CInMED

Institute for Medicines and Medical Devices of Montenegro

DEVELOPMENT STRATEGY

2022 – 2026

Institute for Medicines and Medical Devices of Montenegro ready to become part of European family

CInMED's role is
to actively contribute to the creation of conditions for the development of pharmaceutical sector,
as well as to the protection of public health through the regulation of medicines and medical devices
in accordance with the EU acquis

CONTENTS

1. FOREWORD

Becoming part of Europe's best in class (word of management)

This Strategic plan determines strategic priorities and guidelines for the development of the Institute for Medicines and Medical Devices (CInMED) as a public authority of Montenegro for a five-year period, from 2022 to 2026, taking into account environmental dynamics within Montenegro, region and the European Union.

This Strategy defines general and specific strategic objectives and sets goals that are aimed to the development of core activities, as well as goals that are aimed to the development of ancillary activities. The expected achievement of the set goals depends on the adequacy and availability of necessary resources, as well as the ability of the Institute for Medicines and Medical Devices (hereinafter: the Institute) to respond to the requirements of national and EU legislation.

Institute was established by the Law on Medicines ("Official Gazette of Montenegro", No. 80/20), as an independent regulatory authority in the field of medicines and medical devices and it is registered as a scientific-research and innovative organization.

By the decision of the Ministry of Science No 01-760/2 of April 21, 2017, the Institute obtained the license to perform scientific-research activities in the field of medical sciences and interdisciplinary research. By the Decision of the Ministry of Economic Development No 002-350/22-4441/2 of February 28, 2022, it was determined that the Institute met the conditions for performing innovation activities and was entered in the Register of Innovative Organizations. Due to numerous and complex changes brought about by social circumstances, scientific and technological innovations, as well as unfulfilled health requirements, it is necessary to continuously monitor and provide an adequate and timely response.

Based on challenges the Institute faces, CInMED must define its key strategic areas and goals and analyse its strengths and weaknesses, threats and opportunities, as well as develop an action plan to meet strategic goals. Therefore, the strategic planning of the Institute's development is based on setting organizational, professional and technical bases for continuous improvement of working operation and business results, through regulatory harmonization, digitalization and process optimization, as well as through establishing partnership relations based on common values.

Development Strategy of the Institute for the period 2022-2026 (hereinafter: Development Strategy) represents an ambition for a period of five years, the fulfilment of which will have a positive impact on public health and development of the pharmaceutical market in Montenegro. Further development of the Institute's business operation should be based on strengthening administrative and technical capacities, as well as increasing the level of competencies and further training of employees to perform precisely defined expert tasks, within legally prescribed time limits.

It is necessary for the Institute to be ready to respond to challenges posed by continuous expansion of the scope of competencies, i.e. increasing complexity of processes with the implementation of European standards.

Building partnership relations with other key participants in the health system, as well as getting the industry, public and patients involved in the regulatory process is crucial for creating conditions conducive to the development of the market of medicines and medical devices, i.e. greater availability of a wide range of products to patients, especially the ones costs of which are covered by compulsory health insurance.

Taking into account significant amendments of regulations of the European Union in the field of clinical trials, veterinary medicines, medical devices and in vitro diagnostics that will significantly affect the operation of relevant regulatory system, the Institute will participate in major projects requiring contribution to national legislation, extensive engagement with all stakeholders and development of information systems affected by regulations.

In times of intensive information exchange, special attention should be paid to the visibility and respectability of the institution, with a focus on transparency in process management and decision-making, timely communication through appropriate channels, identification and risk management to prevent unreliable sources and conflicting information that could jeopardize critical importance of the regulatory system. It is necessary to establish visibility of the Institute as a key regulatory entity responsible for providing quality, safe and effective medicines and medical devices and to build stable channels of communication with the media and the public.

There has been a remarkable progress in scientific and technological innovations during previous years, especially in the field of personalized therapies, connection of medical devices to digital information and new technologies in the manufacture. Although innovative products greatly affect the improvement of patient's health and final outcome of treatment, they can also be challenging for the existing regulatory framework and can create the need for appropriate support and in this regard attention should be paid to monitoring and timely transposition of European regulations related to these products.

Having in mind legal obligations, as well as the importance of clinical trials in terms of early availability of modern therapies to patients and contribution to the education of healthcare professionals and the development of medical and pharmaceutical science in general, the Institute should establish and continuously maintain conditions for increasing the number of clinical trial institutions in Montenegro, primarily by fully regulating this area.

It is necessary to develop necessary expertise for effective implementation of regulatory activities in digital environment. The implementation of the Development Strategy requires a high level of motivation, commitment and effort of both the management and employees of the Institute, which is enabled by continuous improvement of personnel expertise, working methods and digital transformation programs. Detailed activities are planned and implemented through the annual cycle of business operations planning, and implementation is monitored through reporting to senior management and the administration.

CInMED looks forward to working with the Steering Board, members of the Expert-Scientific Board, employees, pharmaceutical industry, the Ministry of Health and all other members of the health system of Montenegro.

MANAGING DIRECTOR

MD, MSc, PhD, spec. Snežana Mugoša

1.1 Protecting public health

The Institute for Medicines and Medical Devices (CInMED) is the independent national competent body of Montenegro which is the regulator in the field of medicines and medical devices. The role of the Institute is to actively contribute to the development of the sustainability of pharmaceutical market as well as protection and promotion of public health through the regulation of medicines and medical devices. One of the most important goals of the Institute is to improve legislation and procedures in order to become one of Europe's best in class in the near future, once Montenegro becomes a member state.

CInMED does this by:

- mobilizing highly-skilled and experienced experts and healthcare professionals in order to achieve high quality assessment of medicinal products and medical devices, promoting research and development programs, as well as providing clear and useful information to the public and healthcare professionals;
- developing effective and transparent procedures aimed at providing the public with prompt access to medicinal products based on decisions taken in the interests of public health;
- supervising the safe use of medicinal products and medical devices across the entire product lifecycle by monitoring adverse reactions and the quality of medicinal products and medical devices marketed in Montenegro;
- collaborating with authorities competent for medicinal products and medical devices on a regional, EU and global level; and
- developing collaboration with all stakeholders including national health regulatory authorities, healthcare professionals, academics and researchers, patient associations, wholesale and manufacturing industries, in order to maximise the availability of medicines and medical devices with a positive benefit/risk profile.

The pharmaceutical sector is a significant contributor to Montenegrin economic development and it is set by Government of Montenegro as one of the most important strategic sectors that has to play an important role in the future. This is why CInMED's strategic orientation is to support this sector through providing regulatory and technical advice in relation to authorization of products, as well as approving research, wholesale and manufacturing activities and ensuring compliance with all the standards of good practices.

1.2 What has been achieved

During past years significant organisational changes have taken place, scientific knowledge has been successfully increased and staff capacities have been improved and well trained in order to prepare the Institute for new challenges in the EU environment.

In 2020, a new Law on Medicines was adopted and published in the "Official Gazette of Montenegro" No. 80/20. The Law on Medicines is in line with the Acquis communautaire (a positive opinion of the European Commission has been obtained on the text of the Law). Bearing in mind that Montenegro is in the process of accession to the European Union, continuous progress in the legislative field requires further harmonization of legislation with the acquis.

