Lyfjastofnun
Icelandic Medicines Agency

INSTRUCTIONS FOR SUBMITTING EDUCATIONAL MATERIALS

1. GENERAL REQUIREMENTS

The Icelandic Medicines Agency (IMA) evaluates, reviews and amends educational materials if needed as it is a part of additional risk minimisation measures (aRMM) set as a condition to the marketing authorisation. This refers to medicinal 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 (RMP) which are approved within the marketing authorisation or variation procedure.
When new conditions are approved after the marketing authorisation or a change is made to the conditions the Marketing Authorization Holder is responsible to fulfil the new/changed conditions.

If the changes to the educational material are only concerning a change in the MAH and the content itself remains the same, the material still needs to be sent in for IMA to review. If the material is aimed for patients (e.g. a patient leaflet or a patient card), distribution of the material is applicable.
When the black triangle is removed (as the only update to the educational material) IMA needs to review the changes, however the material does not need to be distributed.

For generic products the applicant or marketing authorisation holder should develop the risk minimisation measures in line with the scope, content and format of the tools used for the reference medicinal product.

If a medicinal product is a part of competitive bidding, this needs to be clearly stated in the application for request of review of the educational material. If the product does not win the bidding, the applicant needs to withdraw their application for review of the material.

2. SUBMISSION

a) MAH or their agents must submit to IMA a complete request for review of educational materials. Please download the form every time an education material is sent to IMA since it may have been updated.
b) Documents that the IMA must evaluate, and review should be in WORD format (.doc/docx).
c) Latest approved aRMM (RMP/Annex II) are required.
d) Only the Icelandic version of the educational material should be submitted, do not send the English version. IMA will request the English version if necessary.
e) The educational materials should not include or be combined with promotional elements either direct or indirect.
f) The educational materials should focus on clearly defined actions related to specific safety concerns in the aRMM and should not be unnecessarily diluted by including information that is not immediately relevant to the safety concern being addressed and that is adequately presented in the SmPC or package leaflet.
g) If the use of images (picture, drawings, figures) is intended they must be a part of the educational material when submitted to IMA for review. Images may not be added to the educational material after IMA has completed the review.

h) The use of product logo is prohibited. The use of the MAH/agents' logo is allowed once, either on the front or back page and should not be larger than the educational material title.
i) In case of updated educational material (repeated submission), changes to text must be kept visible with track-changes when submitted to IMA for review.
j) If the SmPC is a part of the educational material it does not have to be disseminated in a printed version to recipients. The cover letter can refer to that the SmPC can be found on IMA's webpage: www.serlyfjaskra.
k) Completed Request for review of educational materials and relevant documents (educational materials in Icelandic along with a cover letter for HCP's and aRMM/Appendix IID) should be sent to: ima@ima.is. In the email subject line write: EDUMAT and [the name of the relevant product].
l) The application must be sent in a timely manner, IMA takes up to 60 days to evaluate and review educational materials.

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

3.1 COVER LETTER

A short cover letter intended for physicians/HCPs shall at least contain the following:

a) The logo that identifies important safety information. MAHs can apply for membership, see the instructions here.
b) The purpose of the educational material (the reason why it is required)
c) If an update has occurred, the changes from last version should be specified.
d) That the educational material contains important information regarding safe and effective use of the product and that the information is provided at the request of the authorities. The following sentence can be used: *Fræðsluefnið er útbúið og því miðlað/dreift til að uppfylla kröfur lyfjayfirvalda, en markmiðið er að auka öryggi og tryggja rétta notkun lyfsins.*
e) If the product is subject to additional monitoring ▼, it must be accompanied by the relevant warning text and the black triangle should be present on all components of the educational (see instructions for using the black triangle here).
f) A list of all components of the educational material (please keep consistency in titles). Instructions should also be given for which component is intended to which recipient group.
g) The cover letter should inform where and how all the components of the educational materials can be found.
h) If updated material is sent an encouragement to discard the older/outdated version of the material along with version numbers should be included. The following sentence can be used: *Meðfylgjandi er uppfært fræðsluefni ætlað [læknum/ heilbrigðisstarfsfólki/ sjúklingum], útgáfa xxx. Útgáfa yyy sem áður var dreift er nú úrelt, vinsamlegast fargið eldra efni.*
i) If the content is not printed but only available on website, the website should be include (e.g. www.serlyfjaskra.is).
j) An encouragement to report any adverse reactions to IMA. The following text can be used: *Heilbrigðisstarfsmenn eru hvattir til að tilkynna allar aukaverkanir sem grunur er um að tengist lyfinu til Lyfjastofnunar: www.lyfjastofnun.is, eða í gegnum vefeyðublað (Tilkynning um aukaverkun) sem er að finna í Sögu*.

k) The cover letter should state the recipients of the material and a request to notify other HCP about the educational materials. The following sentence can be used (depending on recipients): *Viðtakendur eru: Allir sérfræðingar í xxx (sérgrein) og lyfjafræðingar í lyfjabúðum/sjúkrahúsapótekum. Viðtakendur eru hvattir til að láta aðra heilbrigðisstarfsmenn vita um fræðsluefnið eftir því sem við á.*
l) Please keep in mind laws and regulation regarding data protection and the processing of personal data, further information can be found on www.personuvernd.is.

