Ministry of Health
National Agency for Medicine and Medical Devices of Romania
Str. Av. Sănătescu, nr. 48, Sector 1, 011478 București
Tel: +4021-317.11.00
Fax: +4021-316.34.97
www.anm.ro

Instructions regarding the submission for review and approval by the National Agency for Medicine and Medical Devices of Romania (NAMMDR) – Pharmacovigilance and Risk Management Unit of educational tools/materials provided as additional measures to minimise the risk of a medicinal product

I. INTRODUCTION

Educational tools/materials are additional risk minimisation measures (aRMM) for a medicinal product and represents Conditions of Marketing Authorisation and/or are included in the Risk Management Plan (RMP) of the medicinal product. The Romanian version of the educational materials and other risk minimisation tools are intended to be used by healthcare professionals or patients from Romania and therefore must be assessed and approved at national level by NAMMDR before dissemination in Romania.

A clear distinction should be made between educational materials included in RMP and other educational materials regulated by Order No. 194/23.02.2015 on Rules for assessment and approval of advertising of medicinal products for human use. The educational materials regulated by Order No. 194/23.02.2015, are not included in RMP and not subject to the pharmacovigilance activities, these are managed by the Advertising Unit from NAMMDR.

The Pharmacovigilance and Risk Management Unit from NAMMDR is responsible for the national assessment and approval of educational tools/materials which are Conditions of Marketing Authorisation and/or are included in RMP.

The NAMMDR have the autonomy in deciding the appropriateness of national educational tools/materials in accordance with the agreed key elements and outlined in the RMP.

II. CONSIDERATIONS FOR PREPARATION AND IMPLEMENTATION OF EDUCATIONAL TOOLS/MATERIALS

Guidance on the principles for development and implementation of additional risk minimisation measures, including educational tools/materials, as well as the evaluation of the effectiveness of risk minimisation measures are available in GVP module V –Risk Management Systems and GVP module XVI – Risk minimisation measures: selection of tools and effectiveness indicators, including GVP Module XVI Addendum I – Educational materials.

GVP module XVI and GVP Module XVI-Addendum I are adopted and translated in Romanian language through the following Scientific Council Decisions of NAMMDR: HCS no. 2/14.06.2018 and HCS no. 3 /24.10.2018.

Where tools/educational materials are considered necessary for a generic product, the educational tools/materials should be aligned with those for the reference medicinal product.

Ministry of Health
National Agency for Medicine and Medical Devices of Romania
Str. Av. Sănătescu, nr. 48, Sector 1, 011478 București
Tel: +4021-317.11.00
Fax: +4021-316.34.97
www.anm.ro

Without affecting the uniqueness of the format of the educational material, it is the interest of public health that the educational materials used by several Marketing Authorization Holders (MAHs) for the same active substance to be kept as similar as possible to ensure consistency of the message and avoid confusion among the target audience. Therefore, MAHs are encouraged to share the content of their educational materials with another MAH, upon request, as recommended in Module XVI – ADDENDUM I – EDUCATIONAL MATERIALS.

In addition, educational tools/materials disseminated in Romania should contain, if applicable, details related to the "additional monitoring" status of the medicinal product and also a wording to encourage adverse reactions reporting.

If the medicine product is not placed on the Romanian market, the dissemination of educational materials is not necessary.

III. SUBMISSION OF THE REQUEST FOR APPROVAL OF EDUCATIONAL MATERIALS TO NAMMDR

The applicant submits to the NAMMDR the request of approval of the educational materials using one of the following methods:

- Transmission in electronic format (by e-mail) to the registration office of NAMMDR at registratura@anm.ro, specifying that the request is addressed to the Pharmacovigilance and Risk Management Unit. Please add farmacovigilenta@anm.ro to the distribution list of the e-mail.

- Transmission/submission in physical format to the registration office of NAMMDR, specifying that the request is addressed to the Pharmacovigilance and Risk Management Unit. In this case, the documentation should be presented either on CD, by e-mail (farmacovigilenta@anm.ro) or using the Upload platform (by selecting the recipient: Pharmacovigilance and Risk Management Unit).

The documentation shall contain the following:

A. The **Cover letter** outlining the context for the educational materials submission (the name of the procedure which the materials relates to, together with supporting documents such as the CHMP opinion, the CMDh position and/or the decision of the European Commission, including the conditions specified in marketing authorization and other annexes) and also the objectives of these educational materials, according to the RMP in force at the time of submission, specifying the RMP version number;

B. **Application Form**

C. **Form payment of fee for assessment of educational material** (the fee is 350 euros per material, regardless of the distribution period or the number of distribution channels)

D. **Educational Material(s):**

- in Romanian language and in English language (the Romanian version should be in editable format - Word) and in accordance with last version of the approved RMP;

Ministry of Health
National Agency for Medicine and Medical Devices of Romania
Str. Av. Sănătescu, nr. 48, Sector 1, 011478 București
Tel: +4021-317.11.00
Fax: +4021-316.34.97
www.anm.ro

Observation: For visual or audio/visual materials, it should be submitted a text indicating the scenario, describing or representing the image and transcribing the audio (the Romanian version should be in editable format - Word).

E. **A detailed implementation plan for the educational material(s):**

- Should be submitted in Romanian language, editable format (Word)

F. **Other supporting documentation**:

- The last version of the approved RMP (including its annexes);
- The opinion of the CHMP, the position of the CMDh and/or the decision of the European Commission, if applicable;
- Other supporting data accompanying the submission.

Submissions should be made at least three months prior to product launch in Romania for facilitating the assessment of the educational tools/materials.
The average period for approving educational materials is 60 days from the moment of payment of the evaluation fee and submission of all documents (in case the documentation submitted is incomplete).
During the evaluation procedure, NAMMDR sends to the applicant (by e-mail) changes/comments to the proposals for educational materials/the detailed plan for implementing the educational materials, in order to be agreed. The applicant is requested to respond in maximum 30 days.
Once the educational materials have been agreed with the applicant, the NAMMDR approval process will be finalized.
The official address for educational materials approval by NAMMDR will be available at the registration office of NAMMDR.
The approved educational materials (word format) will be sent to the MAH by e-mail.
The MAH should send to NAMMDR the educational materials in the format that will be distributed to HCP/patients, before being sent to them.
In the interest of public health, the educational materials approved by the NAMMDR are published on the Agency website, section Medicines for Human Use – Pharmacovigilance – Educational Materials.

IV. UPDATES OF EDUCATIONAL MATERIALS

Following a variation of the marketing authorization (with an impact on key elements of the educational materials) or following an update of the RMP, the updated educational materials should be submitted to the NAMMDR for assessment and approval. The NAMMDR approval will follow the same assessment process.

The documentation should be submitted in Word format. The Word format should be drafted with track changes in order to highlight the changes made to the previous approved version of the educational materials (and also justification of the changes, for example, by including a cross-reference to the variation procedure).

In case of major modifications to the document (paragraphs added, moved or major rephrasing), it is recommended to format it as a three-column table (original text, modified text and justification of modification).

The modification of educational materials in terms of format, administrative data or following a minor marketing authorisation variation, without an impact on the scientific medical information (for example

modification of a section of the SmPC without an impact on the scientific medical information of the approved educational material) does **NOT** require approval from NAMMDR. In this case, MAH just notifies NAMMDR about the changes performed.

In case the approved educational materials are no longer necessary for a medicinal product and no longer included in the RMP, the MAH should inform NAMMDR on this aspect, through a notification.

V. CONTACT DETAILS

Queries for the educational materials included in RMPs should be sent to the following e-mail address:

farmacovigilenta@anm.ro

Date: April 2023