPC), Package Leaflet (PIL) and the outer and inner packaging labelling with regulatory requirements concerning the safety and efficacy of medicinal products in procedures for the granting and renewal of marketing authorisations and variations;
- Responsible for the technical editing (formatting) of the Summary of Product Characteristics (SmPC), Package Leaflet (PIL) and the outer and inner packaging labelling;
- Responsible for communicating with applicants regarding mutual agreement on amendments to relevant information texts;
- Participates in the preparation of notifications to applicants requesting the submission of supplementary documentation, in coordination with the employees responsible for the assessment of the relevant documentation;
- Acts in accordance with the Institute's integrity principles and ethical standards;
- Uses work resources and materials in a purposeful, efficient and economical manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements and performs duties in a manner that does not endanger or adversely affect the environment, while safeguarding his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of any significant circumstances that affect or may affect the performance of duties, result in material damage, or impact his/her own safety and health, the safety and health of other employees, or the environment;
- Performs other duties commensurate with his/her qualifications and competencies, in accordance with the law, the Statute, and the general and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	41
CENTRE FOR MEDICINES AUTHORISATION DEPARTMENT FOR CLINICAL TRIALS AND MEDICINES, SAFETY AND EFFICACY ASSESSMENT		
(name of the organisational unit)		
EXPERT ASSOCIATE I FOR THE ASSESSMENT OF DOCUMENTATION ON BIOAVAILABILITY AND BIOEQUIVALENCE OF MEDICINAL PRODUCTS		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural or technical-technological field	
Work experience	5 years of experience in activities within the competences of the Department	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Specialised expertise and independence in work	
Other requirements	Successful completion of professional examination for work in state administration bodies; Advanced knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes the orders ofthe Managing director, the Head of the Centre, and the Head of the Department;
- Responsible for independently performing the most complex activities related to the assessment of documentation on bioavailability and bioequivalence of medicinal products, assessment of the justification for requests for waiver of bioequivalence studies (biowaiver), assessment of bridging data, preparation of assessment reports, and monitoring of deadlines, including supervision of the work of other employees within the Department;
- Participates in the oversight of clinical trials authorised by the Institute, in accordance with the Law, the Rulebook on Clinical Trials and the Good Clinical Practice (GCP) Guidelines;
- Responsible for preparing notifications to applicants regarding the need to supplement documentation as an outcome of the substantive assessment of documentation;
- Participates in the preparation of documentation and in the work of commissions for activities within the competence of the Department;
- Responsible for assessing the acceptability of assessment reports issued by other regulatory authorities;
- Responsible for reviewing the compliance of submitted documentation with the proposed type of application for obtaining a marketing authorisation for a medicinal product;
- Responsible for the assessment and verification of compliance of the Summary of Product Characteristics, Package Leaflet, and outer and inner packaging text of medicinal products (SmPC, PIL, labelling) with regard to data on the safety and efficacy of medicinal products in procedures for granting and renewing marketing authorisations and variations;
- Responsible for preparing documentation for submission to external experts;
- Proposes continuous training activities for employees within the Department and participates in the training of lower-level employees;
- Proposes improvements and revisions to standard operating procedures within the competence of the Department;

- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute;
- Uses work equipment and materials in a purposeful and cost-effective manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;

- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	42
CENTRE FOR MEDICINES AUTHORISATION DEPARTMENT FOR CLINICAL TRIALS AND MEDICINES, SAFETY AND EFFICACY ASSESSMENT		
(name of the organisational unit)		
EXPERT ASSOCIATE II FOR THE ASSESSMENT OF DOCUMENTATION ON BIOAVAILABILITY AND BIOEQUIVALENCE OF MEDICINAL PRODUCTS		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural or technical-technological field	
Work experience	3 years of experience in activities within the competences of the Department	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Specialised expertise and independence in work	
Other requirements	Successful completion of professional examination for work in state administration bodies; knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes the orders ofthe Managing director, the Head of the Centre, and the Head of the Department;
- Responsible for independently performing complex activities related to the assessment of documentation on bioavailability and bioequivalence of medicinal products, assessment of the justification for requests for waiver of bioequivalence studies (biowaiver), assessment of bridging data, preparation of assessment reports, and monitoring of deadlines;
- Responsible for preparing notifications to applicants regarding the need to supplement documentation as an outcome of the assessment of documentation;
- Participates in the preparation of notifications for applicants following meetings of commissions within the competence of the Department;
- Responsible for assessing the acceptability of assessment reports issued by other regulatory authorities;
- Responsible for reviewing the compliance of submitted documentation with the proposed type of application for obtaining a marketing authorisation for a medicinal product;
- Responsible for the assessment and verification of compliance of the Summary of Product Characteristics, Package Leaflet, and outer and inner packaging text of medicinal products (SmPC, PIL, labelling) with regard to data on the safety and efficacy of medicinal products in procedures for granting and renewing marketing authorisations and variations;
- Responsible for preparing documentation for submission to external experts;
- Proposes continuous training activities for employees within the Department;
- Proposes improvements and revisions to standard operating procedures within the competence of the Department;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute;
- Uses work equipment and materials in a purposeful and cost-effective manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	43
CENTRE FOR MEDICINES AUTHORISATION DEPARTMENT FOR CLINICAL TRIALS AND MEDICINES, SAFETY AND EFFICACY ASSESSMENT		
(name of the organisational unit)		
EXPERT ASSOCIATE III FOR THE ASSESSMENT OF DOCUMENTATION ON BIOAVAILABILITY AND BIOEQUIVALENCE OF MEDICINAL PRODUCTS		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural or technical-technological field	
Work experience	1 year of experience in activities within competences of the Department	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies		
Other requirements	Successful completion of professional examination for work in state administration bodies; Advanced knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes the orders ofthe Managing director, the Head of the Centre, and the Head of the Department;
- Responsible for performing simple tasks related to the assessment of documentation on bioavailability and bioequivalence of medicinal products, assessment of the justification for requests for waiver of bioequivalence studies (biowaiver), assessment of bridging data, preparation of assessment reports, and monitoring of deadlines, under control of Expert Associate I, the Coordinator, the Head of the Department, and the Head of the Centre;
- Participates in the preparation of notifications to applicants regarding the need to supplement documentation as an outcome of theassessment of documentation;
- Participates in the assessment of the acceptability of assessment reports issued by other regulatory authorities;
- Participates in reviewing the compliance of submitted documentation with the proposed type of application for obtaining a marketing authorisation for a medicinal product;
- Responsible for the assessment and verification of compliance of the Summary of Product Characteristics, Package Leaflet, and outer and inner packaging text of medicinal products (SmPC, PIL, labelling) with regard to data on the safety and efficacy of medicinal products in procedures for granting and renewing marketing authorisations and variations;
- Participates in the preparation and submission of documentation to external experts;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute;
- Uses work equipment and materials in a purposeful and cost-effective manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	44
CENTRE FOR MEDICINES AUTHORISATION DEPARTMENT FOR CLINICAL TRIALS AND MEDICINES, SAFETY AND EFFICACY ASSESSMENT		
(name of the organisational unit)		
ASSOCIATE FOR THE ASSESSMENT OF DOCUMENTATION ON BIOAVAILABILITY AND BIOEQUIVALENCE OF MEDICINAL PRODUCTS		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural or technical-technological field	
Work experience	1 year of experience in the relevant field	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies		
Other requirements	Successful completion of professional examination for work in state administration bodies; knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes the orders ofthe Managing director, the Head of the Centre, and the Head of the Department;
- Responsible for performing the simplest tasks in procedures within the Department's remit under the control of Expert Associate I , the Coordinator, the Head of the Department, and the Head of the Centre;
- Participates in the assessment of the acceptability of assessment reports issued by other regulatory authorities relating to the bioavailability and bioequivalence of medicinal products, assessment of the justification for requests for a biowaiver, and assessment of bridging data;
- Participates in the assessment and verification of compliance of the Summary of Product Characteristics, Package Leaflet, and outer and inner packaging text of medicinal products (SmPC, PIL, labelling) with regard to data on the safety and efficacy of medicinal products in procedures for granting and renewing marketing authorisations and variations;
- Participates in the preparation and submission of documentation to external experts
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute;
- Uses work equipment and materials in a purposeful and cost-effective manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	45
CENTRE FOR MEDICINES AUTHORISATION DEPARTMENT FOR CLINICAL TRIALS AND MEDICINES SAFETY AND EFFICACY ASSESSMENT		
(name of the organisational unit)		
EXPERT ASSOCIATE FOR BIOSTATISTICS AND DATA ANALYSIS		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural or technical-technological field	
Work experience	5 years of experience in activities within the competence of the Department	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Specialised expertise and independence in work	
Other requirements	Successful completion of professional examination for work in state administration bodies; Advanced knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes orders issued by the Managing Director, the Head of the Centre and the Head of the Department;
- Independently performs professional duties in the fields of biostatistics, statistical evaluation and regulatory assessment of medicinal products and medical devices, in accordance with the general and specific instructions of the immediate supervisor;
- Performs statistical evaluation of data from clinical trials, non-interventional studies and other medical and pharmaceutical documentation in procedures for the granting and renewal of marketing authorisations, variations and pharmacovigilance activities;
- Participates in the preparation of expert opinions, assessment reports and evaluations in the field of biostatistics;
- Participates in the assessment of clinical trial methodology, statistical analysis plans, data analysis and the interpretation of clinical study results;
- Participates in scientific advice and regulatory support related to the design of pre-clinical and clinical studies and the statistical aspects of medicinal product development;
- Participates in the assessment of the benefit-risk ratio of medicinal products from the perspective of statistical analysis and interpretation of data;
- Participates in the assessment and analysis of pharmacovigilance data, including signal detection;
- Cooperates with internal and external experts, regulatory authorities, international institutions and working bodies of international organisations;
- Participates in the preparation, alignment and implementation of European Union and international legislation, guidelines and standards within the scope of the Department's activities;
- Monitors developments in statistical methodologies, regulatory requirements and scientific advances in the fields of biostatistics and clinical evaluation;
- Participates in study design, statistical processing, analysis and interpretation of data for scientific research conducted by the Institute's employees, including the preparation of scientific publications and doctoral dissertations;
- Participates in the statistical processing and analysis of data within the Institute's scientific research activities;
- Performs duties in accordance with the Institute's Quality Management System and the requirements for data protection and confidentiality of information;
- Responsible for preparing reports relating to activities within his/her area of responsibility;
- Responsible for the preparation and revision of standard operating procedures within his/her area of responsibility;

- Acts in accordance with the Institute's integrity principles and ethical standards and ensures their observance and implementation;
- Uses work resources and materials in a purposeful, efficient and economical manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements and performs duties in a manner that does not endanger or adversely affect the environment, while safeguarding his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of any significant circumstances that affect or may affect the performance of duties, result in material damage, or impact his/her own safety and health, the safety and health of other employees, or the environment;
- Performs other duties commensurate with his/her qualifications and competencies, in accordance with the law, the Statute, and the general and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	46
CENTRE FOR MEDICINES AUTHORISATION **QUALITY ASSESSMENT DEPARTMENT**		
(name of the organisational unit)		
HEAD OF THE QUALITY ASSESSMENT DEPARTMENT		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural or technical-technological field	
Work experience	5 years of experience in activities within the competence of the Department	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Organisational and communication skills	
Other requirements	Successful completion of professional examination for work in state administration bodies; Advanced knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes the orders ofthe Managing director and the Head of the Centre;
- Manages the work of the Department and is responsible for planning, organising, implementing, and controlling business processes within the competence of the Department, and supervises their implementation;
- Responsible for performing the most complex tasks and activities within the competence of the Department;
- Responsible for assigning tasks to associates within the Department and ensuring coordination and cooperation in their execution;
- Ensures that activities within the competence of the Department are carried out in the manner and within the deadlines prescribed by law;
- Responsible for preparing/controlling minutes from meetings of commissions within the competence of the Department;
- Responsible for issuing official acts and documents in procedures within the competence of the Department;
- Proposes and participates in the continuous education of employees within the Department;
- Responsible for preparing/controlling information and documents published on the Institute's web portal within the competence of the Department;
- Provides guidance for maintaining records of received applications within the competence of the Department;
- Supervises the processing of applications within the competence of the Department;
- Ensures the timely informing of applicants regarding the need to supplement documentation, as well as the status of files processed within the Department;
- Participates in planning, coordinatingand supervising the execution of expert and operational activities related to the assessment of quality defects/falsified medicinal products;
- Participates in decision-making related to risk minimisation measures (e.g. medicinal product alerts, Direct Healthcare Professional Communications (DHPCs), etc.) in procedures concerning medicinal product quality defects;
- Responsible for preparing and drafting reports related to activities within the competence of the Department;
- Responsible for preparing and revising standard operating procedures within the competence of the Department;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute, and for ensuring compliance with and implementation of such principles and standards within the organisational unit under his/her management;
- Uses work equipment and materials in a purposeful and cost-effective manner;

- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	47
CENTRE FOR MEDICINES AUTHORISATION **QUALITY ASSESSMENT DEPARTMENT**		
(name of the organisational unit)		
COORDINATOR IN THE QUALITY ASSESSMENT DEPARTMENT		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural or technical-technological field	
Work experience	3 years of experience in activities within the competence of the Department	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Organisational and communication skills	
Other requirements	Successful completion of professional examination for work in state administration bodies; Advanced knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes the orders ofthe Managing director, the Head of the Centre, and the Head of the Department;
- In agreement with the Head of the Department, coordinates the implementation of business processes within the competence of the Department and participates in their planning, organisation, and supervision;
- Responsible for assigning tasks to associates within the Department and ensuring coordination and cooperation in their execution;
- Responsible for independently performing the most complex tasks and activities within the competence of the Department;
- Ensures that activities within the competence of the Department are carried out in the manner and within the deadlines prescribed by law;
- Responsible for preparing/controlling minutes from meetings of commissions within the competence of the Department;
- Responsible for issuing official acts and documents in procedures within the competence of the Department;
- Proposes and participates in the continuous education of employees within the Department;
- Responsible for preparing/controlling information and documents published on the Institute's web portal within the competence of the Department;
- Provides guidance for maintaining records of received applications within the competence of the Department;
- Supervises the processing of applications within the competence of the Department;
- Ensures timely informing of applicants regarding the need to supplement documentation, as well as the status of files processed within the Department;
- Participates in planning, coordinating, and supervising the execution of expert and operational activities related to the assessment of quality defects/falsified medicinal products;
- Responsible for preparing and drafting reports related to activities within the competence of the Department;
- Participates in preparing and revising standard operating procedures within the competence of the Department;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute,;
- Uses work equipment and materials in a purposeful and cost-effective manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;

- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	48
CENTRE FOR MEDICINES AUTHORISATION **QUALITY ASSESSMENT DEPARTMENT**		
(name of the organisational unit)		
EXPERT ASSOCIATE I FOR QUALITY ASSESSMENT OF MEDICINAL PRODUCTS		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural or technical-technological field	
Work experience	5 years of experience in activities within the competence of the Department	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Specialised expertise and independence in work	
Other requirements	Successful completion of professional examination for work in state administration bodies; Advanced knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes the orders ofthe Managing director, the Head of the Centre and the Head of the Department;
- Responsible for independently performing the most complex activities related to the assessment of medicinal product for human use and veterinary medicinal product quality documentation in procedures for granting and renewing marketing authorisations and variations, including preparation of assessment reports and monitoring of deadlines, as well as supervising the work of other employees within the Department;
- Responsible for preparing notifications to applicants regarding the need to supplement documentation as an outcome of the assessment of documentation;
- Responsible for the assessment of the pharmaceutical part of the Summary of Product Characteristics, Package Leaflet, and labelling of medicinal products (SmPC, PIL, labelling) in procedures for granting and renewing marketing authorisations and variations;
- Responsible for assessing the applicability of assessment reports issued by other regulatory authorities;
- Responsible for carrying out expert and operational activities related to the assessment of medicinal product quality defects, including assessment of documentation related to reports of suspected quality defects and evaluation of risks to patients;
- Participates in decision-making on the recall of disputed medicinal product batches from the market;
- Participates in activities related to decision-making on risk minimisation measures (e.g. medicinal product alerts, Direct Healthcare Professional Communications, etc.) in procedures for the assessment of medicinal product quality defects;
- Participates in documentation-based quality control of medicinal products on the market;
- Participates in the preparation of documentation and in the work of commissions for activities within the competence of the Department;
- Responsible for preparing and submitting documentation to external experts in the field within the competence of the Department;
- Proposes continuous training activities for employees within the Department and participates in the training of lower-level employees;
- Proposes improvements and revisions to standard operating procedures within the competence of the Department;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute;
- Uses work equipment and materials in a purposeful and cost-effective manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;

- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	49
CENTRE FOR MEDICINES AUTHORISATION **QUALITY ASSESSMENT DEPARTMENT**		
(name of the organisational unit)		
EXPERT ASSOCIATE II FOR QUALITY ASSESSMENT OF MEDICINAL PRODUCTS		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural or technical-technological field	
Work experience	3 years of experience in activities within the competence of the Department	
Completed traineeship	NO	
Prior knowledge assessment	YES	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Specialised expertise and independence in work	
Other requirements	Successful completion of professional examination for work in state administration bodies; knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes the orders ofthe Managing director, the Head of the Centre, and the Head of the Department;
- Responsible for independently performing complex activities related to the assessment of medicinal product for human use and veterinary medicinal product quality documentation in procedures for granting and renewing marketing authorisations and variations, including preparation of assessment reports and monitoring of deadlines, under the supervision and control of Expert Associate I, the Head of the Department, and the Head of the Centre;
- Responsible for preparing notifications to applicants regarding the need to supplement documentation as an outcome of the assessment of documentation;
- Responsible for the assessment of the pharmaceutical part of the Summary of Product Characteristics, Package Leaflet, and labelling of medicinal products (SmPC, PIL, labelling) in procedures for granting and renewing marketing authorisations and variations;
- Responsible for assessing the applicability of assessment reports issued by other regulatory authorities;
- Participates in carrying out expert and operational activities related to the assessment of medicinal product quality defects, including assessment of documentation related to reports of suspected quality defects and evaluation of risks to patients;
- Participates in activities related to decision-making on risk minimisation measures (e.g. medicinal product alerts, Direct Healthcare Professional Communications, etc.) in procedures for the assessment of medicinal product quality defects;
- Participates in documentation-based quality control of medicinal products placed on the market;
- Participates in the preparation of documentation for the work of commissions responsible for matters within the Department's remit.
- Responsible for preparing and submitting documentation to external experts in the field within the competence of the Department;
- Proposes continuous training activities for employees within the Department and participates in the training of lower-level employees;
- Proposes improvements and revisions to standard operating procedures within the competence of the Department;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute;
- Uses work equipment and materials in a purposeful and cost-effective manner;

- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	50
CENTRE FOR MEDICINES AUTHORISATION **QUALITY ASSESSMENT DEPARTMENT**		
(name of the organisational unit)		
EXPERT ASSOCIATE III FOR QUALITY ASSESSMENT DEPARTMENT		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural or technical-technological field	
Work experience	1 year experience in activities within the competence of the Department	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies		
Other requirements	Successful completion of professional examination for work in state administration bodies; knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes the orders ofthe Managing director, the Head of the Centre, and the Head of the Department;
- Responsible for performing activities related to the assessment of medicinal product for human use and veterinary medicinal product quality documentation in procedures for granting and renewing marketing authorisations and variations, including preparation of assessment reports and monitoring of deadlines, under the supervision and control of Expert Associates I and II, the Coordinator, the Head of the Department, and the Head of the Centre;
- Participates in the preparation of notifications to applicants regarding the need to supplement documentation as an outcome of the assessment of documentation;
- Responsible for the assessment of the pharmaceutical part of the Summary of Product Characteristics, Package Leaflet, and labelling of medicinal products (SmPC, PIL, labelling) in procedures for granting and renewing marketing authorisations and variations;
- Participates in assessing the applicability of assessment reports issued by other regulatory authorities;
- Participates in the preparation of the documentation for commissions activities within the competence of the Department;
- Participates in the preparation of notifications for applicants following meetings of commissions within the competence of the Department;
- Participates in documentation-based quality control of medicinal products placed on the market, under the supervision and control of the Expert Associate I, the Coordinator, the Head of the Department and the Head of the Centre;
- Responsible for the preparation and sending of documentation to external experts in the field within the competence of the Department;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute;
- Uses work equipment and materials in a purposeful and cost-effective manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	51
CENTRE FOR MEDICINES AUTHORISATION **QUALITY ASSESSMENT DEPARTMENT**		
(name of the organisational unit)		
ASSOCIATE FOR QUALITY ASSESSMENT OF MEDICINAL PRODUTS		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural or technical-technological field	
Work experience	1 year of experience in the relevant field	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies		
Other requirements	Successful completion of professional examination for work in state administration bodies; knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes the orders ofthe Managing director, the Head of the Centre, and the Head of the Department;
- Responsible for performing simple tasks in procedures within the competence of the Department, including assessment of medicinal product for human use and veterinary medicinal product quality documentation and monitoring of deadlines, under the continuous supervision and control of Expert Associate I , the Coordinator, the Head of the Department, and the Head of the Centre;
- Participates in assessing the applicability of assessment reports issued by other regulatory authorities;
- Participates in the assessment of the pharmaceutical part of the Summary of Product Characteristics, Package Leaflet, and labelling of medicinal products (SmPC, PIL, labelling) in procedures for granting and renewing marketing authorisations and variations;
- Participates in the preparation and submission of documentation to external experts in the field within the competence of the Department;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute;
- Uses work equipment and materials in a purposeful and cost-effective manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	52
CENTRE FOR MEDICINES AUTHORISATION **QUALITY ASSESSMENT DEPARTMENT**		
(name of the organisational unit)		
SENIOR ASSOCIATE FOR QUALITY DEFECT MANAGEMENT AND SUPPORT FOR THE MEDICINES QUALITY ASSESSMENT		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VI/VII	
Level of educational and professional qualifications	University degree, qualification comprising 180, 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 3, 4 or 3+1 or 3+2 years). Completed studies in medical, natural or technical-technological field	
Work experience	1 year of experience in activities within the competence of the Department	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Specialised expertise and independence in work	
Other requirements	Successful completion of professional examination for work in state administration bodies; knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes orders issued by the Managing Director, the Head of the Centre and the Head of the Department;
- Responsible for the receipt, administrative processing and initial evaluation of reports of medicinal product quality defects, including the collection of relevant information;
- Responsible for recording and continuously monitoring reports of quality defects through the Institute's Information System;
- Responsible for managing documentation relating to quality defect reports, including archiving, updating, and ensuring the traceability of all activities and communications;
- Responsible for receiving, processing and distributing notifications received through the Rapid Alert Network (RAN), as well as information on serious non-compliance identified during Good Manufacturing Practice (GMP) inspections;
- Responsible for coordinating and communicating with the Quality Defect Working Group, including the timely forwarding of reports, collection of feedback and monitoring the implementation of follow-up activities;
- Responsible for maintaining complete records of communications with reporters, manufacturers, marketing authorisation holders and other relevant stakeholders, ensuring full documentation and traceability;
- Participates in documentation-based quality control of medicinal products placed on the market;
- Participates in the preparation and distribution of notifications, official correspondence and other documents relating to quality defect reports, in accordance with the instructions of supervisors and assessors;
- Coordinates the receipt of Active Substance Master File (ASMF) documentation, including providing instructions to the registry office regarding its registration in the Institute's Information System;
- Communicates with ASMF holders regarding the submission, supplementation and validation of documentation;
- Maintains records of received ASMF documentation, its status and availability to assessors;
- Provides operational support to assessors, the Coordinator and the Head of the Department in organising and implementing quality assessment procedures;
- Responsible for preparing and submitting documentation to external experts for assessment, and for monitoring deadlines and the receipt of assessment reports;
- Participates in the preparation of internal reports, reviews and analyses relating to quality defect reports and the Department's activities;
- Performs administrative, technical and operational tasks to ensure the efficient functioning of quality assessment procedures and quality defect management processes;
- Acts in accordance with the Institute’s integrity principles and ethical standards;
- Uses work resources and materials in a purposeful, efficient and economical manner;

