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

# MANNER OF SUBMISSION OF APPLICATION AND DOCUMENTATION FOR THE TRANSFER OF MARKETING AUTHORISATION TO THE OTHER MARKETING AUTHORISATION HOLDER

In accordance with the Article 81 of the Law on medicines („Official Gazette of Montenegro“ No 80/20), marketing authorisation holder shall submit to the Institute for medicines and medical devices (hereinafter: the Institute) the application for the transfer of marketing authorisation to the other marketing authorisation holder that fulfils conditions referred to in the Article 44 of the Law on Medicines.

Application for the transfer of marketing authorisation shall contain the following:

1. Cover letter of the applicant containing the following:
   - logo, name and address of the marketing authorisation holder,
   - subject: Application for the transfer of marketing authorisation,
   - information on the medicine (brand name, INN or generic name, pharmaceutical form, strength, package),
   - information on a manufacturer of the medicine (name and address),
   - date and number of the Decision by which marketing authorisation was issued,
   - name and address of a new marketing authorisation holder,
   - date and signature of a person responsible for the procedure of the transfer of marketing authorisation.

2. Completed Form for the transfer of marketing authorisation to a new marketing authorisation holder
   - Form is available on the portal of the Institute.
     Form is the Annex 8 of the *Rulebook on more detailed conditions for issuance of marketing authorisation for a medicine („Official Gazette of Montenegro“No 30/09).*
     Form shall be signed and sealed by both responsible person of current marketing authorisation holder and responsible person of new marketing authorisation holder.

3. Copy of the Decision by which marketing authorisation was issued.

4. Evidence that new marketing authorisation holder meets conditions for marketing authorisation holder prescribed by the Law.
   Necessary documentation is provided in the *„Instruction on submitting application and documentation for obtaining marketing authorisation for medicines for human use“* that is available on the portal of the Institute.

5. Evidence that prescribed fees have been paid to the Institute, in accordance with the *Decision on payment method and fees for the performance of legally defined competences of the Institute for medicines and medical devices.*

   Information on payment method and the Decision are available on the portal of the Institute.