18 November 2015
EMA/772528/2015

Comments received from public consultation on good pharmacovigilance practices (GVP)

GVP Module XVI Addendum I – Educational materials (EMA/61341/2015)

The draft of this module was released for public consultation between 27 April and 30 June 2015. The module has been revised, taking the comments received into account.

Those who participated in the public consultation were asked to submit comments using a specific template.

The comments received are published, identifying the sender's organisation (but not name). Where a sender has submitted comments as an individual, the sender's name is published.

The European Medicines Agency thanks all those who participated in the public consultation for their contributions.

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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

<30Jun2015>

Submission of comments on GVP Module XVI Addendum I – Educational materials (EMA/61341/2015)

Comments from:

Name of organisation or individual
Spanish Association of Pharmacists in Industry (AEFI)

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received (please see privacy statements: http://www.ema.europa.eu/ema/index.jsp?curl=pages/home/general/general_content_000516.jsp&mid *and* http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/02/WC500123144.pdf*).*

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF) (see Introductory cover note for the public consultation of GVP under Practical advice for the public consultation: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/02/WC500123145.pdf).

1. General comments

2. Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
132	1	Comment: It should be very useful for the MAH if the module could specify the period to perform the assessment of educational materials. Proposed change (if any):

Please add more rows if needed.

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 June 2015

Submission of comments on GVP Module XVI Addendum I – Educational materials (EMA/61341/2015)

Comments from:

Name of organisation or individual
Association of the European Self-Medication Industry (AESGP)

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received (please see privacy statements: http://www.ema.europa.eu/ema/index.jsp?curl=pages/home/general/general_content_000516.jsp&mid *and* http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/02/WC500123144.pdf*).*

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF) (see Introductory cover note for the public consultation of GVP under Practical advice for the public consultation: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/02/WC500123145.pdf).

1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment
2	Throughout the document, we suggest replacing “package leaflet (PL)” with “patient information leaflet (PIL)”.
2	In case of national application, there should be a dialogue and agreement between concerned competent authorities of Member States on key elements of educational materials. It would be beneficial to include provisions on process to follow for national competent authorities to ensure harmonisations of educational materials across different markets.
2	This amendment does not apply to the HCP stakeholders. Implementation of the measures by this group and patients however is the most important factor and is measured during effectiveness studies. Is an awareness campaign planned for the concept of risk minimisation / educational materials at the HCP and/or patient level?

2. Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
9	2	**Comment**: Clarification is needed on "*educational programmes*" – please specify the difference between an educational programme and educational material.
14	2	**Proposed change:** *When the development and distribution of educational material are 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.*
15-16	2	**Comment**: We recommend specifying which key elements are referred to and to add a link between the educational materials and the RMP which is agreed at the EU level. **Proposed change:** *…key elements included in annex 10 of the RMP may be agreed at EU level.*
18-20	2	**Comment**: It is mentioned that "alternatively, the exact content of educational materials could be agreed at EU level and also become part of the SmPC and/or PIL…". This sentence is misleading. Indeed, it is previously stated that the aim of the educational material is "to supplement information in the SmPC/PIL" (line 10). It is also not clear what is meant by the alternative. How can educational material become part of SmPC/PIL? How can the exact content of the educational material be agreed at EU level? As stated above and in Module XVI

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
		only key elements to be agreed at EU level to ensure that national particulars can be reflected. Additionally, why should the very same content/text of the educational material added to SmPC/PIL? Again, Module XVI states that it is the purpose of an educational material to amend the information provided in SmPC/PIL but not to duplicate the information.
24-25	2	**Comment:** *"Individual Member States may have additional requirements."* We suggest it is recommended that national competent authorities only have specific requirements/changes when they are required because of specificities of the national health care system relevant to the management of the particular risk(s) addressed.
28-29	2	**Comment:** This sentence seems to contradict in case the exact content of educational materials could be agreed at EU level and both EMA and PRAC/CHMP are involved in the assessment. **Proposed change:** *At the time of implementation, submission of draft educational materials to the European Medicines Agency (the Agency) is not required as the responsibility for the implementation lies with competent authorities of Member States.*
32	2	**Comment**: Suggest amending "will be agreed" to "may be agreed". **Proposed change:** *The need for educational materials may be agreed during a regulatory procedure, at the moment of the initial marketing authorisation or in the post-authorisation phase*
35	2	**Proposed change:** *It should focus on the specific safety concern(s) and provide clear statements and concise messages describing*

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
		actions to be taken in order to prevent and minimise these risks.
37-39	2	**Comment:** We suggest that the Agency clearly defines this principle and states what they consider to be 'promotional material' to avoid potential discrepancy between the Agency and the MAH. We suggest providing clear guidance for this principle (perhaps reinforce points from lines 125-129 in this section and/or expand on those points)
45	2	**Comment:** In different EU member states MAH affiliates can submit their educational materials at different time points. Most affiliates can submit at CHMP opinion; however some NCAs only allow submission at EC decision. These differences in timelines result in some countries in a delay in implementation of these materials, as some EC decisions can take up to almost 1 year after CHMP opinion. **Proposed change:** Align on submission timelines to NCAs in the member states as this will result in availability of the educational materials in the same versions without delays in the individual countries.
46-47	2	**Comment:** What is meant by "or the risk management plan (RMP)."? Shall it be read as "or an approval of a variation for an updated a risk management plan"? A variation to update the RMP is covered by the previous term "variation of the marketing authorisation"
52-53	2	**Proposed change:** *The marketing authorisation holder should provide a proposal detailing the target audience of the material.*
57-58	2	**Comment:**