- Ensures compliance with occupational health and safety regulations and environmental protection requirements and performs duties in a manner that does not endanger or adversely affect the environment, while safeguarding his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of any significant circumstances that affect or may affect the performance of duties, result in material damage, or impact his/her own safety and health, the safety and health of other employees, or the environment;
- Performs other duties commensurate with his/her qualifications and competencies, in accordance with the law, the Statute, and the general and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	53
CENTRE FOR MEDICINES AUTHORISATION **QUALITY ASSESSMENT DEPARTMENT**		
(name of the organisational unit)		
ASSOCIATE FOR QUALITY DEFECTS MANAGEMENT AND SUPPORT FOR THE MEDICINES QUALITY ASSESSMENT		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VI/VII	
Level of educational and professional qualifications	University degree, qualification comprising 180, 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural or technical-technological field	
Work experience	1 year of experience in relevant field	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies		
Other requirements	Successful completion of professional examination for work in state administration bodies; knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes orders issued by the Managing Director, the Head of the Centre and the Head of the Department;
- Participates in the receipt and administrative processing of reports of medicinal product quality defects, under the supervision and guidance of superiors;
- Participates in recording quality defect reports in the Institute's Information System, subject to verification by an Expert Associate;
- Participates in the collection and organisation of documentation relating to quality defect reports;
- Participates in the technical processing of notifications received through the Rapid Alert Network (RAN), under supervision;
- Participates in the preparation of documentation for the Quality Defect Working Group, under the supervision and guidance of superiors;
- Participates in documentation-based quality control of medicinal products placed on the market, under the supervision and review of Expert Associate I, the Coordinator, the Head of the Department and the Head of the Centre;
- Participates in maintaining records and archiving documentation in accordance with the instructions provided;
- Participates in the preparation of more simple draft correspondence and notifications documents, under supervision;
- Participates in the receipt and registration of Active Substance Master File (ASMF) documentation in the Institute's Information System, under supervision;
- Participates in maintaining records of ASMF documentation and its status;
- Provides administrative and technical support to assessors and other employees of the Department, under supervision;
- Participates in the preparation of documentation for submission to external experts for assessment;
- Acts in accordance with the Institute's integrity principles and ethical standards;
- Uses work resources and materials in a purposeful, efficient and economical manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements and performs duties in a manner that does not endanger or adversely affect the environment, while safeguarding his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of any significant circumstances that affect or may affect the performance of duties, result in material damage, or impact his/her own safety and health, the safety and health of other employees, or the environment;
- Performs other duties commensurate with his/her qualifications and competencies, in accordance with the law, the Statute, and the general and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	54
CENTRE FOR MARKET AFFAIRS AND SAFE USE OF MEDICINES		
(name of the organisational unit)		
HEAD OF THE CENTRE FOR MARKET AFFAIRS AND SAFE USE OF MEDICINES		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural, or technical-technological field	
Work experience	5 years of experience in activities within the competence of the Centre	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Organisational and communication skills	
Other requirements	Successful completion of professional examination for work in state administration bodies; Advanced knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		
DUTIES OF THE POSITION		

- Executes the orders ofthe Managing director;
- Manages the work of the Centre and is responsible for planning, organising, implementing, and controlling business processes within the competence of the Centre, and supervises their implementation;
- Responsible for performing the most complex tasks and activities within the competence of the Centre;
- Responsible for assigning tasks to associates within the Centre and ensuring coordination and cooperation in their execution;
- Responsible for organising and participating in the continuous education of employees within the Centre;
- Responsible for preparing/controlling information and documents published on the Institute's web portal within the competence of the Centre;
- Supervises the issuance of official acts and documents in procedures within the competence of the Centre;
- Responsible for minutes from meetings of commissions within the competence of the Centre;
- Ensures that activities within the competence of the Centre are carried out in the manner and within the deadlines prescribed by law;
- Ensures the accuracy and completeness of records relating to received applications within the competence of the Centre;
- Supervises the processing of applications within the competence of the Centre;
- Supervises activities related to informing applicants about the need to supplement documentation and about the status of files processed within the Centre;
- Supervises the issuance of official acts and documents in procedures within the competence of the Centre;
- Participates in the preparation of expert background materials for drafting correspondence, responses to inquiries, announcements, media statements, and other informational content within the competence of the Centre;
- Responsible for supervising standard operating procedures within the competence of the Centre;
- Responsible for organising and participating in the continuous training of employees within the Centre;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute, and for ensuring compliance with and implementation of such principles and standards within the organisational unit under his/her management;
- Uses work equipment and materials in a purposeful and cost-effective manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	55
CENTRE FOR MARKET AFFAIRS AND SAFE USE OF MEDICINES		
(name of the organisational unit)		
TECHNICAL AFFAIRS OFFICER		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	III/IV1	
Level of educational and professional qualifications	Secondary education, qualification comprising 180 (ECTS) credits (study programme lasting 3 years), or 240 (ECTS) credits (study programme lasting 4 years)	
Work experience	1 year of experience in technical and administrative affairs	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies		
Other requirements	Successful completion of professional examination for work in state administration bodies; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes tasks assigned by the Managing Director and the Head of the Centre;
- Ensures that each document, submission, or file is directed to the appropriate Centre or Department in accordance with its content and the regulatory framework governing medicinal products;
- Performs activities related to the classification, allocation, recording, and distribution of documents according to the specificities of the medicinal products field through file management in the Institute's information system;
- Performs activities related to maintaining the Institute's basic records concerning the receipt of submissions, acts, and other consignments, as well as the dispatch of mail;
- Performs activities related to the classification, allocation, recording, and distribution of documents according to the specificities of the fields of medicinal products and medical devices through file management in the Institute's information system;
- Archives all documentation relating to all departments within the Centre;
- Cooperates with the external archive for the purpose of archiving documentation;
- Performs simple administrative tasks;
- Delivers documentation received at the Registry Office to the respective departments;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute;
- Uses work equipment and materials in a purposeful and cost-effective manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	56
CENTRE FOR MARKET AFFAIRS AND SAFE USE OF MEDICINES **DEPARTMENT FOR PHARMACOVIGILANCE**		
(name of the organisational unit)		
HEAD OF THE DEPARTMENT FOR PHARMACOVIGILANCE		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural, or technical-technological field	
Work experience	5 years of work in activities within the competence of the Department	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Organisational and communication skills	
Other requirements	Successful completion of professional examination for work in state administration bodies; Advanced knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		
DUTIES OF THE POSITION		

- Executes tasks assigned by the Managing director and the Head of the Centre;
- Manages the work of the Department and is responsible for planning, organising, implementing, and controlling business processes within the competence of the Department, and supervises their implementation;
- Responsible for performing the most complex tasks and activities within the competence of the Department;
- Responsible for assigning tasks to associates within the Department and ensuring coordination and cooperation in their execution;
- Ensures that activities within the competence of the Department are carried out in the manner and within the deadlines prescribed by law;
- Proposes and participates in the continuous education of employees within the Department;
- Responsible for preparing/controlling information and documents published on the Institute's web portal within the competence of the Department;
- Supervises the processing of applications within the competence of the Department;
- Responsible for preparing and drafting reports related to activities within the competence of the Department;
- Provides guidance for maintaining records of received applications within the competence of the Department;
- Provides guidance for the processing of applications within the competence of the Department;
- Ensures timely informing of applicants regarding the need to supplement documentation, as well as the status of files processed within the Department;
- Responsible for issuing official acts and documents in procedures within the competence of the Department;
- Responsible for preparing/controlling information and documents published on the Institute's web portal within the competence of the Department;
- Responsible for preparing/controlling minutes from meetings of commissions within the competence of the Department;
- Cooperates with the World Health Organization (WHO) Programme for International Drug Monitoring through The Uppsala Monitoring Centre (WHO Collaborating Centre);
- Responsible for preparing standard operating procedures within the competence of the Department;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute, and for ensuring compliance with and implementation of such principles and standards within the organisational unit under his/her management;
- Uses work equipment and materials in a purposeful and cost-effective manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	57
CENTRE FOR MARKET AFFAIRS AND SAFE USE OF MEDICINES **DEPARTMENT FOR PHARMACOVIGILANCE**		
(name of the organisational unit)		
EXPERT ASSOCIATE I FOR PHARMACOVIGILANCE		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural, or technical-technological field	
Work experience	5 years of experience in activities within the competence of the Department	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Specialised expertise and independence in work	
Other requirements	Successful completion of professional examination for work in state administration bodies; Advanced knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		
DUTIES OF THE POSITION		

- Executes tasks assigned by the Managing director, the Head of the Centre, and the Head of the Department;
- Responsible for independently performing the most complex tasks within procedures under the competence of the Department, including assessment of documentation and monitoring of deadlines, as well as supervising the work of other employees within the Department;
- Responsible for preparing notifications to applicants regarding the need for supplementation of documentation;
- Prepares minutes from commission meetings related to activities within the competence of the Department;
- Responsible for collecting and analysing data on the safety profile of medicinal products marketed in Montenegro and medicinal products subject to post-authorisation studies in Montenegro, proposing regulatory measures, and monitoring the fulfilment of obligations by marketing authorisation holders, importers of medicinal products, and sponsors of post-authorisation studies;
- Responsible for collecting and assessing data on important safety issues arising from non-interventional PASS (Post-authorisation Safety Studies) or other post-marketing studies, scientific literature, signal detection, with the aim of possible implementation of new safety information;
- Cooperates with the World Health Organization (WHO) Programme for International Drug Monitoring through The Uppsala Monitoring Centre (WHO Collaborating Centre);
- Responsible for the assessment of reports of suspected adverse medicine reactions submitted by healthcare professionals, patients, marketing authorisation holders, and sponsors of post-marketing studies, and for providing expert responses to received reports;
- Enters reports into the national database and forwards them to the global database;
- Processes Direct Healthcare Professional Communications (DHPCs);
- Monitors safety of medicinal products undergoing clinical trials (through reports submitted by applicants/sponsors and individual reports from clinical trials conducted in Montenegro), in cooperation with the Department for Clinical Trials and Assessment of the Safety and Efficacy of Medicinal Products;
- Responsible for maintaining the register of qualified persons responsible for pharmacovigilance/their deputies;
- Participates in pharmacovigilance inspections of marketing authorisation holders in the capacity of a pharmacovigilance assessor;
- Responsible for the assessment of Periodic Safety Update Reports (PSURs), Risk Management Plans (RMPs) and associated risk minimisation measures, summaries of the pharmacovigilance system of marketing authorisation holders, and the assessment of safety-related variations;
- Participates in the work of medicinal product commissions considering applications for marketing authorisations and other regulatory procedures related to marketing authorisations;
- Participates in the work of the Commission for Safety, as instructed by the Head of the Department;
- Participates in the process of withdrawal of medicinal products from the market due to safety reasons/reports of suspected adverse reactions resulting from deviations from quality standards;
- Responsible for the assessment of pharmacovigilance documentation in procedures for granting approval for the import of medicinal products requiring additional risk minimisation measures;
- Participates in the work of the joint Expert group for vaccines together with representatives of the Institute of Public Health and healthcare institutions;
- Responsible for preparing the Report on adverse medicine reactions for the previous calendar year for publication on the Institute's portal;
- Participates in the development of the Integrated Health Information System (IHIS) in the area of adverse medicine reaction reporting, as well as in the development and implementation of other digital pharmacovigilance tools;
- Responsible for monitoring news related to the safe use of medicinal products and for timely informing of expert and general public;
- Cooperates in the field of medicinal product safety with healthcare institutions, professional chambers, and associations of healthcare professionals and patients (interinstitutional cooperation);
- Participates in educational activities and promotion of the importance of the safe and rational use of medicinal products;
- Creates invoices for the collection of annual pharmacovigilance fees in the Institute's information system;
- Proposes continuous education activities for Department employees and participates in the training of lower-level employees;
- Proposes improvements and revisions of standard operating procedures within the competence of the Department;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute;
- Uses work equipment and materials in a purposeful and cost-effective manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	58
CENTRE FOR MARKET AFFAIRS AND SAFE USE OF MEDICINES **DEPARTMENT FOR PHARMACOVIGILANCE**		
(name of the organisational unit)		
EXPERT ASSOCIATE II FOR PHARMACOVIGILANCE		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural, or technical-technological field	
Work experience	3 years of experience in activities within the competence of the Department	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Specialised expertise and independence in work	
Other requirements	Successful completion of professional examination for work in state administration bodies; knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		
DUTIES OF THE POSITION		

- Executes tasks assigned by the Managing director, the Head of the Centre, and the Head of the Department;
- Responsible for independently performing complex tasks within procedures under the competence of the Department, including assessment of documentation and monitoring of deadlines, as well as supervising the work of other employees within the Department;
- Responsible for preparing notifications to applicants regarding the need for supplementation of documentation;
- Prepares minutes from commission meetings related to activities within the competence of the Department;
- Responsible for collecting and analysing data on the safety profile of medicinal products marketed in Montenegro and medicinal products subject to post-authorisation studies in Montenegro, proposing regulatory measures, and monitoring the fulfilment of obligations by marketing authorisation holders, importers of medicinal products, and sponsors of post-authorisation studies;
- Responsible for collecting and assessing data on important safety issues arising from non-interventional PASS (Post-authorisation Safety Studies) or other post-marketing studies, scientific literature, signal detection, with the aim of possible implementation of new safety information;
- Cooperates with the World Health Organization (WHO) Programme for International Drug Monitoring through The Uppsala Monitoring Centre (WHO Collaborating Centre);
- Responsible for the assessment of reports of suspected adverse medicine reactions submitted by healthcare professionals, patients, marketing authorisation holders, and sponsors of post-marketing studies, and for providing expert responses to received reports;
- Enters reports into the national database and forwards them to the global database;
- Processes Direct Healthcare Professional Communications (DHPCs);
- Monitors the safety of medicinal products undergoing clinical trials (through reports submitted by applicants/sponsors and individual reports from clinical trials conducted in Montenegro), in cooperation with the Department for Clinical Trials and Assessment of the Safety and Efficacy of Medicinal Products;
- Responsible for maintaining the register of qualified persons responsible for pharmacovigilance/their deputies;
- Responsible for the assessment of Periodic Safety Update Reports (PSURs), Risk Management Plans (RMPs) and associated risk minimisation measures, summaries of the pharmacovigilance system of marketing authorisation holders, and the assessment of safety-related variations;
- Participates in the process of withdrawal of medicinal products from the market due to safety reasons/reports of suspected adverse reactions resulting from deviations from quality standards;
- Responsible for the assessment of pharmacovigilance documentation in procedures for granting approval for the import of medicinal products requiring additional risk minimisation measures;
- Participates in the work of the joint Expert group for vaccines together with representatives of the Institute of Public Health and healthcare institutions;
- Responsible for preparing the Report on adverse medicine reactions for the previous calendar year for publication on the Institute's portal;
- Participates in the development of the Integrated Health Information System (IHIS) in the area of adverse medicine reaction reporting, as well as in the development and implementation of other digital pharmacovigilance tools;
- Responsible for monitoring international developments related to the safe use of medicinal products and for timely informing of healthcare professionals and/or the general public;
- Cooperates in the field of monitoring the safety of medicinal products with healthcare institutions, professional chambers, and associations of healthcare professionals and patients (interinstitutional cooperation);
- Creates invoices for the collection of annual pharmacovigilance fees in the Institute's information system;
- Uses work equipment and materials in a purposeful and cost-effective manner;
- Proposes continuous education activities for Department employees and participates in the training of lower-level employees;
- Proposes improvements and revisions of standard operating procedures within the competence of the Department;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute;
- Uses work equipment and materials in a purposeful and cost-effective manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	59
CENTRE FOR MARKET AFFAIRS AND SAFE USE OF MEDICINES **DEPARTMENT FOR PHARMACOVIGILANCE**		
(name of the organisational unit)		
EXPERT ASSOCIATE III FOR PHARMACOVIGILANCE		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural, or technical-technological field	
Work experience	1 year of experience in activities within the competence of the Department	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies		
Other requirements	Successful completion of professional examination for work in state administration bodies; knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		
DUTIES OF THE POSITION		

- Executes tasks assigned by the Managing director, the Head of the Centre, and the Head of the Department;
- Responsible for performing less complex tasks within procedures under the competence of the Department, including assessment of documentation and monitoring of deadlines, under the continuous supervision and control of Expert Associates I and II, the Head of the Department, and the Head of the Centre;
- Responsible for collecting and analysing data on the safety profile of medicinal products marketed in Montenegro and medicinal products subject to post-authorisation studies in Montenegro, proposing regulatory measures, and monitoring the fulfilment of obligations by marketing authorisation holders, importers of medicinal products, and sponsors of post-authorisation studies;
- Responsible for collecting and assessing data on important safety issues arising from non-interventional PASS (Post-authorisation Safety Studies) or other post-marketing studies, scientific literature, signal detection, with the aim of possible implementation of new safety information;
- Cooperates with the World Health Organization (WHO) Programme for International Drug Monitoring through the Uppsala Monitoring Centre (WHO Collaborating Centre);
- Responsible for the assessment of reports of suspected adverse medicine reactions submitted by healthcare professionals, patients, marketing authorisation holders, and sponsors of post-marketing studies, and for providing expert responses to received reports;
- Enters reports into the national database and forwards them to the global database;
- Processes Direct Healthcare Professional Communications (DHPCs);
- Responsible for maintaining the register of qualified persons responsible for pharmacovigilance/their deputies;
- Responsible for the assessment of Periodic Safety Update Reports (PSURs), Risk Management Plans (RMPs) and associated risk minimisation measures, summaries of the pharmacovigilance system of marketing authorisation holders, and the assessment of safety-related variations;
- Participates in the process of withdrawal of medicinal products from the market due to safety reasons/reports of suspected adverse reactions resulting from deviations from quality standards;
- Responsible for the assessment of pharmacovigilance documentation in procedures for granting approval for the import of medicinal products requiring additional risk minimisation measures;
- Participates in the work of the joint Expert group for vaccines together with representatives of the Institute of Public Health and healthcare institutions;
- Responsible for preparing the Report on adverse medicines reactions for the previous calendar year for publication on the Institute's portal;
- Participates in the development of the Integrated Health Information System (IHIS) in the area of adverse medicine reaction reporting, as well as in the development and implementation of other digital pharmacovigilance tools;
- Responsible for monitoring international developments related to the safe use of medicinal products and for the timely informing of healthcare professionals and/or the general public;
- Cooperates in the field of monitoring the safety of medicinal products with healthcare institutions, professional chambers, and associations of healthcare professionals and patients (interinstitutional cooperation);
- Creates invoices for the collection of annual pharmacovigilance fees in the Institute's information system;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute;
- Uses work equipment and materials in a purposeful and cost-effective manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	60
CENTRE FOR MARKET AFFAIRS AND SAFE USE OF MEDICINES **DEPARTMENT FOR PHARMACOVIGILANCE**		
(name of the organisational unit)		
ASSOCIATE FOR PHARMACOVIGILANCE		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural, or technical-technological field	
Work experience	1 year of experience in the relevant field	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies		
Other requirements	Successful completion of professional examination for work in state administration bodies; knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes tasks assigned by the Managing director, the Head of the Centre, and the Head of the Department;
- Responsible for performing the simplest tasks within procedures under the competence of the Department, including assessment of documentation and monitoring of deadlines, under the control of Expert Associate I , the Head of the Department, and the Head of the Centre;
- Responsible for the assessment of reports of suspected adverse medicine reactions submitted by healthcare professionals, patients, marketing authorisation holders, and sponsors of post-marketing studies, and for providing expert responses to received reports;
- Enters reports into the national database and forwards them to the global database;
- Processes Direct Healthcare Professional Communications (DHPCs);
- Performs administrative processing of PSURs and RMPs;
- Responsible for maintaining the register of qualified persons responsible for pharmacovigilance/their deputies;
- Participates in the assessment of pharmacovigilance documentation in procedures for granting approval for the import of medicinal products requiring additional risk minimisation measures;
- Participates in the preparation of the Report on adverse medicine reactions for the previous calendar year for publication on the Institute's portal;
- Creates invoices for the collection of annual pharmacovigilance fees in the Institute's information system;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute;
- Uses work equipment and materials in a purposeful and cost-effective manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	61
CENTRE FOR MARKET AFFAIRS AND SAFE USE OF MEDICINES **DEPARTMENT FOR MEDICINES CONSUMPTION MONITORING AND SETTING MAXIMUM PRICES**		
(name of the organisational unit)		
HEAD OF THE DEPARTMENT FOR MEDICINES CONSUMPTION MONITORING AND SETTING MAXIMUM PRICES		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural, or technical-technological field	
Work experience	5 years of experience in activities within the competence of the Department	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Organisational and communication skills	
Other requirements	Successful completion of professional examination for work in state administration bodies; Advanced knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		
DUTIES OF THE POSITION		

- Executes tasks assigned by the Managing director and the Head of the Centre;
- Manages the work of the Department and is responsible for planning, organising, implementing, and controlling business processes within the competence of the Department, as well as supervising their implementation;
- Responsible for performing the most complex tasks and duties within the competence of the Department;
- Responsible for assigning duties to employees within the Department and ensuring coordination and cooperation in the execution of such duties;
- Ensures that activities within the competence of the Department are performed in the manner and within the deadlines prescribed by law;
- Responsible for the preparation/control of information/documents published on the Institute's website within the competence of the Institute;
- Supervises the processing of applications under the competence of the Department;
- Responsible for preparing and compiling reports related to activities within the competence of the Department;
- Provides guidance for maintaining records of data on applications received within the competence of the Department;
- Provides guidance for carrying out/supervising the processing of applications within the competence of the Department;
- Ensures timely notification of applicants regarding the need for supplementation of documentation/statuses of files processed within the Department;
- Responsible for issuing outgoing acts and documents in procedures within the competence of the Department;
- Responsible for the preparation/control of information/documents published on the Institute's website within the competence of the Department;
- Responsible for entering parameters into the information system necessary for the entry of master data on medicinal products into the Institute's information system, as well as entering other parameters;
- Responsible for preparing standard operating procedures within the competence of the Department;
- Proposes and participates in the continuous education of employees within the Department;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute, and for ensuring compliance with and implementation of such standards within the organisational unit under his/her management;
- Uses work equipment and materials in a purposeful and cost-effective manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	62
CENTRE FOR MARKET AFFAIRS AND SAFE USE OF MEDICINES **DEPARTMENT FOR MEDICINES CONSUMPTION MONITORING AND SETTING MAXIMUM PRICES**		
(name of the organisational unit)		
EXPERT ASSOCIATE I FOR MEDICINES CONSUMPTION MONITORING AND SETTING MAXIMUM PRICES		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural, or technical-technological field	
Work experience	5 years of experience in activities within the competence of the Department	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Specialised expertise and independence in work	
Other requirements	Successful completion of professional examination for work in state administration bodies; Advanced knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		
DUTIES OF THE POSITION		