In line with the Law on medicines, the Institute is established as regulatory and scientific institution and internal organization of the Institute is reorganized in 6 divisions: Centre for medicines, Centre for medical devices, Centre for medicines post-marketing surveillance, Inspectorate and Laboratory, as well as 4 support divisions for economic, legal, IT and general affairs. Office of the managing director performs quality management, EU harmonization and international cooperation, as well as public relations affairs.

In accordance with the Law on Medicines, an Expert-Scientific Boards is formed at the Institute, which consists of at least five employees with specialist and scientific titles from the activities of the Institute.

Centre for Medicines was decentralized into the Centre for medicines authorisation and Centre for medicines quality, safety and efficacy assessment. Centre for medicines authorisation consist of Department for Marketing Authorisation, Department for Variations and Department for Veterinary Medicines. Moreover, overall expertise, especially in preclinical and clinical assessment, as well as quality assessment was strengthened and the number of staff has increased significantly.

Centre for marketing and safe use of medicines was formed for area of Pharmacovigilance, Medicines Consumption Monitoring, Setting Maximum Prices and Import/Export Authorisation. The number of staff has increased significantly in order to properly meet all regulatory requirements.

Quality Manager was appointed in order to integrate the quality system of CInMED and organized in accordance with the international standards and best practices of the EU regulatory network.

The Institute has the following quality standards: ISO 9001:2015, ISO/IEC 27001:2013 and ISO/IEC 17020:2013.

The Institute gives great importance to the quality management system through which it continuously improves its business operation. The Institute conducts a large number of business processes and good organization and maximum engagement and commitment of employees are key to positive business performance. It is through the quality management system that work processes are established and controlled by creating relevant documents and performing checks in order to improve business operation. In order to fulfil all assigned tasks, the Quality Policy was adopted and in 2010 the quality management system was certified according to the requirements of the ISO 9001: 2008 standard by the world's leading certification body SGS. In October 2013, recertification was done, also by SGS. In addition to the quality management

system, in 2013 the Institute implemented the Information Security Management System according to the requirements of the ISO 27001 standard. Successful implementation and compliance with this standard was also confirmed by SGS by its certificate in October 2013.

Business policy of the Institute determines continuous improvement of what has been achieved, implementation of the abovementioned and also new standards in specific areas of business operation, which contributes to the overall increase in the work quality in the institution. The implementation of quality standards requires hiring of new employees and their continuous training and checking of their performances.

Also, new organizational units were formed – Inspectorate and Laboratory:

Inspectorate conducts inspections in the field of medicines in the field of the manufacture, wholesale of medicines, pharmacovigilance, clinical trials of medicines, as well as supervision over compliance with guidelines of Good Manufacturing Practice (GMP), Good Distribution Practice (GDP), Good Clinical Practice (GCP) and Good Practice in Pharmacovigilance (GVP). Expert assessment of compliance with principles and guidelines of the European Union (whose translations are published on the portal of the Institute and the Ministry of Health) is performed by pharmaceutical inspectors of the Institute.

Laboratory determines the fulfilment of conditions regarding quality standards by laboratory quality control of each medicine for which doing so is prescribed by the Law, in accordance with European, or national pharmacopoeia, other recognized pharmacopoeias, or other validated methods of analysis. The Laboratory is of great importance for monitoring and detection of substandard (quality defect), and especially counterfeit medicines. Bearing in mind that taking such medicines can lead to deterioration of health and even death, as well as that the opening of the market increases possibility of their occurrence in legal supply chains, the Institute timely establishes mechanisms for their detection. Laboratory is essential for the reliability in the quality of medicines on the Montenegrin market, and thus for patients' safety.

In the field of medical devices, a new Law was passed and drafting of bylaws has started in accordance with new EU regulation.

All these achievements point CInMED towards the new perspectives and challenges of the coming years.

1.3 History

The Institute for Medicines and Medical Devices was established by the Law on Medicines ("Official Gazette of Montenegro", No. 80/20), as an independent regulatory authority of Montenegro in the field of medicines and medical devices and as a scientific research organization. The Institute is a legal successor and continues the work of the Agency for Medicines and Medical Devices, established by the Decision of the Government of Montenegro in 2008.

In accordance with the new Law on Medicines, the founder of the Institute is the Government. The Institute has the status of a legal entity with rights, obligations and responsibilities determined by the Law and the statute of the Institute. The governing body of the Institute is the Steering Board. The Institute is represented by the Director, who is responsible for his/her work to the Steering Board.

The Institute, in cooperation with the faculties of medicine, natural and technological-technical orientations, develops and exchanges expert knowledge in order to raise quality and education, participates in the realization of scientific research in the field of medical sciences and interdisciplinary research and scientific work in the field of medicines and medical devices and related areas. The Institute is the teaching base of the faculties of health and other scientific fields within its jurisdiction, based on the contract, in accordance with the Law.

Funds for the work of the Institute are provided from its own revenues, from fees determined for the performance of tasks prescribed by Law, as well as from other sources in accordance with the Law. The Institute uses these funds to fulfil its prescribed competencies.

Pursuant to the new Law on Medicines, the Institute was entered in the Central Register of Business Entities on October 5, 2020. After that, the Steering Board of the Institute adopted the Statute of the Institute for Medicines and Medical Devices, as well as the Rulebook on internal organization and systematization of the Institute.

The abbreviated name of the Institute, in accordance with the Statute, is CInMED.

Since its establishment, the Institute has continuously strived to implement the highest European and international standards and achieve quality, impartiality and transparency in its work. The Law on Medicines extends the field of activity to scientific research and thus continues its work as the Institute for Medicines and Medical Devices of Montenegro.

By the decision of the Ministry of Science No: 01-760/2 from April 21, 2017, the Institute was issued a license to perform scientific research activities in the field of medical sciences and interdisciplinary research. By the decision of the Ministry of Science No: 03/2-051/20-1482/2 from September 9, 2020, it was determined that the Institute met the conditions for performing innovation activities and it was entered in the Register of Innovative Organizations. Due to the harmonization with the new legal regulations, by the Decision of the Ministry of Economic Development, the Institute was entered in the Register of Innovation Activities, No. 002-350 / 22-4441/ 2 from 28.02.2022.

1.4 Looking forward

In the next five years, the Institute will maintain its mission and vision that are completely focused on creation of conditions for development of pharmaceutical market and protecting public health.

CInMED will continue collaboration with other national competent authorities, within the region and the EU as well as the European Medicines Agency (EMA). It is CInMED’s goal to

become an important and respectable player within the EU regulatory network in the field of medicine marketing authorisation and GxP inspections, and to continue the development of the pharmacovigilance process in order to contribute to building a safe and effective public health system. CInMED will intensify its efforts in marketing surveillance for medicines and medical devices, as well as combating illegal and falsified medicines and medical devices through strong cooperation with the national police, custom services and other stakeholders.

CInMED will further develop its quality management system to achieve the highest standards as defined in the principles of Benchmarking of the European Medicines Agencies (BEMA), and finalize the building of CInMED's integrated IT system that will facilitate the planning, monitoring and performance of all CInMED activities. Furthermore, CInMED will build a strong risk management system that will encompass all the key processes and professional duties of CInMED, bearing in mind the strengthening of its business continuity capabilities, as well as specific risk-based pharmacovigilance and inspection activities.