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
		Proposal to include a statement that the listed requirements for the submission of draft EM are strongly recommended but it is up to the national agency to decide on layout, format and content of this submission package. **Proposed change:** *The draft educational material should be submitted to the competent authority(ies) of (the) Member State(s) as follows if no other national requirements apply:*
59	2	**Comment:** All the points to be listed in the cover letter are part of the Belgian RMA application form. To avoid any repetition of the information (it can be in cover letter or national form or elsewhere), we could propose: **Proposed change:** *The following information must be included in the package:*
60	2	**Comment**: Suggest amending “contact point” to “contact details”. **Proposed change:** *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);*
63-65	2	**Comment**: Include opinion of national competent authority as origin of the request of RMM. **Proposed change:** 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, national competent authority opinion, approved RMP, assessment report identifying the need for this RMM);

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
66	2	**Comment:** "detailed implementation plan for the educational material" can also include frequency of intended dissemination. **Proposed change:** Add a bullet point "intended dissemination frequency"
67	2	**Proposed change:** *- target population(s)*
69	2	**Comment:** Clarification needed regarding "*Intended dissemination time*" – will it be possible to have an "*ongoing*" dissemination time status, if the material has to be disseminated over a longer time period?
71	2	**Comment:** Suggest to give example of "common open text processing electronic format" **Proposed change:** *as documents in a common open text-processing electronic format (such as MS word, XML format) of the proposed materials in language(s) required by the Member State(s);*
75-76	2	**Comment:** Is "**a** Member State" referring to **another** Member State? We assume this is not the case. **Proposed change:** …agreed with the competent authority of the Member State…

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
79-81	2	**Comment:** It is recommended to use the active substance name instead of the invented name. It must obviously be avoided that the educational material looks like promotional material. However, patients are usually familiar with the invented name and not with the active substance name. It should be clear that the same principle applies as for SmPC (predominately use of active substance) and PIL (predominately use of invented name) i.e. who is the target audience.
81-84	2	**Comment:** Each MAH is responsible for its Educational Material (EM). If a combined EM for different MAHs is required, it is suggested that this be coordinated by the Competent Authority (CA) with delegation of this coordination role if appropriate e.g. to national trade associations, in countries where such a system may already be in place to manage communications/activities between the MAHs, and forward this as 'one voice' to the CA. Therefore additional guidance in XVI. Add I.6., would be warranted.
87 & 92	2	**Comment:** The terminology "risk minimisation" is not clear to HCP and/or patients as it is for MAHs and NCAs. The same is true for "important selected risks" in line 92. **Proposed change:** If this terminology is kept as header of the materials, awareness should be created what is mentioned with this terminology. It should not scare the patients, or lead to patients not taking medication.
87-93	2	**Comment:** A specific wording and ordering (Main title, type of material, statement) is imposed in these paragraphs. In Belgium, the following information is present on page 2 of all Educational material:

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		 ance will have to be updated. dispensing" as examples of type of educational . nation for <Healthcare Professionals, Patients>" to clarify the purpose of the educational material; • identifying listing of the type of educational material, e.g. administration guide, dispensing guide, checklist for prescribing, checklist for dispensing, alert card, educational leaflet for the patient; • 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;
93	2	**Comment:** The behaviours of "prescribing/dispensing/administering" usually refer to healthcare professionals. Since educational materials can also target patients, "using" which refers to patient's behaviour can be added to the sentence. **Proposed change:** *…it is advised to be read carefully before prescribing/dispensing/administering/using the product;*
94	2	**Comment:**

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
		When in case of a PRAC referral the educational material is reviewed in detail, the necessity of inclusion of the black inverted triangle might not be given as feedback. **Proposed change:** For efficiency reasons, can the PRAC review of educational materials also address this topic, instead of all individual NCAs afterwards when reviewing the individual local language translations?
106	2	**Comment:** "*No product logos or slogans should be used*." In accordance with national guidelines, we suggest that, to increase recognition, the option to use a product logo should not be excluded. **Proposed changes:** *No product slogans should be used.*
113	2	**Comment**: Key elements are not necessarily agreed at EU level in the case of country specific RMMs. **Proposed changes**: *The educational material should contain the key elements as agreed at EU level or with competent authority of the Member States (in case of national application) 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.*
118-119	2	**Comment:** References to other websites will not be accepted unless it refers to SmPC/PL.

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
		Proposed change: Add that it is allowed to refer to a MAH website or NCA website where the educational material can be downloaded, as this is preferred by stakeholders.
118-119	2	**Comment**: Suggest replacing “unless it refers to” with “unless they refer to”. **Proposed changes:** *References to other websites for “more information” will usually not be accepted unless they refer to the SmPC/PIL.*
120-122	2	**Comment:** It is not clear what the “data” refers to and where the “data” comes from to “support the implementation and hence effectiveness of the RMM” considering the RMM has not been in place yet. **Proposed change:** If supporting data from medical / scientific knowledge/literature is mentioned, this should be mentioned.
125	2	**Comment**: Suggest to amend “the key elements” to “any key elements”. Key elements are not necessarily agreed at EU level in the case of country specific RMMs. **Proposed changes**: *The scope of the information in the educational material should be limited to any key elements agreed at EU level or with competent authority of the Member States (in case of national application).*

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
130-131	2	**Comment**: In certain EU countries (e.g. Italy), the lower reporting rate is also related to the difficulty to retrieve AE reporting forms. To facilitate consumer reporting, it would be beneficial to include relevant AE forms used at national level as part of educational material (as opposed to general statement currently proposed).
130-131	2	**Comment:** Revise or add instructions for educational material in case the medicinal product is under additional monitoring as is done in lines 94-96.
134-136	2	**Comment:** Timelines vary extremely between NCA for approval even if the educational materials do not differ between countries. **Proposed change:** A maximum of 60 days of first round of review at the NCA and feedback to the MAH, with an additional review period of 30 days for the updated materials as submitted by the MAH. In this way the materials are available across EU countries at the same time and this is important for the setup of PASS studies and measuring effectiveness of the materials in different countries.
134-136	2	**Comment:** Current work priorities should not prevent the timely assessment of educational materials and thus impact upon their subsequent distribution to the intended audience. **Proposed changes:** *…e.g. the RMM, the kind of requested educational materials or the quality of the submitted drafts .*

