



MONTENEGRO
INSTITUTE FOR MEDICINES AND MEDICAL DEVICES

STATUTE
OF THE INSTITUTE FOR MEDICINES AND MEDICAL DEVICES

Pursuant to Article 14 paragraph 1 item 2 and Article 20 of the Law on medicines („Official Gazette of Montenegro”, No 80/20), the Steering Committee of the Institute for Medicines and Medical Devices, at the session held on 18 June 2025 adopted

S T A T U T E

OF THE INSTITUTE FOR MEDICINES AND MEDICAL DEVICES

I GENERAL PROVISIONS

Contents of the Statute

Article 1

This Statute shall regulate the following: legal position of the Institute for Medicines and Medical Devices (hereinafter: Institute); name and headquarters; seal, stamp, logo and letterhead; competences; rights, obligations and responsibilities in legal transactions; presentation and representation; property and financing; use of funds; governing bodies and decision-making methods; internal organization and rights and obligations of employees; affairs and work of advisory bodies; method of appointment and termination of the term of the members of the Expert-scientific Committee; general acts; legality of operations; public nature; cooperation with other state bodies and international cooperation; and other issues of importance for the business operation of the Institute.

Terms used for natural persons in masculine gender shall mean the same terms in feminine gender.

Legal position of the Institute

Article 2

Founder of the Institute is the Government of Montenegro (hereinafter: founder).

Institute is a legal successor of the Agency for Medicines and Medical Devices, in accordance with the law regulating the area of medicines.

Institute has a status of a legal person with rights and obligations established by the Law and this Statute.

Institute is registered in the Central Register of Business Entities.

Institute is independent and serves the interests of public health and the development of scientific and research activity.

Name and headquarters

Article 3

Full name of the Institute is: Institut za lijekove i medicinska sredstva Crne Gore”.

Full name of the Institute in English is: Institute for Medicines and Medical Devices of Montenegro”.

Abbreviation of the name of the Institute is: CInMED”.

Headquarters of the Institute is in Podgorica, Bulevar Ivana Crnojevića 64a.

Institute Day is 5 October.

Seal and stamp

Article 4

Institute shall have a seal and a stamp.

The seal of the Institute is round in shape, diameter 32 mm, contains the emblem of Montenegro, Montenegro name and full name and headquarters of the Institute written in a concentric circle around the emblem.

The stamp of the Institute is rectangular, with dimensions 70 mm x 30 mm and contains the name Montenegro and full name and headquarters of the Institute and is written horizontally, with an empty space between them for inserting the document number and the date of its entry into the records.

Wording of the seal and stamp of the Institute is in Montenegrin, using the Latin alphabet.

Article 5

Institute may have other seals of different shapes and sizes in accordance with the Law.

Number of seals, type, size, safekeeping and manner of its use, as well as handling of the Institute's seal shall be regulated in more details by the decision of the Managing Director of the Institute.

Logo and letterhead

Article 6

Institute shall have its logo which shall be regulated by the decision of the Managing Director of the Institute.

Logo of the Institute shall be registered in line with the law regulating trademarks.

Institute shall have a letterhead containing the following: logo with the abbreviated name of the Institute and the full name of the Institute (centrally positioned on the letterhead), as well as the full name of the Institute, headquarters, contact phone, *webpage* and e-mail address (at the bottom of the letterhead).

Independence of the Institute

Article 7

Institute is an independent state body which, in the exercise of public powers in the field of medicines and medical devices, independently performs tasks established by the Law and other general acts, in accordance with principles of legality, objectivity and transparency.

Institute is legally separated from other state bodies and from all legal and natural persons performing the manufacture, marketing and testing of medicines and medical devices, as well as drugs and precursors, and related activities.

II COMPETENCES

Article 8

Institute shall perform duties under its competences determined by the law regulating medicines, the law regulating medical devices, the law regulating the prevention of drug abuse and the law regulating the control of the manufacturing and marketing of substances that can be used in the manufacture of narcotic drugs and psychotropic substances.

Institute's employees, members of the bodies and commissions of the Institute, as well as engaged experts from the list of experts, cannot perform in their own name and on their own account, or in the name and on the account of another legal or natural person the manufacturing, marketing and testing of medicines, narcotic drugs and precursors, nor can they have any other personal or financial interest (ownership, shares, membership in governing bodies, or contractual relationship) with persons engaged in this activity, about which they annually sign a declaration of interest.