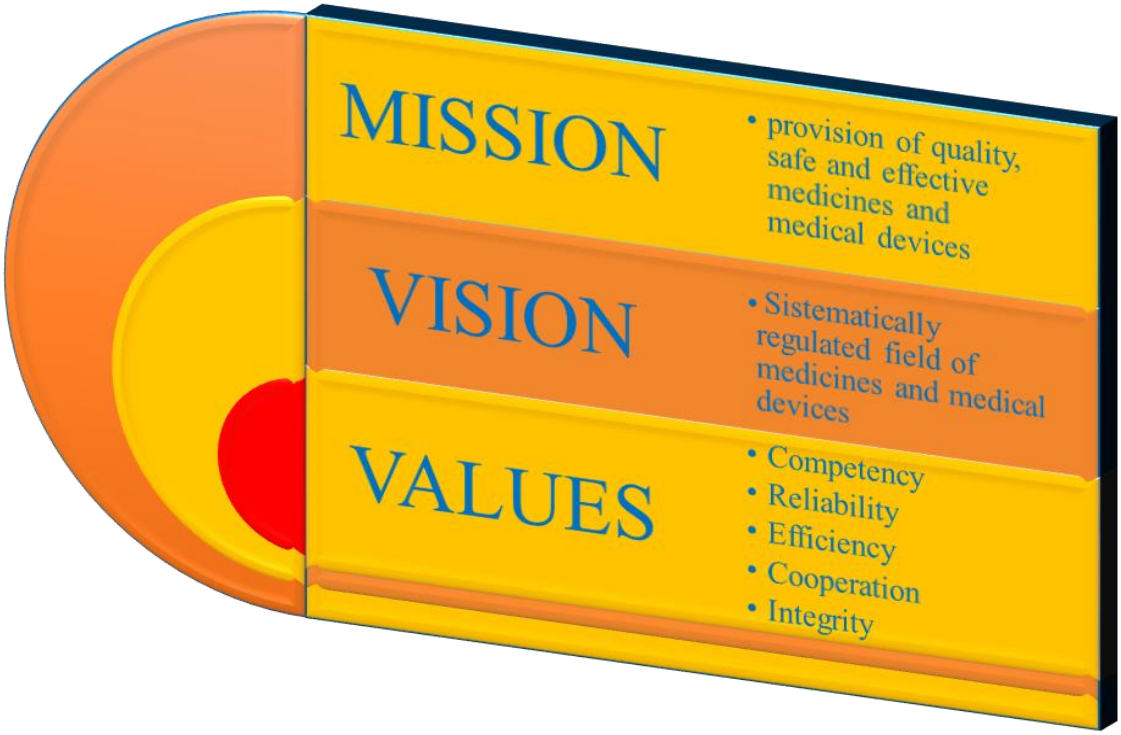
CInMED's stakeholders are a focus of its interest and communication with them is of crucial importance to CInMED. CInMED will establish new ways of communication and maintain those that are already well established. Introducing of the annual stakeholders meeting and redesigning of the website will be a part of these activities.

CInMED will continue participation in all the initiatives of Montenegro in EU activities that will lead us to a stronger and more efficient legal framework of medicines and medical devices which is fully harmonized with EU standards, in order to fulfill necessary conditions for becoming member state in the forthcoming period.

In order to achieve all its goals, CInMED will continue building its capacities focusing on strengthening its expertise, scientific knowledge and necessary skills needed in the EU environment.

2. ORGANISATIONAL TENETS

The Institute for Medicines and Medical Devices was established by the Law on Medicines ("Official Gazette of Montenegro", No. 80/20), as an independent regulatory authority of Montenegro in the field of medicines and medical devices and as a scientific research organization. The Institute is a legal successor and continues the work of the Agency for Medicines and Medical Devices, established by the Decision of the Government of Montenegro in 2008. The activities of the Institute are defined by Article 22 of the Law on Medicines ("Official Gazette", No. 80/20) and Article 12 of the Law on Medical Devices ("Official Gazette", No. 24/19).



2.1 Mission

Mission of the Institute is **provision of quality, safe and effective medicines and medical devices of appropriate performances.**

Mission of the Institute is to protect human and animal health by promoting rational use of medicines and medical devices and supporting the development of the pharmaceutical sector.

Expert activities of the Institute are focused on regulatory processes, conducting supervision and providing support to the market of medicines and medical devices, with the aim of ensuring and promoting timely availability of medicines and medical devices, as well as on activities contributing to science and profession for the benefit of public health, economy and society as a whole. In the field of medicines and medical devices, CInMED cares about human and animal health and it is committed to continuing to provide complete and timely high quality services, proposing policies and coordinating activities to create a conducive social environment for the development of timely availability of safe, quality and effective medicines and medical devices of appropriate performances.

2.2 Vision

Vision of the Institute is **systemically regulated field of medicines and medical devices**.

Institute endeavours to become a respected and internationally well-established national regulatory body, responsible for proposing policies and systemic solutions in the field of medicines and medical devices. Vision of the Institute is to fulfil its responsibilities in a systemically regulated and predictable regulatory environment which provides the ability to plan and certainty in the business operation of its partners in pharmaceutical industry and health system. A stable market of medicines and medical devices with a tendency of continuous development guarantees the fulfilment of the obligation to protect public health.

Institute strives to become a competent and efficient regulatory body that provides information on medicines and medical devices in an appropriate manner. In a regulated environment, preconditions are created for the performance of tasks entrusted by the Law to the Institute within the prescribed time limits. Timely and efficient handling of applications will enable informing professional and general public about all amendments to the information on the medicine and medical device in a timely manner. This way of regulating the system of medicines and medical devices will increase the visibility of the Institute in the network of European and international regulatory bodies and establish its respectability in terms of taking stands and making decisions.

Expertise, independence and impartiality will contribute to the ambition that the visibility and respectability of the Institute, both regionally and internationally, is a result of its full commitment to the Institute's mission and vision, while respecting principles of integrity, partnership, reliability and efficiency.

Along with intensive expert work, the vision of a systemically regulated environment will ensure developing of partnership relations and respect for interests and priorities in the business operation of the pharmaceutical industry, and thus affect market development and economic growth, and consequently, the disappearance of the black market (stolen and counterfeit medicines), as well as employment growth. In this way, a positive contribution is made to a higher level of public health by providing a larger number of authorised innovative and generic therapies. Additionally, it is necessary to fully respect the fact that the independence of the Institute stems from public authority, which enables the state as a founder to achieve one of the noblest goals of society – care for the health of its inhabitants.

Achieving the mission and vision of the institute means:

- **Active dialogue and cooperation - teamwork with its partners;**
- **Quality and timely services – clients' satisfaction;**
- **Professional expertise and dedication - an attractive place to work;**
- **Institute as an initiator of regional and international cooperation - a strong international position.**

2.3 Values

COMPETENCY Highly educated and continuously trained personnel who perform tasks within the area of competence of the Institute at a high level in terms of expertise, setting ambitious goals, in a professional and impartial manner, applying modern scientific standards and European legislation and also achievements in medicine and pharmacy.