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
137-139	2	Comment: The meaning of the following sentence is not understandable: *"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."* Why does the assessment of the educational material need to be agreed if there is the request for implementation of educational material? Is there not in any case an assessment /approval procedure done by NCAs necessary if implementation of educational material is requested? Irrespective of what regulatory procedure is the trigger?
139	2	**Comment:** In case of a referral with multiple MAHs and/or including MAHs of generic products, the implementation and dissemination also deserves attention during the review at the NCA addressing the multiple involved MAHs. **Proposed change:** Add the following at the end of the 2nd paragraph: *The competent authorities in the member states should decide on an approach for MAHs to implement educational materials in a combined way and one of the MAHs is appointed as the lead MAH. The competent authority interacts with the MAHs as a consortium.*
141	2	**Comment:** The nature of format and the way to send the documents should be decided locally. **Proposed changes:** *The final version of the educational materials, as agreed for dissemination, should be provided to the competent authorities of Member States.*

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
145-147	2	**Comment:** "*Specific websites*" and "*specifically dedicated website*" – Please clarify what is meant by this. It is expected that prescribing physicians would look in the first instance to the product website or company website to get further information about a product. Thus it is felt to be important to have a link to the related educational material on the product website or at least on the company website in order facilitate access to the risk minimisation information. A link to the competent authority website can be an additional tool.
147	2	**Comment:** Specifically dedicated website for educational materials If it is allowed to publish in addition also SmPC and/or PIL on this website to have to complete package of product information, this should become clear from the text. **Proposed change:** Explain clearly that it's not a dedicated website for educational materials in the context as written in the GPV module, but explain clearly that this website is only allowed to give information (via educational materials, PL, SmPC) to patients / HCPs and not intended for any commercial activity.
144-160	2	**Comment:** It should be clarified whether publication of educational materials on the MAH website is seen as a proactive way of dissemination and may replace any other dissemination route or whether publication of educational materials on MAH website is just an additional way of dissemination and may be done in parallel to e-mailing or dissemination performed by sales force during visits.
150-151	2	**Proposed changes:** *A statement that the information of the website is consistent with the material agreed with competent authority*

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
		should be submitted;
150-151	2	**Comment:** Recommend to specify to whom statement of confirmation of consistency needs to be submitted **Proposed changes:** *A statement that the information of the website is consistent with the agreed material should be submitted to the competent authority of the Member State;*
152	2	**Comment:** How should the MAH inform the NCA of the specific website? Via agreement of the initial implementation plan? If after agreement the MAH wants to link to e.g. a patient organisation website with information should the MAH ask for approval at the NCA for each and every update? Is it possible to give guidance to MAHs which links are possible and which are not possible? The background of this bullet point is to not mix up between education/information and commercial activities, but is not clearly written down here.

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12th June 2015

Submission of comments on 'EMA Guideline on good pharmacovigilance practices (GVP) - draft addendum I to module XVI - educational materials' (EMA/61341/2015 DRAFT)

Comments from: AstraZeneca PLC

Name of organisation or individual
AstraZeneca

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received.

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF).

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Send a question via our website www.ema.europa.eu/contact

1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)
3	1) Propose that a portal is set up (as for that for SPC/PILs) where these materials could be placed. That way, all customers (HCPS, patients etc) can be directed from the SPC/PIL to a common place rather than using emails or product specific websites.
3	2) There is no explicit reference to generics; if education applies to all brands for a given generic name (implied by the other GVP modules) then this document should be clear that a combined communication should be distributed by all manufacturers in the concerned territory and that they share equal responsibility for the measure of effectiveness.
3	3) Timelines can be dependent on the current work priorities of the authority – suggest these are more defined – see comment relating to Line 136.

2. Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
Line 37	3	Comment: Line 37 indicates that educational materials should not be combined with promotional materials – we recommend a clarification on this point. Proposed change (if any): " ....not combined with promotional materials but this does not preclude distribution or reinforcement of the message by commercial colleagues".
Line 68	3	Comment: - dissemination method Proposed change (if any): - dissemination method - alternative and new distribution methods should be evaluated
Lines 113/119	3	Comment: This section suggests that it will not be acceptable for Companies to refer to their websites for further information on products. Consumers want information in electronic format so not allowing RMP materials to be on the web is an issue not only for Companies but also for customers. "… 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

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
		"more information" will usually not be accepted unless it refers to the SmPC/PL." Proposed change (if any): Delete or clarify last sentence: "… 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."~~
Line 136	3	Comment: - Timelines Proposed change (if any): - Timelines should be defined in order to avoid different distribution in different countries due to late approval by the local regulatory agencies.

Please add more rows if needed.

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 June 2015

Submission of comments on GVP Module XVI Addendum I – Educational materials (EMA/61341/2015)

Comments from:

Name of organisation or individual
BAGSO Service GmbH
On behalf of “AG Beipackzettel” (Working group for patient-friendly package leaflets)

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received (please see privacy statements: http://www.ema.europa.eu/ema/index.jsp?curl=pages/home/general/general_content_000516.jsp&mid *and* http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/02/WC500123144.pdf*).*

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF) (see Introductory cover note for the public consultation of GVP under Practical advice for the public consultation: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/02/WC500123145.pdf).

