

INSTRUCTIONS FOR SUBMITTING APPLICATION AND DOCUMENTATION FOR THE TRANSFER OF MARKETING AUTHORISATION FOR MEDICINES FOR HUMAN USE

In accordance with the Article 81 of the Law on medicines (“*Official Gazette of Montenegro*“ No. 14/26) (hereinafter: Law on Medicines), marketing authorisation holder shall submit to the Institute for medicines and medical devices (hereinafter: Institute) the application for the transfer of marketing authorisation to the other marketing authorisation holder that fulfills conditions referred to in the Article 33 of the Law on Medicines. The application for the transfer of marketing authorisation shall be submitted to the registry office of the Institute or via the portal for electronic submission of documentation.

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

1. Cover letter of the applicant containing the following:
 - name and address of the marketing authorisation holder,
 - subject: Application for the transfer of marketing authorisation,
 - information on a medicine (name, pharmaceutical form, strength, packaging, manufacturer and date and number of the Decision on the issuance of marketing authorisation),
 - name and address of a new marketing authorisation holder,
 - date and signature of a qualified person.
2. Completed Form for the transfer of marketing authorisation to a new marketing authorisation holder which is available on the portal of the Institute.
3. Documentation for a new marketing authorisation holder:
 - Excerpt from the Central Register of Business Entities (CRPS) in Montenegro;
 - Written authorisation from the marketing authorisation holder in the European Union or the manufacturer of the medicinal product, confirming that the applicant is authorized to represent them in the marketing authorisation procedure in Montenegro, using the form available on the CInMED portal. The original document shall be submitted in paper or electronic form, in accordance with the law governing electronic identification and electronic documents, or as a notarized copy.
 - Responsible person for issuing the marketing authorisation, variation and renewal of the authorisation
 - Statement of the responsible person of the applicant/Marketing Authorisation Holder (MAH) appointing the responsible person for issuing the marketing authorisation, variation and renewal of the authorisation;
 - Proof of employment - the applicant/MAH shall submit full-time employment contract with the responsible person, defining the obligations of the appointed person in relation to obtaining, varying, amending and renewing the marketing authorisation, in accordance with the applicable regulations;
 - Proof of professional qualifications;
 - Confirmation from Tax Administration on registered employment insurance;
 - Curriculum Vitae (CV).

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- Responsible person for pharmacovigilance
 - Statement of the responsible person of the applicant/Marketing Authorisation holder appointing responsible person for pharmacovigilance, including confirmation that the appointed person for pharmacovigilance is available 24 hours a day. The statement must specify 24-hour contact details of the pharmacovigilance responsible person (mobile phone, e-mail);
 - Proof of employment or other type of engagement with the marketing authorisation holder;
 - Proof of residence - copy of ID card or confirmation of residence issued by the competent authority;
 - Proof of appropriate professional qualifications - Article 33 paragraph 6 of the Law on Medicines;
 - Confirmation from Tax Administration on registered employment insurance;
 - Curriculum Vitae (CV).

If the applicant submitted given documentation with one of the previous applications, it is not necessary to submit the same documentation when submitting new applications (as long as given documents are valid), but only to specify with which previous application the documentation in question was submitted.

4. Evidence that prescribed fees have been paid to the Institute, 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*. Information on payment method and the Decision are available on the portal of the Institute.