Persons referred to in paragraph 2 of this Article cannot participate in the preparation of documentation that is submitted with applications for obtaining authorisations, approvals, i.e. registration performed by the Institute in accordance with competences prescribed by Law.

Institute shall delete the expert from the list of experts, i.e. dismiss the member of the commission who acts contrary to paragraphs 2 and 3 of this Article, as well as in case non-performance of entrusted tasks, or if these tasks are performed irresponsibly.

III RIGHTS, DUTIES AND RESPONSIBILITIES IN LEGAL TRANSACTIONS

Article 9

In legal transactions, the Institute shall act independently in its own name and on its own account, conclude legal transactions and undertake other legal actions of importance for the Institute's business operation, in accordance with the Law.

Institute is liable to third parties for obligations arising in legal transactions with all of its assets.

Institute has one, or more business accounts for regular business operation in accordance with regulations on payments.

Institute may have separate accounts for allocating funds based on reserves, joint spending, investments, donations and other assigned channelling.

IV PRESENTATION AND REPRESENTATION

Article 10

In legal transactions, the Institute shall be presented and represented by the Managing Director, in accordance with powers prescribed by the Law and this Statute.

Managing Director may authorize an employee of the Institute, or another person to present or represent the Institute in specific affairs and proceedings before the court or other bodies, with the power of attorney specifying the scope and content of the given authorizations.

Administrative and other acts of the Institute shall be signed by the Managing Director, except for acts the adoption of which is within the responsibility of the Steering Committee.

Special records are kept on the right to sign and the authorizations given for signing.

V PROPERTY AND FINANCING

Article 11

Property of the Institute is state-owned.

Property of the Institute consists of property rights of movable and immovable property, funds, securities and other propriety rights.

All fixed assets are accounted for as property of the Institute.

Assets for carrying out activities of the Institute, along with other assigned assets, are kept in the Institute's account, in accordance with the Law.

Employees of the Institute are obliged to conscientiously and purposefully use the property of the Institute that they use in the performance of their tasks.

Article 12

Institute acquires the funds for the financing of business operation by the following:

- 1) charging fees for the exercise of competences prescribed by law;
- 2) charging fees for the provision of laboratory services;
- 3) charging fees for the provision of education and training services;
- 4) charging fees for scientific research and other publications;
- 5) participating in national and international projects;
- 6) from other sources.

Term funds from other sources shall mean the following; gifts, donations, funds from the budget realized on the basis of carrying out activities for the needs of the ministry responsible for health affairs or other state body, and other revenue generated in accordance with the Law.

Payment method of fees, as well as the amount of fees referred to in paragraph 1 items 1 to 4 of this Article shall be determined by the Institute, i.e. the Government in accordance with the Law.

VI USE OF FUNDS

Article 13

Financial plan and financial report with the final account shall be adopted by the Steering Committee.

Total revenues and expenditures shall be projected by the Annual financial plan.

At the end of the year for which the financial plan was adopted, the Institute shall prepare a Financial report with a final account and submit it to the Steering Committee no later than 15 April of the current year for the previous year.

Institute's final account is subject to an annual audit by an independent authorized auditor chosen by the Steering Committee.

Surplus of revenues over expenditures is used by the Institute for the fulfilment of legal obligations and the development of the Institute for the exercise of competences prescribed by Law based on the decision of the Managing Director or the Steering Committee, in accordance with the Law.

Financial plan and financial report are public and are published on the portal of the Institute.

VII GOVERNING BODIES AND DECISION-MAKING BODIES

Bodies of the Institute

Article 14

Bodies of the Institute are Steering Committee and Managing Director.

Steering Committee

Article 15

Governing body of the Institute is a Steering Committee.

Steering Committee is consisted of the President and four members who are appointed and dismissed by the Government.

Chair and members of the Steering Committee are appointed from among professionals in the field of health, veterinary medicine and environmental protection and one member is a representative of employees proposed by the Institute.

Steering Committee Chair and members shall be appointed for a four-year period and may be reappointed.