1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment
4	Although GVP Module XVI requests selection of appropriate tools, there are no clear standards for appropriateness for meeting principles of patient-friendliness when the material is directed to patients. Therefore we include some points to consider for draft, submission and assessment in these cases. In addition, we would like to point out that the term “educational material” may be conceived negatively. Therefore we suggest “explanatory material”.

2. Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
Lines 52-53	4	Comment: It should be mentioned that the educational material needs to be appropriate for the target population, especially if it is directed to patients. Proposed change (if any): The target population is decisive for medium, format, language and readability of the educational material, especially if it is directed to patients.
Lines 79 -84	4	Comment: The active ingredient will not be meaningful for patients. In the implementation the invented name should be included in the heading or the active ingredient explained in such a way that the patient will be able to refer it back to the product they are taking. Proposed change (if any): 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 for the proposal submitted to the agency, nevertheless in the implementation phase each MAH should insert the applicable invented name for reference for the patient;
Lines 120-122	4	Comment: Patients expect to be provided with a leaflet containing all relevant information. Additional material needs to be weighed carefully in order not to confuse patients about what is to be referred at and what not. This evaluation of course needs happen during the respective procedure. The need and / or appropriateness for any additional

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
		material should be discussed with patient representatives. Proposed change (if any): The need and / or appropriateness for any additional material should be discussed with patient representatives during the respective procedure as Risk Management Plan creation/assessment. The purpose of the educational material should be clarified especially for patients. The relation to the SmPC and the patient leaflet should be clear, again especially for the patients.
Lines 123-124	4	Comment: It remains unclear who is up to decide whether or not in a given material text alone is sufficient or not; in case patient materials are concerned this should be assessed in close co-operation with patient representatives. It is agreed that images and graphic presentations, respectively, should not be promotional. In terms of user-friendliness images and graphic presentations in several cases might be more appropriate to adequately convey a message or are a valuable means to support text and thus preferable to text-only solutions, which is why we feel there should be no unnecessary limitations regarding their use. Proposed change (if any): Update guidance wording in order to soften or remove limitations of use and to reflect patient representative involvement in case patient materials are concerned.
Lines 131	4	Comment: Please add some principles on patient friendliness to be followed. Proposed change (if any): Some key points as suggested by patient representatives for patient leaflets should apply for the educational material as well: The medium should take into account the target population and should make it possible to meet the following criteria:

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
		1. Readable font 2. Comprehensible language – medical terms only if necessary and always in brackets 3. Clear information on disease and mode of action / risk and benefit of the drug 4. Well structured and clear layout 5. Use of pictures and icons / pictograms / visual aids should be also really be visible in the respective medium 6. Use of information boxes 7. Listing additional information / support
Lines 132-143	4	Comment: Authorities should also assess the patient-friendliness of the educational material. Authorities should establish criteria for assessment in cooperation with patient representatives. Proposed change (if any): Especially educational material that is directed to patients should be assessed for appropriateness for patients and patient-friendliness. Authorities should establish criteria for assessment in cooperation with patient representatives.
Lines 142-143 and lines 157-158	4	Comment: The websites should be barrier-free and patient-friendly. Proposed change (if any): The websites should be barrier-free and patient-friendly. Again, criteria should be established in cooperation with patient representatives.

Please add more rows if needed.

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 June 2015

Submission of comments on GVP Module XVI Addendum I – Educational materials (EMA/61341/2015)

Comments from:

Name of organisation or individual
Bundesverband der Pharmazeutischen Industrie e. V. (BPI) - German Pharmaceutical Industry Association

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received (please see privacy statements: http://www.ema.europa.eu/ema/index.jsp?curl=pages/home/general/general_content_000516.jsp&mid *and* http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/02/WC500123144.pdf*).*

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF) (see Introductory cover note for the public consultation of GVP under Practical advice for the public consultation: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/02/WC500123145.pdf).

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1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment
5	With exception of some points outlined below it is clear and appropriate guideline regarding the educational materials.
5	This document should be linked to GVP Module XVI AND GVP Module V

2. Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
9	5	**Comment**: Clarification needed on “educational programmes” –please specify the difference between an educational programme and educational material.
15-16	5	**Comment:** Recommend to specify which key elements are referred to and to add a link between the educational materials and the RMP, which is agreed at the EU level **Proposed change:** key elements included in annex 10 of the RMP
17-20	5	**Comment:** A clear statement should be given under which circumstances which competent authority is responsible for approval of the content of educational material. In cases of disagreement, competent authorities need to agree. Thus, a clear delineation of responsibilities should be mentioned here.
21-25	5	**Comment:** The addendum should also provide clearer guidance to the national competent authorities to ensure that educational material is consistent across Europe and to avoid delays in distribution of educational material due to delayed feedback and discrepant feedback from national competent authorities. **Proposed change:** … as well as guidance for these competent authorities on the assessment of such materials , in particular as regards the format and content, and consistent and timely assessment.
24-25	5	**Comment:** Individual Member States may have additional requirements.