RELIABILITY Decision-making based on diligent assessment of all known aspects with the application of the principle of impartiality both in relation to clients and colleagues. CInMED strives for meaningful and purposeful solutions while respecting set priorities. It conducts a detailed analysis of its decisions, with consideration and learning from its own mistakes.

EFFICIENCY Proactive identification of the area of business performing and giving contributions by initiating discussions and negotiations, as the only right way to the necessary changes and finalization of started projects. Respect for the value of its own, but also time dedicated by its partners.

COOPERATION Openness to proposals and cooperation on ideas and projects that support the development of the pharmaceutical sector. CInMED respects expectations of its partners and agreements and understanding made between the parties in order to reach a broad social consensus. CInMED makes maximum effort to recognize the role and effort of its partners and colleagues and in this way it plays a connecting and initiating role, taking into account mutual respect, openness and trust.

INTEGRITY Business is performed in a transparent and impartial manner, eliminating any possibility of corruption and discrimination, i.e. exclusively in accordance with applicable laws and regulations, as well as moral and ethical principles. CInMED creates an environment that provides encouragement and motivation and makes dedicated, determined, courageous, creative, professional and satisfied employees, devoted to respecting these values.

CInMED believes in the power of diversity that brings equality to everyone.

2.4 Legal framework

Bearing in mind that Montenegro is in the process of joining the European Union, continuous progress in the legislative field requires further harmonization of regulations with the acquis communautaire. As a large number of bylaws require compliance with European Union regulations, the Institute envisages this activity as a component of the TWINNING project to support the Institute in the EU accession process, by supporting the harmonization and implementation of regulations in Chapter 1 – Free movement of goods, focusing on transposition EU acquis and support in the application of international good practices. The project was approved in 2020 and will be implemented in cooperation with the Republic of Croatia, as an EU partner country in 2021/2022.

Pharmacovigilance

Although significant changes have been made in relation to the system for pharmacovigilance (medicine safety monitoring) for human medicines, full adoption of all EU Modules into the legal framework is still to be done. Thus, the Pharmacovigilance system will be completed and able to serve as a valuable tool in the protection of public health.

Medical devices

Having in mind the entry into force of new regulations in the EU and that the existing Law on Medical Devices is harmonized with previously valid EU regulations, further harmonization through bylaws and, if necessary, revision of the Law in the coming period will be required.

Falsified medicines

The Institute pays significant attention to the issue of falsified medicines. Namely, the laboratory of the Institute is focused on the fight against substandard and falsified medicines. Additionally, in the forthcoming period, the Institute will work on further harmonization with EU regulations in this area, as well as establishing cooperation with other competent authorities in Montenegro and on the international level.

2.5 Role of CInMED

The Institute performs competencies prescribed by:

- Law on Medicinal Products ("Official Gazette of Montenegro", No. 080/20);
- Law on Medical Devices ("Official Gazette of Montenegro", No. 024/19);
- Law on Prevention of Drug Abuse ("Official Gazette of Montenegro", No. 028/11 and 035/13);
- Law on control of manufacture and marketing of substances that can be used in the manufacture of narcotic drugs and psychotropic substances ("Official Gazette of Montenegro", No. 083/09 and 040/11).

The Institute for Medicines and Medical Devices was established by the Law on Medicines ("Official Gazette of Montenegro", No. 80/20) as an independent regulatory authority of Montenegro in the field of medicines and medical devices and as a scientific research

organization. The Institute is a legal successor and continues the work of the Agency for Medicines and Medical Devices, established by the Decision of the Government of Montenegro in 2008. Since its establishment, the Institute has been continuously endeavoring to improve innovation and implement the highest European and international standards and achieve quality, impartiality and transparency in its business operation.

In accordance with the Law on Medicinal Products ("Official Gazette of Montenegro", No. 080/20), the Institute is competent to:

- issue of marketing authorisation;
- issue manufacturing and wholesale authorisations for medicinal products for human use;
- issue a clinical trials authorisation, amendments to the authorisation, conduct inspection and monitor the safety of the investigational medicinal product;
- record non-interventional clinical trials;
- establish and organize a pharmacovigilance system in order to monitor safety of medicinal products on the market and detect any changes in relation to benefits and risks of their use;
- issue certificates on Good Manufacturing Practice, Good Clinical Practice and other certificates in accordance with this Law;
- issue certificates for the purpose of export of medicinal products in accordance with recommendations of World Health Organisation;
- issue consent to import of unauthorised medicinal products;
- issue authorization for narcotic drugs and psychotropic substances in line with the legislations regulating this areas;
- issue approval for import and export of immunological medicinal products and medicinal products from the blood and plasma;
- conduct quality control in accordance with this Law;
- participate in international standardization in the field of medicinal products;
- perform collecting and processing of data on marketing and consumption of medicinal products;
- keep the registers stipulated by this Law;
- conduct inspection surveillance on implementation of this Law;
- inform and educate on medicinal products, organise professional and educational conferences and provide information of importance for the conducting measures of rational use of medicinal products;
- carry out the cooperation with international entities and national regulatory bodies in the field of medicinal products;
- participate in the harmonisation of regulations in the field of medicinal products with regulations of the European Union and regulations and guidelines of international institutions;

- issue expert opinions on the classification of the products into the medicinal product or group of medicinal products as well as other expert opinion and professional consultancies within its jurisdiction;
- carry out activities related to disposal and destruction of waste for its own purposes;
- establish maximum prices of medicinal products for human use, in accordance with criteria established by the Government;
- perform activities in the field of medical devices in accordance with special Law;
- perform educational, scientific and research work in cooperation with the faculties for health sciences in the field of medicinal products and medical devices and other related fields of interdisciplinary research;
- perform other tasks in accordance with the law.

In accordance with the Law on Medical Devices ("Official Gazette of Montenegro", No. 024/19), the Institute is competent to:

- enter, delete and keep a register of manufacturers and legal persons that perform wholesale, import and export of medical devices, as well as a register of specialized retail stores;
- enter, delete and keep a register of medical devices that may be marketed in Montenegro;
- grant authorization for import of unregistered medical devices;
- grant authorization for the commencement of clinical investigations and control the implementation of clinical investigations;
- implement a system of vigilance;
- decide on the classification of medical devices when it comes to the combination of medicines and medical devices, medical devices and objects of general use or classification of medical devices and gives expert opinions from their jurisdiction;
- in the procedure for determining the conformity of medical devices with the requirements prescribed by this Law, give opinion to a designated and authorized body;
- cooperate with international entities and national regulatory bodies in the field of medical devices;
- perform other tasks, in accordance with the law.

In accordance with the Law on Prevention of Drug Abuse ("Official Gazette of Montenegro", No. 028/11 and 035/13), the Institute is competent to:

- give an opinion on the List of drugs, psychotropic substances and herbs that can be used for drug manufacture;
- issue a license for the manufacture and marketing of drugs;
- determine the annual needs for drugs for medical and pharmaceutical purposes;
- approve the maximum quantity of drugs that a legal entity which has a manufacture and marketing authorization can produce, i.e. keep in storage during a calendar year;
- issue a special authorization for import, export or transit of drugs to legal entities that have manufacture and marketing authorization;

- within three months from the day of expiration of the authorization, return the authorization for import of drugs to the competent authority of the state that issued that authorization, with the notification that the export of drugs has not been performed;
- issue a permit for ships and aircraft in international traffic to be able to possess drugs used to provide first aid, in the quantities necessary for that purpose.

