CInMED
Institute for Medicines and Medical Devices of Montenegro

FAQs

On this page you may find answers to frequently asked questions related to competences and work of the Institute for Medicines and Medical Devices (CInMED).

We hope that among them you will be able to find answers to some of your questions.

If answer to your question is not on this page, you may send us an e-mail to **info@cinmed.me**, or contact us by phone (+382 20 310 280) in specified terms.

1. **QUESTION: Is the Institute responsible for regulation of import and marketing of dietary supplements and cosmetic products?**

   ANSWER: The Institute is responsible only for products which are medicines and medical devices, in accordance with applicable laws, i.e. is not responsible for products belonging to dietary supplements and cosmetic products.

   The Institute is responsible for issuance of an expert opinion on the classification of the product into a medicine or group of medicines or medical devices, i.e. decides which products are considered to be medicines and medical devices. For products for which the Institute issues expert opinion that they are not medicines or medical devices, it is necessary to contact Department of Health and Sanitary Inspection within the Administration for Inspection Affairs.

2. **QUESTION: Is the Institute responsible for regulation of the issue of pharmaceutical waste?**

   ANSWER: The Institute is not responsible for destruction and disposal of pharmaceutical waste.

3. **QUESTION: Does the Institute give advice on prescribed therapy and medical condition of the patients?**

   ANSWER: The Institute does not give advice on treatment, but the patients should consult their chosen doctor or pharmacist.

4. **QUESTION: Can patient who comes in Montenegro bring medicines needed for his/her treatment during the stay in Montenegro?**

   ANSWER: Pursuant to article 110 of the Law on Medicines, the person entering or leaving the country can bring reasonable amount of medicines needed for personal use or for animal traveling with him/her for six months at most, except those medicines that contain drugs and psychotropic substances, in accordance with separate law.

5. **QUESTION: What documentation is required of patient who use medicines containing drugs as a therapy, when entering Montenegro?**

   ANSWER: In accordance with the Law about preventing drugs abuse, a person crossing the state border is allowed to possess a medicinal product that contains drugs in the amount needed for personal therapy for the period of no longer than 30 days based on the confirmation (report) of a selected doctor, or mental health specialist. When crossing the state border, a person is obliged to have the confirmation (report) on the necessity of possession of a medicinal product, which must not be older than 90 days, and to present it to the customs authority.

6. **QUESTION: The medicine I need is not available on our market, how can you help me?**

   ANSWER: The Institute is responsible for issuance of marketing authorization for a medicine, a procedure within which the assessment of its quality, safety and efficacy is performed, as well as for monitoring of safe use of medicines on the market. On our portal, in section Medicines for human use/Register, you are able to find whether a certain medicine has been granted marketing authorisation in Montenegro, or whether other medicines of same composition and form have been granted marketing authorisation. The marketing authorization issued by the Institute, does not mean automatic obligation to market the medicine, but it is sole decision of the manufacturer and marketing authorisation holder, and it does not mean that every medicine that has been granted marketing authorisation is also marketed in Montenegro. The Institute does not affect the decision concerning marketing of the medicine, has no commercial interests and does not participate in any way in the procurement and distribution of medicines and does not have information on the supply of pharmacies and other health institutions with medicines and medical devices. If the medicine has been placed on the market, the continuous supply of the market, in accordance with the Law on Medicines, is obligation of legal persons performing wholesale of medicines – wholesalers that shall provide the necessary supplies of medicines and initiate timely procurement and import in order to avoid an interruption in the supply of market of medicines. In accordance with provisions of the Law, the Institute may approve import of medicine that has not been granted marketing authorization if it is necessary for treatment of certain patient or group of patients and if adequate parallel of that medicine may not be found on the market.

Such procurement of medicines is based on needs of health institutions and the request for approval of it is submitted to the Institute by wholesalers.

7. **QUESTION: Is certain medical device entered into the medical devices register?**

   ANSWER: All medical devices that are entered into the register of medical devices of the Institute may be found on the portal in the section Medical Devices/Register.

8. **QUESTION: Is it safe to buy medicines on the Internet?**

   ANSWER: In accordance with the Law on Medicines, citizens may be supplied with medicines only in pharmacies. In pharmacies only medicines with mode of dispensing "without prescription" may be bought, i.e. medicines intended for self-treatment of mild conditions; still it is advised to consult doctor or pharmacist when choosing this group of medicines.

   Medicines come to pharmacies through approved, reliable and controlled system of distribution chain, starting from manufacturers, over authorized distributors – wholesalers, and consequently, only medicines of assured quality, safety and efficacy may be found in pharmacies.