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
		Suggest it is recommended that national competent authorities only have specific requirements/changes when they are required because of specificities of the national health care system relevant to the management of the particular risk(s) addressed.
28-29	5	**Comment:** This sentence seems to contradict in case the exact content of educational materials could be agreed at EU level and both EMA and PRAC/CHMP are involved in the assessment. **Proposed change**: **At the time of implementation,** ~~Submission~~ **submission** of draft educational materials to the European Medicinal Agency (the Agency) is not required as the **responsibility for** implementation lies with competent authorities of Member States.
37-39	5	**Comment:** Suggest that the Agency clearly define this principle and state what they consider to be 'promotional material' to avoid potential discrepancy between the Agency and the MAH. Suggest providing clear guidance for this principle (perhaps reinforce points from line 125-129 in this section and/or expand on those points)
40-41	5	**Comment:** It should also be a principle for the competent authorities that the review time and feedback on the educational material is aligned across Europe in case the educational material is required in more than 1 national country. In general there should be timelines for reviewing the educational material by the competent authorities of the Member State. **Proposed change:** 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 within XXX weeks of submission and will take into

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
		account the core text as agreed at EU Level.
52-53	5	**Comment:** Is it really necessary, that the MAH should provide a proposal of the target population of the material as in 48-51 it is clearly stated that target audience is determined by competent authority(ies)?
69	5	**Comment:** Clarification needed regarding "Intended dissemination time" – will it be possible to have an "ongoing" dissemination time status, if the material has to be disseminated over a longer time period?
81-84	5	**Comment:** Each MAH is responsible for their Educational Material (EM). If a combined EM for different MAHs is required it is suggested that this be coordinated by the Competent Authority (CA) with delegation of this coordination role if appropriate eg to national trade associations, in countries where such a system may already be in place to manage communications/activities between the MAHs, and forward this as 'one voice' to the CA. Therefore additional guidance in XVI. Add I.6., would be warranted.
106	5	**Comment:** "*No product logos … should be used*." Suggest, if in accordance with national guidelines, that to increase recognition, the option to include a product logo should not be excluded. **Proposed change:** No product ~~logos or~~ slogans should be used.
113-119	5	**Comment:**

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
		In case educational material from originator should be used as standard the national competent authority(ies) requesting to follow this educational material should ensure that this educational material is available to the other MAHs. **Proposed change:** In case the educational material should contain the key elements as agreed with the originator, this educational material from the originator shall be submit to the other MAH(s) to ensure that the MAH(s) can use the last valid version.
123-124	5	**Comment:** Why such restriction of use of images and graphical presentation, as it is well known that using these tools may exceedingly helpful to explain and understand many issues.
130-131	5	**Comment:** Revise or add instructions for educational material in case the medicinal product is under additional monitoring as is done in lines 94-96
134-136	5	**Comment**: The timelines for assessment should be specified. Otherwise no harmonised and quick implementation across Europe will be possible. **Proposed change**: The timelines for the assessment of draft educational materials by the different competent authorities of Member States shall be XXX weeks. The feedback to the MAH should be provided in one summarised document.
136	5	**Comment:** Current work priorities should not prevent the timely assessment of educational materials and thus impact upon their subsequent distribution to the intended audience. **Proposed change:**

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
		or the quality of the submitted drafts ~~or the current work priorities of the authority~~
137-139	5	**Comment:** Currently, some national competent authorities are requesting changes to the core text which was agreed on EU level. This should be avoided to ensure a harmonised core text across Europe. Also, different feedback from the same competent authority was received. A standardised process within the competent authorities should be established and followed. **Proposed change:** The national competent authority(ies) shall follow the core text as agreed on EU level. The internal assessment of the national competent authority(ies) shall follow their internal standardised review guidance document(s).
141	5	**Comment:** "… in pdf-format by e-mail". This format may not always be appropriate e.g. in the case that the material is in video format. **Proposed change**: ….provided to the competent authorities of Member states~~ in pdf format by email~~
145-147	5	**Comment:** "Specific websites" and "specifically dedicated website" – Please clarify what is meant by this? It is expected that prescribing physicians would look in the first instance to the product website or company website to get further information about a product. Thus it is felt to be important to have a link to the related educational material on the product website or at least on the company website in order facilitate access to the risk minimization information. A link to the competent authority website can be an additional tool.
144-160	5	**Comment:** It should be clarified whether publication of educational materials on the MAH website is seen as a proactive way of dissemination and may replace any other dissemination route or whether publication of educational

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
		materials on MAH website is just an additional way of dissemination and may be done in parallel to e-mailing or dissemination performed by sales force during visits.
150-151	5	**Comment:** Recommend to specify to whom statement of confirmation of consistency needs to be submitted **Proposed change:** Should be submitted **to the competent authority of the Member State;**

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 June 2015

Submission of comments on 'Guideline on good pharmacovigilance practices (GVP) – Module XVI Addendum I – Educational materials' - EMA/61341/2015 Draft

Comments from:

Name of organisation or individual
EFPIA [redacted]

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received.

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF).

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1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)
6	EFPIA welcome the opportunity to comment on the addendum.
6	The rules set out in the addendum to GVP module XVI should only be applicable to new educational materials.
6	The addendum makes no difference between educational materials for HCPs and those for patients. Some of the principles outlined in the draft may be acceptable for HCPs, but are too limiting for materials prepared for patients. Consideration should be given in adapting the guidance to highlight best practices for each target audience.
6	Educational materials are currently approved at Member States (MS) level based on key messages agreed at EU level. EFPIA prefers the option of providing the exact content (and text) of the material to be agreed at EU level rather than each National Competent Authority (NCA) separately receiving a draft version and then approving individually. Rationale: – Providing the exact content at EU level will be quicker and simpler and ensure greater control over content and format to ensure the objective of the EU RMP is captured correctly. – Awaiting member countries authorisation will likely take additional time and could delay RMP educational material being implemented in the individual countries depending on resourcing and local country timelines. – The RMP educational material should not differ significantly between countries as it is based on the SmPC. Therefore there is no necessity driving any requirements for local variation in content.
6	In the introduction the document should be linked not only to GVP Module XVI but also to GVP Module V.
6	**Comment:** It would be worth considering the addition of the requirement to harmonise the content of educational materials between the reference medicinal product and the generic product. **Proposed change (if any):** In case educational material is requested for a generic product the content of the material should be aligned with the reference medicinal product.

2. Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
Lines 8-32	6	**Comment (see general comments):** EFPIA would prefer a harmonised process for the preparation and approval of educational material at EU level. **Proposed change (if any):** Text needs to be changed as necessary.
Lines 12-14	6	**Comment:** The guideline applying also to nationally approved products including those approved via MRP/DCP, CMD(h) may give a position on key elements at EU level following PRAC recommendations, and marketing authorisations are granted by National Competent Authorities. **Proposed change (if any):** Please add 'CMD(h)' and 'National Competent Authority', in the sentence as follows: "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 Decentralized Procedures (CMD(h)), and are included as a requirement in the marketing authorisation granted by the European Commission or the National Competent Authority for the medicinal product in question, as applicable,...
Lines 15-16	6	**Comment (see general comment):** EFPIA would prefer a harmonised process for the preparation and approval of educational material at EU level. **Proposed change (if any):** Please complete the sentence as follows: "..., as applicable, ~~key elements may~~ the exact content of what should be included in the educational material should be agreed at EU level."

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
Lines 18-20	6	**Comment:** It should be clarified that the existence of educational material is referenced in the SmPC/PL but not their actual content. **Proposed change (if any):** '~~Alternatively, t~~The exact content of educational materials ~~could~~ should be agreed at EU level and also be referenced ~~become part of the~~ in the summary of product characteristics (SmPC) and/or the package leaflet (PL), as applicable.'
Lines 24-25	6	**Comment** (see also general comments): The objective of this guidance should be to replace existing national guidances and reduce the national diversity. This document does not allow the agreement at EU level on the exact content of the educational materials, unless they are included in the SmPC or PL. In addition, the document alludes to individual member states having additional requirements. As educational materials are a key risk minimisation measure, it would be more efficient to 1. Allow for a procedure through which all national educational materials are agreed at EU level. 2. Suggest it is recommended that NCAs only have specific requirements/changes when they are required because of specificities of the national health care system relevant to the management of the particular risk(s) addressed. All national requirements should be documented in this addendum.
Lines 28-29	6	**Comment:** This sentence seems to contradict in case the exact content of educational materials could be agreed at EU level and both EMA and PRAC/CHMP are involved in the assessment. In addition, draft educational materials might be submitted as part of a EU RMP (mock-ups in annexes 10 and 11) for EMA evaluation so the statement that they do not need to be submitted to EMA is possibly not correct.
Lines 32-33	6	**Comment:** It would be helpful to provide more information about various regulatory procedures which may result in the

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
		need to prepare or update educational materials. It is likely, for example, that they may be required when such a procedure requires EU RMP creation or update (i.e. initial MAA, safety variation, PSUR procedure). **Proposed change (if any):** '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, e.g. after review of a new RMP or update to an existing RMP.'
Lines 35-36; 97	6	**Comment:** The text says that statements should be "clear" and "concise", but it fails to make clear the need to limit the number of messages. Many educational materials suffer from information "overload" instead of focussing on the main safety concerns (often patients with no medical education). **Proposed change (if any):** Mention the need to focus on the most essential risks and how to prevent them.
Line 37	6	**Comment:** It would be helpful to include the statement that the material itself should not be promotional and thus does not need to follow the rules on promotion.
Line 38	6	**Comment:** The document mentions the need to draft the text in the official language(s) as required by the MSs. In case of educational material for patients the need to write in user-friendly language that is easy to understand for the lay reader should be highlighted as well. **Proposed change (if any):** Include focus on patient-friendly language.
Lines 40-42	6	**Comment 1:** Some NCAs only require the submission and subsequent approval of educational materials under certain circumstances, e.g. for new/extended indications or only for the first approval. It should be clarified in general

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		that only new educational material or major updates require approval. It should be added that simple layout changes do not need to be approved again. **Comment 2:** Educational materials do not need to be disseminated by the MAH only. They could, for example, also be distributed by the NCAs which should be reflected in the text. In addition, it would be worth specifying the situation when the product is authorised but not placed on the market. **Proposed change (if any):** Agreement should be reached before it is disseminated ~~by the marketing authorisation holder~~ at national level. In case the product is authorised but not placed on the market in the respective country it is not required to submit the materials for approval to the competent authority of that Member State. **Comment 3:** The text (in various sections) refers to the dissemination of the material by the MAH at national level. It does not address the need for parallel distributors and parallel importers to disseminate material although they can also be MAHs. It should be made clear that parallel distributors – if they hold a marketing authorisation - also need to prepare and disseminate educational material. For centrally authorised products, parallel trade does not require additional national licenses. Patient safety, however, should not depend on the regulatory status of the product. If, for MRP and DCP, all MAHs are obliged to disseminate educational material, parallel distributors of CAP should also participate in this task. **Proposed change (if any):** Include obligation for all parallel traders/ distributors to prepare and disseminate educational material.
Lines 43-47	6	**Comment:** In specific cases where additional information (e.g. black triangle) is introduced to the SmPC via a variation procedure the educational material needs to be updated accordingly. In such cases it would take quite a long

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		time until the new information appears in the educational material if an extra submission is required at national level. **Proposed change (if any):** No extra national submission and approval of the educational material should be required for such changes.
Line 45	6	**Comment:** In different EU member states MAH affiliates can submit the national version of the educational materials at different time points. Most NCAs allow the material to be submitted after CHMP opinion/ CMDh position. However, some NCAs allow for submission only after the EC decision is available. These differences in timelines can result in significant delays regarding the implementation of the materials. This could be avoided if a harmonised process for the preparation and approval of educational materials is introduced (see general comments). **Proposed change (if any):** Harmonise the submission timelines across MSs (see also comment lines 134-136).
Lines 48-51	6	**Comment:** The document states that dissemination of educational materials agreed at EU level is mandatory. It should be made clear that dissemination is only required in those MS where the product is/ will be placed on the market. In addition, the pattern of use of some products may vary greatly from one MS to the other and systematic distribution in all MSs may not be necessary. Therefore it should be made clear that it is appropriate for a NCA to decide that dissemination is not required. **Proposed change (if any):** "...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."
Lines 52-53	6	**Comment:** Consider to delete the bullet point as this is covered under 'XVI Add I.3 Submission of educational materials'.

