

## **INSTRUCTIONS FOR SUBMITTING EDUCATIONAL MATERIALS (aRMM) FOR EVALUATION AND REVIEW**

### **1. GENERAL REQUIREMENTS**

The Icelandic Medicines Agency (IMA) evaluates, reviews and amends educational materials in case they are a part of additional risk minimisation measures (aRMM) set as a condition regarding safe and effective use of the product. This refers to products for which aRMM educational materials are set as a condition in EC decision Annex II D/opinion or prepared according to Risk Management Plan which are approved within the assessment report.

### **2. SUBMISSION**

- a) Marketing Authorization Holders (MAH) or their agents must submit to IMA an [application form](#) along with relevant educational materials and documents.
- b) Fill out the application-form and send by e-mail along with relevant documents to: [ima@ima.is](mailto:ima@ima.is).
- c) In the email subject line write: EDUMAT following the name of the relevant product.
- d) The application must be sent in a timely manner, IMA takes up to 60 days to evaluate and review educational materials.
- e) Please submit the educational materials in Icelandic along with a cover letter (intended to HCP's) and the relevant approved requirements (aRMM/Appendix IID, commission decision/opinion). Documents that the IMA must evaluate and review should be in WORD format (.doc / docx).
- f) In case of updated educational materials (repeated submission), changes to text must be kept visible with track-changes when submitted to IMA for review.
- g) If the use of images (pictures, drawings, figures) is intended they must be a part of the educational materials when submitted to IMA for review. Images may not be added to the educational materials after IMA has completed the review. The educational materials may not contain images that do not aim to ensure the safety of the product.
- h) The use of product logo is prohibited. Company logo may appear one time on each component on the front or back page.
- i) Only the Icelandic version of the educational materials should be submitted but IMA may request the English version if necessary.
- j) If the SmPC is required as part of the educational materials it can be referred to in the cover letter on IMA's webpage: [www.serlyfjaskra.is](http://www.serlyfjaskra.is) and does not have to be disseminated in a printed version to recipients.

### **3. INSTRUCTIONS ON CONTENT, LAY-OUT, DISTRIBUTION AND PUBLICATION**

#### **3.1 COVER LETTER**

A short cover letter intended for physicians/HCP's shall at least contain the following:

- a) The purpose of the educational materials.
- b) That the educational materials contain important information regarding safe and effective use of the product and that the information provided is at the request of the authorities.



- c) The logo that identifies important safety information. MAH's can request to [be part of the agreement](#) and thereby accept its conditions.
- d) An encouragement to report any adverse reactions to IMA.
- e) The black triangle ▼ (in case the product is on the list of medicinal products under additional monitoring) should be present on all components of the educational materials ([instructions for using the black triangle](#)).
- f) If an update has occurred, the changes from last edition should be specified.
- g) An encouragement to discard the older/outdated version of the materials along with which version numbers should be discarded.
- h) If the content is not printed but only available on a website, the url should be included (eg [www.serlyfjaskra.is](http://www.serlyfjaskra.is)).
- i) A list of all components of the educational materials. Instructions should also be given for which component is intended to which recipient group.
- j) If the SmPC is required as a part of the educational materials it can be referred to in the cover letter on IMA's webpage: [www.serlyfjaskra.is](http://www.serlyfjaskra.is) and does not have to be disseminated in a printed version to recipients.
- k) Please note that during the review of the cover letter, IMA will provide a reference number (V-xxxxxx) in the footer of the letter. Please accept the reference number, the number shall be present when the cover letter is sent to relevant recipients.

### 3.2 EDUCATIONAL MATERIALS INTENDED FOR HEALTHCARE PROFESSIONALS:

When preparing the educational materials it is advised to consult a specialist (working in Iceland) in the relevant field/therapeutic area, as needed. It is important to customize the educational materials to local conditions and requirements.

- a) All requirements according to the aRMM should be addressed in the educational materials.
- b) The materials should not contain any information other than the relevant safety information.
- c) The logo that identifies important safety information should be present on the materials (at least on the front page of each component).
- d) If the black triangle ▼ is applicable, it must be accompanied by the relevant warning text and should be present on all components of the educational materials ([instructions](#)).
- e) All components of the educational materials must have a date and version number.

### 3.3 EDUCATIONAL MATERIALS INTENDED FOR PATIENTS:

When preparing the educational materials it is advised to consult a specialist (working in Iceland) in the relevant field/therapeutic area, as needed. It is important to customize the educational materials to local conditions and requirements.

- a) All requirements according to the aRMM should be addressed in the educational materials.



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Icelandic Medicines Agency

- b) The logo that identifies important safety information should be present on the material (at least on the front page of each component). Exemptions can be granted by IMA regarding patient cards.
- c) If the black triangle ▼ is applicable, it must be accompanied by the relevant warning text and should be present on all components of the educational materials ([instructions](#)).
- d) All components of the educational materials must have a date and version number

#### **4. COMPLETED REVIEW**

Upon completion of IMA's review, the Agency sends the educational materials with amendments/corrections and/or comments to the MAH/agent. Please send IMA clarifications/answers to any comments/questions by e-mail within 30 days. If all the MAH accepts all amendments/corrections and/or comments made by IMA MAH, please send a confirmation thereof to IMA by e-mail within 30 days.

#### **5. DISTRIBUTION/COMMUNICATION PLAN:**

- a) The Icelandic Medicines Agency shall be sent a copy of the final printed educational materials at the same time as it is sent to other relevant recipients.
- b) The cover letter intended for physicians/healthcare professionals must be sent to relevant recipients (HCP's) in print or by e-mail.
- c) Printed copies of educational materials intended for patients must always be distributed/sent to appropriate recipients, even though it is also available on a website for example IMA's: [www.serlyfjaskra.is](http://www.serlyfjaskra.is)

#### **6. PUBLICATION OF EDUCATIONAL MATERIALS ON THE IMA WEBSITE ([www.serlyfjaskra.is](http://www.serlyfjaskra.is))**

- a) [Instructions on electronic publication of educational materials.](#)

#### **7. EXCEPTIONS**

Please apply to the IMA if any exceptions to the above are proposed.