8 December 2015
EMA/61341/2015

Guideline on good pharmacovigilance practices (GVP)

Module XVI Addendum I – Educational materials

Draft finalised by the Agency in collaboration with Member States for submission to ERMS FG	24 March 2015
Draft agreed by the European Risk Management Strategy Facilitation Group (ERMS FG)	30 March 2015
Draft adopted by the Executive Director	18 April 2015
Released for public consultation	27 April 2015
End of consultation (deadline for comments)	30 June 2015
Revised draft finalised by the Agency in collaboration with Member States	17 November 2015
Revised draft agreed by ERMS FG	24 November 2015
Revised draft adopted by Executive Director as final	8 December 2015
Date for coming into effect	16 December 2015

This version is not valid anymore, but kept on the Agency's website for the purpose of public access to historical documents. For the valid version, please refer to the Agency's GVP webpage for the latest revision of the related GVP Module, where this guidance has been incorporated.

See websites for contact details

European Medicines Agency www.ema.europa.eu
Heads of Medicines Agencies www.hma.eu

XVI. Add I.1. Introduction

Educational programmes are additional risk minimisation measures (aRMM) (see GVP Module XVI) and usually include educational material(s) aimed to minimise an important risk and/or to maximise the risk-benefit balance of a medicinal product. The content of any educational material should be fully aligned with the currently authorised product information for the medicinal product, i.e. the summary product characteristics (SmPC), the package leaflet (PL) and the labelling, and should add rather than replicate SmPC and PL information.

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) or the Coordination Group for Mutual Recognition and Decentralised Procedures-Human (CMDh), key elements of any educational material are agreed at EU level. Thereafter, drafts of the educational material(s) addressing the key elements should be submitted by the marketing authorisation holder to the competent authorities of Member States for assessment and then be implemented in Member States upon approval by the competent authorities.

Guidance on the requirements for including the key elements of the educational material(s) and/or the educational material(s) addressing the key elements as distributed in the Member States in an annex to the risk management plan (RMP) is provided in GVP Module V.

This Addendum to GVP Module XVI provides further guidance for marketing authorisation holders on the submission of draft educational material(s) to the competent authorities of Member States, as well as, guidance for these authorities to support the assessment of such materials, in particular with regard to format and content. Because of the specificities of the national healthcare systems and of how particular risk(s) are managed within these systems, individual Member States may have additional requirements. In this case, the guidance in this Addendum to GVP Module XVI should be followed together with national guidelines.

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

XVI. Add I.2. Principles for educational materials

The following principles apply to educational materials:

- The need for educational materials may be agreed during a regulatory procedure, at the time of the initial marketing authorisation or in the post-authorisation phase, e.g. after introduction of a new RMP or an update of an existing RMP.
- Any educational material should be specifically designed to fulfil the risk minimisation objectives.
- It should focus on the specific safety concern(s) and provide clear statements and concise messages describing actions to be taken in order to prevent and minimise these risks.
- The national versions of the educational material should only be submitted, by the marketing authorisation holder, to the respective competent authorities of Member States, following the conclusion of the regulatory procedure in which the aRMM was agreed.
- Educational materials should be drafted in the official language(s) as required by the Member State.
- Educational materials should not include or be combined with promotional elements either direct or veiled (e.g. suggestive images and pictures).

- The methods for dissemination and the target audience in each Member State are determined at national level by the respective competent authority of the Member State.
- Based on the respective target audience, the marketing authorisation holder should provide to each national competent authority a proposal for the educational material(s). The target population determines which tool, content, format, language type and readability level is appropriate for the educational material. Specific efforts in adaption should be made when targeting patients (see GVP Module XV).
- The competent authorities of Member States where the medicinal product is/will be marketed should review the respective national version(s) of the educational material(s).
- The marketing authorisation holder should disseminate the educational material(s) in a Member State only after approval by the competent authorities of that Member State.
- If the medicinal product is not placed on the market in a Member State dissemination of the material in that Member State is not required. In any case, the need for dissemination of any educational material should be discussed with the competent authority of each Member State.
- The marketing authorisation holder should exercise version control and ensure that only the latest agreed version of the educational material is disseminated. The date of approval by the competent authority the Member State should be included in the educational material, as reference for healthcare professionals and/or patients.
- Without prejudice to the originality of the format of the educational material, it is in the interest of public health that educational material used by different applicants/marketing authorisation holders for the same active substance should be kept as similar as possible, in order to deliver a consistent message and avoid confusion in the target audience. Therefore, marketing authorisation holders are strongly encouraged to share the content of their educational material(s) upon request from other marketing authorisation holders.

