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3 Guideline on good pharmacovigilance practices (GVP)

4 Module XVI Addendum I – Educational materials

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Comments should be provided using this template. The completed comments form should be sent to gvp@ema.europa.eu.

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XVI. Add I.1. Introduction

Educational programmes are additional risk minimisation measures (RMM) (see GVP Module XVI) and usually require educational materials based on targeted communication with the aim to supplement the information in the summary product characteristics (SmPC) and package leaflet (PL).

When the development and distribution of educational material is recommended by the Pharmacovigilance Risk Assessment Committee (PRAC) and endorsed by the Committee for Medicinal Products for Human Use (CHMP) and are included as a requirement in the marketing authorisation granted by the European Commission for the medicinal product in question, as applicable, key elements may be agreed at EU level. In this case, draft educational materials should be submitted to the competent authorities of Member States and these educational materials shall implement the key elements. Alternatively, the exact content of educational materials could be agreed at EU level and also become part of the summary of product characteristics (SmPC) and/or the package leaflet (PL), as applicable.

This Addendum to GVP Module XVI provides guidance for marketing authorisation holders on the submission of draft education materials to the competent authorities of Member States as well as guidance for these competent authorities on the assessment of such materials, in particular as regards the format and content. Individual Member States may have additional requirements, and as such this guidance should be followed together with other national guidelines.

This Addendum is applicable to both centrally and nationally authorised products, including those authorised through the mutual recognition and decentralised procedures.

Submission of draft educational materials to the European Medicinal Agency (the Agency) is not required as the implementation lies with competent authorities of Member States.

XVI. Add I.2. Principles for educational materials

The following principles apply to educational materials:

- The need for educational materials will be agreed during a regulatory procedure, at the moment of the initial marketing authorisation or in the post-authorisation phase.
- Any educational material should focus on the risk minimisation objectives.
- It should focus on the specific safety concerns and provide clear statements and concise messages describing actions to be taken in order to prevent and minimise these risks.
- It should not be combined with promotional materials for the marketing of the medicinal product. Educational materials should be drafted in the official language(s) as required by the Member State.
- The competent authority(ies) of the Member State(s) where the medicinal product is/will be marketed should review the national version of the educational material. Agreement should be reached before it is disseminated by the marketing authorisation holder at national level.
- The national version of the educational material should only be submitted to the competent authorities of Member State following conclusion of the regulatory procedure in which the risk minimisation measure (RMM) was agreed, i.e. a CHMP opinion or CMD(h) position based on a PRAC recommendation, a Commission Decision or a notification of approval of a variation of the marketing authorisation or the risk management plan (RMP).

- When the need for educational material is agreed at EU level (i.e. the European Commission or the competent authority(ies) of (the) Member State(s), depending on the regulatory procedure), the dissemination of the educational material is mandatory. The modalities for dissemination and the target audience are determined by the competent authority(ies) of (the) Member State(s).
- The marketing authorisation holder should provide a proposal of the target population of the material.
- The marketing authorisation holder should exercise version control and ensure that it disseminates only the latest agreed version of the educational material.

XVI. Add I.3. Submission of educational materials

The draft educational material should be submitted to the competent authority(ies) of (the) Member State(s) as follows:

- with a submission cover letter including information on:
  - the contact point of the marketing authorisation holder and, if applicable, another organisation to which it has subcontracted the submission (at least names and e-mail addresses);
  - the route of authorisation;
  - the origin of the request with supportive documents (e.g. CHMP opinion, CMD(h) position and/or Commission Decision including conditions of the marketing authorisation and other annexes, approved RMP, assessment report identifying the need for this RMM);
  - detailed implementation plan for the educational material:

    - target populations;

    - dissemination method;

    - intended dissemination time;

    - estimated date of launch of the product (in the case of a new marketing authorisation).
- as documents in a common open text-processing electronic format of the proposed materials in language(s) required by the Member State(s);
- the intended lay-out and, where applicable, images and graphic presentations of the information (e.g. pictures, charts, diagrams, video).

If the submission concerns an update of educational material previously agreed with a competent authority of a Member State, the changes to the agreed material should be highlighted.