   Purchasing medicines on the internet and through other illegal sources (through advertisments, at the market, etc.) and their administration without consulting a doctor/pharmacist may seriously damage health. Data from even most developed EU countries, with very regulated market of medicines, indicate that the greatest danger of counterfeit medicines comes from online purchasing, as it is estimated that over 50% of medicines purchased in that manner turned out to be counterfeit.

9. **QUESTION: Can manufacturer that is not seated in Montenegro directly apply for marketing authorization in the Institute?**

   ANSWER: Manufacturer that is not seated in Montenegro cannot directly apply for marketing authorization, but such application is submitted by his representative seated in Montenegro.

10. **QUESTION: How manufacturer of medical devices that is not seated in Montenegro can place products on the market?**

    ANSWER: Manufacturer that is not seated in Montenegro can place products on the market through representative, other legal person or entrepreneur seated in Montenegro.

11. **QUESTION: How to prepare documentation required for obtaining marketing authorization?**

    ANSWER: Documentation required for obtaining marketing authorization shall include administrative data, data on pharmaceutical-chemical-biological testing (quality), pharmacological-toxicological testing (safety) and clinical trial of the medicine (efficacy).

Documentation, in accordance with legislation, may vary depending on type of the medicine (human, veterinary, herbal, biological, homeopathic ...), type of application (original medicine, generic medicine...) but each medicine should be given positive assessment of the quality, safety and efficiency by CInMED before granting marketing authorisation. Necessary documentation for obtaining marketing authorisation is prescribed by the Law, secondary legislation – rulebooks and adequate instructions prepared by CInMED in order to facilitate clients applying for marketing authorisation. All these documents may be found on our portal in section – Legislation.

12. **QUESTION: What is required documentation for entering medical device into the medical devices register?**

    ANSWER: Necessary documentation for entering medical device into the register may be found in appropriate instructions prepared by CInMED in order to facilitate clients submitting applications. All these documents may be found on our portal in section – Legislation.

13. **QUESTION: Do medicines that have been granted marketing authorization in EU have to go through the procedure for obtaining marketing authorization in CInMED, or they are automatically considered to be authorized in Montenegro?**

    ANSWER: Marketing authorization in other country/countries does not automatically become valid in Montenegro, but the medicine must go through national procedure for obtaining marketing authorization in CInMED. Montenegro is not EU member state and does not participate in processes of granting marketing authorization in EU, but in accordance with the Law, there is a possibility that medicines that went through some of the authorizing procedures in EU are authorized in Montenegro under fast-track procedure by submitting complete documentation confirming that medicines in question are of the same quality, safety and efficacy as those in EU member states.
    Also, marketing authorisation of a medicine in CInMED has no legal force on the territory of other countries.

14. **QUESTION: Is it possible to apply for entering several medical devices into the register with one application?**

    ANSWER: Yes, if medical devices in question are of same class and category and manufactured by same manufacturer**.**

15. **QUESTION: What documentation is required for opening of a pharmacy?**

    ANSWER: Issuance of license and opening of pharmacy is competence of the Ministry of Health.

16. **QUESTION: How to register wholesale of medicines and/or medical devices?**

    ANSWER: The Institute issues wholesale licenses for medicines for human use and for medical devices. Appropriate instructions for applicants for wholesale marketing licenses may be found on our portal in the section Legislation/Instructions/Wholesale marketing authorization for medicines and medical devices.

17. **QUESTION: What should I do if I suspect an adverse reaction to the medicine I use?**

    ANSWER: Report your suspicion to your chosen doctor or pharmacist who will report it to the Institute using the form for report of adverse reactions.

18. **QUESTION: As the health professional, should I report to the Institute suspected adverse reactions which are not serious and which are expected after administration of the medicine?**

    ANSWER: The Law on Medicines prescribes that health professionals are obliged to report every suspected adverse reaction regardless of expectancy and seriousness.

19. **QUESTION: As the health professional, should I report to the Institute suspected adverse reaction if I am not completely certain that the manifested symptom is the result of administration of the medicine?**

    ANSWER: To report adverse reaction to the medicine, it is enough to suspect it.

20. **QUESTION: As the health professional, should I report suspected adverse reaction if I have information insufficient for an adequate assessment of the causal relationship between the medicine and adverse reaction to it?**

    ANSWER: Sent report is considered to be valid if it contains: data on the patient (initials and/or age and/or weight…), data on the medicine suspected to have caused adverse reaction, short description of adverse reaction and data on you as the reporter on adverse reaction. All other information significant for adequate assessment may subsequently be submitted to the Institute. (follow up).