Chair and members of the Steering Committee shall submit a request for termination of their term before the end of the term for which they were appointed to the founder and inform the Managing Director of the Institute.

Chair and members of the Steering Committee shall be dismissed in line with the procedure according to which they were appointed.

Article 16

Candidate who the majority of the total number of employees voted for shall be elected as a Steering Committee member.

Election shall be done by anonymous voting by electronic means or in another appropriate manner that guarantees independence in decision-making.

An employee who has at least five years of work experience at the Institute may be elected as a member of the Steering Committee from among the employees.

Scope of the Steering Committee

Article 17

Steering Committee shall perform the following tasks:

- 1) define the business policy of the Institute;
- 2) adopt Statute of the Institute, act on internal organisation and job scheme and other general acts;
- 3) adopt Financial plan and final account;
- 4) decide on the choice of an auditor;
- 5) adopt the Business operation report;
- 6) adopt the annual Activity programme of the Institute;

- 7) make investment decisions;
- 8) adopt a Code of conduct for employees of the Institute;
- 9) take measures to ensure the quality, safety and efficacy of medicines;
- 10) submit at least once a year an Activity report to the Government;
- 11) adopts the Rules of procedure;
- 12) perform other activities determined by the Law and Statute of the Institute.

Steering Committee is responsible to the Government for its work and the work of the Institute.

Sessions

Article 18

Steering Committee shall work and make decisions at sessions attended by the majority of the total number of members.

Steering Committee shall make decisions by majority of votes from the total number of members. In case of an equal number of votes, the Chair of the Steering Committee shall have a casting vote.

Sessions of the Steering Committee shall be convened and presided over by the Chair of the Steering Committee or a member authorized by him/her.

The Chair of the Steering Committee shall convene sessions of the Steering Committee on his/her own initiative, at the request of at least two members of the Steering Committee, as well as at the request of the Managing Director of the Institute.

The Chair of the Steering Committee shall convene an emergency session at the request of the Managing Director of the Institute within 24 hours of receiving the request.

Sessions of the Steering Committee may be attended by the Managing Director of the Institute and the preparer of the material to be discussed at the session, without voting rights.

Session of the Steering Committee may be attended by employees of the Institute or a third party, upon invitation of the Chair of the Steering Committee.

The Chair, i.e. Steering Committee member, shall not have the right to vote when deciding on their responsibility or the work in the Steering Committee.

Article 19

Manner of work of the Steering Committee shall be regulated in more detail by the Rules of Procedure.

Minutes shall be kept on the work of the Steering Committee.

Administrative and technical tasks for the needs of work of the Steering Committee shall be carried out by the secretary from among employees of the Institute, who is appointed in accordance with the Rules of Procedure.

Steering Committee may establish permanent and temporary working bodies in order to perform specific tasks and tasks within its scope of work.

Duties of the Chair of the Steering Committee

Article 20

The Chair of the Steering Committee shall carry out in particular the following duties:

- 1) presiding over the sessions of the Steering Committee;
- 2) signing decisions and other acts of Steering Committee;
- 3) proposing measures to improve the work of the Steering Committee;
- 4) performing also other tasks determined by the Law.

Duties of the Chair and members of the Steering Committee

Article 21

The Chair and a member of the Steering Committee are obliged to act with due care, conscientiousness and in the best interest of the Institute during the performance of their duties.

The Chair and the member of the Steering Committee are entitled to a monthly compensation for their work.

Amount of the compensation referred to in paragraph 2 of this Article shall be determined in accordance with the Law.

The Chair and the member of the Steering Committee shall have the right to waive the compensation by giving a statement in writing.

The Chair and members of the Steering Committee shall be entitled to travel expenses if they reside outside the headquarters of the Institute, in the manner prescribed for employees of the Institute.

Managing Director

Article 22

The Institute shall be presented and represented by the Managing Director.

Managing Director shall be responsible to the Steering Committee for his/her work.

Appointment of a Managing Director of the Institute

Article 23

Managing Director of the Institute shall be appointed and dismissed by the Steering Committee on the basis of a public competition in accordance with the Law.

Public competition referred to in paragraph 1 of this Article shall be carried out in accordance with the decision of the Steering Committee, which contains general and special conditions for establishing an employment relationship, the period during which the public competition is announced, as well as the manner and procedure for a Managing Director appointment.

