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

METHOD OF SUBMISSION OF APPLICATIONS AND DOCUMENTATION FOR NOTIFICATIONS

In accordance with Article 68 of the Law on Medicines (*Official Gazette of Montenegro*, Nos. 80/20, 84/24 and 35/25), the marketing authorization holder may propose to the Institute for Medicines and Medical Devices (hereinafter: the Institute) amendments relating to the approved Package Leaflet and/or the approved packaging of the medicinal product, which are not related to changes in the Summary of Product Characteristics.

Proposals of this type of amendments are to be submitted to the Institute in the form of a notification, by prior appointment, using the application form available on the Institute's portal under *Human Medicines / Marketing Authorization / Guidelines and Forms*. The appointment for submission of the notification can be scheduled by calling: +382 20 310 280.

The application form must be completed electronically and signed by the person responsible for obtaining the marketing authorization, bearing the applicant's official stamp, or signed with a qualified electronic signature and electronic seal in accordance with the law governing electronic identification and electronic documents. All accompanying documentation must be submitted exclusively in electronic form, in the following formats: Word document (.docx), Excel worksheets (.xlsx) and PDF.

Notification is applicable in the case of minor changes to the labelling or Package Leaflet that do not require an update of the Summary of Product Characteristics and are not subject to a variation procedure. These changes include, but are not limited to:

- Changes to the instructions for use provided in the Package Leaflet, which do not result in changes to the Summary of Product Characteristics;
- Changes in the wording of storage conditions that do not result in changes to the Summary of Product Characteristics (e.g. reformulation of the instruction "Store below 25°C" to "Store at a temperature up to 25°C");
- Updating of mandatory warnings in line with new legislation and guidance (e.g. changing "Keep out of the reach of children" to "Keep out of the sight and reach of children");
- Changes in the way adverse reactions are presented in the Package Leaflet, which do not result in changes to the Summary of Product Characteristics;
- Updating of the Package Leaflet following readability testing, if the changes cannot be incorporated into one of the subsequent regulatory procedures involving product information updates;
- Changes to Braille information (addition/deletion/correction of errors);
- Changes to the company/manufacturer logo on the approved packaging or Package Leaflet;
- Correction of typographical errors on the approved packaging or Package Leaflet;
- Changes to packaging dimensions;
- Changes in colour, addition/deletion of symbols or pictograms;
- Changes to the abbreviation used for the batch number on the packaging;

- Changes to packaging labelled in an official language or in a foreign language approved for marketing in Montenegro with additional sticker labelling, provided these do not affect the information approved by the Institute;
- Changes in the language combination (number and structure of languages) on packaging from a centrally authorized product (CAP) approved for marketing in Montenegro with additional sticker labelling (provided this does not affect the approved sticker text);
- Embossing/printing of the information from the approved sticker in Montenegro directly onto the medicinal product carton (in cases where the product is marketed in packaging labelled in an official language of Montenegro);
- Introduction of multilingual packaging or multilingual Package Leaflet; changes in the number of languages on multilingual packaging (addition/deletion of languages).

Documentation to be submitted when filing a notification includes:

- Duly completed application form for notification;
- Updated labelling and Package Leaflet, in Word format, showing incorporated changes (using the *track changes* option) as well as a consolidated (*clean*) version. The changes must be implemented in the latest version of the document approved by the Institute;
- A document (Word or PDF) providing a comparative overview of existing and proposed information (*present/proposed*), if the changes are too extensive to be presented in detail within the application form;
- Other supporting documentation, where applicable (e.g. packaging mock-up, packaging samples (upon request by the Institute), results of readability testing of the Package Leaflet, etc.).

In the case of notifications concerning the introduction of multilingual packaging or a multilingual Package Leaflet, in addition to the above-mentioned documentation, the following must also be submitted:

- The approved Summary of Product Characteristics, Package Leaflet and labelling from the country whose language is being added;
- Mock-up in colour of the proposed multilingual packaging;
- Text of the Package Leaflet and labelling in all languages to appear on the packaging (*track changes* and *clean* versions, to allow identification of changes to the data);
- A statement by the marketing authorization holder confirming that the documentation approved in Montenegro is identical (in scope and content) to the documentation approved in the country/countries whose language(s) are being introduced, with a list of any differences (if applicable);
- Samples of the proposed multilingual packaging (only upon request by the Institute).

In the case of deletion of one or more languages from multilingual packaging, an updated mock-up must be submitted, whereas for the addition of a language the same documentation is required as for the introduction of multilingual packaging.

In the case of a notification that the information from the approved sticker in Montenegro will be embossed/printed directly on the carton of the medicinal product, in addition to the above-mentioned documentation, confirmation must be provided that the competent authority of the country in which the approved packaging is authorised has agreed with such embossing/printing of sticker information.

It is recommended that, whenever possible, changes of this type be submitted within a planned or ongoing regulatory procedure that affects the text of the Package Leaflet and/or labelling.

Multiple changes of this type may be submitted within a single notification, provided they relate to the same medicinal product.

Changes not indicated in the application form for notification will not be taken into consideration during the evaluation of the request. Furthermore, minor editorial changes to the Summary of Product Characteristics cannot be submitted through the notification procedure.

Changes to labelling texts resulting from a variation updating the Summary of Product Characteristics are assessed and evaluated within that variation and do not need to be submitted as a separate notification.

If the results of readability testing of the Package Leaflet indicate that further changes to the text of the Summary of Product Characteristics are required, such changes must be submitted through the appropriate variation procedure.

The submission of results from readability testing of the Package Leaflet cannot be filed as a notification but must be submitted as the appropriate variation (IB C.I.z).

The Institute will inform the applicant that:

- ✓ the proposed change is acceptable;
- ✓ the proposed change is not acceptable;
- ✓ additional corrections to the labelling text and/or Package Leaflet are required, in addition to those proposed through the notification;
- ✓ the proposed change cannot be considered within the scope of a notification and must instead be submitted through the appropriate variation procedure.

In accordance with Article 68 of the Law on Medicines (*Official Gazette of Montenegro*, Nos. 80/20, 84/24, and 35/25), if the Institute does not object to the proposed change within 90 days from the date of receipt of the notification, the applicant may implement the change. This

represents the maximum deadline, and the procedure may be extended only in exceptional circumstances when the marketing authorization holder is required to amend the Package Leaflet or labelling before the notification can be accepted.

The revision date indicated in the approved Package Leaflet will correspond to the date on which the marketing authorization holder was informed of the acceptance of the notification.

Marketing authorization holders should bear in mind that responsibility for the information presented on the packaging and in the Package Leaflet lies solely with the marketing authorization holder.