In accordance with the Law on control of manufacture and marketing of substances that can be used in the manufacture of narcotic drugs and psychotropic substances ("Official Gazette of Montenegro", No. 083/09 and 040/11), the Institute is competent to:

- propose a List of precursors classified by categories;
- issue a manufacture authorization for the of precursors;
- issue a marketing authorization of precursors;
- issue approval for the use of precursors to pharmacies, veterinary institutions, police, customs, laboratories, the Army of Montenegro, institutions engaged in teaching and research and other legal entities that need precursors to perform activities, in accordance with their needs;
- propose annual needs for precursors that are pharmacologically active substances used in the medicinal products manufacture;
- issue authorization for import, export, transit and transportation of precursors of the first category which are pharmacologically active substances used for the medicinal products manufacture;
- before issuing export authorization of precursors, submit the prescribed data to the competent authority of the state to whose territory the precursor is to be exported;
- keep a register of legal entities that perform manufacture, marketing, import, export, transit and transportation of precursors and a special register of authorizations issued.

New competencies of the Institute

In addition to the tasks performed by the Institute in the previous period and the scope of which has been expanded by new laws, the Institute has been assigned entirely new competencies, some of which are:

- *Inspectorate* – Conducts inspections in the field of medicines, with regard to manufacture, wholesale of medicines, pharmacovigilance, clinical trials of medicines, as well as supervision over compliance with guidelines of Good Manufacturing Practice (GMP), Good Distribution Practice (GDP), Good Clinical Practice (GCP) and Good Practice in Pharmacovigilance (GVP). Expert assessment of compliance with principles and guidelines of the European Union (whose translations are published on the portal of the Institute and the Ministry of Health) is performed by pharmaceutical inspectors of the Institute:

  - Guidelines on Good Manufacturing Practice (GMP),
  - Guidelines on Good Distribution Practice (GDP),
  - Guidelines on Good Clinical Practice (GCP),
  - Guidelines on Good Pharmacovigilance Practice (GVP).

It is noted in this regard that in order to acquire the status of a pharmaceutical inspector, detailed and long-term initial training is necessary, especially external (e.g. attending an inspection of an EU member state), which requires hiring personnel in a continuous period.

- *Laboratory* – Determines the fulfillment of conditions regarding quality standards by laboratory quality control of each medicine for which doing so is prescribed by the Law, in accordance with European, or national pharmacopoeia, other recognized pharmacopoeias, or other validated methods of analysis. The Laboratory is of great importance for monitoring and detection of substandard (quality defect), and especially counterfeit medicines. The fact is that in the last period there has been a quite noticeable increase in the number of counterfeit medicines (globally, according to WHO data: no active substance 43%; poor quality 24%; low content 21%; wrong substance 7%; wrong packaging 5%). In the global market, about 30% of the total number of medicines are counterfeit, in European countries about 1%, while in the region this percentage is slightly higher (about 10%). Bearing in mind that taking such medicines can lead to deterioration of health and even death, as well as that the opening of the market increases possibility of their occurrence in legal supply chains, the Institute timely establishes mechanisms for their detection. Laboratory is essential for the reliability in the quality of medicines on the Montenegrin market, and thus for patients' safety.

- *Amendment of provisions governing clinical trials* – In the field of clinical trials of medicines, as well as of medical devices, new laws have changed the manner and procedure of their approval. Defining a procedure for approving the conduct of clinical trials that is more efficient creates conditions for encouraging and conducting a larger number of clinical trials in healthcare institutions and by healthcare professionals in Montenegro. Not only is the development of medical science encouraged, but healthcare professionals and scientists are enabled to have access to the latest scientific achievements in medicine, while patients are provided with modern and innovative therapies, without burdening the health system of Montenegro. Given the average number of clinical trials per year and parallel procedures for approving a clinical trial by the Institute and the Central Ethics Committee (Ethics Committee of the Ministry of Health), the number of applications for clinical trials is expected to increase continuously from the date of application of the Law to the level of number of applications in the EU Member States, or at least to the level of countries with the same population size. This is why the Institute must be ready to respond to the increased number of applications in practice, by determining and training the appropriate number of employees.

- *Participation in the harmonization of regulations in the field of medicines with regulations of the European Union and regulations and guidelines of international institutions* – In accordance with this competency, the Institute will independently work on the drafting bylaws for the implementation of laws governing medicines, as well as on the transposition, harmonization and translation of European Union regulations. To perform these tasks, it is necessary to provide appropriate expert personnel with experience in normative affairs, harmonization of regulations with European Union regulations in the areas of competencies of the Institute, with knowledge of national and European regulations in the areas of competencies of the Institute and advanced knowledge of English language. Although this competency is not explicitly prescribed in the field of medical devices, the Institute will perform the

abovementioned activities in this area in accordance with the achieved cooperation with the Ministry of Health in the previous period.

2.6 Organisational structure

The governing bodies of the Institute are the Steering Board and the Managing Director.

Steering Board

The body governing the Institute is the Steering Board.

The Steering Board is consisted of the head and four members who are appointed and dismissed by the Government.

Members of the Steering Board are the Government representatives from among professionals in the field of health, veterinary medicine and environmental protection and one member is a representative of the employees proposed by the Institute.

Steering Board members shall be appointed for the four-year period and may be reappointed.

The Steering Board shall perform the following tasks:

- define the business policy of the Institute;
- adopt statute of the Institute, act on internal systematisation and organisation and other general acts;
- adopt financial plan and final account;
- decide on the choice of an auditor;
- adopt the business report;
- adopt the yearly working program of the Institute;
- make investment decisions;
- adopt a Code of conduct for employees of the Institute;
- take measures to ensure the quality, safety and efficacy of medicinal products;
- submit the work report to the Government at least once a year;
- make decisions in second instance on the Institute employees' rights;
- adopts the Rules of procedure regarding its work; and
- perform other activities determined by the Law and Statute of the Institute.

Managing Director

The Institute is represented by the Managing Director.

Managing Director is appointed and dismissed by the Steering Board based on the public announcement.

Managing Director shall be appointed for the five-year period and may be re-elected.

Managing Director shall:

- organise and manage operating of the Institute;
- be responsible for the legality, efficiency and economical effectiveness of the Institute;
- be responsible for the implementation of working programs and plans of the Institute;
- be responsible for keeping prescribed documentation and records;
- pass the decisions, i.e., administrative acts within the competence of the Institute, which are not the responsibility of the Steering Board of the Institute;
- act upon the decisions of the Steering Board;
- make decisions on the rights of the employees in accordance with the Law.

Expert-scientific Board

The Expert-scientific Board is established within the Institute that consists of at least five employees of the Institute with specialty and scientific occupations related to activities of the Institute.

The members of the Expert-scientific Board are appointed and dismissed by the Steering Board on the proposal of the Managing Director of the Institute.