Member of the Steering Committee, as well as a member of the Expert-scientific Committee shall be exempted from voting, i.e. giving an opinion in the event of a conflict of public and private interest.

Contract on establishing the Managing Director's employment relationship shall be concluded between the Chair of the Steering Committee and the Managing Director, for the period until the end of the term in accordance with the Law. The contract shall establish rights, obligations and responsibilities of the Managing Director, as well as conditions for early termination of the term office.

In the event of termination of the Managing Director's term of office, as well as in the case of a repeated competition for the election of a new Managing Director, the Steering Committee shall appoint an Acting Managing Director for a period of up to 6 months.

End of the term of office and dismissal of the Managing Director

Article 24

Managing Director's term of office shall end at the end of the term for which he/she was appointed or by dismissal.

Reasons for the Managing Director's dismissal shall be explained separately.

Steering Committee shall agree with the Managing Director on severance pay in case of dismissal before the end of the Managing Director's term of office.

Managing Director of the Institute may be dismissed even before the end of the term for which he/she was appointed, if he/she:

- 1) does not carry out duties of a Managing Director in accordance with the Law, Statute and other general acts of the Institute;
- 2) does not implement the decisions and conclusions of the Steering Committee;
- 3) submits dismissal request in writing.

Scope of the Managing Director

Article 25

Managing Director of the Institute shall:

- 1) organise and manage the operations of the Institute;
- 2) be responsible for the legality, efficiency and economic efficiency of the Institute;
- 3) be responsible for the implementation of working programs and plans of the Institute;
- 4) pass the decisions, i.e., administrative acts within the competence of the Institute, which are not the responsibility of the Steering Committee of the Institute;
- 5) act upon the decisions of the Steering Committee;
- 6) make decisions on the rights of the employees in accordance with the Law.

At the request of the Steering Committee or the founder (directly or through the Steering Committee), the managing director shall provide written information regarding specific issues related to the work and business operation of the Institute, i.e. to provide insight into the Institute's documentation.

Rights and obligations from the employment relationship

Article 26

Managing Director and employees of the Institute shall exercise rights and obligations from the employment relationship in accordance with general regulations on labor and general acts of the Institute.

Employees of the Institute shall have the right to organize a trade union in accordance with the Law.

Managing Director of the Institute shall ensure conditions necessary for the work of the trade union and trade union trustees in accordance with the Law and the Collective agreement.

Institute shall provide conditions for work, safety at work and protection of people and property in accordance with the law governing the field of safety at work and the general act of the Institute.

VIII INTERNAL ORGANIZATION AND JOB SCHEME OF THE INSTITUTE

Article 27

Institute shall have an organizational structure that describes transferred affairs in the field of medicines, medical devices, drugs and precursors, quality and training affairs, regulatory harmonization and international cooperation affairs, laboratory, scientific research and other expert, administrative and technical affairs.

Transferred affairs shall include competences of the Institute prescribed by the Law.

Quality and training affairs shall include the development and maintenance of the quality management system in accordance with international standards that the Institute implements within its business operation, and the organization of training in the implementation of those standards.

Regulatory harmonization and international cooperation affairs shall include harmonization of regulations and standards with regulations and standards of the European Union and regulations and guidelines of international institutions, presentation and representation of interests of the Institute and Montenegro in the areas of competence of the Institute in international and European organizations and bodies, as well as cooperation with national bodies of other states.

Legal, human resources, economic, accounting, financial, IT and other affairs shall also be carried out at the Institute.

Article 28

Internal organization of the Institute shall be determined in a manner that ensures efficient and high-quality performance of the competences determined by the Law, as well as expert, administrative and technical affairs.

Operations of the Institute shall be carried out through organizational units.

Organizational units shall cooperate with each other and coordinate their activities in performing tasks within the competences of the Institute, as well as to perform their tasks in accordance with the work plan and organization of the Institute's tasks.

Article 29

Act on internal organization and job scheme at the Institute shall determine internal organization of the Institute, job titles, job description, number of employees and necessary conditions for performing a job.

Employees of the Institute shall perform work and tasks in accordance with the act on internal organization and job scheme at the Institute.

An employee who is appointed to the position of a manager and an expert associate shall carry out continuous education of employees in the areas from the scope of work of the Institute for which he/she was trained.