XVI. Add I.3. Submission of educational materials

If no other national requirements apply, the draft educational material should be submitted to the competent authorities of Member States as follows:

- with a cover letter and/or request form including the following information:
  - the contact details 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 regulatory procedure which has led to the need of the educational material(s) with supportive documents (e.g. CHMP opinion, CMDh position and/or European Commission decision including conditions of the marketing authorisation and other annexes, national competent authority opinion, approved RMP, assessment report identifying the need for this aRMM);
  - a detailed implementation plan for the educational material with the following information:
    - target population(s);
    - dissemination method (e.g. paper, e-mail, via social media, learned societies and/or patient associations, publication on websites);

- time point when dissemination is anticipated to start and frequency of further disseminations;
- estimated date of launch or date of start of the marketing 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 layout and, where applicable, images and graphic presentations of the information (e.g. pictures, charts, diagrams, video).

When changes of the risk and/or the need for aRMM have been identified and changes in the key elements and/or in the content of the educational material(s) have been agreed at EU level and/or by the national competent authorities, the marketing authorisation holder should submit to the competent authorities of Member States revised proposals of the educational material for assessment and approval. In the revised educational material, the changes to the materials previously approved by the competent authority should be highlighted.

XVI. Add I.4. Format and layout of educational materials

Educational materials should have an appropriate format and layout.

A title line identifying the type of educational material, e.g. administration guide, checklist for prescribing, alert card, educational leaflet for the patient, is recommended.

The format of educational material should include the following:

- the invented name of the medicinal product followed by the name of the active substance(s) and/or therapeutic class in brackets. However, if the educational material is applicable to several products from different marketing authorisation holders in the Member State, the educational material should refer to the active substance only and a list of the invented names applicable in the Member State should be annexed;
- the black symbol next to the invented or active substance name, along with the explanatory standard statement for additional monitoring if the medicinal product is under additional monitoring (see GVP Module X).

The material should be formatted as follows:

- 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;
- if the marketing authorisation holder`s and/or product`s logo appear, it should appear only once in each educational material, preferably on the first or last page, respectively, and should not be larger than the document title;
- for version control, a unique document identifier should be used on each sheet of the educational material, and the date of last revision of the text (i.e. the approval date of the material by the applicable national competent authority) in the format of "<month> <year>" should be provided on the first and the last page, unless the type of educational material requires appropriate exceptions (e.g. a video should have the unique document identifier appearing at its beginning and ending).

XVI. Add I.5. Content of educational materials

The reference documents to be used in the preparation of educational materials are the agreed RMP (including its annexes), the product information and the conditions of the marketing authorisation.

The educational material should contain the messages of the key elements agreed, depending on the regulatory procedure, at EU level or with the competent authority of the Member State and laid down in the 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).

The educational material may also contain a reference to the website of the competent authority of the Member State, the Agency or the marketing authorisation holder`s specific website (see XVI. Add I.7.), if the SmPC and/or PL are made publicly available on these websites.

References to other websites for "more information" will usually not be acceptable unless they refer to the SmPC/PL or unless specific circumstances apply, e.g. in order to refer to a specific antibody test or to refer to a video that instructs the patient how to take the medicine and/or to use a device, if agreed with the competent authority(ies)of Member State(s).

Images and graphic presentations of the information should only be used when text alone is insufficient to adequately convey the messages of the key element(s) and should not be promotional (e.g. use of a particular device to administer the medicinal product).

The scope of the information in the educational material should be limited to the agreed key elements. 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. However, in certain circumstances the competent authorities of Member States might consider the inclusion of efficacy data provided that this is duly justified by the marketing authorisation holder. Referring to other medicinal products outside the scope of the educational material is not allowed.

A statement which encourages the reporting of any suspected adverse reaction and information on the modalities how to report in the Member State should be also included.

XVI. Add I.6. Assessment and publication of educational materials by the competent authorities 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 aRMM, the kind of requested educational materials, or the quality of the submitted drafts. Nevertheless, an average timeline of 60 days should be considered for assessment. This is without prejudice to any other timeline defined by competent authorities at national level.

In the interest of public health, the competent authorities of Member States, in accordance with national legislation, may publish the agreed educational material(s) in a dedicated section of their websites.

Marketing authorisation holders are solely responsible for the provision, to the competent authorities, of the latest agreed versions of the educational materials.

XVI. Add I.7. Publication of educational materials on the marketing authorisation holder's specific website

The marketing authorisation holder may publish the educational material(s) on a specifically dedicated (or other suitable) website, provided that the marketing authorisation holder respects the following:

- The way in which dissemination via the website occurs should be agreed with the competent authority of the Member State, i.e. as primary or as an additional way for dissemination.
- The website address should be given to the competent authority of the Member State.
- A statement that the information of the website is consistent with the educational material approved by the competent authority should be submitted to the competent authority of the Member State.
- 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.