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Guideline on good pharmacovigilance practices (GVP)

Module XVI Addendum I – Educational materials

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This track-change version identifies the majority of changes introduced to the public consultation version of this document as the Agency's response to the comments received from the public consultation. This track-change version is published for transparency purposes and must not be taken or quoted as the final version.

* For this reason, the timetable above, and in particular the date of coming into effect, apply only the clean version published as final.

For the final version of this module and any future updates, please see the GVP webpage of the Agency's website.

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XVI. Add I.1. Introduction

Educational programmes are additional risk minimisation measures (aRMM) (see GVP Module XVI) and ~~and~~ usually ~~require~~includ~~eing~~ educational material(s) ~~based on targeted communication with the aim~~aimed to minimise an important risk and/or to maximise the ~~benefit~~ risk-benefit balance ~~of a~~ medicinal product. The content of any educational material ~~is~~should be fully aligned with the currently approved product information for ~~a~~the medicinal product, ~~such as~~i.e. ~~supplement the information in~~ the summary product characteristics (SmPC), ~~and~~ the package leaflet (PL) and the labelling, and should add rather than ~~du~~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 Decentrali~~z~~sed Procedures-Human (CMDh) ~~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 of any educational material~~ may be~~are agreed at EU level. ~~In this case~~Thereafter, drafts of the educational material(s) addressing the key elements should be submitted ~~for assessment~~ by the marketing authorisation holder~~s~~ to the competent authorities of Member States for assessment ~~to~~~~by~~and then be implemented in Member States ~~to the competent authorities of Member States and these educational materials shall implement the key elements~~upon approval ~~of~~by the~~se~~ competent authorities~~of Member States~~.

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.

~~More extensive guidance on requirements for inclusion as an Annex to the risk management plan (RMP) of key elements of the educational material and/or educational materials addressing key elements distributed in the Member States is provided in GVP module V.~~

~~Alternatively, in some casesthe the complete the exact content of educational materials could be agreed at EU levelthe 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 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 the~~se~~~~se~~ ~~national competent~~ authorities ~~on to assist with~~supporting the assessment of such materials, in particular ~~as~~ with regard to ~~thes~~ ~~the~~ format and content. Because of the specificities of the national health-care systems and of how particular risk(s) are ~~relevant to the~~ managed ~~ment of the particular risk(s) addressed~~within these systems, ~~I~~individual Member State~~ss~~ may have additional requirements~~,~~. In this case, ~~and as such~~ the~~is~~ guidance in this Addendum to GVP Module XVI 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.

~~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.~~

~~**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~~ may be agreed during a regulatory procedure, at the ~~moment~~ time of the initial marketing authorisation or in the post-authorisation phase, e.g. after ~~review~~introduction of a new RMP or an update of ~~to~~ 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 ~~ly specific~~ 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.

- ~~Any educational material should focus~~ be specifically designed to fulfil~~on 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.~~

- Educational materials ~~It~~ should not include or be combined with promotional ~~materials~~ elements~~,~~ either direct or veiled (e.g. suggestive images and pictures) ~~for the marketing of the medicinal product~~. ~~Educational materials should be drafted in the official language(s) as required by the Member State.~~

- The methods for dissemination and the target audience in each Member State are determined at national level by the respective ~~each~~ competent authority~~-~~ of the Member State~~s~~.

- Based on the respective target audience, t~~T~~he marketing authorisation holder should provide to each national competent authority ~~of Member States~~ a proposal for ~~an~~ the educational material(s) ~~based on the target audience to whom the material will be distributed~~. The target population determines which ~~is decisive for setting up~~ tool~~medium~~, content, format, language type ~~,~~ and readability level is appropriate for ~~of~~ the educational material. Specific efforts in adaption should be made when targeting ~~, especially if it is directed to~~ patients (see GVP Module XV).

- The competent authorit~~y(~~ies~~)~~ of ~~the~~ Member State~~(~~s~~)~~ where the medicinal product is/will be marketed should review the respective national ~~ly specific~~ version(s) of the educational material(s).

- The marketing authorisation holder ~~may~~ should disseminate the educational material(s) ~~at national level~~in a Member State ~~-~~only after ~~upon~~ approval by the competent authority~~ies of~~ of that Member State~~sAgreement 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. 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 ofin each of the Member States.

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 exercise version control and ensure that it disseminates only the latest agreed version of the educational material is disseminated. The dDate ofreview orauthorisation approval by the competent authority the Member States should be included in the educational material, as reference for healthcare professionals and/or patients reference.