Act on internal organization and job scheme shall be adopted by the Steering Committee of the Institute.

IX AFFAIRS AND WORK OF ADVISORY BODIES OF THE INSTITUTE

Article 30

Institute may establish advisory bodies (hereinafter: commissions) in order to carry out specific tasks within its competences.

As a rule, members of the commissions are persons employed at the Institute.

Members of a commission may be permanent, as well as members engaged by invitation for specific types of medicines.

Manner of commissions' work shall in more detail be regulated by Rules of procedure.

In carrying out specific tasks within competences of the Institute, for the purpose of obtaining expert assistance, the Institute may establish a list of experts and use expert services of institutions that have necessary expert and scientific knowledge in the field of medicines.

Costs related to the engagement of experts and commissions members shall be provided from the funds of the Institute and be paid in accordance with the decision of the Managing Director of the Institute.

X EXPERT-SCIENTIFIC COMMITTEE, MANNER OF APPOINTMENT AND TERMINATION OF THE TERM

Article 31

Expert-scientific Committee shall be 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.

Members of the Expert-scientific Committee may also be employees who are distinguished experts and scientists in the field of regulation of medicines and medical devices of the highest expert level in accordance with general acts of the Institute.

Member of the Expert-scientific Committee may be also the Managing Director of the Institute, if he/she meets the requirements referred to in paragraphs 1 or 2 of this Article.

Expert-scientific Committee shall:

- 1) 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;
- 2) propose and give opinions on issues of expert work of the Institute;
- 3) give an opinion on the programs of all forms of expert and scientific training for the needs of the Institute;
- 4) adopt a program for scientific-research and development activities;
- 5) analyse, evaluate and adopt reports on the implementation of programs and projects;
- 6) perform other tasks in accordance with the Law and the Statute of the Institute.

Article 32

Members of the Expert-scientific Committee shall be appointed and dismissed by the Steering Committee on the proposal of the Managing Director of the Institute.

Chair of the Expert-scientific Committee shall be appointed by the Expert-scientific Committee from among the members of the Expert-scientific Committee.

Members of the Expert-scientific Committee shall be appointed for a four-year period and they may be reappointed.

The Chair of the Expert-scientific Committee shall be appointed for a two-year period and may be reappointed for a maximum of one additional consecutive term.

Expert-scientific Committee shall work and make decisions at sessions by the majority of the total number of members.

In order to carry out specific tasks within competences of the Institute, the Expert-scientific Committee may appoint commissions and working groups.

Work of the Expert-scientific Committee is regulated by the Rules of Procedure.

Managing Director of the Institute may make a decision determining the compensation for the work of the Chair and members of the Expert-scientific Committee in accordance with the Financial plan of the Institute.

Article 33

The term of the Chair and members of the Expert-scientific Committee shall end by the following:

- 1) end of the term for which they were appointed;
- 2) personal request;
- 3) dismissal in accordance with the Law and this Institute;
- 4) justified request of the Managing Director of the Institute;
- 5) if their employment ceases, i.e. the capacity based on which they were appointed;
- 6) appointment to a position that excludes membership in the Expert-scientific Committee.

XI GENERAL ACTS

General acts of the Institute

Article 34

General acts of the Institute are listed as follows:

- 1) Statute;
- 2) Rulebook on internal organization and job scheme;
- 3) Code of conduct for the members of the Steering Committee, Expert-scientific Committee and employees of the Institute;
- 4) Rulebook on occupational safety at the Institute;
- 5) Rulebook on classified information and business secrets;
- 6) Rulebook on carrying out financial and accounting activities;
- 7) other general acts in accordance with the Law.

Institute shall publish general acts referred to in paragraph 1 of this Article on its portal, unless otherwise prescribed by the Law and this Statute.

General acts of the Institute shall be adopted in the manner prescribed by the Law and the Statute.

General acts of the Institute, i.e. their amendments may be proposed to the Steering Committee by a member of the Steering Committee and the Managing Director of the Institute and an employee/group of employees through a trade union.

Statute

Article 35

Statute is a basic general act of the Institute.

Other general acts must not contradict the Statute.

Amendments to the Statute shall be made according to the procedure prescribed for the adoption of the Statute.