The President of the Expert-Scientific Board is elected by the Expert-Scientific Board among the members of the Expert-Scientific Board.

The Expert-Scientific Board members shall be appointed for the four-year period and may be reappointed.

President of the Expert-Scientific Board shall be appointed for the two-year period and may be reappointed at most once in a row.

The Expert-Scientific Board shall work and decide at its sessions by a majority of the total number of members.

In order to perform certain tasks within the competence of the Institute, the Expert-Scientific Board may appoint commissions and working groups.

The work of the Expert-Scientific Board is regulated by the Rules of Procedure.

Expert-scientific Board shall:

- propose and give opinions on the development strategy of the Institute and propose expert basis for the program of work and development of the Institute;
- propose and give opinions on issues of expert work of the Institute;
- give an opinion on the programs of all forms of expert and scientific training for the need of the Institute;
- adopt a program for scientific-research and development activities;
- analyse, evaluate and adopt reports on the implementation of programs and projects;
- perform other duties in accordance with the Law and the Statute of the Institute.

Operations of the Institute are conducted through the following **organisational units**:

- Managing Director Office
- Centre for Medicines Authorisation
- Centre for Medicines Quality, Safety and Efficacy assessment
- Centre for Marketing and Safe Use of Medicines
- Centre for Medical Devices
- Inspectorate
- Laboratory
- Department for Legal Affairs
- Department for Financial Affairs
- Department for IT and Technical Affairs
- Registry Office and General Affairs

According to legal requirements, CInMED has an Employees' Union, which is a representative body of employees.

2.7 Qualification structure

CInMED, as an employer, has engaged professionals with specific expertise in the field of medicines and medical devices due to its legal obligations.

In the Institute, 4 of its employees have a PhD degree, 6employees have a Master of Science degree, 10 employees have a specialty in the field of medicine, or pharmacy. Also, CInMED has 10 employees that are about to complete PhD studies.

In addition, 9 employees of the Institute are engaged at the Faculty of Medicine in Podgorica, in the study program Pharmacy: 4 employees in the capacity of lecturers and 4 in the capacity of teaching associates, as well as in the study program Dentistry: 1 employee in the capacity of teaching associate.

2.8 Financing

CInMED is a self-funded Institute that generates its own income through service fees and annual charges for the provision of services in accordance with the laws and other regulations according to the strictest ethical principles in order to ensure the highest quality of service combined with value for money.

2.9 Networking and Communication

CInMED develops its networking activities in the region, EU and international community. CInMED has established intensive cooperation with the European Commission, the Council of Europe – European Directorate for Quality of Medicines and Health Care, the European Medicines Agency, the World Health Organisation and the Uppsala Monitoring Centre, Heads

of Medicines Agencies in the region, as well as with national competent bodies from the EU/EEA. In the future, CInMED plans to broaden its cooperation and to continue its activities as members in boards, working groups and parties bearing in mind that only mutual international efforts will ensure safe, reliable end effective medicines and medical devices in the Montenegro.

CInMED also plans to further develop its established cooperation network in the region as well as to initiate cooperation on the international scale. Also, the Institute plans to strengthen its visibility, primary through its internet portal and via social media.

CInMED will continue to use a variety of means to provide access to clear, accessible, transparent and readily available information on the regulatory system for healthcare products to all stakeholders, such as healthcare professionals, patients, industry and general public.

CInMED is aware that only the proper selection of communication channels for risks associated information regarding medicines and medical devices ensures that new and emerging information on benefits and risks is brought to the attention of healthcare professionals and to the public in a timely manner.

Thus, CInMED will improve its risk management system and adapt it to the EU requirements. Furthermore, the Institute will continue to follow the most recent transparency policy, bearing in mind that the standards of transparency are constantly increasing through time. Additionally, with an aim of continuous improvement in facilitating access to information for specific groups of stakeholders, the Institute's website will be redesigned.

2.10 SWOT Analysis

A SWOT Analysis was performed. The results of the analysis were used for defining the goals and specific objectives of this Strategy.

2.11 Sustainable competitive advantage

Based on its experience, CInMED believes that its sustainable competitive advantage are employees that are willing to gain new knowledge and to share their expertise, who are ready to take on all task in the field of the regulatory network for medicines and medical devices, its employees that are devoted to the development and constant improvement of the Institute.

3. STRATEGIC GOALS AND OBJECTIVES

The strategic direction for CInMED over the next five years will be in line with its policy of creating conditions for the pharmaceutical market development and public health protection, challenges that CInMED identifies in the operating environment in Montenegro and the EU, and the strategies of its regulatory partners. It will be oriented to all possible improvements in service delivery based on building a quality and management system that is dedicated to continuous improvement.

CInMED's high-level strategic goals are:

- **Strategic goal 1** – *Providing adequate and stable regulatory support for pharmaceutical sector*
- **Strategic goal 2** – *Playing significant role in public health protection*
- **Strategic goal 3** – *Enhancing cooperation at the national and international level*
- **Strategic goal 4** – *Optimizing the procedures and operational excellence*
- **Strategic goal 5** – *Establishing scientific research and innovation activities*

CInMED has put its stakeholders in the focus of its interest for the strategic goals. For CInMED, being a public institution, well-timed and adequately formatted information on medicines and medical devices dedicated to health professionals, patients and consumers is of major importance.

In order to realize goals mentioned above, CInMED has to allocate all the necessary resources and ensure a proper level of investment in its staff, IT technologies and equipment. Taking into account accession process of Montenegro to EU, CInMED's goals are directed to its active participation in the creation of fully harmonizing medicines and medical devices legislation, with aim of creating conditions for the development of pharmaceutical sector and better protection of patients and consumers, according to EU standards.

All these high-level goals represent solid ground for establishing and improving the processes and activities of CInMED over the next five years. In the following sections, CInMED will set out the strategic objectives for each of the goals connected to the identified issues.

3.1 Goal #1

Providing adequate and stable regulatory support for pharmaceutical sector

Objective #1.1

Harmonization with best EU regulatory practices and reducing the time frames

Strategy for the objective

By assuring a clear and predictable regulatory framework and adopting best EU regulatory practices CInMED will create stable environment for development of pharmaceutical sector in Montenegro.

Action steps

- Active participation in preparing and drafting proposals for laws and bylaws at the national level and for the purpose of further compliance of legislation with the EU Acquis.
- Exchanging acquired experiences in the area of medicinal products and medical devices with EU Member States.
- Adopting best practices and continually improving regulatory procedures for medicinal products and medical devices with the aim of protecting public health.
- Shortening time frames and simplifying the administrative procedures.
- Providing regulatory and scientific support to pharmaceutical sector.
- Organisation of national conferences and trainings on the topic of medicines and medical devices with the industry.

Risks

- Delayed adoption of new laws and bylaws.
- Insufficient financial resources.

Responsibility

The Managing Director Office and Heads of all CInMED Centres and Departments.

Evaluation of indicators

- Number of adopted laws and bylaws harmonized with the Acquis.
- Increased number of authorized medicinal products and medical devices on the Montenegro market.
- Number of national conferences on the topic of medicines and medical devices held.
- Number of trainings organized for the pharmaceutical sector.

