MRP/DCP: INSTRUCTIONS FOR THE NATIONAL PHASE OF THE MARKETING AUTHORISATION APPROVAL IN SLOVENIA

Medicinal products that will be marketed in Slovenia
For medicinal products that will be marketed in Slovenia approval of Slovenian product information (including labelling mock-ups) corresponding to the final English product information agreed during the procedure is required in order to obtain national approval (please follow the instructions below, Section 1).

Medicinal products that will not be marketed in Slovenia in foreseeable future
For products that will not be marketed in Slovenia, national approval can be granted without Slovenian product information (please follow the instructions below, Section 2).

1. Approval of Slovenian Product information

- **Translations**

After a positive conclusion of the MR/DC procedure, high-quality national translations of the final SmPC/PL/labelling text should be submitted within 5 days, via the e-mail address: mrp_dcp@jazmp.si
The applicant should follow the Best practice guide on the submission of high quality national translations http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/procedural_guidance/01_General_Info/CMDh_255_2012_Rev0_2012_05.pdf published on the CMDh webpage.
JAZMP will then assess the translations, introduce any necessary corrections/comments and inform the applicant. The applicant should accept the corrections proposed by JAZMP or justify their non-acceptance, and submit the clean electronic version of the SmPC, PL and labelling to JAZMP. JAZMP will inform the applicant of the approval of the final version.

JAZMP reserves the right to reject the translation if quality criteria are not met, e.g. if it is not compliant with the SI QRD template, if there are several serious scientific incorrect translations, or if it contains sections translated with automatic translators (such as “Google translate”). The translations of the SmPC, PL and labelling are assessed as a set; **all** the submitted documents are rejected if one or more of them do not meet the quality criteria.

If the translation is rejected by JAZMP, the applicant should submit the re-translated PI and the assessment will then be repeated as described above.

- **Mock-ups of the labelling**

After receiving information from JAZMP that the labelling text in SI language is acceptable, the mock-ups of the outer and inner labelling should be provided by the applicant for review. Please also refer to the JAZMP instructions regarding labelling published on the JAZMP webpage:
http://www.jazmp.si/fileadmin/datoteke/dokumenti/SRZH/Oznacevanje_zdravil.pdf (so far only available in the Slovenian language).

The mock-ups should be provided for each pack size the applicant wishes to market, as a marketing authorisation (MA) is granted for each pack size separately. Afterwards, the MA for any additional pack size within the range approved in the MR/DC procedure can be obtained at any time via a notification (without further fees).

Exceptionally, e.g. if a change in the name and/or the transfer of the MAH is anticipated immediately after granting of the MA, the MA can be issued without the mock-ups, based on the approved Slovenian labelling text only. In such a case, the applicant should provide JAZMP with the justification for non-submission of the mock-ups. A MA can then be issued, but the product cannot be placed on the Slovenian market until the

mock-ups have been approved by JAZMP. Submission of the mock-ups post-authorisation can be done either via a national notification (requiring the notification fee) or within the renewal or a variation procedure concerning the labelling (in this case, there is no additional fee apart from the fee applicable to the renewal/variation).

- **Braille format**

If applicable, the applicant should ensure that the information in Braille format on the medicinal product labelling is in accordance with the *Rules on labelling of medicinal products and on patient information leaflet* (Official Gazette of the Republic of Slovenia, No 21/2012). The "*Form for Braille format on packaging"* should be filled in and can be sent for approval to the ZDSSS (Union of Blind and Partially Sighted of Slovenia). To obtain approval by the ZDSSS, the applicant should send the filled in Braille form(s) by post to the address: Blaž Pavlin, ZDSSS, Groharjeva 2 1000 Ljubljana.
Another option is that an applicant/marketing authorisation holder confirms that the information in Braille format is correctly written in Braille format on labelling. In that case, the evidence that responsible person is capable to assure Braille format in Slovene should be provided to JAZMP.

The template of the form is available on the JAZMP webpage:
https://www.jazmp.si/fileadmin/datoteke/obrazci/SRZH/Obrazec-brajica_EN_rev_marec2017.docx.

Following approval by ZDSSS the signed Braille form(s), should be forwarded to JAZMP (via e-mail), where the consistency with the mock-up is checked.

If the Marketing Authorisation is to be issued without mock-ups based on the labelling texts only (see section "Mock-ups of the labelling"), Braille approval is not necessary. However, it should be obtained later within the notification of the mock-ups.

- **Blue-box requirements**

The applicant should consider the blue-box requirements published on the CMDh webpage:
https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/procedural_guidance/Application_for_MA/CMDh_258_2012_Rev16_2019_07_clean_BlueBox_requirements.pdf
Please note that the required wording regarding the Legal Status should be included in the Slovenian labelling text of the outer packaging (under Section 14), as well as the warning symbols, if applicable (under Section 7).

- **Other**

When national translations of product information are submitted the national phase of any variation procedure concluded within the time of the national phase of the MA approval procedure will be processed separately; the variation will not be included in the initial Marketing Authorisation.

2. Approval without Slovenian Product information

As of 1.10.2013, in case the medicinal product is not intended to be marketed in the foreseeable future in Slovenia, the applicant should inform the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP) of this within 10 days following a positive conclusion of the MR/DC procedure, via the e-mail address: mrp_dcp@jazmp.si. If neither national translations nor any response from the applicant within the stated time limit are received, JAZMP will assume that the medicinal product will not be marketed and a national marketing authorisation will be issued with English SmPC, PL and labelling as finally agreed by the Reference Member State.

In case the applicant later decides to market the product in Slovenia, a national translation of the product information and proposal for mock-ups (labelling) should be submitted to JAZMP for approval (see Section 1). The national translations should be submitted in good time before the planned marketing date. The assessment time for the submitted translations is up to three months. If variation procedures related to product information have been approved since the first MR/DC-procedure, the changes should be implemented in the Slovenian product information. Applicant is also kindly asked to provide us with a list of the variation procedure numbers for variations related to product information and the approval dates, at that time.
The submission of the PI and labelling mock-ups should be processed via a national notification (requiring the notification fee).

3. Additional information

- **Change of the future MAH and name of the medicinal product**

Change of the future MAH during the national phase of the MA approval procedure is not possible in Slovenia. Also, the name of the medicinal product must remain as approved during the European phase of the procedure.