- Executes tasks assigned by the Managing director, the Head of the Centre, and the Head of the Department;
- Responsible for independently performing the most complex tasks within procedures under the competence of the Department, including assessment of documentation and monitoring of deadlines, as well as supervising the work of other employees within the Department;
- Responsible for the independent collection and processing of data on the consumption of medicinal products;
- Responsible for analysing processed data, including comparison with previous years and monitoring trends;
- Responsible for preparing and publishing data on the Institute's portal, including analyses of consumption trends intended for the expert public;
- Prepares publications (brochures) in the field of medicinal product consumption;
- Issues reports on medicinal product consumption at the request of clients through expert opinions;
- Responsible for detecting problems related to the excessive use of a particular group of medicinal products or a specific medicinal product and initiating measures for the rational use of medicinal products;
- Responsible for determining and harmonising maximum prices (establishing maximum prices of medicinal products);
- Monitors medicinal product price trends for the purpose of preparing pharmacoeconomic analyses;
- Publishes reports on established or harmonised medicinal product prices;
- Cooperates with the World Health Organization (WHO) in the field of the rational use of medicinal products;
- Cooperates with the Ministry of Health regarding medicinal product pricing policy;
- Cooperates with reference countries prescribed by the bylaw regulating the criteria for establishing maximum prices, as well as with the competent authorities of those countries in this field;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute, and for ensuring compliance with and implementation of such standards within the organisational unit under his/her management;
- Proposes continuous education activities for Department employees and participates in the training of lower-level employees;
- Proposes improvements and revisions of standard operating procedures within the competence of the Department;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute;
- Uses work equipment and materials in a purposeful and cost-effective manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	63
CENTRE FOR MARKET AFFAIRS AND SAFE USE OF MEDICINES **DEPARTMENT FOR MEDICINES CONSUMPTION MONITORING AND SETTING MAXIMUM PRICES**		
(name of the organisational unit)		
EXPERT ASSOCIATE II FOR MEDICINES CONSUMPTION MONITORING AND SETTING MAXIMUM PRICES		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural, or technical-technological field	
Work experience	3 years of experience in activities within the competence of the Department	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Specialised expertise and independence in work	
Other requirements	Successful completion of professional examination for work in state administration bodies; knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes tasks assigned by the Managing director, the Head of the Centre, and the Head of the Department;
- Responsible for independently performing complex tasks within procedures under the competence of the Department, including assessment of documentation and monitoring of deadlines;
- Participates in the collection and processing of data on the consumption of medicinal products;
- Participates in the analysis of processed data, including comparison with previous years and monitoring trends;
- Issues reports on medicinal product consumption at the request of clients through expert opinions;
- Participates in detecting problems related to the excessive use of a particular group of medicinal products or a specific medicinal product and in initiating measures for the rational use of medicinal products;
- Participates in the preparation of publications (brochures) in the field of medicinal product consumption;
- Participates in determining and harmonising maximum prices (establishing maximum prices of medicinal products);
- Participates in publishing reports on established or harmonised medicinal product prices;
- Proposes continuous education activities for Department employees;
- Proposes improvements and revisions of standard operating procedures within the competence of the Department;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute;
- Uses work equipment and materials in a purposeful and cost-effective manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	64
CENTRE FOR MARKET AFFAIRS AND SAFE USE OF MEDICINES **DEPARTMENT FOR MEDICINES CONSUMPTION MONITORING AND SETTING MAXIMUM PRICES**		
(name of the organisational unit)		
EXPERT ASSOCIATE III FOR MEDICINES CONSUMPTION MONITORING AND SETTING MAXIMUM PRICES		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural, or technical-technological field	
Work experience	1 year of experience in activities within the competence of the Department	
Special health requirements	NO	
Required daily working hours	Full time – 40 hours per week	
Competencies		
Other requirements	Successful completion of professional examination for work in state administration bodies; Advanced knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes tasks assigned by the Managing director, the Head of the Centre, and the Head of the Department;
- Responsible for performing simple tasks within procedures under the competence of the Department, including assessment of documentation and monitoring of deadlines, under control of Expert Associate I , the Head of the Department, and the Head of the Centre;
- Participates in the collection and processing of data on the consumption of medicinal products;
- Participates in the analysis of processed data, including comparison with previous years and trend monitoring, under the supervision of the Head of the Department;
- Issues reports on medicinal product consumption at the request of clients through expert opinions, under the supervision of the Head of the Department;
- Participates in identifying problems related to the excessive use of a particular group of medicinal products or a specific medicinal product and in initiating measures for the rational use of medicinal products, in consultation with the Head of the Department;
- Participates in the preparation of publications (brochures) in the field of medicinal product consumption;
- Participates in determining and harmonising maximum prices (establishing maximum prices of medicinal products), under the supervision of the Head of the Department;
- Participates in publishing reports on established or harmonised medicinal product prices, under the supervision of the Head of the Department;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute;
- Uses work equipment and materials in a purposeful and cost-effective manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	65
CENTRE FOR MARKET AFFAIRS AND SAFE USE OF MEDICINES **DEPARTMENT FOR MEDICINES CONSUMPTION MONITORING AND SETTING MAXIMUM PRICES**		
(name of the organisational unit)		
ASSOCIATE FOR MEDICINES CONSUMPTION MONITORING AND SETTING MAXIMUM PRICES		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural, or technical-technological field	
Work experience	1 year of experience in the relevant field	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies		
Other requirements	Successful completion of professional examination for work in state administration bodies; knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes tasks assigned by the Managing director, the Head of the Centre, and the Head of the Department;
- Responsible for performing the simplest tasks within procedures under the competence of the Department, under the training and control by the Expert Associate I, Head of the Department and Head of the Centre;
- Participates in the collection and processing of data on the consumption of medicinal products;
- Participates in the analysis of processed data, including comparison with previous years and trend monitoring;
- Issues reports on medicinal product consumption at the request of clients through expert opinions;
- Participates in identifying problems related to the excessive use of a particular group of medicinal products or a specific medicinal product and in initiating measures for the rational use of medicinal products;
- Participates in the preparation of publications (brochures) in the field of medicinal product consumption;
- Participates in determining and harmonising maximum prices (establishing maximum prices of medicinal products);
- Participates in publishing reports on established or harmonised medicinal product prices;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute;
- Uses work equipment and materials in a purposeful and cost-effective manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	66
CENTRE FOR MARKET AFFAIRS AND SAFE USE OF MEDICINES **DEPARTMENT FOR MEDICINES IMPORT/EXPORT AUTHORISATION**		
(name of the organisational unit)		
HEAD OF THE DEPARTMENT FOR MEDICINES IMPORT/EXPORT AUTHORISATION		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural, or technical-technological field	
Work experience	5 years of work experience in activities within the competence of the Department	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Organisational and communication skills	
Other requirements	Successful completion of professional examination for work in state administration bodies; Advanced knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		
DUTIES OF THE POSITION		

- Executes tasks assigned by the Managing director and the Head of the Centre;
- Manages the work of the Department and is responsible for planning, organising, implementing, and controlling business processes within the competence of the Department, as well as supervising their implementation;
- Responsible for performing the most complex tasks and duties within the competence of the Department;
- Responsible for assigning tasks to associates within the Department and ensuring coordination and cooperation in the process of their execution;
- Ensures that activities within the competence of the Department are carried out in the manner and within the deadlines prescribed by law;
- Proposes and participates in the continuous professional training of employees within the Department;
- Responsible for the preparation/control of information and documents published on the Institute's website, within the competence of the Institute;
- Supervises the processing of applications within the competence of the Department;
- Responsible for the preparation and drafting of reports related to activities within the competence of the Department;
- Provides guidance for the processing of applications within the competence of the Department;
- Ensures timely notification of applicants regarding the need to supplement documentation and the status of files processed within the Department;
- Responsible for issuing outgoing acts and documents in procedures within the competence of the Department;
- Responsible for the preparation/control of information and documents published on the Institute's website, within the competence of the Department;
- Cooperates with experts from the list of experts established by the Institute;
- Responsible for entering parameters into the information system necessary for the entry of master data on medicinal products into the Institute's information system, as well as other parameters;
- Responsible for processing of applications for authorisations for the possession of narcotic drugs on national ships and aircraft engaged in international traffic;
- Responsible for the analysis and processing of reports from wholesale distributors on annual requirements, consumption, and import of narcotic drugs, as well as annual requirements and import of precursors;
- Responsible for the exchange of information with competent authorities of exporting or importing countries regarding the authenticity of import authorisations for precursors (Pre-Export Notification – PEN Online);
- Responsible for international cooperation with the International Narcotics Control Board (INCB), the United Nations Office on Drugs and Crime (UNODC), and the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA);
- Responsible for cooperation at the national level with the ministry responsible for health affairs, administrative authorities responsible for internal affairs (Forensic Centre), and customs authorities;
- Responsible for preparing and submitting quarterly reports to the ministry responsible for health affairs on the import/export of narcotic drugs and psychotropic substances, as well as annual reports on import, export, consumption, and annual requirements for narcotic drugs, psychotropic substances, and precursors;
- Responsible for monitoring the implementation of imports of controlled substances;
- Responsible for the implementation and fulfilment of obligations arising from the ratified UN international conventions: the 1961 Single Convention on Narcotic Drugs, the 1971 Convention on Psychotropic Substances, and the 1988 United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances;
- Responsible for returning export authorisations to the competent authority of the exporting country in accordance with UN conventions;
- Responsible for preparing lists of narcotic drugs, psychotropic substances, and precursors in accordance with the UN conventions governing this field;
- Proposes and participates in the continuous professional training of employees within the Department;
- Responsible for preparing standard operating procedures within the competence of the Department;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute, and for ensuring compliance with and implementation of these principles within the organisational unit under his/her management;
- Uses work equipment and materials in a purposeful and cost-effective manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	67
CENTRE FOR MARKET AFFAIRS AND SAFE USE OF MEDICINES **DEPARTMENT FOR MEDICINES IMPORT/EXPORT AUTHORISATION**		
(name of the organisational unit)		
EXPERT ASSOCIATE I FOR MEDICINES IMPORT/EXPORT AUTHORISATION		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural, or technical-technological field	
Work experience	5 years of experience in activities within the competence of the Department	
Special health requirements	NO	
Working hours	40 hours per week	
Competencies	Specialised expertise and independence in work	
Other requirements	Successful completion of professional examination for work in state administration bodies; Advanced knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		
DUTIES OF THE POSITION		

- Executes tasks assigned by the Managing director, the Head of the Centre, and the Head of the Department;
- Responsible for independently performing the most complex tasks within procedures under the competence of the Department, including assessment of documentation and monitoring of deadlines, as well as supervision of the work of other employees within the Department;
- Responsible for receiving applications within the competence of the Department;
- Responsible for the independent processing of the most complex applications for granting approval for the procurement or import of medicinal products without a marketing authorisation;
- Responsible for the independent processing of applications and issuing authorisations for the import/export/transit of narcotic drugs and precursors;
- Responsible for independent processing of applications for authorisations for the possession of narcotic drugs on national ships and aircraft engaged in international traffic;
- Responsible for analysing and processing reports from wholesale distributors regarding annual requirements, consumption, and import of narcotic drugs, as well as annual requirements and import of precursors;
- Responsible for processing applications for authorisations for the import and export of immunological medicinal products and medicinal products derived from blood and plasma;
- Ensures the issuance of outgoing acts in procedures for issuing certificates required for the export of medicinal products in accordance with WHO recommendations (CPP certificate);
- Responsible for entering master data on medicinal products into the database for emergency import/export;
- Responsible for entering data on medicinal products for import/export into the application processing form;
- Responsible for issuing expert opinions related to the import/export of medicinal products, exemptions from approved packaging requirements, and similar matters;
- Ensures timely notification of applicants regarding the need to supplement documentation;
- Monitors compliance with deadlines for file processing;
- Participates in decision-making regarding the justification for importing medicinal products without a marketing authorisation;
- Responsible for the exchange of information with competent authorities of exporting or importing countries regarding the authenticity of import authorisations for precursors (Pre-Export Notification – PEN Online);
- Responsible for international cooperation with the International Narcotics Control Board (INCB), the United Nations Office on Drugs and Crime (UNODC), and the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA);
- Responsible for cooperation at the national level with the ministry responsible for health affairs, administrative authorities responsible for internal affairs (Forensic Centre), and customs authorities;
- Responsible for preparing and submitting quarterly reports to the ministry responsible for health affairs on the import/export of narcotic drugs and psychotropic substances, as well as annual reports on import, export, consumption, and annual requirements for narcotic drugs, psychotropic substances, and precursors;
- Monitors the implementation of imports of controlled substances;
- Ensures implementation and fulfilment of obligations arising from the ratified UN international conventions: the 1961 Single Convention on Narcotic Drugs, the 1971 Convention on Psychotropic Substances, and the 1988 United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances;
- Ensures the return of export authorisations to the competent authority of the exporting country in accordance with UN conventions;
- Participates in preparing lists of narcotic drugs, psychotropic substances, and precursors in accordance with the UN conventions governing this field;
- Prepares outgoing acts of the Department;
- Proposes continuous professional training for employees within the Department and participates in the training of employees at lower levels;
- Proposes improvements and revisions of standard operating procedures within the competence of the Department;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute;
- Uses work equipment and materials in a purposeful and cost-effective manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	68
CENTRE FOR MARKET AFFAIRS AND SAFE USE OF MEDICINES **DEPARTMENT FOR MEDICINES IMPORT/EXPORT AUTHORISATION**		
(name of the organisational unit)		
EXPERT ASSOCIATE II FOR MEDICINES IMPORT/EXPORT AUTHORISATION		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural, or technical-technological field	
Work experience	3 years of work experience in activities within the competence of the Department	
Special health requirements	NO	
Working hours	40 hours per week	
Competencies	Specialised expertise and independence in work	
Other requirements	Successful completion of professional examination for work in state administration bodies; knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		
DUTIES OF THE POSITION		

- Executes tasks assigned by the Managing director, the Head of the Centre, and the Head of the Department;
- Responsible for independently performing complex tasks within procedures under the competence of the Department, including assessment of documentation and monitoring of deadlines,;
- Ensures the receipt of applications within the competence of the Department;
- Processes more complex applications for approval for the procurement or import of medicinal products without a marketing authorisation, under the supervision of superiors;
- Processes more complex applications for authorisations for the import and export of immunological medicinal products and medicinal products derived from blood and plasma, under the supervision of superiors;
- Participates in issuing outgoing acts in procedures for issuing certificates required for the export of medicinal products in accordance with WHO recommendations (CPP certificate);
- Participates in entering master data on medicinal products into the database for emergency import/export;
- Participates in entering data on medicinal products for import/export into the application processing form within his/her competence;
- Participates in issuing expert opinions related to the import/export of medicinal products, exemptions from approved packaging requirements, and similar matters;
- Prepares notifications to applicants regarding the need to supplement documentation, under the supervision of superiors;
- Monitors compliance with deadlines for file processing;
- Prepares outgoing acts of the Department, under the supervision of superiors;
- Participates in decision-making regarding the justification for importing medicinal products without a marketing authorisation;
- Processes more complex applications for authorisations for the import/export/transit of narcotic drugs and precursors, under the supervision of superiors;
- Processes applications for authorisations for the possession of narcotic drugs on national ships and aircraft engaged in international traffic, under the supervision of superiors;
- Participates in issuing authorisations for the use of precursors within the competence of the Institute;
- Monitors the implementation of imports of controlled substances, under the supervision of superiors;
- Participates in analysing and processing reports from wholesale distributors regarding annual requirements, consumption, and import of narcotic drugs, as well as annual requirements and import of precursors;
- Participates in collecting, preparing, and submitting quarterly reports to the ministry responsible for health affairs on the import/export of narcotic drugs and psychotropic substances, as well as annual reports on import, export, consumption, and annual requirements for narcotic drugs, psychotropic substances, and precursors;
- Participates in implementing and fulfilling obligations arising from the ratified UN international conventions: the 1961 Single Convention on Narcotic Drugs, the 1971 Convention on Psychotropic Substances, and the 1988 United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances;
- Ensures the return of export authorisations to the competent authority of the exporting country in accordance with the aforementioned UN conventions, under the supervision of superiors;
- Participates in the exchange of information with competent authorities of exporting or importing countries regarding the authenticity of import authorisations for precursors (Pre-Export Notification – PEN Online);
- Proposes professional training for employees within the Department;
- Proposes improvements and revisions of standard operating procedures within the competence of the Department;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute;
- Uses work equipment and materials in a purposeful and cost-effective manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	69
CENTRE FOR MARKET AFFAIRS AND SAFE USE OF MEDICINES **DEPARTMENT FOR MEDICINES IMPORT/EXPORT AUTHORISATION**		
(name of the organisational unit)		
EXPERT ASSOCIATE III FOR MEDICINES IMPORT/EXPORT AUTHORISATION		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural, or technical-technological field	
Work experience	1 year of work experience in activities within the competence of the Department	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies		
Other requirements	Successful completion of professional examination for work in state administration bodies; knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		
DUTIES OF THE POSITION		

- Executes tasks assigned by the Managing director, the Head of the Centre, and the Head of the Department;
- Responsible for performing simple tasks within procedures under the competence of the Department, including assessment of documentation and monitoring of deadlines, under control of Expert Associate I , the Coordinator, the Head of the Department, and the Head of the Centre;
- Ensures the receipt of applications within the competence of the Department;
- Processes simpler applications for approval for the procurement or import of medicinal products without a marketing authorisation, under the supervision of superiors;
- Processes simpler applications for authorisations for the import and export of immunological medicinal products and medicinal products derived from blood and plasma, under the supervision of superiors;
- Participates in issuing outgoing acts in procedures for issuing certificates required for the export of medicinal products in accordance with WHO recommendations (CPP certificate);
- Participates in entering master data on medicinal products into the database for emergency import/export;
- Participates in entering data on medicinal products for import/export into the application processing form within his/her competence;
- Participates in issuing expert opinions related to the import/export of medicinal products, exemptions from approved packaging requirements, and similar matters;
- Prepares notifications to applicants regarding the need to supplement documentation, under the supervision of superiors;
- Monitors compliance with deadlines for file processing;
- Prepares outgoing acts of the Department, under the supervision of superiors;
- Participates in decision-making regarding the justification for importing medicinal products without a marketing authorisation;
- Processes simpler applications for authorisation for the import/export/transit of narcotic drugs and precursors, under the continuous supervision of superiors;
- Processes applications for authorisations for the possession of narcotic drugs on national ships and aircraft engaged in international traffic, under the supervision of superiors;
- Participates in issuing authorisations for the use of precursors within the competence of the Institute;
- Monitors the implementation of imports of controlled substances, under the supervision of superiors;
- Participates in analysing and processing reports from wholesale distributors regarding annual requirements, consumption, and import of narcotic drugs, as well as annual requirements and import of precursors;
- Participates in collecting, preparing, and submitting quarterly reports to the ministry responsible for health affairs on the import/export of narcotic drugs and psychotropic substances, as well as annual reports on import, export, consumption, and annual requirements for narcotic drugs, psychotropic substances, and precursors;
- Participates in implementing and fulfilling obligations arising from the ratified UN international conventions: the 1961 Single Convention on Narcotic Drugs, the 1971 Convention on Psychotropic Substances, and the 1988 United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances;
- Ensures the return of export authorisations to the competent authority of the exporting country in accordance with the aforementioned UN conventions, under the supervision of superiors;
- Participates in the exchange of information with competent authorities of exporting or importing countries regarding the authenticity of import authorisations for precursors (Pre-Export Notification – PEN Online);
- Participates in the work of working groups, commissions, and working bodies;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute;
- Uses work equipment and materials in a purposeful and cost-effective manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	70
CENTRE FOR MARKET AFFAIRS AND SAFE USE OF MEDICINES **DEPARTMENT FOR MEDICINES IMPORT/EXPORT AUTHORISATION**		
(name of the organisational unit)		
ASSOCIATE FOR MEDICINES IMPORT/EXPORT AUTHORISATION		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural, or technical-technological field	
Work experience	1 year of experience in the relevant field	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies		
Other requirements	Successful completion of professional examination for work in state administration bodies; knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		
DUTIES OF THE POSITION		

- Executes tasks assigned by the Managing director, the Head of the Centre, and the Head of the Department;
- Responsible for performing the simplest tasks within procedures under the competence of the Department, including assessment of documentation and monitoring of deadlines, under the training and control by the Expert Associate I, the Head of the Department and the Head of the Centre;
- Ensures the receipt of applications within the competence of the Department;
- Participates in the processing of applications for approval for the procurement or import of medicinal products without a marketing authorisation, under the supervision of superiors;
- Processes applications for authorisations for the import and export of immunological medicinal products and medicinal products derived from blood and plasma;
- Participates in issuing outgoing acts in procedures for issuing certificates required for the export of medicinal products in accordance with WHO recommendations (CPP certificate);
- Participates in entering master data on medicinal products into the database for emergency import/export;
- Participates in entering data on medicinal products for import/export into the application processing form within his/her competence;
- Participates in issuing expert opinions related to the import/export of medicinal products, exemptions from approved packaging requirements, and similar matters;
- Prepares notifications to applicants regarding the need to supplement documentation;
- Monitors compliance with deadlines for file processing;
- Participates in the preparation of outgoing acts of the Department;
- Participates in decision-making regarding the justification for importing medicinal products without a marketing authorisation;
- Processes applications for authorisations for the import/export/transit of narcotic drugs and precursors;
- Processes applications for authorisations for the possession of narcotic drugs on national ships and aircraft engaged in international traffic;
- Participates in issuing authorisations for the use of precursors within the competence of the Institute;
- Monitors the implementation of imports of controlled substances;
- Participates in analysing and processing reports from wholesale distributors regarding annual requirements, consumption, and import of narcotic drugs, as well as annual requirements and import of precursors;
- Participates in collecting, preparing, and submitting quarterly reports to the ministry responsible for health affairs on the import/export of narcotic drugs and psychotropic substances, as well as annual reports on import, export, consumption, and annual requirements for narcotic drugs, psychotropic substances, and precursors;
- Participates in implementing and fulfilling obligations arising from the ratified UN international conventions: the 1961 Single Convention on Narcotic Drugs, the 1971 Convention on Psychotropic Substances, and the 1988 United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances;
- Ensures the return of export authorisations to the competent authority of the exporting country in accordance with the aforementioned UN conventions, under the supervision of superiors;
- Participates in the exchange of information with competent authorities of exporting or importing countries regarding the authenticity of import authorisations for precursors (Pre-Export Notification – PEN Online);
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute;
- Uses work equipment and materials in a purposeful and cost-effective manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	71
INSPECTORATE		
(name of the organisational unit)		
HEAD OF THE INSPECTORATE		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in pharmacy, medicine, veterinary medicine, chemistry, pharmaceutical chemistry, technology, or biology.	
Work experience	5 years of experience in the area of medicines/medical devices inspection	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Organisational and communication skills	
Other requirements	Successful completion of professional examination for work in state administration bodies; Advanced knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		
DUTIES OF THE POSITION		

- Executes the orders of the Managing director;
- Manages the work of the Inspectorate and is responsible for planning, organizing, implementing, and controlling business processes within the competence of the Inspectorate, and supervises their implementation;
- Responsible for performing the most complex tasks and duties within the competence of the Inspectorate;
- Responsible for assigning tasks to employees within the Inspectorate and ensuring coordination and cooperation in the process of their execution;
- Ensures that activities within the competence of the Inspectorate are carried out in the manner and within the deadlines prescribed by law;
- Proposes and participates in the continuous education of employees within the Inspectorate;
- Responsible for the preparation/control of information/documents published on the Institute's website portal within the competence of the Inspectorate;
- Supervises the processing of applications within the competence of the Inspectorate;
- Participates in the work of working groups, commissions, and working bodies;
- Performs/supervises the issuance of outgoing acts and documents in procedures within the competence of the Inspectorate;
- Responsible for procedures for issuing manufacturing authorisations for medicinal products containing narcotic drugs and psychotropic substances, and precursors (Category 1 precursors used in the manufacture of medicinal products and Category 4 precursors);
- Responsible for procedures for issuing wholesale distribution authorisations for medicinal products for human use, medicinal products for human use containing narcotic drugs and psychotropic substances, precursors (Category 1 precursors used in the manufacture of medicinal products and Category 4 precursors), and poppy and/or cannabis derivatives intended for medical or pharmaceutical purposes;
- Responsible for procedures for entry into the Register of manufacturers, importers, and wholesalers of active substances;
- Conducts inspections within the competence of the Inspectorate;
- Prepares or controls and approves the annual inspection plan for inspections conducted within the country and abroad;
- Participates in procedures for quality control of medicinal products on the market;
- Participates in the process of the assessment of quality defects reports and in decision-making regarding the recall of disputed medicinal product batches from the market;
- Participates in market surveillance concerning the presence of falsified and substandard medicinal products;
- Participates in sending Rapid Alerts within the Rapid Alert Network (RAN);
- Participates in cooperation with the state administration authority responsible for inspection affairs;
- Monitors the work and participates in the activities of the EMA, Pharmaceutical Inspection Co-operation Scheme (PIC/S) and other international inspection organizations;
- Participates in commissions assessing compliance with requirements for carrying out the manufacture/wholesale distribution of medical devices;
- Undertakes administrative measures and actions in accordance with the law;
- Responsible for preparing and drafting reports related to activities within the competence of the Inspectorate;
- Responsible for the preparation and control of standard operating procedures within the competence of the Inspectorate;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute, and for ensuring compliance with and implementation of the same within the organizational unit under his/her management;
- Uses work resources and materials purposefully and rationally;
- Ensures compliance with occupational health and safety regulations and environmental protection regulations, and performs duties in a manner that does not endanger or harm the environment or the life and health of himself/herself and others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, cause material damage, or affect his/her own safety and health, the safety and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competencies, in accordance with the law, the Statute, general acts, and other acts of the Institute

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	72
INSPECTORATE		
(name of the organisational unit)		
PHARMACEUTICAL INSPECTOR FOR GOOD MANUFACTURING AND GOOD DISTRIBUTION PRACTICE I (GMDP INSPECTOR I)		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in pharmacy, medicine, veterinary medicine, chemistry, pharmaceutical chemistry, technology, or biology.	
Work experience	5 years of experience in activities in the field of manufacture and/or distribution of medicinal products, or inspection of the manufacture and/or distribution of medicinal products	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Specialised expertise and independence in work	
Other requirements	Successful completion of professional examination for work in state administration bodies; Advanced knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		
DUTIES OF THE POSITION		