Time

All the actions regarding this objective will start in 2022 and are supposed to be finished by 2026.

Objective #1.2

Increasing the number of employees and upgrading their expertise in accordance with the needs of patients and health system of Montenegro

Strategy for the objective

In order for CInMED to provide adequate and stable regulatory support for pharmaceutical sector in accordance with the needs of patients and health system of Montenegro, continuous development of CInMED, both in terms of increasing the number of employees and upgrading their expertise is crucial.

Action steps

- Careful and selective recruitment of new staff.
- Training of existing and new employees.
- Introduction of a system for assessing competencies.
- Strengthening the awareness among all employees in CInMED about the importance of continuous education and training.
- Strict monitoring of the implementation of annual education plans and assessing the effectiveness of the education performed.
- Permanent re-assessment of competence needs and adoption of necessary adjustments of education plans.

Risks

- Insufficient number of available experts on the market.
- Insufficient financial resources.

Responsibility

The Managing Director Office and heads of all CInMED's organizational units.

Evaluation of indicators

- Adequate number of employees is engaged and trained for all CInMED tasks.
- System for assessing competencies is introduced.

Time

All the actions regarding this objective will start in 2022 and are supposed to be finished by 2026.

3.2 Goal #2

Playing significant role in public health protection

Objective #2.1

Availability of modern therapies to patients

Strategy for the objective

Ensure timely authorization of innovative medicinal products and medical devices in Montenegro.

Action steps

- Establishing transparent conditions for the functioning of the pharmaceutical market based on European principles and standards.
- Creating a clear and predictable regulatory framework.
- Shortening time frames and simplifying of administrative procedures.

Risks

- Market instability.
- Duration of procedures for enactment of laws and other regulations.
- Political instability.
- Insufficiently educated and trained staff.
- Adequate IT tools and databases.

Responsibility

The Managing Directors Office and Heads of all CInMED's organizational units.

Evaluation of indicators

- Wider range of available medicines and medical devices on the market.
- Wider range of medicines on the Reimbursement list (provided from the compulsory health insurance).
- Lower prices of medicines and medical devices on the market.
- Lower costs for the compulsory health insurance funds.

Time

All the actions regarding this objective will start in 2022 and are supposed to be finished by 2026.

Objective #2.2

Providing adequate and updated information to healthcare professionals and patients

Strategy for the objective

The healthcare professionals and patients require adequate information about medicines and medical devices that are in line with current data of the competent authorities of the European Union and the international community.

Action steps

- To perform prescribed jurisdictions in a timely manner.
- To regularly update Summary of product characteristics (SmPC) and Package leaflet (PL) on CInMED portal.
- Develop training programmes for healthcare professionals.
- To adapt risk minimisation measures to national specificities.

Risks

- Insufficiently educated and trained staff.
- Insufficient financial resources.
- Increase of import of medicines and medical devices that are not authorised for marketing (so-called "emergency import").
- Inadequate national healthcare professional's willingness for collaboration.

Responsibility

The Managing Director Office and Heads of all CInMED's organizational units.

Evaluation of indicators

- Increased number of marketing authorisations renewal issued.
- Increased number of marketing authorisations variations issued.
- Summary of product characteristics (SmPC) and Package leaflet (PL) on CInMED 's portal are up to date.
- Training programmes for healthcare professionals are developed and performed.
- High awareness of risk minimisation measures among healthcare professionals.

Time

All the actions regarding this objective will start in 2022 and are supposed to be finished by 2026.

Objective #2.3

Ensuring CInMED's visibility as an effective, independent and reliable regulatory institution

Strategy for the objective

Through promotion of CInMED's activities together with a well-established transparency policy, the level of trust in CInMED will be increased. CInMED will be perceived as an

effective institution for the regulation of medicines and medical devices that is independent in its decisions and a reliable source of information for patients and healthcare professionals.

Action steps

- Publish all relevant approved education material dedicated to healthcare professionals and patients.
- Review the current provision of information to all stakeholders with a special emphasis on industry, healthcare professionals and the public in respect of legal requirements and best practice models in EU agencies for medicines.
- Create an action plan for improving transparency.
- Ensure that all communication channels are appropriate and customised to the needs of patients and healthcare professionals.
- Publish minutes, CVs and declarations of interest for members of CInMED's boards.
- Results of Stakeholder survey published on CInMED's website.
- Participate in national and regional, health, online and specialized media in topics related to safety, efficacy and quality issues concerning medicinal products and medical devices.

Risks

- Insufficient staff responsible for public relations capable of prompt actions.
- Inadequate public awareness importance of CInMED's role.

Responsibility

The Managing Director Office together with the Heads of all organizational units.

Evaluation of indicators

- CInMED is recognised as the regulatory authority responsible for ensuring public health in respect of safety, efficacy and quality issues concerning medicinal products and medical devices.
- All relevant approved education material dedicated to healthcare professionals and patients is published on CInMED's website.
- Transparency policy is adopted.
- Minutes, CVs and declarations of interest for members of the CInMED's boards are on the website of CInMED, all data is frequently updated.
- Results of Stakeholder survey published on CInMED's website.
- Number of active participation in national and regional, health, online and specialised media in topics related to safety, efficacy and quality issues concerning medicinal products and medical devices.

Time

All the actions regarding this objective will start in 2022 and are supposed to be finished by 2026.

3.3 Goal #3

Enhancing cooperation at the national and international level

Objective #3.1

Establish cooperation with all important participants in the health system of Montenegro

Strategy for the objective

CInMED will establish cooperation with all important participants in the system, based on clearly defined business operation rules, mutual respect and trust, expertise, as well as the synergy of mission and vision and coordinated mutual values.

Action steps

- Improve and enhance communication with citizens, pharmaceutical companies, collaborating partners, patients and consumer's organizations, as well as legislators on the national level.
- Review patient and public engagement models of other regulatory and state agencies and implement a plan for the more profound involvement of patients in regulatory activities of CInMED.
- Stakeholder survey on CInMED's website on adequacy and communication policy performed.
- Active collaboration with the Ministry of Health in national legislation development.

Risks

- Inadequate willingness of national institutions and healthcare professionals for collaboration.

Responsibility

The Managing Director Office and Heads of all organizational units.

Evaluation of indicators

- Stakeholders are well informed on safety, efficacy and quality issues, as well as on medicine shortages.
- CInMED is involved in public health activities carried out in cooperation in other bodies and stakeholders in the health system.
- Public and patient representatives are engaged in the activities of CInMED and their knowledge, experience and views are taken into account in decisions and communications.
- Stakeholder survey on CInMED's website on adequacy and communication policy is performed.
- CInMED Communication Action Plan developed.

Time
All the actions regarding this objective will start in 2022 and are supposed to be finished by 2026.

Objective #3.2

Promote CInMED's international activities

Strategy for the objective
Creating an international perception of CInMED as relevant partner in region, EU and international community, especially in the context of European integration.