Majority of members of the Steering Committee and the Managing Director of the Institute may submit a proposal for adoption, i.e. amendment to the Statute.

Other general acts must be in accordance with the Law and this Statute.

Regulations in the field of medicines and medical devices

Article 36

The Institute participates in the preparation of acts that may have a significant impact on the market of medicines and medical devices and/or public health.

In the preparation of the acts referred to in paragraph 1 of this Article, working groups shall be formed and meetings, trainings and public consultations shall be organized.

On the implementation of the activities referred to in paragraph 2 of this Article, the Institute shall prepare a written report, which shall contain an explanation of the Institute's positions in relation to the proposals submitted in the process of preparing the acts referred to in paragraph 1 of this Article.

XII LEGALITY OF OPERATIONS

Article 37

Operation of the Institute is carried out in accordance with provisions of the law regulating medicines, medical devices, drugs and precursors, other laws and regulations, this Statute and acts adopted on the basis of the Law and the Statute.

Managing Director of the Institute is responsible for the legality and success of the Institute's operation and the implementation of its planning documents, in accordance with the Law.

Managing Director of the Institute shall inform the Steering Committee in writing about all important issues from the scope of the operations of the Institute.

XIII PUBLIC NATURE

Giving official statements and notifications

Article 38

The Institute operates in a transparent manner, unless the Law or general act of the Institute prescribes otherwise.

Public nature is achieved by publishing information and data about the operations of the Institute on the Institute's portal, in special publications of the Institute, as well as by providing information about the Institute's operation to general and expert public, as well as in the media.

Managing Director along with another employee based on written authorization of the Managing Director, shall be responsible for providing information about the Institute' operation to the media and other persons.

Provision of information shall be carried out in accordance with the Law and general acts of the Institute.

Confidential information and business secret

Article 39

Confidential information is all information that, in accordance with the law regulating data confidentiality and the general act of the Institute, is prescribed as information of a certain degree of secrecy.

Business secret is all information that, in accordance with the law regulating medicines and the law regulating medical devices, is prescribed to be considered a business secret.

Documents, data and information that, in accordance with the Law, represent confidential information or business secret, the level of secrecy, as well as the manner of handling such data, is determined in more detail by the general act of the Institute, which is adopted by the Steering Committee.

XIV COOPERATION WITH OTHER INSTITUTIONS AND INTERNATIONAL COOPERATION

Cooperation at the national level

Article 40

Institutions which the Institute cooperates with under its competences in accordance with the Law are listed as follows:

- 1) ministry responsible for health affairs;
- 2) ministry responsible for economic affairs;
- 3) ministry responsible for science affairs;
- 4) national chamber of commerce and other associations in the area of economy;
- 5) health, natural sciences and technological-technical faculties, for the purpose of developing and exchanging expert knowledge, realization of expert, scientific and interdisciplinary research and scientific work in the field of medicines and medical devices and other related fields;
- 6) body responsible for the competition protection, by submitting an application for giving an opinion and by proposing and initiating proceedings before the body in question in cases of preventing, limiting or distorting competition on the market, in accordance with this Law and the law regulating the competition protection on the market;
- 7) state administration body responsible for consumer protection;
- 8) state administration body responsible for environmental protection;
- 9) body responsible for the personal data protection;

10) institutions within the health care system and other governmental and non-governmental bodies and organizations.

Institute is a teaching base of health faculties for scientific areas of its activity, based on the contract, in accordance with the Law.

International cooperation

Article 41

Institute shall cooperate and exchange data with international competent authorities and organizations with the aim of achieving effective regulatory and other cooperation and creating incentive for the development of activities and exchange of experiences in areas within the Institute's competences, in accordance with the Law and concluded agreements.

Agreements referred to in paragraph 3 of this Article more closely define the goal and method of achieving cooperation, as well as the method and scope of information exchange.

XV TRANSITIONAL AND FINAL PROVISION

Article 42

With the entry into force of this Statute, the Statute of the Institute for Medicines and Medical Devices No 3020/25/98/4-1664 of 12 March 2025 shall cease to be valid.

This Statute shall enter into force on the day of its adoption.

**CHAIR OF THE
STEERING COMMITTEE**
dr subspec. Vasilije Đurašković