3.2 EDUCATIONAL MATERIAL FOR HEALTHCARE PROFESSIONALs:

When preparing the educational material, 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 material to local conditions and requirements.

a) All requirements according to the aRMM (Annex II/RMP) should be addressed in the educational material. The material should not contain other information than relevant safety information or information that is already adequately presented in the SmPC.
b) Educational material should refer the reader to the SmPC.
c) The logo that identifies important safety information should be present on the material (at least on the front page of each component).
d) If indication/s are included in the education material it/they should be verbatim from the SmPC.
e) If the product is subject to additional monitoring , it must be accompanied by the relevant warning text and the black triangle ▼ should be present on all components of the educational material (see instructions for using the black triangle
f) That the educational material contains important information regarding safe and effective use of the product and that the information is provided at the request of the authorities. The following sentence can be used: *Fræðsluefnið er útbúið og því miðlað/dreift til að uppfylla kröfur lyfjayfirvalda, en markmiðið er að auka öryggi og tryggja rétta notkun lyfsins.*
g) The titles of the components should be descriptive.
h) The date of last revision of the text in the format of <month> <year> should be provided on the first and the last page of the education materials.
i) All educational materials must have a version number/unique document identifier on all pages of the material for version control.

3.3 EDUCATIONAL MATERIAL FOR PATIENTS:

When preparing the educational material, 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 material to local conditions and requirements.

a) All requirements as according to the aRMM (Annex II/RMP) should be addressed in the educational material. The patient material should not contain any irrelevant information or information that is already adequately presented in the package leaflet.
b) Educational material should refer the reader to the package leaflet.
c) 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 e.g. small patient cards.
d) If the product is subject to additional monitoring , it must be accompanied by the relevant warning text and the black triangle ▼should be present on all components of the educational material (see instructions for using the black triangle)
e) That the educational material contains important information regarding safe and effective use of the product and that the information is provided at the request of the authorities. The following sentence can be used: *Fræðsluefnið er útbúið og því miðlað/dreift til að uppfylla kröfur lyfjayfivalda, en markmiðið er að auka öryggi og tryggja rétta notkun lyfsins.*
f) If information needs to be written/filled in, in the educational material for patients (for example dates of dosing of medication or if patient needs to contact a specific doctor due to adverse reactions, it needs to be clear who is responsible for filling out the information on the material. The following sentence can be used: *Fyllist út af lækni/heilbrigðisstarfsmanni* or *Fyllist út af sjúklingi/aðstandanda.*
g) The titles of the components should be descriptive.
h) The date of last revision of the text in the format of <month> <year> should be provided on the first and the last page of the education materials.
i) All educational materials must have a date and version number/unique document identifier on all pages of the material for version control.

4. COMPLETED REVIEW

Upon completion of IMA‘s review, the Agency sends the educational material with amendments/corrections and comments to the MAH/agent. If the MAH accepts the changes a confirmation e-mail should be sent within 30 days. If IMA has made comments/corrections that the MAH needs to respond to, IMA will request a response within 2 weeks.

5. DISTRIBUTION/COMMUNICATION PLAN:

a) Approved educational material should not be distributed with other material not reviewed by IMA.
b) The cover letter intended for physicians/healthcare professionals must always be sent to relevant recipients 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 IMA‘s website: www.serlyfjaskra.is.
d) A copy of the final educational material shall be sent to IMA via email, at the same time as it is sent to other relevant recipients.
e) Please place the logo that identifies important safety information on the envelopes if sent via mail and in a prominent place at the top of the mail if sent via email.

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6. PUBLICATION OF EDUCATIONAL MATERIALS ON THE IMA WEBSITE (www.serlyfjaskra.is)

IMA encourages MAH to publish reviewed educational materials on its medicinal product information website, www.serlyfjaskra.is. See instructions here.

7. PUBLICATION OF EDUCATION MATERIALS ON MAH WEBSITE

If the educational materials are to be published on MAH website, please follow the undermentioned:

a) The publication on the website must be approved by IMA.
b) The link to the site shall be provided in the request for review of educational materials.
c) The website cannot have links or references to other documents or websites without IMAs approval.
d) The website cannot have references or information regarding medication that are not marketed in Iceland.
e) A link/reference to approved SmPC, patient leaflet and RMP is permitted on the website.

8. APPLICATION FOR REMOVAL OF EDUCATIONAL MATERIAL ON SERLYFJASKRA

a) Marketing authorisation holder/agent needs to send IMA request of removal of material from serlyfjaskra to ima@ima.is.
b) The following needs to be stated in the e-mail:
   - What medication and strength are applicable
   - What material should be removed
   - Updated RMP/Annex II should be attached to support the request
   - The subject of the e-mail should be “EDUMAT” and (name of the medication)