XVI. Add I.4. Format of educational materials

The format of educational material should include the following:

- invented name of the medicinal product followed by the active substance(s) and/or therapeutic class in brackets. However, the invented name should only appear where strictly necessary and the number of times the invented names appears in the educational material should be limited. If there is educational material applicable to several products from different marketing authorisation holders, the educational material should refer to the active substance only and a list of the invented names in the Member State should be annexed;

- if necessary, mention of the different presentations of the product, e.g. the different pharmaceutical forms, the strengths, the routes of administration;
- the title line "Important Risk Minimisation Information for <Healthcare Professionals, Patients>" to clarify the purpose of the educational material;
- an additional title line identifying the type of educational material, e.g. administration guide, checklist for prescribing, alert card, educational leaflet for the patient;
- thereafter a statement explaining that the educational material is essential to ensure the safe and effective use of the product and appropriate management of the important selected risks and therefore it is advised to be read carefully before prescribing/dispensing/administering the product;
- if the medicinal product is under additional monitoring (see Module X), the black symbol should be included next to the medicinal product name or active substance name, along with the explanatory standard statement for additional monitoring;
- bullet points should be used wherever appropriate to present the information clearly;
- materials should be kept as brief as possible, however, if the educational material is long, an introductory text summarising the key messages should be added and an index may be included;
- for version control, the version number and the date of agreement of the material by the competent authority(ies) of Member State(s) in the format of "<month> <year>" on each sheet of the educational material, unless the type of educational material requires an appropriate exceptions (e.g. a video should have this information appearing at its beginning and end).

If the logo of the marketing authorisation holder appears, the logo should appear only once in each educational material, preferably on the last page. If it however appears on the first page, the logo should not be larger than the document title. No product logos or slogans should be used.

XVI. Add I.5. Content of educational materials

The reference documents to be used in the preparation of educational materials are the agreed risk management plan (RMP) (including its annexes), product information (SmPC and PL) and the conditions of the marketing authorisation, the so-called Annex IIB for centrally authorised products and Annex III for nationally authorised products included in a referral or a single PSUR assessment procedure.

The educational material should contain the key elements as agreed at EU level in the corresponding conditions of the marketing authorisation (as referred to in Article 9(4) of Regulation (EC) No 726/2004 and Article 21a(a) of Directive 2001/83/EC) in an appropriate format and layout. The SmPC and/or PL may be attached to the educational material and disseminated together; or the educational material may contain a reference to the website of the competent authority of the Member State or the Agency when SmPC and/or PL are made publicly available on these websites. References to other websites for "more information" will usually not be accepted unless it refers to the SmPC/PL.

In order to avoid repetition of SmPC and/or PL texts, the messages in the educational material should complement the SmPC and/or PL based on the agreed key elements with important data to support the implementation and hence effectiveness of the RMM.

Images and graphic presentations of the information should only be used when text alone is insufficient to adequately convey the key element(s) and should not be promotional.

The scope of the information in the educational material should be limited to the key elements agreed at EU level. Additional information such as efficacy data, comparisons of safety with other medicinal

products or statements which imply that the medicine is well tolerated or that adverse reactions occur with a low frequency should not be included. Referring to other medicinal products outside the scope of the educational material is not allowed.

A statement encouraging the reporting of any suspected adverse reaction and the modalities to report in the competent authority of the Member State should be included.

XVI. Add I.6. Assessment of educational materials at the level of Member States

The timelines for the assessment of draft educational materials by the different competent authorities of Member States may vary depending on e.g. the RMM, the kind of requested educational materials, the quality of the submitted drafts or the current work priorities of the authority.

If the request for implementation of educational materials follows a referral or a single PSUR assessment procedure, the assessment of the draft educational material will be agreed as part on the procedure outcome.

The final version of the educational materials, as agreed for dissemination, should be provided to the competent authorities of Member States in pdf-format by e-mail.

Competent authorities of Member States may publish agreed educational materials on their websites as applicable.

XVI. Add I.7. Publication of educational materials on marketing authorisation holders on specific websites

When agreed by the competent authority of the Member State, the marketing authorisation holder may publish educational materials on a specifically dedicated website, provided that the marketing authorisation holder respects the following:

- Access to the website should be given to the competent authority of the Member State;
- A statement that the information of the website is consistent with the agreed material should be submitted;
- The specific website should not include any reference to documents or to other websites/pages or weblinks not agreed with the competent authority of the Member State;
- All elements and information on the specific website should be expressed in the official language(s) as required by the Member State or, in exceptional cases with the agreement of the competent authority of the Member State, in English;
- The specific website should not contain references to or information about medicinal products not marketed in that Member State.

Other relevant documents such as the SmPC, the PL and the summary of the RMP may be referred to.