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Without prejudice to the originality of the format of the educational material, it is in the interest of Additionally, for public health that educational material used by different reasons, 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 patient confusion in the target audience. Therefore, marketing authorisation holders are strongly encouraged to share the content of their educational material(s) for the above purposes, upon request from other marketing authorisation holders.may be required by the Member State(s) to have risk minimisation materials with as similar as possible layout, content, colour and format and the use of a common material for all products containing the same active substance is strongly encouraged.

- 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

If no other national requirements apply, Tthe draft educational material should be submitted to the competent authority(ies) ofof (the) Member State(s) as follows:

- with a submission cover letter including information onwith a cover letter and/or request form including the following information should be included in the cover letter and/or request form:
  - the contact point details of the marketing authorisation holdermarketing authorisation holders 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 regulatory procedure which hasving led to the need of the educational material(s) with supportive documents (e.g. CHMP opinion, CMD(h) position and/or European Commission dDecision 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 ~~intended dissemination time~~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 lay-out and, where applicable, images and graphic presentations of the information (e.g. pictures, charts, diagrams, video).

When changes of~~to~~ the risk and/or the need for RMM~~risk minimisation measures~~ ~~are~~have been identified and ~~agreed i.e. resulting in~~ 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 ~~a~~ revised proposals of the educational material for assessment and approval. In ~~If t~~the submission concerns ~~of~~ the revised~~an update of~~ educational material ~~previously agreed with a competent authority of a Member State~~,, the changes to the materials previously approved by the competent authority ~~the agreed material~~ 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~~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;~~;
- ~~-~~a title line 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~~ is recommend~~;~~

- ~~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~~invented ~~name~~ 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:

- b~~B~~bullet points should be used wherever appropriate to present the information clearly;

- m~~M~~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, an unique document identifier should be used on each sheet of the educational material the version number and the date of last revision of the text as the and the date of agreement date of the material by each the national competent authority(ies) of Member State(s) in the format of "<month> <year>" should be provided in the first and last pageon 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).~~

- ~~i~~if the marketing authorisation holder`s and/or product`s logo~~s~~ appear, it~~they~~ should appear only once in each educational material, preferably on the first or ~~and~~ last page, respectively, and should not be larger than the document title.~~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.~~

- ~~F~~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 ~~risk management plan (~~RMP~~)~~ (including its annexes), the product information, ~~(SmPC and PL)~~ and the conditions of the marketing authorisation., ~~i.e. the so-called Annex IIB IID for centrally authorised products and Annex III for nationally authorised products included in a referral or a single PSUR assessment~~PSUSA ~~procedure.~~

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

~~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.~~

~~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.~~

~~be .~~ ~~The SmPC and/or PL may be attached to the educational material and disseminated together; or t~~The educational material may also contain a reference to the website of the ~~national~~ competent authority ~~of~~of the Member State, ~~or~~ the Agency~~,~~ or the marketing authorisation holder`s specific website (see XVI. Add I.7.)~~, as described under section I.7,~~ ~~it~~if ~~when~~ the SmPC and/or PL are made publicly available on these websites.

References to other websites for "more information" will usually not be accept~~ed~~able unless ~~it~~ they refer~~s~~ to the SmPC/PL or unless ~~under~~ 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 ~~as~~ agreed with the competent authority(ies) ~~of~~of Member State(s).

~~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 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.

~~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. 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 MAH. Referring to other medicinal products outside the scope of the educational material is not allowed.~~

~~A statement which encouragesencouraging the reportinging of any suspected adverse reaction and the modalities to report in the competent authority of the Member State should should be also included.~~

XVI. Add I.6. Assessment and publication of educational materials by ~~at~~ the ~~level of~~ 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 ~~or the current work priorities of the authority~~. Nevertheless, an

average timeline of 60 days should be considered for assessment. This is without prejudice to any other timeline defined by ~~the~~ competent authorities at national level.

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

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 ~~holders~~holder's~~'~~ ~~on~~ specific website~~s~~

~~When agreed by the competent authority of the Member State, the marketing authorisation holder~~The m~~M~~arketing authorisation holder~~s~~ may publish ~~-~~the educational material(s) on a specifically dedicated (or other suitable) website~~(or other suitable websites)~~ ~~website~~, provided that the ~~marketing authorisation holder respects~~marketing authorisation holder~~s~~ respects the following:

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