



MONTENEGRO
INSTITUTE FOR MEDICINES AND MEDICAL
DEVICES

GUIDE FOR ACCESS TO INFORMATION OF THE INSTITUTE FOR MEDICINES AND
MEDICAL DEVICES

Based on the Article 11 of the Law on free access to information (“Official Gazette of Montenegro” No. 44/12 and 030/17), Institute for Medicines and Medical devices hereby issues

GUIDE FOR ACCESS TO INFORMATION THAT ARE IN THE POSSESSION OF THE INSTITUTE FOR MEDICINES AND MEDICAL DEVICES

General information:

Headquarters and address of the Institute for Medicines and Medical Devices: Podgorica, Bulevar Ivana Crnojevića 64A.

Person responsible for decisions issuance: Managing Director of the Institute for Medicines and Medical Devices MD, MSc, PhD, spec. Snežana Mugoša.

Telephone: 020 310 280; 020 310 281; 020 310 580

Fax: No. 020 310 280

E-mail: info@cinmed.me

Website: www.cinmed.me

1. Types of information that are in the possession of the Institute

Public records:

1. Document registry;
2. Registers of the following: medicines, medical devices, manufacturers, wholesalers, specialised retail stores of medical devices;
3. Mail delivery book;
4. Other records in accordance with regulations on office operations and archival activity;
5. Records on employees of the Institute.

Information:

Information on the performance of state administration tasks within the scope of competences.

Legislative acts:

1. Law on medicines;
2. Law on medical devices;
3. Law about preventing drugs abuse;
4. Law on control of manufacture and trade of substances that can be used in the manufacture of narcotic drugs and psychotropic substances
5. Law on labour;
6. Law on administrative procedure.

Secondary legislation (rulebooks, application forms for the procedure conduct at the Institute, instructions, etc.) within the scope of competences of the Institute, such as:

1. Rulebooks within the scope of competences of the Institute;
2. Instructions;
3. Guidelines;
4. Rulebook on internal organisation and sistematization of work places at the

Institute.

5. Rulebook on office operations;
6. Rulebook on data secrecy and business secret;
7. Financial report;
8. Work report;
9. Documents on public procurement;
10. Documents on basic assets and equipment;
11. Financial records

Data on the employees:

1. Employment booklets;
2. Certificates on professional qualifications and competencies;
3. Employment agreements;
4. Decisions on annual leave;
5. Decisions on determining responsibility for violation of work obligations and material liability.

2. Procedure for the access to information

Procedure for the access to information shall be initiated by a written request from the requesting party.

Request must be complete and comprehensible, and in order to act on it, it shall contain the following: data on requested information, data on the requesting party (for natural persons: name and surname, residence, address, phone number, e-mail; for legal persons and NGOs: registered company name, headquarters, phone number and email), data on the attorney, agent, or representative of the requesting party. The requesting party may provide other information that facilitates finding the requested information.

3. Manner of submitting a request

Request can be submitted directly to the Registry Office of the Institute, every working day from 09:00 to 12:00, by mail (address: Institute for Medicines and Medical Devices, Bulevar Ivana Crnojevića 64A, Podgorica), in electronic form (e-mail: info@cinmed.me or fax number: 020 310 280) or by the statement on the minutes to a responsible person.

4. Manner of exercising the right of access

Information to which access is provided is a document or part of a document that the Institute for Medicines and Medical Devices actually possesses in written, printed, video, audio, electronic or other form, including copies, regardless of content, source (author), time of creation or classification system (Article 10, paragraph 1 of the Law on free access to Information).

Access to information that are in the possession of the Institute can be gained in the following manners:

- by immediate consultation of the public records, original, or a copy of the information in the premises of the Institute for Medicines and Medical Devices;
- by copying or scanning the information done by the requesting party in the premises of the Institute for Medicines and Medical Devices;
- by sending a copy of the information to the requesting party by the Institute for Medicines and Medical Devices, directly, by mail or e-mail (Article 21 paragraph 1 of the Law on Free Access to Information).

5. Acting upon the request and legal protection

Appeal against the decisions of the Institute for Medicines and Medical Devices, can be filed with the Agency for personal data protection of and free access to information within 15 days from the day of receipt, through the Institute for Medicines and Medical Devices.

Decision allowing access to information or part of it determines the time period and manner of access, as well as the expenses to be paid before enforcement of the decision. An appeal against the decision rejecting the request for access to information due to incompleteness or incomprehensibility is permitted within 15 days.

6. Legal expenses

Legal expenses shall be borne by the person requesting access to the information.

Legal expenses refer only to actual costs of copying, scanning, photocopying, translation and delivery.

Legal expenses of the procedure for the access information shall be paid before enforcement of the decision.

Person with disability shall not pay legal expenses (disability is proven by a decision of the competent authority or another appropriate decision).

Legal expenses shall be paid to the account number 520-3603-33, at Hipotekarna banka AD Podgorica, TIN 02739658.

7. Persons authorized to act upon requests for access to information

Persons authorized to act upon requests for access to information are listed as follows:

1. Vesna Kostić, LLB
2. Žana Vukčević, LLB

Contact information - telephone: 020 310 280 and fax number 020 310 280, e-mail: info@cinmed.me.

8. Publishing of the Guide

This Guide is published on the notice board and on portal of the Institute for Medicines and Medical Devices.

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Podgorica, 10 June 2022

MANAGING DIRECTOR

MD, MSc, PhD, spec. Snežana Mugoša