- Executes the orders of the Managing director and the Head of the Inspectorate;
- Responsible for independently performing the most complex tasks within procedures falling under the competence of the Inspectorate in the field of the manufacture of medicines, or Good Manufacturing Practice and the area of wholesale distribution of medicines for human use, or Good Distribution Practice;
- Responsible for preparing notifications to applicants regarding the need to supplement documentation;
- Organizes the preparation of inspections for the purpose of determining compliance with Good Manufacturing Practice and Good Distribution Practice guidelines;
- Conducts procedures for the issuance of manufacturing authorisations for medicinal products, medicinal products containing narcotic drugs and psychotropic substances, and precursors (Category 1 precursors used in the manufacture of medicinal products and Category 4 precursors);
- Independently conducts inspections of the manufacture of medicinal products, investigational medicinal products, active substances and excipients, medicinal products containing narcotic drugs and psychotropic substances, and precursors (Category 1 precursors used in the manufacture of medicinal products and Category 4 precursors);
- Conducts procedures for the issuance of wholesale distribution authorisations for medicinal products for human use, medicinal products for human use containing narcotic drugs and psychotropic substances, precursors (Category 1 precursors used in the manufacture of medicinal products and Category 4 precursors), and poppy and/or cannabis derivatives intended for medical or pharmaceutical purposes;
- Independently conducts inspections of the wholesale distribution of medicinal products for human use, medicinal products for human use containing narcotic drugs and psychotropic substances, precursors (Category 1 precursors used in the manufacture of medicinal products and Category 4 precursors), and poppy and/or cannabis derivatives intended for medical or pharmaceutical purposes;
- Conducts procedures for the issuance of GMP Certificates for medicinal products and active substances;
- Conducts procedures for the issuance of GDP Certificates for medicinal products for human use;
- Ensures that procedures within the Inspectorate's remit for which he/she is responsible are carried out in the manner and within the time limits prescribed by law and the Institute's internal acts;
- Conducts procedures for registration in the Register of Manufacturers, Importers and Distributors of Active Substances;
- Independently conducts GDP inspections of importers and distributors of active substances and issues GDP Certificates for active substances;
- Participates in carrying out other inspections within the Inspectorate's remit, in accordance with his/her level of training, operational needs, or upon the instruction of the Head of the Inspectorate;
- Participates in the preparation of the annual inspection plan;
- Participates in procedures related to the monitoring of substandard and falsified medicinal products;
- Participates in the procedure of the assessment of quality defects reports by order of the the Head of the Inspectorate;
- Participates in sending Rapid Alerts within the Rapid Alert Network (RAN);
- Collects samples of medicinal products and raw materials for quality control purposes;
- Participates in commissions assessing compliance with requirements for the manufacture of medical devices;
- Participates in commissions assessing compliance with requirements for the wholesale distribution of medical devices;
- Participates in cooperation with the state administration authority responsible for inspection affairs and other authorities;
- Undertakes administrative measures and actions in accordance with the law;
- Proposes continuous education for employees within the Inspectorate and participates in the training of lower-level employees;
- Participates in the preparation and revision of standard operating procedures and other quality system documents within the competence of the Inspectorate;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute;
- Uses work resources and materials purposefully and rationally;
- Ensures compliance with occupational health and safety regulations and environmental protection regulations, and performs duties in a manner that does not endanger or harm the environment or the life and health of himself/herself and others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, cause material damage, or affect his/her own safety and health, the safety and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competencies, in accordance with the law, the Statute, general acts, and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	73
INSPECTORATE		
(name of the organisational unit)		
PHARMACEUTICAL INSPECTOR FOR GOOD MANUFACTURING AND GOOD DISTRIBUTION PRACTICE II (GMDP INSPECTOR II)		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in pharmacy, medicine, veterinary medicine, chemistry, pharmaceutical chemistry, technology, or biology.	
Work experience	3 years of work experience in activities in the field of manufacture and/or distribution of medicinal products or inspection of the manufacture and/or distribution of medicinal products	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Specialised expertise and independence in work	
Other requirements	Successful completion of professional examination for work in state administration bodies; Advanced knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		
DUTIES OF THE POSITION		

- Executes the orders of the Managing director and the Head of the Inspectorate;
- Responsible for independently performing complex tasks within procedures falling under the competence of the Inspectorate in the field of the manufacture of medicines or Good Manufacturing Practice and in the field of wholesale distribution of medicinal products for human use, or Good Distribution Practice;
- Responsible for preparing notifications to applicants regarding the need to supplement documentation
- Participates in the preparation of inspections for the purpose of determining compliance with Good Manufacturing Practice and Good Distribution Practice guidelines;
- Performs activities related to issuing manufacturing authorisations for medicinal products, medicinal products containing narcotic drugs and psychotropic substances, and precursors (Category 1 precursors used in the manufacture of medicinal products and Category 4 precursors);
- Independently conducts inspections of the manufacture of medicinal products, investigational medicinal products, active substances and excipients, medicinal products containing narcotic drugs and psychotropic substances, and precursors (Category 1 precursors used in the manufacture of medicinal products and Category 4 precursors);
- Performs duties related to the issuance of wholesale distribution authorisations for medicinal products for human use, medicinal products for human use containing narcotic drugs and psychotropic substances, precursors (Category 1 precursors used in the manufacture of medicinal products and Category 4 precursors), and poppy and/or cannabis derivatives intended for medical or pharmaceutical purposes;
- Independently conducts inspections of the wholesale distribution of medicinal products for human use, medicinal products for human use containing narcotic drugs and psychotropic substances, precursors (Category 1 precursors used in the manufacture of medicinal products and Category 4 precursors), and poppy and/or cannabis derivatives intended for medical or pharmaceutical purposes;
- Performs duties related to the issuance of GMP Certificates for medicinal products and active substances;
- Performs duties related to the issuance of GDP Certificates for medicinal products for human use;
- Ensures that procedures within the Inspectorate's remit for which he/she is responsible are carried out in the manner and within the time limits prescribed by law and the Institute's internal acts;
- Performs duties related to registration in the Register of Manufacturers, Importers and Distributors of Active Substances;
- Independently conducts GDP inspections of importers and distributors of active substances and issues GDP Certificates for active substances;
- Participates in carrying out other inspections within the Inspectorate's remit, in accordance with his/her level of training, operational needs, or upon the instruction of the Head of the Inspectorate
- Participates in the preparation of the annual inspection plan;
- Monitors procedures related to substandard and falsified medicinal products;
- Participates in the procedure of the assessment of quality defects reports by order of the the Head of the Inspectorate;
- Participates in sending Rapid Alerts within the Rapid Alert Network (RAN);
- Collects samples of medicinal products and raw materials for quality control purposes;
- Participates in commissions assessing compliance with requirements for the manufacture of medical devices;
- Participates in commissions assessing compliance with requirements for the wholesale distribution of medical devices;
- Participates in cooperation with the state administration authority responsible for inspection affairs and other authorities;
- Undertakes administrative measures and actions in accordance with the law;
- Proposes continuous education for employees within the Inspectorate and participates in the training of lower-lever employees;
- Participates in the preparation and revision of standard operating procedures and other quality system documents within the competence of the Inspectorate;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute;
- Uses work resources and materials purposefully and rationally;
- Ensures compliance with occupational health and safety regulations and environmental protection regulations, and performs duties in a manner that does not endanger or harm the environment or the life and health of himself/herself and others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, cause material damage, or affect his/her own safety and health, the safety and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competencies, in accordance with the law, the Statute, general acts, and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	74
INSPECTORATE		
(name of the organisational unit)		
PHARMACEUTICAL INSPECTOR FOR GOOD MANUFACTURING AND GOOD DISTRIBUTION PRACTICE III (GMDP INSPECTOR III)		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in pharmacy, medicine, veterinary medicine, chemistry, pharmaceutical chemistry, technology, or biology.	
Work experience	1 year of experience in activities within the field of manufacture and/or distribution of medicinal products, or inspection of the manufacture and/or distribution of medicinal products	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies		
Other requirements	Successful completion of professional examination for work in state administration bodies; knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		
DUTIES OF THE POSITION		

- Executes the orders of the Managing director and the Head of the Inspectorate;
- Responsible for performing simple tasks within procedures falling under the competence of the Inspectorate in the field of Good Manufacturing Practice, including assessment of documentation and monitoring of deadlines, under control of Pharmaceutical Inspectors I and II and the Head of the Inspectorate;
- Carries out the tasks relating to preparing notifications to applicants regarding the need to supplement documentation;
- Monitors the preparation of inspections for the purpose of determining compliance with Good Manufacturing Practice and Good Distribution Practice guidelines;
- Performs duties in procedures for the issuance of manufacturing authorisations for medicinal products, medicinal products containing narcotic drugs and psychotropic substances, and precursors (Category 1 precursors used in the manufacture of medicinal products and Category 4 precursors);
- Conducts inspections of the manufacture of medicinal products, investigational medicinal products, active substances and excipients, medicinal products containing narcotic drugs and psychotropic substances, and precursors (Category 1 precursors used in the manufacture of medicinal products and Category 4 precursors), under supervision;
- Performs duties in procedures for the issuance of wholesale distribution authorisations for medicinal products for human use, medicinal products for human use containing narcotic drugs and psychotropic substances, precursors (Category 1 precursors used in the manufacture of medicinal products and Category 4 precursors), and poppy and/or cannabis derivatives intended for medical or pharmaceutical purposes, under supervision;
- Conducts inspections of the wholesale distribution of medicinal products for human use, medicinal products for human use containing narcotic drugs and psychotropic substances, precursors (Category 1 precursors used in the manufacture of medicinal products and Category 4 precursors), and poppy and/or cannabis derivatives intended for medical or pharmaceutical purposes, under supervision;
- Performs duties in procedures for the issuance of GMP Certificates for medicinal products and active substances, under supervision;
- Performs duties in procedures for the issuance of GDP Certificates for medicinal products for human use, under supervision;
- Performs duties in procedures for registration in the Register of Manufacturers, Importers and Distributors of Active Substances, under supervision;
- Conducts GDP inspections of importers and distributors of active substances and performs duties related to the issuance of GDP Certificates for active substances, under supervision;
- Participates in carrying out other inspections within the Inspectorate's remit, in accordance with his/her level of training, operational needs, or upon the instruction of the Head of the Inspectorate;
- Participates in the preparation of the annual inspection plan;
- Monitors procedures related to substandard and falsified medicinal products;
- Participates in the procedure of the assessment of quality defects reports by order of the the Head of the Inspectorate;
- Participates in sending Rapid Alerts within the Rapid Alert Network (RAN);
- Collects samples of medicinal products and raw materials for quality control purposes;
- Participates in commissions assessing compliance with requirements for the manufacture of medical devices;
- Participates in commissions assessing compliance with requirements for the wholesale distribution of medical devices;
- Participates in cooperation with the state administration authority responsible for inspection affairs and other authorities;
- Undertakes administrative measures and actions in accordance with the law;
- Proposes continuing professional development activities for employees of the Inspectorate;
- Participates in the preparation and revision of standard operating procedures and other quality system documents within the Inspectorate's remit;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute;
- Uses work resources and materials purposefully and rationally;
- Ensures compliance with occupational health and safety regulations and environmental protection regulations, and performs duties in a manner that does not endanger or harm the environment or the life and health of himself/herself and others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, cause material damage, or affect his/her own safety and health, the safety and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competencies, in accordance with the law, the Statute, general acts, and other acts of the Institute

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	75
INSPECTORATE		
(name of the organisational unit)		
PHARMACEUTICAL INSPECTOR FOR GOOD PHARMACOVIGILANCE PRACTICE AND GOOD CLINICAL PRACTICE I (GVP/GCP INSPECTOR I)		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in pharmacy, medicine, veterinary medicine, chemistry, pharmaceutical chemistry, technology, or biology.	
Work experience	5 years of experience in activities in the field of pharmacovigilance and/or clinical trials	
Special health requirements	NO	
Wworking hours	Full time – 40 hours per week	
Competencies	Specialised expertise and independence in work	
Other requirements	Successful completion of professional examination for work in state administration bodies; Advanced knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes the orders of the Managing director and the Head of the Inspectorate;
- Responsible for independently performing the most complex tasks within procedures falling under the competence of the Inspectorate in the field of Good Pharmacovigilance Practice and Good Clinical Practice, including assessment of documentation and monitoring of deadlines
- Responsible for preparing notifications to inspected entities regarding the need to supplement documentation;
- Organises the preparation of inspections for the purpose of verifying compliance with pharmacovigilance system requirements, including compliance with the Good Pharmacovigilance Practices (GVP) Guidelines, and compliance with Good Clinical Practice (GCP) requirements and the Good Clinical Practice Guidelines;
- Independently conducts inspections for the purpose of verifying compliance with pharmacovigilance system requirements and the Good Pharmacovigilance Practices (GVP) Guidelines;
- Conducts inspections for the purpose of verifying compliance with Good Clinical Practice (GCP) requirements, including inspections to verify that clinical trials are conducted in accordance with the clinical trial protocol, the Good Clinical Practice (GCP) Guidelines and the applicable legislation;
- Conducts official inspections of documents, facilities, records and any other data considered relevant to a clinical trial at the clinical trial site, the sponsor and/or the Contract Research Organisation (CRO), or at other institutions deemed appropriate for inspection by the competent authorities;
- Conducts inspections to verify compliance of clinical trials (before, during and after completion of the clinical trial) as part of the procedure for granting a marketing authorisation, as well as during the validity period of the marketing authorisation;
- Suspends or prohibits the conduct of a clinical trial where it is not conducted in accordance with the clinical trial protocol, the Good Clinical Practice (GCP) Guidelines and the applicable legislation;
- Participates in carrying out other inspections within the Inspectorate's remit, in accordance with his/her level of training, operational needs, or upon the instruction of the Head of the Inspectorate;
- Participates in the preparation of the annual inspection plan;
- Participates in activities related to monitoring substandard and falsified medicinal products in files where there is suspicion that the benefit-risk balance of their use is unfavourable;
- Conducts sampling of medicinal products for the purpose of quality testing;
- Undertakes administrative measures and actions in accordance with the law;
- Proposes continuous education for employees within the Inspectorate and participates in the training of lower-level employees;

- Participates in the preparation and revision of standard operating procedures and other quality system documents within the Inspectorate's remit;
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- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute;
- Uses work resources and materials purposefully and rationally;
- Ensures compliance with occupational health and safety regulations and environmental protection regulations, and performs duties in a manner that does not endanger or harm the environment or the life and health of himself/herself and others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, cause material damage, or affect his/her own safety and health, the safety and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competencies, in accordance with the law, the Statute, general acts, and other acts of the Institute

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	76
INSPECTORATE		
(name of the organisational unit)		
PHARMACEUTICAL INSPECTOR FOR GOOD PHARMACOVIGILANCE PRACTICE AND GOOD CLINICAL PRACTICE II (GVP/GCP INSPECTOR II)		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in pharmacy, medicine, veterinary medicine, chemistry, pharmaceutical chemistry, technology, or biology.	
Work experience	3 years of work experience in activities in the field of pharmacovigilance and/or clinical trials	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Specialised expertise and independence in work	
Other requirements	Successful completion of professional examination for work in state administration bodies; knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes the orders of the Managing director and the Head of the Inspectorate;
- Responsible for independently performing complex tasks within procedures falling under the competence of the Inspectorate in the field of Good Pharmacovigilance Practice and Good Clinical Parctice, including assessment of documentation and monitoring of deadlines;
- Responsible for preparing notifications to inspected entities regarding the need to supplement documentation;
- Organises the preparation of inspections for the purpose of verifying compliance with pharmacovigilance system requirements, including compliance with the Good Pharmacovigilance Practice (GVP) Guidelines, and compliance with Good Clinical Practice (GCP) requirements and the Good Clinical Practice (GCP) Guidelines;
- Independently conducts inspections for the purpose of verifying compliance with pharmacovigilance system requirements and the Good Pharmacovigilance Practice (GVP) Guidelines;
- Conducts inspections for the purpose of verifying compliance with Good Clinical Practice (GCP) requirements, including verifying that clinical trials are conducted in accordance with the clinical trial protocol, the Good Clinical Practice (GCP) Guidelines and the applicable legislation;
- Conducts official inspections of documents, facilities, records and all other data considered to be related to a clinical trial and located at the clinical trial site, the sponsor and/or the Contract Research Organisation (CRO), or at other institutions deemed appropriate for inspection by the competent authorities;
- Conducts inspections to verify compliance of clinical trials (before, during and after completion of the clinical trial) as part of the procedure for granting a marketing authorisation, as well as during the validity period of the marketing authorisation;
- Suspends or prohibits the conduct of a clinical trial where it is not conducted in accordance with the clinical trial protocol, the Good Clinical Practice (GCP) Guidelines and the applicable legislation;
- Participates in carrying out other inspections within the Inspectorate's remit, in accordance with his/her level of training, operational needs, or upon the instruction of the Head of the Inspectorate;

Participates in the preparation of the annual inspection plan;

- Monitors activities related to substandard and falsified medicinal products in files where there is suspicion that the benefit-risk balance of their use is unfavourable;
- Conducts sampling of medicinal products for the purpose of quality testing;
- Undertakes administrative measures and actions in accordance with the law;
- Proposes continuous education for employees within the Inspectorate and participates in the training of lower-level employees;

- Proposes improvements and revisions of standard operating procedures within the competence of the Inspectorate;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute;
- Uses work resources and materials purposefully and rationally;
- Ensures compliance with occupational health and safety regulations and environmental protection regulations, and performs duties in a manner that does not endanger or harm the environment or the life and health of himself/herself and others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, cause material damage, or affect his/her own safety and health, the safety and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competencies, in accordance with the law, the Statute, general acts, and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	77
INSPECTORATE		
(name of the organisational unit)		
PHARMACEUTICAL INSPECTOR FOR GOOD PHARMACOVIGILANCE PRACTICE AND GOOD CLINICAL PRACTICE III (GVP/GCP INSPECTOR III)		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in pharmacy, medicine, veterinary medicine, chemistry, pharmaceutical chemistry, technology, or biology.	
Work experience	1 year of experience in activities in the field of pharmacovigilance and/or clinical trials	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies		
Other requirements	Successful completion of professional examination for work in state administration bodies; knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes the orders of the Managing director and the Head of the Inspectorate;
- Responsible for performing routine tasks within procedures falling under the competence of the Inspectorate in the field of Good Pharmacovigilance Practice and Good Clinical Practice, including assessment of documentation and monitoring of deadlines, under control of the Head of the Inspectorate or pharmaceutical inspectors;
- Responsible for preparing notifications to inspected parties regarding the need to supplement documentation;
- Monitors the preparation of inspections for the purpose of verifying compliance with pharmacovigilance system requirements, including compliance with the Good Pharmacovigilance Practice (GVP) Guidelines, and compliance with Good Clinical Practice (GCP) requirements and the Good Clinical Practice (GCP) Guidelines;
- Conducts inspections for the purpose of verifying compliance with pharmacovigilance system requirements and the Good Pharmacovigilance Practice (GVP) Guidelines, under supervision;
- Conducts inspections for the purpose of verifying compliance with Good Clinical Practice (GCP) requirements, including verifying that clinical trials are conducted in accordance with the clinical trial protocol, the Good Clinical Practice (GCP) Guidelines and the applicable legislation, under supervision;
- Conducts official inspections of documents, facilities, records and all other data considered to be related to a clinical trial and located at the clinical trial site, the sponsor and/or the Contract Research Organisation (CRO), or at other institutions deemed appropriate for inspection by the competent authorities, under supervision;
- Conducts inspections to verify compliance of clinical trials (before, during and after completion of the clinical trial) as part of the procedure for granting a marketing authorisation, as well as during the validity period of the marketing authorisation, under supervision;
- Participates in carrying out other inspections within the Inspectorate's remit, in accordance with his/her level of training, operational needs, or upon the instruction of the Head of the Inspectorate;
- Participates in the preparation of the annual inspection plan;
- Monitors activities related to substandard and falsified medicinal products in files where there is suspicion that the benefit-risk balance of their use is unfavourable;
- Conducts sampling of medicinal products for the purpose of quality testing;
- Undertakes administrative measures and actions in accordance with the law;
- Proposes continuing professional development activities for employees of the Inspectorate;
- Participates in the preparation and revision of standard operating procedures and other quality system documents within the Inspectorate's remit;

- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute;
- Uses work resources and materials purposefully and rationally;
- Ensures compliance with occupational health and safety regulations and environmental protection regulations, and performs duties in a manner that does not endanger or harm the environment or the life and health of himself/herself and others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, cause material damage, or affect his/her own safety and health, the safety and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competencies, in accordance with the law, the Statute, general acts, and other acts of the Institute.

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INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	77
INSPECTORATE		
(name of the organisational unit)		
ASSOCIATE FOR INSPECTION AFFAIRS		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in pharmacy, medicine, veterinary medicine, chemistry, pharmaceutical chemistry, technology, or biology.	
Work experience	1 year of experience in the relevant field	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies		
Other requirements	Successful completion of professional examination for work in state administration bodies; knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes the orders of the Managing director and the Head of the Inspectorate;
- Responsible for performing the simplest tasks within the procedures under the competence of the Inspectorate, assessment of documentation and monitoring of deadlines, under continuous supervision and control by Expert Associates I and II, the Head of the Inspectorate;
- Participates in the preparation of notifications to applicants regarding the need for supplementation of documentation, as well as regarding the formal completeness of applications;
- Participates in the preparation of outgoing acts and monitors the preparation of inspections for the purpose of determining compliance with the requirements of Good Manufacturing Practice;
- Monitors the preparation of inspections for the purpose of determining compliance with the requirements of Good Distribution Practice;
- Monitors the preparation of inspections for the purpose of determining compliance with the requirements of Good Clinical Practice;
- Monitors the preparation of inspections for the purpose of determining compliance with pharmacovigilance system requirements;
- Monitors the procedures for issuing manufacturing authorisations for medicinal products, narcotic drugs (active substances and finished medicinal products) and precursors (active substances) used for medical and pharmaceutical purposes;
- Monitors the procedures for issuing wholesale distribution authorisations for medicinal products for human use, poppy and/or cannabis preparations used for medical or pharmaceutical purposes, narcotic drugs (active substances and finished medicinal products) and precursors (active substances);
- Monitors the procedures for preparation and issuance of certificates of compliance with good practices and Report on the implementation of Good Pharmacovigilance Practice Guidelines;
- Monitors the procedures for entry into the Register of manufacturers, importers and wholesalers of active substances;
- Participates in inspections within the competence of the Inspectorate, in the capacity of an observer;
- Participates in medicinal product sampling procedures in the presence of a pharmaceutical inspector;
- Provides administrative support to pharmaceutical inspectors;
- Responsible for acting in accordance with the principles of integrity and ethical standards of the Institute;
- Uses work equipment and materials purposefully and rationally;

- Ensures compliance with occupational health and safety regulations and environmental protection regulations, and performs tasks in a manner that does not endanger or harm the environment and protects his/her own life and health, as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or may affect the performance of duties, cause material damage, or affect his/her own protection and health, the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competencies, in accordance with the law, the Statute, general acts and other acts of the Institute

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	78
LABORATORY		
(name of the organisational unit)		
HEAD OF THE LABORATORY		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural or technical-technological field.	
Work experience	5 years of experience in physicochemical laboratory testing activities	
Special health requirements	YES - in accordance with the law governing protection against ionising radiation and radiation practices	
Working hours	Full time – 40 hours	
Competencies	Organisational and communication skills	
Other requirements	Successful completion of professional examination for work in state administration bodies; Advanced knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office), Certificate of training for internal auditor according to ISO 17025 standard	
POSITION COEFFICIENT		
C1		
DUTIES OF THE POSITION		

- Executes the orders of the Managing director;
- Manages the work of the Laboratory and is responsible for the planning, organisation, implementation and control of business processes within the competence of the Laboratory, and supervises their implementation;
- Responsible for performing the most complex tasks and duties within the competence of the Laboratory;
- Responsible for assigning duties to employees within the Laboratory and ensuring coordination and cooperation in the process of their execution;
- Ensures that tasks within the competence of the Laboratory are carried out in the manner and within the deadlines prescribed by law;
- Responsible for the preparation/control of information/documents published on the Institute's website, within the competence of the Laboratory;
- Supervises the processing of applications within the competence of the Laboratory;
- Responsible for the preparation and drafting of reports related to activities within the competence of the Laboratory;
- Performs/supervises the issuance of outgoing acts and documents in procedures within the competence of the Laboratory;
- Plans, organises, implements and supervises the execution of all expert and operational activities of the Laboratory;
- Participates in expert teams responsible for making the most significant decisions within the competence of the Institute;
- Analyses challenges in the performance of duties, prepares guidelines and instructions for employees for harmonisation and implementation of best practices;
- Approves laboratory testing reports;
- Approves qualification protocols and reports;
- Approves specifications for laboratory equipment;
- Performs activities related to monitoring, cooperation and implementation of WHO, EDQM, EMA, ICH, ISO and other international expert guidelines and standards, as well as activities related to Laboratory accreditation;
- Participates in the process of quality control of medicinal products on the market;
- Prepares the annual sampling plan for medicinal products on the market based on risk assessment, communication and cooperation with all organisational units of the Institute, including decision-making regarding medicinal products to be subject to control and the scope of testing based on risk assessment;
- Participates in combating counterfeit medicinal products;
- Communicates with relevant organisations (EDQM, EMA, OMCL, WHO) in files involving counterfeit or substandard medicinal products;
- Participates in the preparation of notifications to the authority responsible for inspection affairs or the authority responsible for veterinary affairs regarding suspected counterfeit medicinal products and their detection on the market;
- Performs activities related to planning, coordination and execution of activities concerning the development, implementation, maintenance and improvement of the Laboratory quality management system, in accordance with ISO/IEC 17025 requirements;
- Coordinates activities and expert tasks related to the Laboratory quality system, such as drafting new quality system documents (procedures, instructions), processing them in the information system, distribution, implementation and monitoring of the application of new procedures and instructions;
- Prepares and updates the Laboratory Quality Manual;
- Coordinates activities related to initiating corrective and preventive actions in the Laboratory, and monitors the implementation and effectiveness of such actions;
- Prepares reports on the status of the Laboratory quality system, internal audits, corrective and preventive actions;
- Defines the list of records and the place, duration and method of record retention;
- Participates in the supplier verification process, assessment of their quality systems and preparation of the list of verified suppliers;
- Proposes measures and procedures for the introduction and maintenance of the quality system in accordance with the requirements of relevant national and international standards in the field of medicinal product testing and control;
- Proposes and participates in the continuous training of Laboratory employees;
- Responsible for the preparation of standard operating procedures within the competence of the Laboratory;
- Responsible for acting in accordance with the principles of integrity and ethical standards of the Institute, and for ensuring compliance with and implementation of the same within the organisational unit under his/her management;
- Uses work equipment and materials purposefully and rationally;
- Ensures compliance with occupational health and safety regulations and environmental protection regulations, and performs duties in a manner that does not endanger or damage the environment and protects his/her own life and health, as well as the life and health of others;
- Informs the immediate supervisor of important circumstances that affect or may affect the performance of duties, occurrence of material damage, or the protection and health of himself/herself, other employees and the environment;
- Performs other duties, within the level of qualifications and competencies, in accordance with the law, the Statute, general acts and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	79
LABORATORY		
(name of the organisational unit)		
EXPERT ASSOCIATE I FOR INSTRUMENTAL ANALYSES AND EQUIPMENT QUALIFICATION		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural or technical-technological field.	
Work experience	5 years of experience in physico-chemical laboratory testing activities	
Special health requirements	YES - in accordance with the law governing protection against ionising radiation and radiation practices	
Working hours	Full time - 40 hours	
Competencies	Specialised expertise and independence in work	
Other requirements	Successful completion of professional examination for work in state administration bodies; Advanced knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package, Certificate of training for internal auditor according to ISO 17025 standard	
POSITION COEFFICIENT		
C1		
DUTIES OF THE POSITION		

