

## DOCUMENTATION REQUIRED FOR ISSUANCE AUTHORISATION FOR IMPORT/EXPORT OF PRECURSORS AND MEDICINES CONTAINING PRECURSORS AND INSTRUCTION FOR COMPLETING THE APPLICATION FORM

### **A. When applying for the import authorisation for precursors and medicines containing precursors, the applicant shall submit the following documentation:**

- 1) Application form for import of precursors and medicines containing precursors available on the portal of the Institute ([www.cinmed.me](http://www.cinmed.me)) in the section Human medicines/Controlled substances;
- 2) The documentation prescribed by the Rulebook on the content of the application, documentation and content of precursor import and export authorisation
- 3) Batch release certificate, including certificate of analysis for each batch of precursor/medicine containing precursor the import of which is applied for.

**In order to obtain the import authorisation for medicines containing precursors that do not have marketing authorization in Montenegro, the applicant shall, in addition to the listed documentation, also submit the documentation prescribed by the Rulebook on more detailed conditions for the issuance of import authorization for a medicine that does not have marketing authorisation:**

### **B. When applying for the issuance of export authorisation for precursors and medicines containing precursors, the applicant shall submit the following documentation:**

- 1) Application form for export of precursors and medicines containing precursors available on the portal of the Institute ([www.cinmed.me](http://www.cinmed.me)) in the section Human medicines/Controlled substances;
- 2) The documentation prescribed by the Rulebook on the content of the application, documentation and content of precursor import and export authorization.
- 3) Batch release certificate, including certificate of analysis for each batch of precursor/medicine containing precursor the export of which is applied for.

After receiving the application with the documentation given in items A. and B., an invoice in accordance with the *Decision on the payment method and amount of fees for the exercise of competences of the institute for medicines and medical devices that are determined by the law* shall be issued to the applicant on the basis of which it is necessary to make payment with a reference to the invoice number/file number.

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

In case of applying for import/export of the same batch that was previously approved for import/export by the Institute, the applicant shall refer to the file number within which the batch release certificate for was submitted.

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The Institute shall retain the right to request additional documentation that is not listed in this instruction during the procedure of issuing the import/export authorisation.

The application, as well as all documentation original of which is required (all official statements of the applicant, or other documents, at the request of the Institute) 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](mailto: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](mailto:pisarnica@cinmed.me) , or to [kontrolisanesubstance@cinmed.me](mailto:kontrolisanesubstance@cinmed.me) with reference to the file number).