Action steps
- CInMED is verified by international organisations/bodies responsible for the verification of the performance (e.g. Joint Audit Programme – JAP; Benchmarking of European Medicines Agencies – BEMA; Pharmaceutical Inspection Co-operation Scheme PIC/S; Mutual recognition agreements – MRAs).
- Cooperation protocol and international agreements signed.
- Proactive participation in international working groups and bodies.
- Contributing to policy proposals and discussions on regulatory system effectiveness improvements in EDQM, WHO and EMA's working groups and boards.
- Active and constructive participation in the process of drafting guidelines, official forms and other documents conducted by the EDQM and WHO working groups.

Risks
- Insufficient financial resources.
- Insufficiently educated and trained staff.
- Inadequate quality management system.

Responsibility
The Managing Director Office and Heads of all organizational units

Evaluation of indicators
- CInMED's work is verified by at least one international organisation/body responsible for the verification of the performance.
- Number of cooperation protocol and international agreements signed.

Time
All the actions regarding this objective will start in 2022 and are supposed to be finished by 2026.

3.4 Goal #4

Optimizing the procedures and operational excellence

Objective #4.1

Further development of the quality management system

Strategy for the objective

This objective is supported by the BEMA system that is designed for the continuous improvement of all aspects and processes within medicines agencies. BEMA requirements are to be integrated completely into all areas of CInMED's business processes, the achieved results are to be measured and evaluated, and new plans for improvements are to be done.

Action steps

- Finalisation of the Integrated quality system that will, besides the exiting standards, fully include the following norms ISO 9001, ISO/IEC 27001, ISO/IEC 17020.
- Including Inspectorate to the ISO/IEC 17020.
- Accreditation for National Control Laboratory according to the ISO/IEC 17025.
- Strengthening crisis management and business continuity management.
- Strengthening project management.
- Strengthening risk management.

Risks

- Insufficient financial resources.
- Inadequate staff training.
- Lack of intra-organisational cooperation between responsible employees for IT, quality management, project management and the heads of all organizational units.

Responsibility

The Managing Director Office and the Heads of all organizational units.

Evaluation of indicators

- An integrated quality system is operational and in accordance with the selected international norms.
- The CInMED Risk management registry exists, risk minimisation actions are implemented and monitored, potential risk is re-assessed.
- Crisis management and business continuity management is implemented and checked, either in real case situation or planned simulation.
- Project methodology exists, projects are planned, monitored, and improvement actions for future projects are defined.
- Inspectorate accredited according to the ISO/IEC 17020.
- CInMED NCL 17025 accreditation successfully conducted.

Time
All the actions regarding this objective will start in 2022 and are supposed to be finished by 2026.

Objective #4.2

Further development of the Information System and Digitalisation

Strategy for the objective
Finalizing an integrative IT system as a strong supportive tool for CInMED's processes and activities.

Action steps
- Perform design work for IT projects.
- Monitor the development of projects and verify them.
- Monitor the intra-operability of developed IT tools.
- Finalisation of an Integrated IT system on the level of CInMED.

Risks
- Insufficient financial resources.
- Inadequate IT human resources.
- Inadequate cooperation within CInMED in relation to the realization of IT projects.

Responsibility
The Managing Director Office, Heads of all organizational units together with the Head of the IT Department.

Evaluation of indicators
- The developed IT tools are reliable and fit for use.
- The integrated IT system is operational in all units of CInMED.

Time
All the actions regarding this objective will start in 2022 and are supposed to be finished by 2026.

Objective #4.3

Ensure balance between income and costs

Strategy for the objective
CInMED will regularly review its financial situations regarding income and cost based on the fee structure in order to be ready to inform its Steering Board and the Government about the sustainability of the financial system through regular reporting mechanisms.

Action steps
- Perform a permanent cost income ratio.

Risks

- Inadequate tools for monitoring the cost income ratio.
- Inaccurate cost estimate or unpredicted costs.

Responsibility

The Managing Director Office and Head of Department for economic affairs.

Evaluation of indicators

- The fee model ensures adequate incomes that are in line with the planned costs of the CInMED.
- CInMED price lists are updated with fees for new services/competences.

Time

All the actions regarding this objective will start in 2022 and are supposed to be finished by 2026.

3.5 Goal #5

Establishing scientific research and innovation activities

Objective #5.1

Encourage innovation in medical products by cooperation with academic and research sector

Strategy for the objective

As a scientific-research organization CInMED will strive to improve innovation and implement the highest European and international standards in its operation in performing scientific-research activities and innovation activities in the field of medical sciences and interdisciplinary research.

Action steps

- Improve the environment for the development of innovation and innovative culture.
- Cooperation with academic, research and economy sectors, to coordinate and establish synergies in the exchange of knowledge, skills and infrastructural capacities necessary for innovation.
- Publishing scientific articles and papers.
- Improving the capacity to participate in European Union innovation programmes and creating partnerships between science and economy in order to successfully prepare and realisation of specific projects.
- Establish mechanisms for monitoring the possibility of participation in scientific development at the national level, especially through the establishment of infrastructure for research in the European Union (Horizon 2020 and the Research Infrastructures Landscape).
- Improve Laboratory capacities - X-ray diffraction and X-ray fluorescence techniques.

Risks

- Insufficient expertise, experience and knowledge of CInMED's staff.

Responsibility

The Managing Director and the heads of the all CInMED's organizational units.

Evaluation of indicators

- Involvement in research and innovative projects and actions.
- Number of published scientific articles and papers.
- Laboratory capacities - X-ray diffraction and X-ray fluorescence techniques improved.

Time

All the actions regarding this objective will start in 2022 and are supposed to be finished by 2026.

Objective #5.2

Use CInMED expertise for academic purposes

Strategy for the objective

CInMED is determined to further develop the collaboration with academia in the field of regulatory activities relating to medicines and medical devices in order to support innovation.

Action steps

- Negotiation and defining agreements with selected academic institutions, which are closely connected to the health issues and activities of CInMED, with a purpose of providing the lectures for students.
- Developing academic activities.

Risks

- Insufficient time available for academic activities.
- Non-permanent agreements between CInMED staff and academic institutions.

Responsibility

The Managing Director, Heads of the Centres and the Expert-Scientific Board.

Evaluation of indicators

- The staff is ready to respond to the requirements of academia.
- CInMED is included in academic lecturing.

Time

All the actions regarding this objective will start in 2022 and are supposed to be finished by 2026.

4. IMPLEMENTATION AND MONITORING

This Strategic plan defines the direction for CInMED over the next five years from 2022 to 2026, including its service delivery, as well as supporting functions. The expected achievement of the set objectives depends on the adequacy of the resources available in CInMED, on the ability of CInMED to respond to governmental and public demands, and the requirements of national and EU legislation.

The plan defines the framework for the development of annual business plans based on CInMED's strategic goals identified in this plan and the performance standards to be achieved by 2026.

The annual business plans define the specific tasks to be implemented for each strategic objective, the timeframes involved and the responsibilities within CInMED for their implementation. The annual plans are developed to levels of the departments, allowing each employee to see how their work contributes to the achievement of the organisation's goals and objectives.

CInMED will monitor its accomplishments against the strategic plan through business planning and reporting system. The progress in respect of the plan will be reported to the CInMED's Steering Board in its annual reports.

Strategic goals of CInMED determine priorities in business operation for a period of five years, the implementation of which will strengthen CInMED and prepare it to take over related duties upon joining the family of EU regulators.

CONTACT US

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