- Executes the orders of the Managing director and the Head of the Laboratory;
- Responsible for independently performing the most complex tasks within the procedures under the competence of the Laboratory, assessment of documentation and monitoring of deadlines, including supervision of the work of other employees within the Laboratory;
- Plans and executes all expert and operational activities within the Laboratory;
- Participates in combating counterfeit medicinal products;
- Introduces new laboratory procedures and improves existing working methods in the field of laboratory activities;
- Plans and conducts laboratory quality control activities;
- Performs statistical processing of results and prepares reports on laboratory quality control of medicinal products;
- Controls and approves testing results in the Laboratory;
- Performs activities related to drafting and amending specifications for laboratory equipment;
- Participates in procurement procedures and tenders for laboratory equipment and consumables;
- Participates in the preparation of procurement and validation plans for laboratory equipment and in defining project specifications for equipment;
- Participates in activities related to installation, operational and performance qualification of equipment;
- Initiates urgent procurement of equipment parts;
- Participates in the preparation of the annual sampling plan for medicinal products on the market based on risk assessment, communication and cooperation with all organisational units of the Institute, including decisions on medicinal products to be subject to control and the scope of testing based on risk assessment;
- Participates in the preparation of qualification protocols and reports;
- Performs control of manufacturer documentation and/or preparation of qualification protocols (installation, operational and performance qualification);
- Verifies and harmonises qualification criteria and acceptance limits, and reviews equipment qualification results;
- Performs activities related to defining, preparing and amending specifications for items required by the Institute's Laboratory (chemicals, laboratory glassware, etc.), as well as incoming inspection of all items in the Institute's Laboratory;
- Carries out activities related to calibration, servicing and repair of equipment;
- Maintains records on equipment, types of maintenance, equipment status and accompanying documentation;
- Performs activities related to monitoring equipment functionality and maintaining records in accordance with established methodology;
- Controls requisitions and prepares requests for procurement of reagents and consumables;
- Maintains records of withdrawn standards and expired chemicals;
- Maintains records and manages disposal of pharmaceutical and chemical waste from the Laboratory;
- Prepares and carries out activities necessary for proper handling of hazardous substances and maintaining related records;
- Proposes continuous training of Laboratory employees and participates in training of lower-level staff;
- Proposes improvements and revisions of standard operating procedures within the competence of the Laboratory;
- Responsible for acting in accordance with the principles of integrity and ethical standards of the Institute;
- Uses work equipment and materials purposefully and rationally;
- Ensures compliance with occupational health and safety regulations and environmental protection regulations, and performs tasks in a manner that does not endanger or damage the environment and protects his/her own life and health, as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or may affect the performance of duties, occurrence of material damage, or the protection and health of himself/herself, other employees and the environment;
- Performs other duties, within the level of qualifications and competencies, in accordance with the law, the Statute, general acts and other acts of the Institute

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	80
LABORATORY		
(name of the organisational unit)		
EXPERT ASSOCIATE II FOR INSTRUMENTAL ANALYSES AND EQUIPMENT QUALIFICATION		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural or technical-technological field.	
Work experience	3 years of experience in laboratory testing activities	
Special health requirements	YES - in accordance with the law governing protection against ionising radiation and radiation practices	
Working hours	Full time – 40 hours per week	
Competencies	Specialised expertise and independence in work	
Other requirements	Successful completion of professional examination for work in state administration bodies; Advanced knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package; Certificate of training about requirements of ISO 17025 standard	
POSITION COEFFICIENT		
C1		
DUTIES OF THE POSITION		

- Executes the orders of the Managing director and the Head of the Laboratory;
- Responsible for independently performing complex tasks within the procedures under the competence of the Laboratory, assessment of documentation and monitoring of deadlines, including supervision of the work of other employees within the Laboratory;
- Participates in planning and execution of all expert and operational activities within the Laboratory;
- Participates in combating counterfeit medicinal products;
- Introduces new laboratory procedures and improves existing working methods in the field of laboratory activities;
- Participates in planning and conducting laboratory quality control activities;
- Performs statistical processing of results and prepares reports on laboratory testing;
- Drafts and amends specifications for laboratory equipment;
- Participates in procurement procedures and tenders for laboratory equipment and consumables;
- Prepares procurement and validation plans for laboratory equipment and defines project specifications for equipment;
- Participates in activities related to installation, operational and performance qualification of equipment;
- Initiates urgent procurement of equipment parts;
- Prepares qualification protocols and reports;
- Participates in the preparation of the annual sampling plan for medicinal products on the market based on risk assessment, communication and cooperation with all organisational units of the Institute, including decisions on medicinal products to be subject to control and the scope of testing based on risk assessment;
- Performs control of manufacturer documentation and/or prepares qualification protocols (installation, operational and performance qualification);
- Verifies and harmonises qualification criteria and acceptance limits, and reviews equipment qualification results;
- performs defining, drafting and amending specifications for items required by the Institute's Laboratory (chemicals, laboratory glassware, etc.), as well as in the incoming inspection process for all items in the Institute's Laboratory;
- carries out activities related to calibration, servicing and repair of equipment;
- Maintains records on equipment, types of maintenance, equipment status and accompanying documentation;
- Monitors equipment functionality and maintains records in accordance with the established methodology;
- Prepares requisitions and requests for procurement of reagents and consumables;
- Maintains records of withdrawn standards and expired chemicals;
- Maintains records and manages disposal of pharmaceutical and chemical waste from the Laboratory;
- Prepares and performs activities necessary for proper handling of hazardous substances and maintaining records;
- Proposes training for Laboratory employees and participates in training activities;
- Proposes improvements and revisions of standard operating procedures within the competence of the Laboratory;
- Responsible for acting in accordance with the principles of integrity and ethical standards of the Institute;
- Uses work equipment and materials purposefully and rationally;
- Ensures compliance with occupational health and safety regulations and environmental protection regulations, and performs tasks in a manner that does not endanger or damage the environment and protects his/her own life and health, as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or may affect the performance of duties, occurrence of material damage, or the protection and health of himself/herself, other employees and the environment;
- Performs other duties, within the level of qualifications and competencies, in accordance with the law, the Statute, general acts and other acts of the Institute

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	81
LABORATORY		
(name of the organisational unit)		
EXPERT ASSOCIATE III FOR INSTRUMENTAL ANALYSES AND EQUIPMENT QUALIFICATION		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural or technical-technological field.	
Work experience	1 year of experience in laboratory testing activities	
Special health requirements	YES - in accordance with the law governing protection against ionising radiation and radiation practices	
Working hours	Full time – 40 hours per week	
Competencies	Specialised expertise and independence in work	
Other requirements	Successful completion of professional examination for work in state administration bodies; knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package;	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes orders issued by the Managing Director and the Head of the Laboratory;
- Responsible for performing duties in procedures within the Laboratory's remit, assessing documentation and monitoring deadlines, under the supervision of ExpertAssociate I and the Head of the Laboratory;
- Participates in carrying out all professional and operational activities of the Laboratory;
- Participates in combating the occurrence of falsified medicinal products;
- Proposes the introduction of new laboratory procedures and improvements to existing laboratory working methods;
- Participates in planning and implementing laboratory quality control;
- Performs statistical processing of results and prepares laboratory testing reports;
- Revises specifications for laboratory equipment;
- Participates in procurement procedures and tender processes for laboratory equipment and consumables;
- Participates in activities related to installation, operational and performance qualification of equipment;
- Initiates emergency procurement of equipment spare parts;
- Prepares qualification protocols and qualification reports;
- Participates in the preparation of the annual risk-based sampling plan for medicinal products on the market, through communication and cooperation with all organisational units of the Institute, including decision-making on medicinal products to be sampled and the scope of testing based on risk assessment;
- Performs manufacturer's inspections and/or prepares protocols for equipment qualification (installation, operational and performance qualification);
- Verifies and aligns qualification acceptance criteria and acceptance limits, and verifies equipment qualification results;
- Participates in defining, preparing and revising specifications for items required by the Institute's Laboratory (chemicals, laboratory glassware, etc.), as well as in the incoming inspection of all items received by the Laboratory;
- Participates in activities related to equipment calibration, servicing and repair;
- Maintains records of equipment, maintenance activities, equipment status and related documentation;
- Monitors equipment operational status and maintains records in accordance with the established methodology;
- Prepares requisitions and procurement requests for reagents and consumables;
- Maintains records of withdrawn standards and expired chemicals;

- Maintains records of and arranges the disposal of pharmaceutical and chemical waste generated by the Laboratory;
- Prepares and performs activities necessary for the proper handling of hazardous materials and maintains the relevant records;
- Proposes improvements to and revisions of Standard Operating Procedures (SOPs) within the Laboratory's remit;
- Participates in the work of working groups, committees and other working bodies;
- Acts in accordance with the Institute's integrity principles and ethical standards;
- Uses work resources and materials in a purposeful, efficient and economical manner;
- Complies with occupational health and safety regulations and environmental protection requirements and performs duties in a manner that does not endanger or adversely affect the environment, while safeguarding his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of any significant circumstances that affect or may affect the performance of duties, result in material damage, or impact his/her own safety and health, the safety and health of other employees, or the environment;
- Performs other duties commensurate with his/her qualifications and competencies, in accordance with the law, the Statute, and the general and other acts of the Institute

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	82
LABORATORY		
(name of the organisational unit)		
ASSOCIATE FOR INSTRUMENTAL ANALYSES AND EQUIPMENT QUALIFICATION		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VI/VII	
Level of educational and professional qualifications	University degree, qualification comprising 180, 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 3, 4 or 3+1 or 3+2 years). Completed studies in medical, natural or technical-technological field.	
Work experience	1 year of experience in relevant field	
Special health requirements	YES - in accordance with the law governing protection against ionising radiation and radiation practices	
Working hours	Full time – 40 hours per week	
Competencies		
Other requirements	Successful completion of professional examination for work in state administration bodies; knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		
DUTIES OF THE POSITION		

- Executes the orders of the Managing director and the Head of the Laboratory;
- Participates in the performance of the simplest tasks within the competence of the Laboratory, under training and control of the Expert Associate I and the Head of the Laboratory;
- Participates in the performance of expert and operational activities within the Laboratory;
- Proposes introduction of new laboratory procedures and the improvement of existing working methods in the field of laboratory activities;
- Participates in statistical processing of results and prepares reports on laboratory testing;
- Participates in drafting and amending of specifications for laboratory equipment;
- Monitors the preparation of procurement plans and validation of laboratory equipment, as well as the definition of project specifications for equipment;
- Participates in activities related to installation, operational and performance qualification of equipment;
- Initiates urgent procurement of equipment parts;
- Participates in the preparation of qualification reports;
- Participates in the preparation of the annual sampling plan for medicinal products on the market based on risk assessment and the instructions of the immediate supervisor;
- Participates in activities related to calibration, servicing and repair of equipment;
- Maintains records on equipment, types of maintenance, equipment status and accompanying documentation;
- Monitors equipment functionality and maintains records in accordance with the established methodology;
- Initiates requisitions and requests for procurement of reagents and consumables;
- Implements and maintains records on withdrawal of expired standards and chemicals;
- Implements and maintains records and disposal of pharmaceutical and chemical waste from the Laboratory;
- Prepares and performs activities necessary for proper handling of hazardous substances and maintaining records;
- Responsible for acting in accordance with the principles of integrity and ethical standards of the Institute;
- Uses work equipment and materials purposefully and rationally;
- Ensures compliance with occupational health and safety regulations and environmental protection regulations, and performs tasks in a manner that does not endanger or damage the environment and protects his/her own life and health, as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or may affect the performance of duties, occurrence of material damage, or the protection and health of himself/herself, other employees and the environment;
- Performs other duties, within the level of qualifications and competencies, in accordance with the law, the Statute, general acts and other acts of the Institute

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	83
LABORATORY		
(name of the organisational unit)		
CHEMICAL TECHNICIAN		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	IV/IV1	
Level of educational and professional qualifications	Secondary education, qualification comprising 180 (ECTS) credits (study programme lasting 4 years)	
Work experience	6 months of experience in the laboratory activities	
Special health requirements	YES - in accordance with the law governing protection against ionising radiation and radiation practices	
Working hours	Full time – 40 hours per week	
Competencies		
Other requirements	Successful completion of professional examination for work in state administration bodies; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes orders issued by the Managing Director and the Head of the Laboratory;
- Performs technical tasks within the Laboratory's remit;
- Prepares samples for analysis within the organisational unit;
- Participates in method validation within the organisational unit;
- Responsible for maintaining equipment in a clean and operational condition;
- Monitors the introduction of new laboratory procedures and improvements to existing laboratory working methods;
- Initiates emergency procurement of equipment spare parts;
- Prepares qualification reports;
- Participates in activities related to equipment calibration, servicing and repair;
- Monitors equipment operational status and maintains records in accordance with the established methodology;
- Washes and distributes laboratory glassware and other supplies required for the Laboratory's activities;
- Initiates requisitions and procurement requests for reagents and consumables;
- Maintains records of withdrawn standards and expired chemicals;
- Maintains records of and arranges the disposal of pharmaceutical and chemical waste generated by the Laboratory;
- Acts in accordance with the Institute's integrity principles and ethical standards;
- Uses work resources and materials in a purposeful, efficient and economical manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements and performs duties in a manner that does not endanger or adversely affect the environment, while safeguarding his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of any significant circumstances that affect or may affect the performance of duties, result in material damage, or impact his/her own safety and health, the safety and health of other employees, or the environment;
- Performs other duties commensurate with his/her qualifications and competencies, in accordance with the law, the Statute, and the general and other acts of the Institute

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	84
CENTRE FOR MEDICAL DEVICES		
(name of the organisational unit)		
HEAD OF THE CENTRE FOR MEDICAL DEVICES		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural or technical-technological field.	
Work experience	5 years of experience in activities within the competences of the Centre	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Organisational and communication skills	
Other requirements	Successful completion of professional examination for work in state administration bodies; Advanced knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		
DUTIES OF THE POSITION		

- Executes the orders of the Managing director;
- Manages the work of the Centre and is responsible for planning, organising, implementing and controlling business processes within the competence of the Centre, and supervises their implementation;
- Responsible for performing the most complex tasks and duties within the competence of the Centre;
- Responsible for assigning duties to employees within the Centre and ensuring coordination and cooperation in the process of their execution;
- Responsible for issuing outgoing acts and documents in procedures within the competence of the Centre;
- Responsible for organising and participating in the continuous training of employees within the Centre;
- Responsible for preparing/controlling information and documents published on the Institute's website within the competence of the Centre;
- Ensures that tasks within the competence of the Centre are carried out in the manner and within the deadlines prescribed by law;
- Ensures the accuracy and completeness of records relating to applications received within the competence of the Centre;
- Supervises the processing of applications within the competence of the Centre;
- Supervises activities related to informing applicants about the need to supplement documentation and the status of files being processed within the Centre;
- Participates in activities related to harmonisation of regulations in the field of medical devices with the regulations and guidelines of the European Union and international institutions;
- Responsible for preparing and drafting reports related to activities within the competence of the Centre;
- Cooperates with experts from the list of experts established by the Institute;
- Responsible for supervising standard operating procedures within the competence of the Centre;
- Participates in the work of working groups, commissions and working bodies;
- Participates in the preparation of expert background materials for drafting letters, responses to inquiries, announcements, media statements and other informational content within the competence of the Centre;
- Responsible for acting in accordance with the principles of integrity and ethical standards of the Institute, and for ensuring compliance with and implementation of the same within the organisational unit under his/her management;
- Uses work equipment and materials purposefully and rationally;
- Ensures compliance with occupational health and safety regulations and environmental protection regulations, and performs duties in a manner that does not endanger or damage the environment and protects his/her own life and health, as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or may affect the performance of duties, occurrence of material damage, or the protection and health of himself/herself, other employees and the environment;
- Performs other duties, within the level of qualifications and competencies, in accordance with the law, the Statute, general acts and other acts of the Institute

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	85
CENTRE FOR MEDICAL DEVICES		
(name of the organisational unit)		
EXPERT ASSOCIATE I FOR MEDICAL DEVICES		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural or technical-technological field.	
Work experience	5 years of experience in activities within the competences of the Centre	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Specalised expertise and independence in work	
Other requirements	Successful completion of professional examination for work in state administration bodies; Advanced knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes the orders of the Managing director and the Head of the Centre;
- Responsible for independently performing most complex tasks within the procedures under the competence of the Centre, assessment of documentation and monitoring of deadlines;
- Responsible for preparing notifications to applicants regarding the need for supplementation of documentation/status of files being processed within the Centre;
- Responsible for maintaining the register of medical devices (registration of medical devices, renewal of registration, amendment to the registration, and deletion of medical devices from the register);
- Responsible for authorising clinical investigations of medical devices and overseeing the conduct of clinical investigations of medical devices;
- Responsible for establishing the medical device vigilance system (collection and analysis of post-market data on medical devices);
- Prepares medical device vigilance reports and participates in the preparation and review of information and documents published on the Institute's website;
- Participates in the alignment of legislation in the field of medical devices with European Union legislation and the regulations and guidelines of international organisations;
- Participates in the work of expert groups at the European Union level;
- Responsible for preparing and issuing expert opinions on the classification of medical devices, where combinations of medicinal products and medical devices, medical devices and general use products, or classification of medical devices are concerned;
- Participates in and issues decisions in procedures for determining compliance with requirements for manufacturing, wholesale distribution and retail sale of medical devices, as well as entry into/deletion from the registers of manufacturers and legal entities engaged in wholesale distribution of medical devices, and the register of specialised retail establishments;
- Performs the most complex tasks in procedures for approving the import of unregistered medical devices;
- Responsible for preparing and issuing the most complex outgoing acts and documents in procedures within the competence of the;
- Prepares minutes from commission meetings related to activities within the competence of the Centre;
- Actively participates in revisions of standard operating procedures within the competence of the Centre;
- Proposes continuous training for employees within the Centre and participates in training of lower-level staff;
- Responsible for acting in accordance with the principles of integrity and ethical standards of the Institute;
- Uses work equipment and materials purposefully and rationally;

- Ensures compliance with occupational health and safety regulations and environmental protection regulations, and performs tasks in a manner that does not endanger or damage the environment and protects his/her own life and health, as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or may affect the performance of duties, occurrence of material damage, or the protection and health of himself/herself, other employees and the environment;
- Performs other duties, within the level of qualifications and competencies, in accordance with the law, the Statute, general acts and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	86
CENTRE FOR MEDICAL DEVICES		
(name of the organisational unit)		
EXPERT ASSOCIATE II FOR MEDICAL DEVICES		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural or technical-technological field.	
Work experience	3 years of experience in expert activities within the competences of the Centre	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Specalised expertise and independence in work	
Other requirements	Successful completion of professional examination for work in state administration bodies; knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes the orders of the Managing director and the Head of the Centre;
- Responsible for independently performing complex tasks within the procedures under the competence of the Centre, assessment of documentation and monitoring of deadlines;
- Participates in the preparation of notifications to applicants regarding the need for supplementation of documentation/status of files being processed within the Centre;
- Participates in the authorisation of clinical investigations of medical devices and in overseeing the conduct of clinical investigations of medical devices;
- Participates in the establishment of the medical device vigilance system (collection and analysis of post-market data on medical devices);
- Prepares draft medical device vigilance reports and participates in the preparation and review of information and documents published on the Institute's website;
- Participates in the organisation of workshops for healthcare professionals;
- Participates in the alignment of legislation in the field of medical devices with European Union legislation and the regulations and guidelines of international organisations;
- Participates in maintaining the register of medical devices (registration of medical devices, renewal of registration, amendment to the registration, and deletion of medical devices from the register);
- Prepares expert opinions on the classification of medical devices where combinations of medicinal products and medical devices, medical devices and general use products, or classification of medical devices are concerned;
- Participates in procedures for determining compliance with requirements for manufacturing, wholesale distribution and retail sale of medical devices, as well as entry into/deletion from the registers of manufacturers and legal entities engaged in wholesale distribution of medical devices, and the register of specialised retail establishments;
- Performs complex tasks in procedures for approving the import of unregistered medical devices;
- Responsible for preparing and issuing complex outgoing acts and documents in procedures within the competence of the Centre;
- Participates in drafting minutes from commission meetings related to activities within the competence of the Centre;
- Proposes improvements and revisions of standard operating procedures within the competence of the Centre;
- Proposes continuous training for employees within the Centre and participates in training of lower-level staff;
- Responsible for acting in accordance with the principles of integrity and ethical standards of the Institute;
- Uses work equipment and materials purposefully and rationally;

- Ensures compliance with occupational health and safety regulations and environmental protection regulations, and performs tasks in a manner that does not endanger or damage the environment and protects his/her own life and health, as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or may affect the performance of duties, occurrence of material damage, or the protection and health of himself/herself, other employees and the environment;
- Performs other duties, within the level of qualifications and competencies, in accordance with the law, the Statute, general acts and other acts of the Institute

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	87
CENTRE FOR MEDICAL DEVICES		
(name of the organisational unit)		
EXPERT ASSOCIATE III FOR MEDICAL DEVICES		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural or technical-technological field.	
Work experience	1 year of experience in activities within the competences of the Centre	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies		
Other requirements	Successful completion of professional examination for work in state administration bodies; knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes the orders of the Managing director and the Head of the Centre;
- Responsible for performing simple tasks within the procedures under the competence of the Centre, assessment of documentation and monitoring of deadlines, under control of Expert Associate I and the Head of the Centre;
- Responsible for preparing notifications to applicants regarding the need for supplementation of documentation/status of files being processed within the Centre;
- Participates in the authorisation of clinical investigations and in overseeing the conduct of clinical investigations;
- Participates in the establishment of the medical device vigilance system (collection and analysis of post-market data on medical devices);
- Participates in the preparation of draft medical device vigilance reports and in the preparation and review of information and documents published on the Institute's website;
- Responsible for preparing the basis for maintaining the register of medical devices (registration of medical devices, renewal of registration, amendment to the registration, and deletion of medical devices from the register);
- Participates in procedures for determining compliance with requirements for manufacturing, wholesale distribution and retail sale of medical devices, as well as entry into/deletion from the registers of manufacturers and legal entities engaged in wholesale distribution of medical devices, and the register of specialised retail establishments;
- Responsible for performing simple tasks related to procedures for approving the import of unregistered medical devices;
- Participates in the preparation and issuance of outgoing acts and documents in procedures within the competence of the Centre, under the supervision and control of Expert Associate I and the Head of the Centre;
- Participates in the work of working groups, commissions and working bodies;
- Responsible for acting in accordance with the principles of integrity and ethical standards of the Institute;
- Uses work equipment and materials purposefully and rationally;
- Ensures compliance with occupational health and safety regulations and environmental protection regulations, and performs tasks in a manner that does not endanger or damage the environment and protects his/her own life and health, as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or may affect the performance of duties, occurrence of material damage, or the protection and health of himself/herself, other employees and the environment;
- Performs other duties, within the level of qualifications and competencies, in accordance with the law, the Statute, general acts and other acts of the Institute