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Line 63	6	**Proposed change (if any):** ~~The marketing authorisation holder should provide a proposal of the target population of the material.~~ **Comment:** Considering that the development and distribution of educational material could result from a voluntary initiative from the MAH and is part of the RMP for both centrally and nationally authorised products (including those authorized via MRP/DCP), the wording "request" in the paragraph below may not be appropriate: "- the origin of the request with supportive documents..."
Line 65	6	**Proposed change (if any):** "- the origin of the regulatory procedure ~~request~~ having led to the need for educational materials with supportive documents..." **Comment:** Insert 'additional' before risk minimisation measure
Line 68	6	**Proposed change (if any):** '...for this additional RMM.' **Comment:** Examples for dissemination could be given.
Line 69	6	**Proposed change (if any):** - dissemination method (paper, electronic formats such as QR codes or publication on websites); **Comment:** The item "intended dissemination time" is ambiguous and can be interpreted both as the time when dissemination is anticipated to start and/ or the period during which the dissemination is required. Please clarify.
Lines 77-106	6	**Comment:**

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		There is too much focus on the format. In fact, customer feedback so far shows that educational material is often regarded as too stale, too long and just not encouraging to read. In reality any material that is longer than 1 page has little chance of being read at all. If standard phrases are to be included, they should be clearly separated and put towards the end of the document. **Proposed change (if any):** The important safety messages should be highlighted and the focus should be to get the PV-message through.
Lines 79-81	6	**Comment:** It is recommended to use the active substance name instead of the invented name. However, patients are usually more familiar with the invented name and not with the active substance name. It should be made clear that – according to the target audience - the same principle as for SmPC (predominately use of active substance) and PIL (predominately use of invented name) should be applied.
Lines 79-84	6	**Comment:** In case multiple MAHs are concerned Outside a pre-existing agreement such as licensing or multiple licences from one single licensor, an agreement between companies may not be possible/ easy to reach. Are there any plans to coordinate the content and format of the educations material at the level of the competent authorities? What will be the review procedure? **Proposed change (if any):** Clarification required on the coordination and agreement on the content of the educational material in case of multiple MAHs (a MAH cannot impose a text to another MAH). Additional guidance and provisions regarding the joint preparation in sections XVI. Add I.3. and XVI. Add I.6. would be warranted.
Lines 87-88; 92	6	**Comment:** EFPIA support the idea of having a common heading for these materials but the proposed title "Important Risk Minimisation Information" is not considered patient friendly. The terms "risk minimisation" and "important

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		selected risks" may not be understood by the target audience. **Proposed change (if any):** "Important safety information approved by the European Medicines Agency"
Line 93	6	**Comment:** Since educational materials can also target patients, "using" which refers to patients could be added. **Proposed change (if any):** "...it is advised to be read carefully before prescribing/dispensing/administering/<u>using</u> the product;"
Lines 98-99	6	**Comment:** Please consider providing further guidance regarding what is meant by "long" educational materials, such as the total word count.
Line 106	6	**Comment:** "No product logos or slogans should be used." Suggest that in order to increase recognition, the option to include a product logo should not be excluded. **Proposed change (if any):** "<u>Product logos should be</u> used <u>restrictively and</u> no product ~~logos or~~ slogans should be included."
Lines 117-118	6	**Comment:** The document suggests that, should the educational material direct the reader towards a website, this should be to the website of the NCA or to the EMA website. However, MAHs are not able to ensure that these websites are updated in a timely manner nor can they guarantee that the SmPC or PL is made available in the easiest format for the end user. Consideration should be given to allowing MAHs to link to a company website, especially to the website described under point I.7. **Proposed change (if any):** "...; or the educational material may contain a reference to the website of the competent authority of the

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		Member State or the Agency when SmPC and/or PL are made publicly available on these websites, or the company website described under point I.7." Add that it is allowed to refer to a MAH website or NCA website where the educational material can be downloaded.
Line 119	6	**Comment:** Suggest deleting the sentence. Reference to a website might be useful under specific circumstances, e.g. to refer to a form on a specific antibody test or to refer to a video that instructs the patient how to take the medicine. **Proposed change (if any):** ~~"References to other~~ websites ~~for 'more information' will usually not be accepted unless it refers to SmPC/PL."~~
Lines 120-122	6	**Comment:** It is not clear what the "data" refers to. **Proposed change (if any):** If supporting data from medical/ scientific knowledge/ literature is meant this should be clarified.
Line 122	6	**Comment:** Insert 'additional' before risk minimisation measure **Proposed change (if any):** '...of the additional RMM.'
Lines 123-124	6	**Comment:** Given health literacy and other factors, images & graphic presentations might optimise receipt of the safety message and are important tools to enhance readability for the user; even when text alone might be sufficient to convey the key elements. **Proposed change (if any):**

