

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 080/20), 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 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:
 - 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:
 - except from the Central Register of Business Entities (CRPS) in Montenegro;
 - representation agreement (which must contain representation authorization for the territory of Montenegro, a list of products and established liability insurance for any damage caused by the use of a medicine in Montenegro). Please submit the original in paper, or electronic form in accordance with the law governing electronic identification and electronic document, or notarized copy of the contract.
 - Qualified person for obtainment, amendment and renewal of marketing authorization:
 - statement of qualified person of the applicant/marketing authorization holder appointing qualified person for obtainment, amendment and renewal of marketing authorization;
 - proof of employment – applicant/marketing authorization holder shall submit full-time employment contract concluded with qualified person for obtainment, amendment, supplement and renewal of marketing authorization that defines duties of the person appointed to perform tasks regarding obtainment, amendment and renewal of marketing authorization in accordance with the Law;
 - evidence of professional qualifications;
 - confirmation from Tax Administration on registered employment insurance;
 - CV
 - Qualified person for pharmacovigilance:
 - statement of the qualified person of the applicant/Marketing Authorization holder appointing qualified person for pharmacovigilance and stating that the qualified person for

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pharmacovigilance is available 24 hours a day. The statement shall provide the 24-hour contact details of qualified person for pharmacovigilance (mobile phone, E-mail)

- proof of employment – applicant/marketing authorization holder shall submit full-time employment contract concluded with qualified person for pharmacovigilance that defines duties of the person appointed to perform tasks regarding pharmacovigilance in accordance with the Law;
- evidence of residence - a copy of ID card, or certificate of residence issued by a competent authority;
- evidence of adequate professional qualifications – Article 44 Paragraph 5 of the Law on Medicines;
- confirmation from Tax Administration on registered employment insurance
- 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.