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INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	88
CENTRE FOR MEDICAL DEVICES		
(name of the organisational unit)		
ASSOCIATE FOR MEDICAL DEVICES		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural or technical-technological field.	
Work experience	1 year of experience in the relevant field	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies		
Other requirements	Successful completion of professional examination for work in state administration bodies; knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes the orders of the Managing director and the Head of the Centre;
- Performsthe simplest tasks in procedures within the competence of the Centre, assessment of documentation and monitoring of deadlines, under the training and control of Expert Associate I and the Head of the Centre;
- Participates in maintaining the register of medical devices (registration of medical devices, renewal of registration, amendment to the registration, and deletion of medical devices from the register);
- Participates in the preparation of documentation for determining compliance with requirements for manufacturing, wholesale distribution and retail sale of medical devices, as well as entry into/deletion from the registers of manufacturers and legal entities engaged in wholesale distribution of medical devices, and the register of specialised retail establishments;
- Participates in establishing the medical devices vigilance system (collection and analysis of data obtained after placing a medical device on the market);
- Participates in the preparation of draft reports on medical devices vigilance and in the preparation/control of information/documents published on the Institute's website;
- Participates in workshops, as well as in organising workshops with healthcare professionals;
- Participates in the preparation and issuance of outgoing acts and documents in procedures within the competence of the Centre, under the training and control of the Head of the Centre;
- Responsible for acting in accordance with the principles of integrity and ethical standards of the Institute;
- Uses work equipment and materials purposefully and rationally;
- Ensures compliance with occupational health and safety regulations and environmental protection regulations, and performs tasks in a manner that does not endanger or damage the environment and protects his/her own life and health, as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or may affect the performance of duties, occurrence of material damage, or the protection and health of himself/herself, other employees and the environment;
- Performs other duties, within the level of qualifications and competencies, in accordance with the law, the Statute, general acts and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	89
CENTRE FOR MEDICAL DEVICES		
(name of the organisational unit)		
ADMINISTRATIVE-TECHNICAL AFFAIRS OFFICER		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	III/IV1	
Level of educational and professional qualifications	Secondary education, qualification comprising 180 (ECTS) credits (study programme lasting 3 years), or 240 (ECTS) credits (study programme lasting 4 years)	
Work experience	1 year of experience in technical and administrative affairs	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies		
Other requirements	Successful completion of professional examination for work in state administration bodies; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes the orders of the Managing director and the Head of the Centre;
- Responsible for administrative and technical tasks within the Centre (scanning, copying, archiving and distributing documentation);
- Responsible for classification of incoming and outgoing documentation, distribution and maintenance of records on documentation in procedures within the competence of the Medical Devices Centre;
- Required to have knowledge of the basic regulatory requirements in the field of medical devices, for the purpose of proper receipt and classification of files;
- Ensures that each document, submission or file is directed to the Centre in accordance with its content and the regulatory framework governing medical devices;
- Performs tasks related to classification, distribution, recording and submission of acts according to the specificities of the medical devices field through files in the Institute's information system;
- Provides support regarding documentation within the competence of the Centre, submits documentation for review, and monitors retention and archiving deadlines;
- Provides support and participates in the organisation of events organised by the Centre.
- Provides support and participates in the organisation of events organised by the Centre;
- Responsible for acting in accordance with the principles of integrity and the ethical standards of the Institute;
- Uses work equipment and materials in a purposeful and cost-effective manner;
- Ensures compliance with occupational health and safety regulations and environmental protection requirements, and performs duties in a manner that does not endanger or adversely affect the environment, while protecting his/her own life and health as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or could affect the performance of duties, the occurrence of material damage, his/her own protection and health or the protection and health of other employees, and the environment;
- Performs other duties, within the level of qualifications and competence, in accordance with the law, the Statute, general acts, and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	90
CENTRE FOR SCIENCE, INTERNATIONAL COOPERATION AND PROJECTS		
(name of the organisational unit)		
HEAD OF THE CENTRE FOR SCIENCE, INTERNATIONAL COOPERATION AND PROJECTS		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VIII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural or technical-technological field.	
Work experience	5 years of work experience in regulatory affairs within the competence of the Institute and/or projects	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Organisational and communication skills	
Other requirements	Successful completion of professional examination for work in state administration bodies; Advanced knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		
DUTIES OF THE POSITION		

- Executes the orders of the Managing director;
- Manages the work of the Centre and is responsible for planning, organising, implementing and controlling business processes within the competence of the Centre, and supervises their implementation;
- Responsible for assigning tasks to associates within the Centre and ensuring coordination and cooperation in the process of their execution;
- Responsible for implementing and achieving the objectives of the Institute's strategic documents;
- Responsible for coordinating the strategic development of innovation in the field of medicinal products and medical devices, as well as the Institute's development within the process of integration into the European regulatory and scientific research area;
- Manages and coordinates the implementation of activities and tasks within the Institute's remit as part of Montenegro's European integration process;
- Monitors developments in regulatory standards, innovations and international practices in the field of medicinal products and medical devices relevant to the Institute's activities;
- Responsible for promoting and implementing cooperation and coordinating dialogue with the pharmaceutical industry, professional, regulatory, scientific and other relevant institutions at the national and international level;
- Participates in drafting strategic and general documents, as well as legislation relevant to the work of the Institute;
- Promotes and develops cooperation with universities, faculties, research institutions and international organisations;
- Coordinates activities related to the preparation and publication of the Institute's professional and scientific publications, as well as scientific papers authored by the Institute's employees;
- Initiates, prepares, coordinates, manages and monitors the implementation of projects financed from European Union funds, international and other funding sources, including the implementation of project activities, objectives, results and reporting;
- Manages and coordinates the Institute's international cooperation activities with European regulatory agencies, European Union institutions, international organisations and professional networks in the field of medicinal products and medical devices;
- Coordinates activities aimed at strengthening the Institute's institutional and administrative capacities in accordance with European Union standards and practices;
- Manages and coordinates activities related to preparing the Institute for full membership and active participation in European regulatory, professional and scientific networks and bodies;
- Coordinates the participation of the Institute's representatives in international initiatives, European projects, working groups, professional forums and networks;
- Responsible for enhancing the Institute's international visibility and positioning within the European regulatory and scientific research environment;
- Supervises activities related to maintaining licences for scientific research and innovation activities;
- Coordinates the organisation of conferences, professional meetings, training activities and other events organised by the Institute, as well as the preparation of professional materials and presentations;
- Initiates and coordinates the implementation of training activities organised by the Institute for the pharmaceutical industry, healthcare professionals, students and other target groups;
- Responsible for preparing reports, analyses, information and other professional materials within the Centre's remit;
- Responsible for supervising standard operating procedures within the competence of the Centre;
- Responsible for encouraging, maintaining and implementing international cooperation in areas within the competence of the Institute;
- Responsible for ensuring cooperation with other expert organisations and the non-governmental sector at national and international levels;
- Responsible for communication on behalf of the Institute at the international level and participation in the work of international organisations and forums;
- Responsible for acting in accordance with the principles of integrity and ethical standards of the Institute, and for ensuring their observance and implementation within the organisational unit under his/her management;
- Uses work equipment and materials purposefully and rationally;
- Ensures compliance with occupational health and safety regulations and environmental protection regulations, and performs tasks in a manner that does not endanger or damage the environment and protects his/her own life and health, as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or may affect the performance of duties, occurrence of material damage, or the protection and health of himself/herself, other employees and the environment;
- Performs other duties, within the level of qualifications and competencies, in accordance with the law, the Statute, general acts and other acts of the Institute

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	91
CENTRE FOR SCIENCE, INTERNATIONAL COOPERATION AND PROJECTS		
(name of the organisational unit)		
EXPERT ASSOCIATE I FOR SCIENTIFIC-RESEARCH AFFAIRS		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural or technical-technological field.	
Work experience	3 years of experience in scientific research and/or project activities	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Specialised expertise and independence in work	
Other requirements	Successful completion of professional examination for work in state administration bodies; Advanced knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes the orders of the Managing director and the Head of the Centre;
- Participates in establishing cooperation in educational and scientific research activities with faculties in the field of healthcare and other higher education and scientific institutions in the country and abroad;
- Plans and prepares technical specifications for the procurement of expert and scientific literature for the needs of the Institute;
- Performs inventory, cataloguing and preservation of books, doctoral dissertations, master's theses, specialist papers, publications, brochures, journals, etc.;
- Participates in the preparation of publications issued by the Institute, as well as scientific papers by employees published in expert and scientific journals;
- Initiates and coordinates activities related to the preparation, acquisition and implementation of projects;
- Coordinates and monitors the implementation of objectives and results of development and scientific research projects;
- Participates in the implementation of international cooperation with expert and scientific institutions in the field of scientific and other research;
- Initiates and coordinates activities related to maintaining licences for scientific research and innovation activities;
- Participates in coordinating and implementing activities related to organising Institute conferences, as well as preparing and reviewing expert materials and presentations for educational activities within Institute conferences;
- Participates in educational activities organised by the Institute for the pharmaceutical industry, healthcare professionals, students, and others;
- Responsible for acting in accordance with the principles of integrity and ethical standards of the Institute;
- Uses work equipment and materials purposefully and rationally;
- Ensures compliance with occupational health and safety regulations and environmental protection regulations, and performs tasks in a manner that does not endanger or damage the environment and protects his/her own life and health, as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or may affect the performance of duties, occurrence of material damage, or the protection and health of himself/herself, other employees and the environment;
- Performs other duties, within the level of qualifications and competencies, in accordance with the law, the Statute, general acts and other acts of the Institute

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	92
CENTRE FOR SCIENCE, INTERNATIONAL COOPERATION AND PROJECTS		
(name of the organisational unit)		
EXPERT ASSOCIATE I FOR LEGAL AFFAIRS AND INTERNATIONAL COOPERATION		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural or social field.	
Work experience	5 years of professional experience	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Organisational and communicational skills	
Other requirements	Successful completion of professional examination for work in state administration bodies; Advanced knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		
DUTIES OF THE POSITION		

- Executes the orders of the Managing director and the Head of the Centre;
- Participates in regulatory affairs and international cooperation activities and is responsible for organising and monitoring the implementation of activities;
- Monitors and participates in the implementation of tasks for which the Institute is responsible within the framework of Montenegro's European integration process;
- Responsible for harmonising activities and regulations within the competence of the Institute with the regulations, standards, principles and guidelines of the European Union;
- Monitors legislation and prepares technical analyses on the implementation of European Union legislation and the work of European institutions in the field of medicinal products, medical devices, narcotic drugs and psychotropic substances, and proposes solutions for regulatory harmonisation;
- Responsible for cooperation with and support to competent organisational units of the Institute in preparing expert bases for drafting regulations, guidelines and forms within the Institute's scope of work, as well as analysing and harmonising draft laws and secondary legislation;
- Responsible for providing expert opinions and advice on the implementation of regulations within the competence of the Institute;
- Participates as a team member in international activities with international and national regulatory authorities;
- Responsible for ensuring cooperation with other expert organisations and the non-governmental sector at national and international levels;
- Oversees the conduct of negotiations, preparation of materials for concluding international cooperation agreements, and organisation and monitoring of their implementation;
- Responsible for organising and monitoring cooperation with national and international pharmaceutical industry associations;
- Responsible for organising and monitoring international and other conferences, expert meetings and lectures organised by the Institute;
- Oversees the preparation of promotional and presentation materials intended for the Institute's international representation;
- Responsible for communication on behalf of the Institute at the international level and participation in the work of international organisations and forums;
- Responsible for organising and participating in the Institute's publishing and educational activities and participating in editing the Institute's website in English;
- Oversees the publication and updating of adopted laws, secondary legislation, guidelines and forms on the Institute's website;
- Participates in working groups, commissions and working bodies;
- Responsible for acting in accordance with the principles of integrity and ethical standards of the Institute;
- Uses work equipment and materials purposefully and rationally;
- Ensures compliance with occupational health and safety regulations and environmental protection regulations, and performs tasks in a manner that does not endanger or damage the environment and protects his/her own life and health, as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or may affect the performance of duties, occurrence of material damage, or the protection and health of himself/herself, other employees and the environment;
- Performs other duties, within the level of qualifications and competencies, in accordance with the law, the Statute, general acts and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	93
CENTRE FOR SCIENCE, INTERNATIONAL COOPERATION AND PROJECTS		
(name of the organisational unit)		
ASSOCIATE FOR ADMINISTRATIVE SUPPORT		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VI/VII	
Level of educational and professional qualifications	University degree, qualification comprising 180, 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 3, 4 or 3+1 or 3+2 years). Completed studies in social sciences or humanities	
Work experience	1 year of experience in administrative activities	
Special health requirements	NO	
Required daily working hours	Full time – 40 hours per week	
Competencies		
Other requirements	Successful completion of professional examination for work in state administration bodies; Advanced knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes the orders of the Managing director and the Head of the Centre;
- Performs tasks related to the preparation and implementation of the annual plan for education, expert and scientific development of employees of the Institute;
- Performs tasks related to the coordination of expert and scientific development of employees of the Institute and maintenance of records (registers);
- Responsible for maintaining records (registers) of development and scientific research projects;
- Responsible for providing translation and proofreading support for the needs of the Managing director and organisational units of the Institute;
- Participates in coordinating and implementing activities related to organising Institute conferences, as well as preparing and reviewing expert materials and presentations for educational activities within Institute conferences;
- Participates in coordinating and implementing educational activities organised by the Institute for the pharmaceutical industry, healthcare professionals, students, and others;
- Participates in activities related to maintaining licences for scientific research and innovation activities;
- Responsible for acting in accordance with the principles of integrity and ethical standards of the Institute;
- Uses work equipment and materials purposefully and rationally;
- Ensures compliance with occupational health and safety regulations and environmental protection regulations, and performs tasks in a manner that does not endanger or damage the environment and protects his/her own life and health, as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or may affect the performance of duties, occurrence of material damage, or the protection and health of himself/herself, other employees and the environment;
- Performs other duties, within the level of qualifications and competencies, in accordance with the law, the Statute, general acts and other acts of the Institute

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	94
CENTRE FOR SCIENCE, INTERNATIONAL COOPERATION AND PROJECTS		
(name of the organisational unit)		
ASSOCIATE FOR PROJECTS		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VI/VII	
Level of educational and professional qualifications	University degree, qualification comprising 180, 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in medical, natural, social or technical-technological field.	
Work experience	1 year of experience in the relevant field	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies		
Other requirements	Successful completion of professional examination for work in state administration bodies; Advanced knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes the orders of the Managing director and the Head of the Centre;
- Participates in the preparation of the annual plan for expert and scientific development of employees of the Institute;
- Participates in the coordination of expert and scientific development of employees of the Institute and maintenance of records (registers);
- Participates in planning and preparing technical specifications for the procurement of expert and scientific literature for the needs of the Institute;
- Performs tasks related to inventorying, cataloguing and maintaining books, doctoral dissertations, master's theses, specialist papers, publications, brochures, journals, and similar materials;
- Participates in the preparation of publications issued by the Institute, as well as scientific papers of employees published in expert and scientific journals;
- Participates in the preparation, acquisition and implementation of projects;
- Performs tasks related to maintaining records (registers) of development and scientific research projects;
- Participates in activities related to maintaining licences for scientific research and innovation activities;
- Participates in providing translation and proofreading support for the needs of the Managing director and organisational units of the Institute;
- Participates in activities related to organising Institute conferences, as well as preparing and reviewing expert materials and presentations for educational activities within Institute conferences;
- Responsible for acting in accordance with the principles of integrity and ethical standards of the Institute;
- Uses work equipment and materials purposefully and rationally;
- Ensures compliance with occupational health and safety regulations and environmental protection regulations, and performs tasks in a manner that does not endanger or damage the environment and protects his/her own life and health, as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or may affect the performance of duties, occurrence of material damage, or the protection and health of himself/herself, other employees and the environment;
- Performs other duties, within the level of qualifications and competencies, in accordance with the law, the Statute, general acts and other acts of the Institute

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	95
CENTRE FOR SUPPORT		
(name of the organisational unit)		
HEAD OF THE CENTRE FOR SUPPORT		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in law or economics.	
Work experience	5 years of experience in complex legal or economic affairs	
Special health requirements	NO	
Required daily working hours	Full time – 40 hours per week	
Competencies	Organisational and communication skills	
Other requirements	Successful completion of professional examination for work in state administration bodies; Advanced knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		
DUTIES OF THE POSITION		

- Executes the orders of the Managing director;
- Manages the work of the Centre and is responsible for planning, organising, implementing and controlling business processes within the competence of the Centre, and supervises their implementation;
- Responsible for performing the most complex tasks and duties within the competence of the Centre;
- Responsible for assigning duties to associates within the Centre and ensuring coordination and cooperation in the process of their execution;
- Ensures that activities within the competence of the Centre are carried out in the manner and within the deadlines prescribed by law;
- Prepares and submits information, analyses and reports to the Managing director of the Institute concerning the work of the Centre;
- Participates in the preparation and consolidation of work programmes and plans, as well as reports on the work of organisational units within the Centre, and prepares draft versions of these documents;
- Ensures the timely fulfilment of obligations arising from the Institute's work programme;
- Coordinates the preparation of the Institute's financial plan and financial reports and monitors their implementation and activities related to the audit of financial statements;
- Ensures compliance with financial control procedures;
- Coordinates the preparation and analysis of financial statements;
- Monitors the Institute's expenditures in accordance with the Institute's Financial Plan;
- Performs the duties of management and control manager;
- Monitors obligations related to the management and control system;
- Coordinates financial and accounting operations and ensures the application of regulations and Institute acts relating to accounting operations;
- Monitors liabilities and receivables and prepares reports on liabilities and receivables;
- Prepares and presents information for the purposes of auditing the Institute's financial statements;
- Prepares statistical and other reports for the needs of the Institute;
- Coordinates and manages public procurement activities;
- Participates in drafting laws and secondary legislation;
- Participates in the development of the Institute's information system within the scope of the Centre's competence and in IT integration with other organisational units of the Institute;
- Applies implemented quality standards;
- Creates and amends IMS documentation in accordance with the defined process and participates in IMS reviews;
- Conducts risk analysis and implements appropriate measures in accordance with the Institute's general acts;
- Identifies opportunities for improving the work of the Centre and implements appropriate measures;
- Responsible for preparing/reviewing information/documents published on the Institute's website, within the competence of the Centre and the Institute;
- Supervises the drafting of general and individual acts, the conduct of administrative procedures and the preparation of acts issued by the Institute;
- Ensures the implementation of the Institute's general acts relating to confidentiality and business secrecy, occupational health and safety, as well as other general acts of the Institute;
- Responsible for organising and participating in the continuous education of employees within the Centre;
- Responsible for preparing standard operating procedures within the competence of the Centre;
- Responsible for acting in accordance with the principles of integrity and ethical standards of the Institute, and for ensuring compliance with and implementation of these principles within the organisational unit under his/her management;
- Uses work equipment and materials purposefully and rationally;
- Ensures compliance with occupational health and safety regulations and environmental protection regulations, and performs duties in a manner that does not endanger or damage the environment and protects his/her own life and health, as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or may affect the performance of duties, occurrence of material damage, or the protection and health of himself/herself, other employees and the environment;
- Performs other duties, within the level of qualifications and competencies, in accordance with the law, the Statute, general acts and other acts of the Institute

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	96
CENTRE FOR SUPPORT **DEPARTMENT FOR LEGAL, PERSONNEL AND GENERAL AFFAIRS**		
(name of the organisational unit)		
HEAD OF THE DEPARTMENT FOR LEGAL, PERSONNEL AND GENERAL AFFAIRS		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in law	
Work experience	5 years of experience in legal affairs and affairs within the competence of the Institute	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Organisational and communication skills	
Other requirements	Successful completion of professional examination for work in state administration bodies; knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		
DUTIES OF THE POSITION		

- Executes the orders of the Managing director and the Head of the Centre;
- Manages the work of the Department and is responsible for planning, organising, implementing and controlling business processes within the competence of the Department, and supervises their implementation;
- Responsible for performing the most complex tasks and duties within the competence of the Department;
- Responsible for assigning duties to associates within the Department and ensuring coordination and cooperation in the process of their execution;
- Ensures that activities within the competence of the Department are carried out in the manner and within the deadlines prescribed by law;
- Responsible for preparing/reviewing information and documents published on the Institute's website, within the competence of the Department and the Institute;
- Supervises the processing of requests within the competence of the Department;
- Responsible for preparing and drafting reports related to the activities within the competence of the Department;
- Participates in drafting general and individual acts, conducting administrative procedures and preparing acts issued by the Institute;
- Performs tasks related to public procurement of goods and services for the needs of the Institute;
- Participates in the preparation of the Public Procurement Plan and implementation of public procurement procedures in accordance with the law;
- Performs legal affairs in the field of medicinal products and medical devices within the competence of the Institute;
- Performs the duties of an authorised person for requests for access to information;
- Performs tasks related to labour relations and human resource management;
- Maintains personnel and employee records;
- Ensures the implementation of the Institute's general acts relating to confidentiality and business secrecy, occupational health and safety, as well as other general acts of the Institute;
- Proposes and participates in the continuous education of employees within the Department;
- Responsible for preparing standard operating procedures within the competence of the Department;
- Participates in activities related to ensuring impartiality and managing conflicts of interest within the Institute;
- Organises and coordinates recruitment procedures for new employees;
- Provides advisory services regarding the interpretation and application of laws and regulations;
- Organises and coordinates the performance of general administrative activities;
- Responsible for acting in accordance with the principles of integrity and ethical standards of the Institute, and for ensuring compliance with and implementation of these principles within the organisational unit under his/her management;
- Uses work equipment and materials purposefully and rationally;
- Ensures compliance with occupational health and safety regulations and environmental protection regulations, and performs duties in a manner that does not endanger or damage the environment and protects his/her own life and health, as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or may affect the performance of duties, occurrence of material damage, or the protection and health of himself/herself, other employees and the environment;
- Performs other duties, within the level of qualifications and competencies, in accordance with the law, the Statute, general acts and other acts of the Institute

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	97
CENTRE FOR SUPPORT **DEPARTMENT FOR LEGAL, PERSONNEL AND GENERAL AFFAIRS**		
(name of the organisational unit)		
EXPERT ASSOCIATE I FOR LEGAL, PERSONNEL AND GENERAL AFFAIRS		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in law	
Work experience	5 years of experience in legal affairs	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Specialised expertise and independence in work	
Other requirements	Successful completion of professional examination for work in state administration bodies; knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		
DUTIES OF THE POSITION		

- Executes the orders of the Managing director, the Head of the Centre and the Head of the Department;
- Responsible for independently performing the most complex tasks in procedures within the competence of the Department;
- Prepares minutes from commission meetings for matters within the competence of the Department;
- Performs legal affairs in the field of medicinal products and medical devices within the competence of the Institute;
- Conducts administrative procedures;
- Performs tasks related to the preparation of general and individual acts of the Institute;
- Prepares draft acts issued by the Institute, independently and in cooperation with other organisational units;
- Drafts laws and secondary legislation within the competence of the Institute;
- Performs tasks related to the exercise of rights arising from employment relationships;
- Performs the duties of an authorised person for handling requests for free access to information;
- Performs tasks related to human resource management;
- Performs tasks related to maintaining personnel and employee records;
- Performs tasks related to public procurement of goods and services for the needs of the Institute;
- Participates in the preparation of the Public Procurement Plan and implementation of public procurement procedures in accordance with the law;
- Participates in processing requests in procedures for issuing acts by the Institute, in cooperation with other organisational units of the Institute;
- Participates, within his/her field of competence, as an expert assessor in conducting GxP inspections;
- Ensures the implementation of the Institute's general acts relating to confidentiality and business secrecy, occupational health and safety, as well as other general acts of the Institute;
- Provides administrative and technical support to the Management Board of the Institute;
- Proposes continuous education activities for employees of the Department and participates in the training of employees at lower levels;
- Proposes improvements and revisions to standard operating procedures within the competence of the Department;
- Participates in activities related to ensuring impartiality and managing conflicts of interest within the Institute;
- Participates in recruitment procedures for new employees;
- Provides advisory services regarding the interpretation and application of laws and regulations;
- Participates in activities related to the performance of general administrative tasks;
- Responsible for acting in accordance with the principles of integrity and ethical standards of the Institute;
- Uses work equipment and materials purposefully and rationally;
- Ensures compliance with occupational health and safety regulations and environmental protection regulations, and performs duties in a manner that does not endanger or damage the environment and protects his/her own life and health, as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or may affect the performance of duties, occurrence of material damage, or the protection and health of himself/herself, other employees and the environment;
- Performs other duties, within the level of qualifications and competencies, in accordance with the law, the Statute, general acts and other acts of the Institute

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	98
CENTRE FOR SUPPORT **DEPARTMENT FOR LEGAL, PERSONNEL AND GENERAL AFFAIRS**		
(name of the organisational unit)		
EXPERT ASSOCIATE II FOR LEGAL, PERSONNEL AND GENERAL AFFAIRS		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in law	
Work experience	3 years of experience in legal affairs	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Specialised expertise and independence in work	
Other requirements	Successful completion of professional examination for work in state administration bodies; knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		
DUTIES OF THE POSITION		

