CInMED
Institut za ljekove i medicinska sredstva Crne Gore
Institute for Medicines and Medical Devices of Montenegro

DOCUMENTATION REQUIRED FOR ISSUING EXPERT OPINION ON THE EXEMPTION FROM APPROVED PACKAGING

Applicant for issuing expert opinion on exemption from approved packaging[1] shall submit to the Institute for medicines and medical devices of Montenegro (hereinafter: Institute) the following documentation:

1. Completed, signed and sealed Application form for issuance of expert opinion within responsibilities of the Institute, available on the portal www.cinmed.me in the section About CInMED/Expert opinions and CPP.

Application form shall be completed with the following information:

- brief description of the application (reason for applying for exemption from approved packaging)
- brand name, pharmaceutical form, strength, type and size of the packaging, manufacturer
- number and date of issuance of marketing authorisation in Montenegro
- quantity of medicine which the exemption from approved packaging is applied for
- batch number that is to be imported into Montenegro (or more batches)
- packaging in which a medicine in question is going to be marketed in Montenegro (information on where that packaging is approved)
- information on where the specific batch that is to be imported into Montenegro is placed onto the market
- Whether the submitted specification for testing the quality of the finished medicine (listed in item 3 of this Instruction) is the last one approved in the country in which the packaging that is to be imported into Montenegro is approved and whether the document in question refers also to the batch that is to be imported into Montenegro
- Whether the submitted manufacturer's flow chart (specified in item 4 of this Instruction) is the last one approved in the country in which the packaging that is to be imported into Montenegro is approved and whether the document in question refers also to the batch that is to be imported into Montenegro

2. Batch release certificate in line with *Internationally harmonised requirements for batch certification* for each batch that is to be imported into Montenegro.

3. Specification for testing the quality of the finished medicine (last approved in the country in whichthe packaging that is to be imported into Montenegro is approved, which is necessary to be confirmed within the Application form for issuance of expert opinion. Specification should refer to the batch that is to be imported in Montenegro).

4. Flow chart of the manufacturer (last approved in the country in which the packaging that is to be imported into Montenegro is approved, which is necessary to be confirmed within the Form for issuance of expert opinion. Flow chart of the manufacturer should refer to the batch that is to be imported in Montenegro), or statement of a qualified person (QP) of the manufacturer listing all manufacturing sites involved in the manufacture of the specific batch that is to be imported into Montenegro (including manufacturers of active pharmaceutical ingredient - API)).

[1] Last approved packaging by the Institute for medicines and medical devices of Montenegro

5. Mock-up of the packaging in which the medicine in question is planned to be marketed in Montenegro.

When the exemption from approved packaging for medicines derived from blood and plasma, and immunological medicines is in question, in order to enable the import of a specific batch of those medicines into Montenegro, in addition to the application for the issuance of expert opinion on the exemption from approved packaging, it is necessary to submit the application for import authorisation, in accordance with the Law on medicines ("Official Gazette of Montenegro", No 080/20).

Receiving the application is followed by issuing the invoice, on the basis of which payment shall be made with a reference to the invoice/file number.

Payment of prescribed fee is a condition for processing the application.

Application shall be submitted:
- in paper form through the Registry Office or
- in electronic form, in accordance with the law governing electronic identification and electronic document, through the Registry Office on CD or to the e-mail address: pisarnica@cinmed.me

All other documentation shall be submitted in electronic form (on a CD, or by e-mail to the address pisarnica@cinmed.me).