CInMED
Institute for Medicines and Medical Devices of Montenegro

DOCUMENTATION REQUIRED FOR IMPORT OF MEDICINES USED IN A CLINICAL TRIAL

The applicant for obtaining import licence for medicines used in a clinical trial shall submit following documentation to the Institute for Medicines and Medical Devices:

1. An application for obtaining import licence for a medicine that contains:
   - logo, name and address of the applicant, contact details, date, signature of the responsible person
   - subject of the request
   - name of the manufacturer
   - name of the medicines supplier
   - country of origin of medicines
   - name of the user, i.e. health institution in which the clinical trial is conducted,
   - full name of the clinical trial
   - total value of import
2. List of medicines for which the import is required, that contains: name of the medicine, pharmaceutical form, strength, packaging; name and country of the manufacturer of the medicine; quantity of the medicine; unit of measure for packaging; individual price of each medicine, gross amount, rebate and total (net) financial amount.
3. Proforma invoice or invoice from a supplier
4. Statement from the principal investigator, that contains: name of the medicine, pharmaceutical form, strength, packaging, name of the manufacturer and quantity of the medicine being imported
5. Proof that prescribed fees have been paid to the Institute.

   Payment should be made to the bank account of the Institute, after issuing the invoice.

   When paying, refer to the invoice number.

Note: After issuing the import license, it is necessary to submit the certificate of analysis for each batch of imported medicine to the Institute, during the period of validity of the license, with a reference to the case number/number of the issued import license.

The documentation shall be submitted both in written and electronic form (CD).