- Executes the orders of the Managing director, the Head of the Centre and the Head of the Department;
- Responsible for independently performing complex tasks in procedures within the competence of the Department;
- Prepares minutes from commission meetings for matters within the competence of the Department;
- Performs legal affairs in the field of medicinal products and medical devices within the competence of the Institute;
- Conducts administrative procedures;
- Prepares general and individual acts of the Institute;
- Performs tasks related to drafting acts issued by the Institute, independently and in cooperation with other organisational units;
- Performs tasks related to drafting laws and secondary legislation within the competence of the Institute;
- Performs tasks related to the exercise of rights arising from employment relationships;
- Performs the duties of an authorised person for handling requests for free access to information;
- Performs tasks related to human resource management;
- Maintains personnel and employee records;
- Performs public procurement tasks for goods and services for the needs of the Institute;
- Prepares the Public Procurement Plan and conducts public procurement procedures in accordance with the law;
- Participates in processing requests in procedures for issuing acts by the Institute, in cooperation with other organisational units of the Institute;
- Participates, within his/her field of competence, as an expert assessor in conducting GxP inspections;
- Ensures the implementation of the Institute's general acts relating to confidentiality and business secrecy, occupational health and safety, as well as other general acts of the Institute;
- Provides administrative and technical support to the Management Board of the Institute;
- Proposes continuous education activities for employees of the Department and participates in the training of employees at lower levels;
- Proposes improvements and revisions to standard operating procedures within the competence of the Department;
- Participates in the work of working groups, commissions and working bodies;
- Responsible for acting in accordance with the principles of integrity and ethical standards of the Institute;
- Uses work equipment and materials purposefully and rationally;
- Ensures compliance with occupational health and safety regulations and environmental protection regulations, and performs duties in a manner that does not endanger or damage the environment and protects his/her own life and health, as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or may affect the performance of duties, occurrence of material damage, or the protection and health of himself/herself, other employees and the environment;
- Performs other duties, within the level of qualifications and competencies, in accordance with the law, the Statute, general acts and other acts of the Institute

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	99
CENTRE FOR SUPPORT **DEPARTMENT FOR LEGAL, PERSONNEL AND GENERAL AFFAIRS**		
(name of the organisational unit)		
EXPERT ASSOCIATE III FOR LEGAL, PERSONNEL AND GENERAL AFFAIRS		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in law	
Work experience	1 year of experience in legal affairs	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies		
Other requirements	Successful completion of professional examination for work in state administration bodies; knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		
DUTIES OF THE POSITION		

- Executes the orders of the Managing director, the Head of the Centre and the Head of the Department;
- Responsible for independently performing simple tasks in procedures within the competence of the Department;
- Prepares minutes from commission meetings for matters within the competence of the Department;
- Performs legal affairs in the field of medicinal products and medical devices within the competence of the Institute;
- Conducts administrative procedures;
- Prepares general and individual acts of the Institute;
- Performs tasks related to drafting acts issued by the Institute, independently and in cooperation with other organisational units;
- Performs tasks related to drafting laws and secondary legislation within the competence of the Institute;
- Performs tasks related to the exercise of rights arising from employment relationships;
- Performs the duties of an authorised person for handling requests for free access to information;
- Performs tasks related to human resource management;
- Participates in maintaining personnel and employee records;
- Participates in public procurement tasks for goods and services for the needs of the Institute;
- Prepares the Public Procurement Plan and conducts public procurement procedures in accordance with the law;
- Participates in processing requests in procedures for issuing acts by the Institute, in cooperation with other organisational units of the Institute;
- Participates, within his/her field of competence, as an expert assessor in conducting GxP inspections;
- Ensures the implementation of the Institute's general acts relating to confidentiality and business secrecy, occupational health and safety, as well as other general acts of the Institute;
- Provides administrative and technical support to the Management Board of the Institute;
- Participates in the work of working groups, commissions and working bodies;
- Responsible for acting in accordance with the principles of integrity and ethical standards of the Institute;
- Uses work equipment and materials purposefully and rationally;
- Ensures compliance with occupational health and safety regulations and environmental protection regulations, and performs duties in a manner that does not endanger or damage the environment and protects his/her own life and health, as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or may affect the performance of duties, occurrence of material damage, or the protection and health of himself/herself, other employees and the environment;
- Performs other duties, within the level of qualifications and competencies, in accordance with the law, the Statute, general acts and other acts of the Institute

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	100
CENTRE FOR SUPPORT **DEPARTMENT FOR LEGAL, PERSONNEL AND GENERAL AFFAIRS**		
(name of the organisational unit)		
ASSOCIATE FOR LEGAL, PERSONNEL AND GENERAL AFFAIRS		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in law	
Work experience	1 year of experience in the relevant field	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies		
Other requirements	Successful completion of professional examination for work in state administration bodies; Advanced knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes the orders of the Managing director, the Head of the Centre and the Head of the Department;
- Responsible for independently performing the simplest tasks in procedures within the competence of the Department;
- Performs tasks related to legal affairs in the field of medicinal products and medical devices within the competence of the Institute;
- Participates in conducting administrative procedures;
- Participates in the preparation of general and individual acts of the Institute;
- Performs tasks related to drafting acts issued by the Institute, independently and in cooperation with other organisational units;
- Participates in drafting laws and secondary legislation within the competence of the Institute;
- Performs tasks related to the exercise of rights arising from employment relationships;
- Performs tasks related to human resource management;
- Maintains personnel and employee records;
- Participates in public procurement tasks for goods and services for the needs of the Institute;
- Participates in the preparation of the Public Procurement Plan and implementation of public procurement procedures in accordance with the law;
- Participates in processing requests in procedures for issuing acts by the Institute, in cooperation with other organisational units of the Institute;
- Ensures the implementation of the Institute's general acts relating to confidentiality and business secrecy, occupational health and safety, as well as other general acts of the Institute;
- Responsible for acting in accordance with the principles of integrity and ethical standards of the Institute;
- Uses work equipment and materials purposefully and rationally;
- Ensures compliance with occupational health and safety regulations and environmental protection regulations, and performs duties in a manner that does not endanger or damage the environment and protects his/her own life and health, as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or may affect the performance of duties, occurrence of material damage, or the protection and health of himself/herself, other employees and the environment;
- Performs other duties, within the level of qualifications and competencies, in accordance with the law, the Statute, general acts and other acts of the Institute

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	101
CENTRE FOR SUPPORT **DEPARTMENT FOR LEGAL, PERSONNEL AND GENERAL AFFAIRS**		
(name of the organisational unit)		
COURIER-DRIVER		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	III	
Level of educational and professional qualifications	Secondary education, qualification with a scope of 180 CSPK credits (three-year programme).	
Work experience	1 year of experience	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies		
Other requirements	Category B driving licence	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes the orders of the Managing director, the Head of the Centre and the Head of the Department;
- Provides administrative support in scanning, copying, and organising/packaging documents for distribution;
- Performs the classification, allocation, registration and routing of documents within case files through the Institute's Information System;
- Performs driving duties for the Director and, with the Director's approval, for other Institute employees, as required;
- Ensures the maintenance of the Institute's vehicles (cleaning, checking fuel, coolant and oil levels, servicing, tyre replacement, etc.);
- Reports any damage to, or maintenance and repair requirements of, the Institute's vehicles to the immediate supervisor;
- Monitors the routine technical maintenance of the Institute's premises and arranges repairs to the building and its facilities;
- Performs minor repairs, installations and maintenance interventions on the premises, as required;
- Reports all building maintenance and repair works to the Head of the organisational unit;
- Monitors the maintenance of green areas surrounding the Institute's premises and takes the necessary measures;
- Responsible for acting in accordance with the principles of integrity and ethical standards of the Institute;
- Uses work equipment and materials purposefully and rationally;
- Ensures compliance with occupational health and safety regulations and environmental protection regulations, and performs duties in a manner that does not endanger or damage the environment and protects his/her own life and health, as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or may affect the performance of duties, occurrence of material damage, or the protection and health of himself/herself, other employees and the environment;
- Performs other duties, within the level of qualifications and competencies, in accordance with the law, the Statute, general acts and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	102
CENTRE FOR SUPPORT **DEPARTMENT FOR LEGAL, PERSONNEL AND GENERAL AFFAIRS**		
(name of the organisational unit)		
BUFFET SERVICES AND HYGIENE ASSISTANT		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	III	
Level of educational and professional qualifications	Secondary education, qualification with a scope of 180 CSPK credits (three-year programme).	
Work experience	1 year of experience	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies		
Other requirements		
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes the orders of the Managing director, the Head of the Centre and the Head of the Department;
- Organises catering services for the needs of the Office of the Managing director of the Institute and the Management Board of the Institute, as well as catering required for meetings and events held on the Institute's premises, and prepares orders for buffet service users;
- Performs tasks related to the procurement, assortment, quality, quantity and expiry date of goods, participates in preparing annual procurement specifications for beverages, food and cleaning supplies for buffet needs, places orders in accordance with specifications, and reports any irregularities in quality, quantity or prices upon delivery to the public procurement officer;
- Participates in planning and selecting equipment for furnishing the buffet area in order to ensure functionality and efficiency in performing work tasks, and ensures procurement and proper maintenance of buffet inventory and correct functioning of appliances, reporting malfunctions to the supervisor;
- Maintains necessary records and prepares reports on consumed goods, including quantities and prices;
- Checks Institute premises in terms of hygiene maintenance and, where necessary, undertakes measures to eliminate deficiencies;
- Performs hygiene maintenance tasks in the Institute's business premises during working hours, as well as hygiene tasks in premises not covered by contracts with hygiene service providers;
- Checks and maintains hygiene of the Institute's surrounding outdoor areas;
- Responsible for acting in accordance with the principles of integrity and ethical standards of the Institute;
- Uses work equipment and materials purposefully and rationally;
- Ensures compliance with occupational health and safety regulations and environmental protection regulations, and performs duties in a manner that does not endanger or damage the environment and protects his/her own life and health, as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or may affect the performance of duties, occurrence of material damage, or the protection and health of himself/herself, other employees and the environment;
- Performs other duties, within the level of qualifications and competencies, in accordance with the law, the Statute, general acts and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	103
CENTRE FOR SUPPORT **DEPARTMENT FOR ECONOMIC AFFAIRS**		
(name of the organisational unit)		
HEAD OF THE DEPARTMENT FOR ECONOMIC AFFAIRS		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in economics	
Work experience	5 years of experience in finance and accounting affairs	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Organisational and communication skills	
Other requirements	Successful completion of professional examination for work in state administration bodies; knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		
DUTIES OF THE POSITION		

- Executes the orders of the Managing director and the Head of the Centre;
- Manages the work of the Department and is responsible for planning, organising, implementing and controlling business processes within the Department's competence, and supervises their implementation;
- Responsible for performing the most complex tasks and duties within the competence of the Department;
- Responsible for assigning duties to employees within the Department and ensuring coordination and cooperation in the execution process;
- Ensures that tasks within the Department's competence are performed in the manner and within the deadlines prescribed by law;
- Responsible for the preparation/control of information/documents published on the Institute's website, within the competence of the Department and the Institute;
- Supervises the processing of requests within the competence of the Department;
- Responsible for preparing and drafting reports related to activities within the competence of the Department;
- Performs tasks related to coordinating the preparation of the Institute's financial plan and financial statements, monitoring their implementation and activities during the audit of financial statements;
- Performs tasks related to management and internal control of the Institute's operations and monitoring obligations related to the management and control system;
- Performs tasks related to ensuring compliance with financial control procedures;
- Performs tasks related to the preparation and analysis of financial statements;
- Performs tasks related to controlling the Institute's expenditures in accordance with the Institute's Financial Plan;
- Performs tasks related to coordinating financial and accounting operations and ensuring the implementation of regulations and acts of the Institute related to financial and accounting affairs;
- Performs tasks related to general ledger postings for financial transactions;
- Performs tasks related to drafting the internal analytical chart of accounts and its further development in accordance with the prescribed synthetic chart of accounts;
- Performs tasks related to monitoring liabilities and receivables and preparing reports on liabilities and receivables;
- Performs tasks related to planning and organising external audits and audits by the State Audit Institution;
- Performs tasks related to preparing and presenting information for the purposes of auditing the Institute's financial statements;
- Performs tasks related to the preparation and processing of salaries, wages and employee benefits, remuneration for Management Board members and other payments;
- Performs tasks related to preparing statistical and other reports for the Institute's needs;
- Proposes and participates in continuous training of employees within the Department;
- Responsible for preparing standard operating procedures within the competence of the Department;
- Responsible for acting in accordance with the principles of integrity and ethical standards of the Institute, and for ensuring compliance with and implementation of the same within the organisational unit he/she manages;
- Uses work equipment and materials purposefully and rationally;
- Ensures compliance with occupational health and safety regulations and environmental protection regulations, and performs duties in a manner that does not endanger or damage the environment and protects his/her own life and health, as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or may affect the performance of duties, occurrence of material damage, or the protection and health of himself/herself, other employees and the environment;
- Performs other duties, within the level of qualifications and competencies, in accordance with the law, the Statute, general acts and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	104
CENTRE FOR SUPPORT **DEPARTMENT FOR ECONOMIC AFFAIRS**		
(name of the organisational unit)		
EXPERT ASSOCIATE I FOR FINANCIAL AND ACCOUNTING AFFAIRS		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in economics	
Work experience	5 years of experience in finance and accounting affairs	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Specialised expertise and independence at work	
Other requirements	Successful completion of professional examination for work in state administration bodies; knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		
DUTIES OF THE POSITION		

- Executes the orders of the Managing director, the Head of the Centre and the Head of the Department;
- Responsible for the independent performance of the most complex tasks within the competence of the Department;
- Performs tasks related to domestic and international payments;
- Performs tasks related to recording daily information on the status of financial assets in bank accounts;
- Performs tasks related to issuing invoices and monitoring their collection;
- Performs tasks related to payments under received invoices and contracts;
- Performs tasks related to recording travel-related information and expenses related to the vehicle fleet;
- Performs tasks related to the calculation and maintenance of records on tax and other financial obligations of the Institute in accordance with the law;
- Performs tasks related to maintaining cash register records and cash reports;
- Performs tasks related to withdrawing cash from giro accounts and maintaining records of cash inflows and outflows;
- Performs tasks related to the preparation and calculation of salaries, wages and employee benefits and remunerations for members of the Management Board;
- Performs tasks related to financial and accounting operations and ensures the implementation of regulations and acts of the Institute related to accounting operations;
- Performs tasks related to maintaining the fixed assets register;
- Performs tasks related to the calculation of depreciation;
- Performs tasks related to reconciling the general ledger with the fixed assets register;
- Performs tasks related to preparing reports on the Institute's movable and immovable property;
- Performs tasks related to preparing statistical and other reports for the needs of the Institute;
- Performs tasks related to monitoring liabilities and receivables and preparing reports on liabilities and receivables;
- Performs tasks related to preparing notices regarding ensettled obligations and reconciling balances with clients;
- Participates in the preparation of data for interim and annual financial statements;
- Prepares information required for the audit of the Institute's financial statements;
- Prepares documentation for reimbursement of paid salary compensation during sick leave;
- Performs tasks related to monitoring obligations concerning the management and control system;
- Performs tasks related to ensuring compliance with financial control procedures;
- Participates in preparing reports on monitoring the implementation of public procurements;
- Ensures the implementation of the Institute's general acts related to confidentiality of data and business secrets, occupational health and safety, as well as other general acts of the Institute;
- Proposes continuous training for employees within the Department and participates in the training of lower-level employees;
- Proposes improvements and revisions of standard operating procedures within the competence of the Department;
- Responsible for acting in accordance with the principles of integrity and ethical standards of the Institute;
- Uses work equipment and materials purposefully and rationally;
- Ensures compliance with occupational health and safety regulations and environmental protection regulations, and performs duties in a manner that does not endanger or damage the environment and protects his/her own life and health, as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or may affect the performance of duties, occurrence of material damage, or the protection and health of himself/herself, other employees and the environment;
- Performs other duties, within the level of qualifications and competencies, in accordance with the law, the Statute, general acts and other acts of the Institute

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	105
CENTRE FOR SUPPORT **DEPARTMENT FOR ECONOMIC AFFAIRS**		
(name of the organisational unit)		
EXPERT ASSOCIATE II FOR FINANCIAL AND ACCOUNTING AFFAIRS		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in economics	
Work experience	3 years of experience in finance and accounting affairs	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Specialised expertise and independence at work	
Other requirements	Successful completion of professional examination for work in state administration bodies; knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		
DUTIES OF THE POSITION		

- Executes the orders of the Managing director, the Head of the Centre and the Head of the Department;
- Responsible for the independent performance of complex tasks within the competence of the Department;
- Performs tasks related to domestic and international payments;
- Maintains records of daily information on the status of financial assets in bank accounts;
- Issues invoices and monitors their collection;
- Performs tasks related to payments under received invoices and contracts;
- Maintains records related to travel and use of official vehicles expenses;
- Performs tasks related to the calculation and maintenance of records on tax and other financial obligations of the Institute in accordance with the law;
- Performs tasks related to maintaining cash register records and cash reports;
- Performs tasks related to withdrawing cash from giro accounts and maintaining records of cash inflows and outflows;
- Performs tasks related to the preparation and calculation of salaries, wages and employee benefits and remunerations for members of the Management Board;
- Performs tasks related to financial and accounting operations and ensures the implementation of regulations and acts of the Institute related to accounting operations;
- Performs tasks related to maintaining the fixed assets register;
- Performs tasks related to the calculation of depreciation;
- Performs tasks related to reconciling the general ledger with the fixed assets register;
- Performs tasks related to preparing reports on the Institute's movable and immovable property;
- Performs tasks related to preparing statistical and other reports for the needs of the Institute;
- Performs tasks related to monitoring liabilities and receivables and preparing reports on liabilities and receivables;
- Performs tasks related to preparing notices regarding outstanding obligations and reconciling balances with clients;
- Participates in the preparation of data for interim and annual financial statements;
- Prepares information required for the audit of the Institute's financial statements;
- Prepares documentation for reimbursement of paid salary compensation during sick leave;
- Performs tasks related to monitoring obligations concerning the management and control system;
- Performs tasks related to ensuring compliance with financial control procedures;
- Participates in preparing reports on monitoring the implementation of public procurements;
- Ensures the implementation of the Institute's general acts related to confidentiality of data and business secrets, occupational health and safety, as well as other general acts of the Institute;
- Proposes continuous training for employees within the Department and participates in the training of lower-level employees;
- Proposes improvements and revisions of standard operating procedures within the competence of the Department;
- Responsible for acting in accordance with the principles of integrity and ethical standards of the Institute;
- Uses work equipment and materials purposefully and rationally;
- Ensures compliance with occupational health and safety regulations and environmental protection regulations, and performs duties in a manner that does not endanger or damage the environment and protects his/her own life and health, as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or may affect the performance of duties, occurrence of material damage, or the protection and health of himself/herself, other employees and the environment;
- Performs other duties, within the level of qualifications and competencies, in accordance with the law, the Statute, general acts and other acts of the Institute

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	106
CENTRE FOR SUPPORT **DEPARTMENT FOR ECONOMIC AFFAIRS**		
(name of the organisational unit)		
EXPERT ASSOCIATE III FOR FINANCIAL AND ACCOUNTING AFFAIRS		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in economics	
Work experience	1 year of experience in finance and accounting affairs	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies		
Other requirements	Successful completion of professional examination for work in state administration bodies; knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		
DUTIES OF THE POSITION		

- Executes the orders of the Managing director, the Head of the Centre and the Head of the Department;
- Responsible for the independent performance of simple tasks within the competence of the Department;
- Performs tasks related to domestic and international payments;
- Records daily information on the status of financial assets in bank accounts;
- Performs invoicing of fees and monitors their collection;
- Processes payments under received invoices and contracts;
- Records information on travelling and use of official vehicles expenses;
- Performs tasks related to the calculation and maintenance of records on tax and other financial obligations of the Institute in accordance with the law;
- Performs tasks related to maintaining cash register records and cash reports;
- Performs tasks related to withdrawing cash from giro accounts and maintaining records of cash inflows and outflows;
- Performs tasks related to the preparation and calculation of salaries, wages and employee benefits and remunerations for members of the Management Board;
- Performs tasks related to financial and accounting operations and ensures the implementation of regulations and acts of the Institute related to accounting operations;
- Performs tasks related to maintaining the fixed assets register;
- Performs tasks related to the calculation of depreciation;
- Reconciles the general ledger with the fixed assets register;
- Prepares reports on the Institute's movable and immovable property;
- Prepares statistical and other reports for the needs of the Institute;
- Performs tasks related to monitoring liabilities and receivables and prepares reports on liabilities and receivables;
- Prepares notices regarding outstanding obligations and reconciles balances with clients;
- Participates in the preparation of data for interim and annual financial statements;
- Prepares information required for the audit of the Institute's financial statements;
- Prepares documentation for reimbursement of paid salary compensation during sick leave;
- Performs tasks related to monitoring obligations concerning the management and control system;
- Performs tasks related to ensuring compliance with financial control procedures;
- Participates in preparing reports on monitoring the implementation of public procurements;
- Ensures the implementation of the Institute's general acts related to confidentiality of data and business secrets, occupational health and safety, as well as other general acts of the Institute;
- Responsible for acting in accordance with the principles of integrity and ethical standards of the Institute;
- Uses work equipment and materials purposefully and rationally;
- Ensures compliance with occupational health and safety regulations and environmental protection regulations, and performs duties in a manner that does not endanger or damage the environment and protects his/her own life and health, as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or may affect the performance of duties, occurrence of material damage, or the protection and health of himself/herself, other employees and the environment;
- Performs other duties, within the level of qualifications and competencies, in accordance with the law, the Statute, general acts and other acts of the Institute

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	107
CENTRE FOR SUPPORT **DEPARTMENT FOR ECONOMIC AFFAIRS**		
(name of the organisational unit)		
ASSOCIATE FOR FINANCIAL AND ACCOUNTING AFFAIRS		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VI/VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in economics	
Work experience	1 year of experience in the relevant field	
Special health requirements	NO	
Required daily working hours	Full time – 40 hours per week	
Competencies		
Other requirements	Successful completion of professional examination for work in state administration bodies; knowledge of the English language, both written and spoken; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		
DUTIES OF THE POSITION		

- Executes the orders of the Managing director, the Head of the Centre and the Head of the Department;
- Responsible for the independent performance of the simplest tasks within the competence of the Department;
- Performs tasks related to domestic and international payments;
- Performs tasks related to maintaining records of daily information on the status of financial assets in bank accounts;
- Performs tasks related to issuing invoices and monitoring their collection;
- Performs tasks related to payments under received invoices and contracts;
- Performs tasks related to maintaining records concerning travel and vehicle fleet expenses;
- Performs tasks related to the calculation and maintenance of records on tax and other financial obligations of the Institute in accordance with the law;
- Performs tasks related to maintaining cash register records and cash reports;
- Performs tasks related to withdrawing cash from giro accounts and maintaining records of cash inflows and outflows;
- Performs tasks related to the preparation and calculation of salaries, wages and employee benefits and remunerations for members of the Management Board;
- Performs tasks related to financial and accounting operations and ensures the implementation of regulations and acts of the Institute related to accounting operations;
- Performs tasks related to maintaining the fixed assets register;
- Performs tasks related to the calculation of depreciation;
- Reconciles the general ledger with the fixed assets register;
- Prepares reports on the Institute's movable and immovable property;
- Prepares statistical and other reports for the needs of the Institute;
- Performs tasks related to monitoring liabilities and receivables and prepares reports on liabilities and receivables;
- Prepares notices regarding outstanding obligations and reconciles balances with clients;
- Participates in the preparation of data for interim and annual financial statements;
- Prepares information required for the audit of the Institute's financial statements;
- Performs tasks related to monitoring obligations concerning the management and control system;
- Performs tasks related to ensuring compliance with financial control procedures;
- Participates in preparing reports on the implementation of public procurements;
- Ensures the implementation of the Institute's general acts related to confidentiality of data and business secrets, occupational health and safety, as well as other general acts of the Institute;
- Responsible for acting in accordance with the principles of integrity and ethical standards of the Institute;
- Uses work equipment and materials purposefully and rationally;
- Ensures compliance with occupational health and safety regulations and environmental protection regulations, and performs duties in a manner that does not endanger or damage the environment and protects his/her own life and health, as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or may affect the performance of duties, occurrence of material damage, or the protection and health of himself/herself, other employees and the environment;
- Performs other duties, within the level of qualifications and competencies, in accordance with the law, the Statute, general acts and other acts of the Institute

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	108
CENTRE FOR SUPPORT **REGISTRY OFFICE**		
(name of the organisational unit)		
HEAD OF THE REGISTRY OFFICE		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	IV	
Level of educational and professional qualifications	Secondary education, qualification comprising 240 (ECTS) credits (study programme lasting 4 years)	
Work experience	3 years of professional experience in administrative and technical tasks, including 2 years of experience in the receipt and classification of the documentation in the field of medicinal products and medical devices	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies		
Other requirements	Successful completion of professional examination for work in state administration bodies; computer literacy (especially Microsoft Office package.	
POSITION COEFFICIENT		
C1		
DUTIES OF THE POSITION		

- Executes the orders of the Managing director and the Head of the Centre;
- Manages the work of the Registry Office and is responsible for planning, organising, implementing and controlling business processes within the competence of the Registry Office, and supervises their implementation;
- Responsible for performing tasks within the competence of the Registry Office;
- Responsible for assigning duties to employees within the Registry Office and ensuring coordination and cooperation in the execution process;
- Proposes improvements and revisions of standard operating procedures within the competence of the Registry Office;
- Performs tasks related to the receipt and dispatch of mail and timely forwards necessary information to the Managing director, centres and other organisational units;
- Required to have knowledge of the basic regulatory requirements in the field of medicinal products and medical devices in order to ensure the proper receipt and classification of files/documents;
- Ensures that each document, submission or file is directed to the competent Centre or Department in accordance with its content and the regulatory framework governing medicinal products and medical devices;
- Performs tasks related to maintaining the Institute's basic records concerning the receipt of submissions, documents and other consignments, as well as outgoing mail;
- Performs tasks related to the classification, allocation, recording and delivery of documents according to the specificities of the field of medicinal products and medical devices through files entered into the Institute's information system;
- Performs tasks related to the recording of incoming and outgoing mail, as well as its archiving and storage;
- Performs tasks related to the safekeeping of documentation and records of files, as well as other registry materials by organisational units;
- Performs tasks related to making records, forwarding for processing, distributing, filing and archiving documents designated as confidential/business secrets, in accordance with internal acts of the Institute;
- Performs tasks related to providing administrative support to other staff and centres in scanning, copying, organising and packaging documents for distribution;
- Responsible for acting in accordance with the principles of integrity and ethical standards of the Institute, and for ensuring compliance with and implementation of the same within the organisational unit he/she manages;
- Uses work equipment and materials purposefully and rationally;
- Ensures compliance with occupational health and safety regulations and environmental protection regulations, and performs duties in a manner that does not endanger or damage the environment and protects his/her own life and health, as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or may affect the performance of duties, occurrence of material damage, or the protection and health of himself/herself, other employees and the environment;
- Performs other duties, within the level of qualifications and competencies, in accordance with the law, the Statute, general acts and other acts of the Institute

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	109
CENTRE FOR SUPPORT **REGISTRY OFFICE**		
(name of the organisational unit)		
OFFICER I FOR REGISTRY OFFICE AFFAIRS		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	IV1	
Level of educational and professional qualifications	Secondary education, qualification comprising 240 (ECTS) credits (study programme lasting 4 years)	
Work experience	2 years of professional experience in administrative and technical tasks, including 1 year of experience in the receipt and classification of the documentation in the field of medicinal products and medical devices	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies		
Other requirements	Successful completion of professional examination for work in state administration bodies; computer literacy (especially Microsoft Office package)	
POSITION COEFFICIENT		
C1		
DUTIES OF THE POSITION		

- Executes the orders of the Managing director, the Head of the Centre and the Head of the Registry Office;
- Responsible for the independent performance of tasks within the competence of the Registry Office;
- Proposes improvements and revisions of standard operating procedures within the competence of the Registry Office;
- Performs tasks related to the receipt and dispatch of mail and timely forwards necessary information to the Managing director, centres and other organisational units;
- Performs tasks related to maintaining the Institute's basic records concerning the receipt of submissions, documents and other consignments, as well as outgoing mail;
- Performs tasks related to the classification, allocation, recording and delivery of documents through files entered into the Institute's information system;
- Required to have knowledge of the basic regulatory requirements in the field of medicinal products and medical devices in order to ensure the proper receipt and classification of files/documents;
- Ensures that each document, submission or files is directed to the competent Centre or Department in accordance with its content and the regulatory framework governing medicinal products and medical devices;
- Performs tasks related to the classification, allocation, recording and delivery of documents according to the specificities of the field of medicinal products and medical devices through files entered into the Institute's information system;
- Performs tasks related to the recording of incoming and outgoing mail, as well as its archiving and storage;
- Performs tasks related to the safekeeping of documentation and records of files, as well as other registry materials by organisational units;
- Performs tasks related to making records, forwarding for processing, distributing, filing and archiving documents designated as confidential/business secrets, in accordance with internal acts of the Institute;
- Performs tasks related to providing administrative support to other staff and centres in scanning, copying, organising and packaging documents for distribution;
- Responsible for acting in accordance with the principles of integrity and ethical standards of the Institute;
- Uses work equipment and materials purposefully and rationally;
- Ensures compliance with occupational health and safety regulations and environmental protection regulations, and performs duties in a manner that does not endanger or damage the environment and protects his/her own life and health, as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or may affect the performance of duties, occurrence of material damage, or the protection and health of himself/herself, other employees and the environment;
- Performs other duties, within the level of qualifications and competencies, in accordance with the law, the Statute, general acts and other acts of the Institute

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	110
CENTRE FOR SUPPORT **REGISTRY OFFICE**		
(name of the organisational unit)		
OFFICER II FOR REGISTRY OFFICE AFFAIRS		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	IV1	
Level of educational and professional qualifications	Secondary education, qualification comprising 240 (ECTS) credits (study programme lasting 4 years)	
Work experience	1 year of professional experience in administrative and technical tasks	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies		
Other requirements	Successful completion of professional examination for work in state administration bodies; computer literacy (especially Microsoft Office package)	
POSITION COEFFICIENT		
C1		

DUTIES OF THE POSITION

- Executes the orders of the Managing director, the Head of the Centre and the Head of the Registry Office;
- Responsible for the independent performance of tasks within the competence of the Registry Office;
- Proposes improvements and revisions of standard operating procedures within the competence of the Registry Office;
- Performs tasks related to the receipt and dispatch of mail and timely forwards necessary information to the Managing director, centres and other organisational units;
- Performs tasks related to maintaining the Institute's basic records concerning the receipt of submissions, documents and other consignments, as well as outgoing mail;
- Performs tasks related to the classification, allocation, recording and delivery of documents through files entered into the Institute's information system;
- Performs tasks related to recording of incoming and outgoing mail, as well as its archiving and storage;
- Performs tasks related to the safekeeping of documentation and records of files, as well as other registry materials by organisational units;
- Performs tasks related to making records, forwarding for processing, distributing, filing and archiving documents designated as confidential/business secrets, in accordance with internal acts of the Institute;
- Performs tasks related to providing administrative support to other staff and centres in scanning, copying, organising and packaging documents for distribution;
- Responsible for acting in accordance with the principles of integrity and ethical standards of the Institute;
- Uses work equipment and materials purposefully and rationally;
- Ensures compliance with occupational health and safety regulations and environmental protection regulations, and performs duties in a manner that does not endanger or damage the environment and protects his/her own life and health, as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or may affect the performance of duties, occurrence of material damage, or the protection and health of himself/herself, other employees and the environment;
- Performs other duties, within the level of qualifications and competencies, in accordance with the law, the Statute, general acts and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	111
CENTRE FOR INFORMATION AND COMMUNICATION SYSTEMS		
(name of the organisational unit)		
HEAD OF THE CENTRE FOR INFORMATION AND COMMUNICATION SYSTEMS		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in electrical engineering or studies in the field of information technology	
Work experience	5 years of professional experience	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Organisational and communication skills	
Other requirements	Successful completion of professional examination for work in state administration bodies; Advanced knowledge of the English language, both written and spoken	
POSITION COEFFICIENT		
C1		
DUTIES OF THE POSITION		

- Executes the orders of the Managing director;
- Manages the work of the Centre and is responsible for planning, organising, implementing and controlling business processes within the competence of the Centre, and supervises their implementation;
- Responsible for performing the most complex tasks and duties within the competence of the Centre;
- Responsible for assigning duties to employees within the Cerntre and ensuring coordination and cooperation in the execution process;
- Ensures that tasks within the Centres's competence are performed in the manner and within the deadlines prescribed by law;
- Responsible for the preparation/control of information/documents published on the Institute's website, within the competence of the Institute;
- Supervises the processing of requests within the competence of the Centre;
- Responsible for preparing and drafting reports related to activities within the competence of the Centre;
- Develops and implements security policies in accordance with the legal framework and adopted standards;
- Leads and participates in activities related to the analysis, design and implementation of ICT and other technical solutions necessary for the regular operation and improvement of the Institute's business processes;
- Plans and manages the digital transformation and digitalisation of the Institute's business processes;
- Manages the development, implementation and maintenance of electronic services (e-services) for the pharmaceutical industry, healthcare institutions, the professional community and citizens;
- Organises the development and maintenance of information systems supporting regulatory processes in the field of medicinal products and medical devices, including European integration processes and data exchange with European Union databases;
- Organises and ensures the establishment and maintenance of interoperability between the Institute's information systems and the information systems of other public authorities and institutions, particularly in the healthcare sector;
- Coordinates the integration of the Institute's information systems with national data exchange platforms, e-government services, and other national and European digital services;
- Establishes technical and organisational solutions for data exchange with European Union bodies, international institutions and other regulatory authorities in the field of medicinal products and medical devices;
- Ensures the compliance of the Institute's information systems with the requirements of European regulatory authorities and international standards in the field of medicinal products and medical devices;
- Establishes and implements an information security and cybersecurity management system;
- Organises the implementation of information security and data protection standards and good practices;
- Ensures the management of digital identities, access to information systems and the protection of sensitive regulatory data;
- Organises the development and maintenance of electronic document exchange and document management systems;
- Plans and develops the Institute's ICT architecture in accordance with the principles of interoperability and digital transformation;
- Participates in and coordinates the Institute's participation in EU and international projects and initiatives in the field of digitalisation, regulatory information systems and data exchange;
- Monitors and ensures the implementation of the recommendations and technical requirements of European regulatory authorities relating to information systems for the regulation of medicinal products;
- Identifies deficiencies and plans and implements their continuous resolution;
- Supervises and coordinates activities related to troubleshooting, maintenance, administration and improvement of existing ICT systems and other technical solutions necessary for the regular operation and improvement of business processes;
- Manages, analyses and performs basic maintenance of network and computer infrastructure;
- Plans improvements to existing solutions in the field of information and communication technologies (ICT) within the Institute's operations;
- Coordinates, organises and participates in training employees of the Institute for the proper and secure use of computer equipment and work within the Institute's computer network;
- Establishes the logical organisation of business processes, documents and data through software solutions and IT infrastructure in order to ensure the regular operation and improvement of the Institute's business processes;
- Leads and participates in activities related to updating content and improving the Institute's website;
- Plans, coordinates and participates in activities related to creating backup copies of data and ICT systems;
- Coordinates activities and monitors the implementation of contracts and other tasks with service providers related to the maintenance and improvement of ICT and other technical systems necessary for the Institute's operations, in order to ensure efficiency and compliance with technical standards for maintaining ICT systems within the Institute;
- Coordinates activities related to the preparation of informational materials, guidelines, bulletins and similar materials within the Institute's field of work;
- Participates in drafting and analysing technical specifications in the field of public procurement related to ICT;
- Participates in projects related to IT integration with other institutions;
- Prepares analyses and information related to the work of the Department and the development and application of new technologies;
- Proposes and participates in continuous training of employees within the Department;

- Responsible for preparing standard operating procedures within the competence of the Department;
- Responsible for acting in accordance with the principles of integrity and ethical standards of the Institute, and for ensuring compliance with and implementation of the same within the organisational unit he/she manages;
- Uses work equipment and materials purposefully and rationally;
- Ensures compliance with occupational health and safety regulations and environmental protection regulations, and performs duties in a manner that does not endanger or damage the environment and protects his/her own life and health, as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or may affect the performance of duties, occurrence of material damage, or the protection and health of himself/herself, other employees and the environment;
- Performs other duties, within the level of qualifications and competencies, in accordance with the law, the Statute, general acts and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	112
CENTRE FOR INFORMATION AND COMMUNICATION SYSTEMS		
(name of the organisational unit)		
EXPERT ASSOCIATE I FOR INFORMATION AND COMMUNICATION SYSTEMS		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VII	
Level of educational and professional qualifications	University degree, qualification comprising 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 4 or 3+1 or 3+2 years). Completed studies in electrical engineering or studies in the field of information technology	
Work experience	5 years of professional experience	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Specialised expertise and independence in work	
Other requirements	Successful completion of professional examination for work in state administration bodies; Advanced knowledge of the English language, both written and spoken	
POSITION COEFFICIENT		
C1		
DUTIES OF THE POSITION		

- Executes the orders of the Managing director and the Head of the Centre;
- Responsible for the independent performance of the most complex tasks within the competence of the Centre;
- Performs the most demanding technical tasks, including activities related to troubleshooting, maintenance, administration and improvement of existing ICT systems and other technical solutions necessary for the regular operation and improvement of the Institute's business processes;
- Identifies deficiencies within the Institute's ICT systems and works continuously on overcoming them;
- Continuously maintains the overall ICT system and provides technical support;
- Provides IT user support (help desk) and technical support to external users of the Institute, including assistance and guidance on the proper use of ICT in the Institute's operations;
- Works on establishing clear procedures, regular monitoring of technical changes and innovations in the ICT field, as well as continuous training and education of employees for new technologies and tools (organisation and implementation of training for employees of the Institute on the proper and secure use of computer equipment and work within the Institute's computer network, in cooperation with the Head of the Centre and employees);
- Performs maintenance, administration and improvement of ICT systems at software and hardware levels;
- Performs tasks aimed at maintaining a high level of information system security in order to protect the Institute's sensitive data and ensure system reliability;
- Performs tasks related to updating and improving the Institute's website;
- Performs tasks related to creating and regularly updating backup copies of data and configurations in order to ensure the security of the Institute's data;
- Participates in drafting and analysing technical specifications in the field of public procurement related to ICT;
- Processes and reproduces audio-video materials for the needs of the Institute;
- Participates in the digitalisation of the Institute's business processes and the implementation of information technology solutions supporting electronic document management and regulatory procedures;
- Participates in the development, implementation and maintenance of the Institute's electronic services (e-services) for internal and external users;
- Participates in activities related to establishing interoperability between the Institute's information systems and the information systems of other public authorities and institutions, particularly in the healthcare sector;
- Participates in the implementation and application of information security and cybersecurity measures to protect the Institute's information systems, network infrastructure and data;
- Participates in monitoring and applying standards and good practices in the field of information security and data protection within the Institute's ICT systems;
- Proposes continuous training for employees within the Centre and participates in the training of lower-level employees;
- Proposes improvements and revisions of standard operating procedures within the competence of the Centre;
- Responsible for acting in accordance with the principles of integrity and ethical standards of the Institute;
- Uses work equipment and materials purposefully and rationally;
- Ensures compliance with occupational health and safety regulations and environmental protection regulations, and performs duties in a manner that does not endanger or damage the environment and protects his/her own life and health, as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or may affect the performance of duties, occurrence of material damage, or the protection and health of himself/herself, other employees and the environment;
- Performs other duties, within the level of qualifications and competencies, in accordance with the law, the Statute, general acts and other acts of the Institute.

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	113
CENTRE FOR INFORMATION AND COMMUNICATION SYSTEMS		
(name of the organisational unit)		
EXPERT ASSOCIATE II FOR INFORMATION AND COMMUNICATION SYSTEMS		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VI/VII	
Level of educational and professional qualifications	University degree, qualification comprising 180, 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 3, 4 or 3+1 or 3+2 years). Completed studies in electrical engineering or studies in the field of information technology	
Work experience	3 years of experience in the relevant field	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies	Specialised expertise and independence in work	
Other requirements	Successful completion of professional examination for work in state administration bodies; Advanced knowledge of the English language, both written and spoken	
POSITION COEFFICIENT		
C1		
DUTIES OF THE POSITION		

- Executes the orders of the Managing director and the Head of the Centre;
- Responsible for the independent performance of complex tasks within the competence of the Centre;
- Performs demanding technical tasks, including activities related to troubleshooting, maintenance, administration and improvement of existing ICT systems and other technical solutions necessary for the regular operation and improvement of the Institute's business processes;
- Identifies deficiencies within the Institute's ICT system and works continuously on overcoming them;
- Continuously maintains the overall ICT system and provides technical support;
- Provides IT user support (help desk) and technical support to external users of the Institute, including assistance and guidance on the proper use of ICT in the Institute's operations;
- Works on establishing clear procedures, regular monitoring of technical changes and innovations in the ICT field, as well as continuous training and education of employees for new technologies and tools (organisation and implementation of training for employees of the Institute on the proper and secure use of computer equipment and work within the Institute's computer network, in cooperation with the Head of the Centre and employees);
- Performs maintenance, administration and improvement of ICT systems at software and hardware levels;
- Performs tasks aimed at maintaining a high level of information system security in order to protect the Institute's sensitive data and ensure system reliability;
- Performs tasks related to updating and improving the Institute's website;
- Performs tasks related to creating and regularly updating backup copies of data and configurations in order to ensure the security of the Institute's data;
- Participates in drafting and analysing technical specifications in the field of public procurement related to ICT;
- Processes and reproduces audio-video materials for the needs of the Institute;
- Proposes continuous training for employees within the Centre and participates in the training of lower-level employees;
- Proposes improvements and revisions of standard operating procedures within the competence of the Centre;
- Participates in the implementation and improvement of information technology solutions supporting the digitalisation of the Institute's business processes;
- Participates in the technical implementation and maintenance of the Institute's electronic services (e-services) and provides user support in their use;
- Participates in activities related to the establishment and maintenance of interoperability between the Institute's information systems and the information systems of other institutions, particularly in the healthcare sector;
- Participates in the implementation of information security and cybersecurity measures, including monitoring security events, applying security policies, and protecting network and server infrastructure;
- Participates in the testing, implementation and improvement of new ICT solutions and application systems introduced into the Institute's operations
- Responsible for acting in accordance with the principles of integrity and ethical standards of the Institute;
- Uses work equipment and materials purposefully and rationally;
- Ensures compliance with occupational health and safety regulations and environmental protection regulations, and performs duties in a manner that does not endanger or damage the environment and protects his/her own life and health, as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or may affect the performance of duties, occurrence of material damage, or the protection and health of himself/herself, other employees and the environment;
- Performs other duties, within the level of qualifications and competencies, in accordance with the law, the Statute, general acts and other acts of the Institute

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	114
CENTRE FOR INFORMATION AND COMMUNICATION SYSTEMS		
(name of the organisational unit)		
EXPERT ASSOCIATE III FOR INFORMATION AND COMMUNICATION SYSTEMS		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VI/VII	
Level of educational and professional qualifications	University degree, qualification comprising 180, 240 or 180+60, 300 or 360 (ECTS) credits (study programme lasting 3, 4 or 3+1 or 3+2 years). Completed studies in electrical engineering or studies in the field of information technology	
Work experience	1 year of experience in the relevant field	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies		
Other requirements	Successful completion of professional examination for work in state administration bodies; knowledge of the English language, both written and spoken	
POSITION COEFFICIENT		
C1		
DUTIES OF THE POSITION		

- Executes the orders of the Managing director and the Head of the Centre;
- Responsible for the independent performance of simplest tasks within the competence of the Centre;
- Performs demanding technical tasks, including activities related to troubleshooting, maintenance, administration and improvement of existing ICT systems and other technical solutions necessary for the regular operation and improvement of the Institute's business processes;
- Identifies deficiencies in the Institute's ICT systems and develops continuous solutions for overcoming them;
- Continuously maintains the overall ICT system and provides technical support;
- Performs tasks related to the maintenance and administration of server and network infrastructure (configuration, maintenance and monitoring of server and network equipment), where necessary in cooperation with third parties with whom the Institute has contractual arrangements for the maintenance of the Institute's ICT systems;
- Establishes and maintains network connections for secure and reliable data flow within the Institute;
- Resolves all detected and potential network issues in order to minimise operational downtime;
- Performs maintenance and optimisation of databases that are essential for the Institute's business applications;
- Provides support related to applications and systems, including troubleshooting technical issues and implementing improvements;
- Regularly creates backup copies of data in order to ensure the security and availability of information;
- Performs tasks related to the maintenance and administration of various ICT system components, including applications, databases, DMS, e-mail systems, the Institute's web portal, file sharing systems, storage systems and other ICT components;
- Coordinates and cooperates with outsourced companies providing technical support and maintenance of server infrastructure and networks;
- Monitors and manages the work of outsourced companies in order to ensure efficiency and compliance with technical standards for maintaining the Institute's ICT systems;
- Organises training and educational activities for system users, particularly regarding the use of application systems and databases;
- Provides support and guidance to users regarding the efficient and secure use of systems;
- Proposes continuous training for employees within the Centre and participates in employee training;
- Proposes improvements and revisions of standard operating procedures within the competence of the Centre;
- Performs maintenance and administration of server and network infrastructure (configuration, maintenance and monitoring of server and network equipment), where necessary in cooperation with a third party with whom the Institute has a contractual arrangement;
- Establishes and maintains network connections to ensure secure and reliable data transmission within the Institute;
- Resolves identified and potential network issues in order to minimise service interruptions;
- Performs maintenance and optimisation of databases that are critical to the Institute's business applications;
- Performs maintenance and administration of various ICT system components, including applications, databases, the DMS, the e-mail system, the Institute's web portal, file sharing services, storage systems and other components;
- Monitors and manages the work of the outsourced service provider to ensure operational efficiency and compliance with technical standards;
- Organises and provides user training, particularly in relation to the use of application systems and databases;
- Provides support and advice to users regarding the efficient and secure use of ICT systems;
- Responsible for acting in accordance with the principles of integrity and ethical standards of the Institute;
- Uses work equipment and materials purposefully and rationally;
- Ensures compliance with occupational health and safety regulations and environmental protection regulations, and performs duties in a manner that does not endanger or damage the environment and protects his/her own life and health, as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or may affect the performance of duties, occurrence of material damage, or the protection and health of himself/herself, other employees and the environment;
- Performs other duties, within the level of qualifications and competencies, in accordance with the law, the Statute, general acts and other acts of the Institute

INSTITUTE FOR MEDICINES AND MEDICAL DEVICES	Position No	115
CENTRE FOR INFORMATION AND COMMUNICATION SYSTEMS		
(name of the organisational unit)		
INFORMATION AND COMMUNICATION SYSTEMS OFFICER		
(job title)		
CONDITIONS FOR THE POSITION		
Qualification level and sublevel	VI	
Level of educational and professional qualifications	Secondary education, qualification comprising 240 (CSPK) credits (four-year programme): technical secondary school or grammar school	
Work experience	1 year	
Special health requirements	NO	
Working hours	Full time – 40 hours per week	
Competencies		
Other requirements	Successful completion of professional examination for work in state administration bodies; Advanced knowledge of the English language, both written and spoken	
POSITION COEFFICIENT		
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DUTIES OF THE POSITION

- Executes the orders of the Managing director and the Head of the Centre;
- Responsible for the independent performance of the simplest tasks within the competence of the Centre, under the continuous supervision and control of Expert Associate I and the Head of the Centre;
- Carries out activities related to troubleshooting, maintenance, administration and improvement of existing ICT systems and other technical solutions necessary for the regular operation and improvement of the Institute's business processes;
- Prepares computers and other computer components for the regular work of employees;
- Provides primary IT user support (help desk) and technical support to external users of the Institute, including assistance and guidance on the proper use of ICT in the Institute's operations;
- Participates in the implementation of activities related to the implementation, troubleshooting, maintenance, administration and improvement of existing ICT systems and other technical systems and solutions necessary for the regular operation and improvement of the Institute's business processes (air conditioning systems, access control systems, fire protection systems, fire alarm control panels with associated elements, sprinkler systems, fire extinguishers and hydrant networks, video surveillance systems, UPS systems, lifts, generators, etc.);
- Manages licences for the use of software and software solutions;
- Conducts/implements training for employees of the Institute on the proper and secure use of computer equipment and work within the Institute's computer network, in cooperation with the Head of the Centre and employees;
- Performs tasks related to updating and improving the Institute's website;
- Performs tasks related to creating backup copies of data and ICT systems;
- Performs tasks related to the preparation of ICT equipment and technical support services for conferences, meetings and other events organised by the Institute;
- Participates in drafting and analysing technical specifications in the field of public procurement related to ICT;
- Performs tasks related to processing and reproducing audio-video materials for the needs of the Institute;
- Responsible for acting in accordance with the principles of integrity and ethical standards of the Institute;
- Uses work equipment and materials purposefully and rationally;
- Ensures compliance with occupational health and safety regulations and environmental protection regulations, and performs duties in a manner that does not endanger or damage the environment and protects his/her own life and health, as well as the life and health of others;
- Informs the immediate supervisor of significant circumstances that affect or may affect the performance of duties, occurrence of material damage, or the protection and health of himself/herself, other employees and the environment;

- Performs other duties, within the level of qualifications and competencies, in accordance with the law, the Statute, general acts and other acts of the Institute

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