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
Lines 134-136	6	Images and graphic presentations of the information may be used along with ~~should only be used when~~ text ~~alone~~ ~~is insufficient~~ to adequately convey the key element(s) and should not be promotional. **Comment:** It is important to define/ harmonise timelines for review and approval of educational materials in order to avoid significant delays in the process, with information being disseminated to the audience several months after the identification of a significant risk. We propose that the exact content of the educational material is already approved during the regulatory procedure from which it originates. The timelines for (national) approval of the translation should be harmonised. Current work priorities should not prevent the timely assessment of educational materials and thus impact upon their subsequent distribution to the intended audience. **Proposed change (if any):** ~~The timelines for the assessment of draft educational materials by the different competent authorities of Member States may vary depending on e.g. the additional RMM, the kind of requested educational materials or the quality of the submitted drafts. or the current work priorities of the authority.~~ Timelines for assessment will be defined at EU level when they are the outcome of a referral or PSUR assessment procedure. In other cases, assessment timelines will be tailored according to the risk. In case of new marketing authorisations the exact content of the educational material should be agreed within the procedure in order to obtain approval before the Commission Decision is available to ensure timely access for patients to the new medicine.
Lines 137-139	6	**Comment:** More information would be helpful. We understand that no national submission and approval is required if the educational material is the outcome of a referral or PSUR assessment procedure. **Proposed change (if any):** Please provide more details.
Lines 140-141	6	**Comment:**

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
		Details how and in which format the final version of the educational material has to be provided to NCAs should allow for flexibility. **Proposed change (if any):** The final version of the educational materials, as agreed for dissemination <u>at EU level</u>, should be provided to the competent authorities of Member States ~~in pdf format by email~~ <u>for information in accordance with national requirements.</u>
Lines 142-143	6	**Comment:** Educational materials are a key RMM, and consideration should be given to ensuring that CAs in all MSs where the product is on the market publish them.
Lines 144-160	6	**Comment:** It should be clarified that - if agreed with the NCA - publication of educational materials on the MAH website is seen as a proactive way of dissemination and may replace any other dissemination route.
Line 147	6	**Comment:** Educational materials on a specifically dedicated website **Proposed change (if any):** Explain clearly that it's not a dedicated website for educational materials alone, but that this website can also contain SmPC/ PIL or RMP summary to provide HCPs and patients with all relevant information
Line 149	6	**Comment:** No access can be given to a publically available website. **Proposed change (if any):** "~~access to~~ the website address should be given to the competent authority of the Member State;"
Lines 150-151	6	**Comment:** Recommend to specify to whom the statement of confirmation of consistency needs to be submitted.

Please add more rows if needed.

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 June 2015

Submission of comments on GVP Module XVI Addendum I – Educational materials (EMA/61341/2015)

Comments from:

Name of organisation or individual

European Generic and Biosimilar Medicines Association (EGA)

[redacted]

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received (please see privacy statements: http://www.ema.europa.eu/ema/index.jsp?curl=pages/home/general/general_content_000516.jsp&mid *and* http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/02/WC500123144.pdf*).*

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF) (see Introductory cover note for the public consultation of GVP under Practical advice for the public consultation: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/02/WC500123145.pdf*)*

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1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment
7	EGA welcomes the opportunity to comment on newly drafted GVP Module XIV Addendum I – Educational materials.
7	As a general comment to the addendum it would be beneficial if information about the role and life cycle management of the RMPs in relation to the educational material would be included, especially as educational materials should be annexed to the RMP. It would also be of advantage to organise the information in individual sections depending on the type educational material, the type of applications/marketing authorisations and the type of assessment, as the same requirements may not always apply: • Individual sections to include guidance for different type of educational materials such as HCP communications, printed brochures/leaflets/posters, on-line material or when the information becomes a part of the PI document, respectively. • Specific sections to include guidance for licenses approved by different types of application e.g. individual sections for innovator, generic and hybrid marketing authorisations respectively. • Specific sections depending on whether the educational material is required based on an assessment of a single marketing authorisation application (such as first in class) or when a number of marketing authorisations from different MA holders are affected (such as PRAC assessment of a safety concern) respectively.
7	Furthermore, EGA fears that this document does not bring any further clarity on how EMA and NCAs intend **to ensure consistent approach in message to patients throughout EU from different MAHs**, taking into account un-matching lifecycles and changes. More thoughts on different levels of harmonisation follow below.
7	**Guidelines for educational materials - innovator products vs. generic products** As mentioned in these draft guidelines, key elements may be agreed at EU level, but the actual draft educational materials are proposed to be submitted on a national level to competent authorities of Member States in order to implement these key elements. However, in most cases, CAs request generic companies to be harmonised with the educational material of the innovator. Therefore, it would be appreciated if the following comments/questions could be addressed in the guidelines:

Stakeholder number (To be completed by the Agency)	General comment
	– As the guidelines are presented now, the key elements should be drafted into educational materials and submitted on a national level. There is no reference to whether generic companies should preferably harmonise to the innovator's educational material for sake of EU harmonisation and for sake of providing same level of information to target groups (i.e. not draft 'new' material based on the key elements). – If the general guidance for generic companies is to follow the educational material of the innovator product, will there be any proposed procedures for providing the latest agreed version of the educational material of the innovator's product? Has EM database for intercompany sharing been considered?
7	**EU harmonisation of educational materials** Since the key elements have been shown to be quite short descriptions of the additional risk minimisation measures, the actual final educational material can be subject to great variations, both between Member States and between MAHs. To ensure harmonisation on EU level, it is strongly preferred that the EU agreement will normally cover more details than only the key elements. This will ensure the same level of information to all patients or healthcare professionals, irrespective of the Member State or if the product is from an innovator or a generic. Different assessment may therefore be avoided across the Member States, thus reducing both the preparation resources and the assessment resources. In return, this can reduce the time from identification of the risk until the information reaches patients and healthcare professionals. EGA believes that for alignment between different MAHs, both for core as well as national documents, NCAs could and should take a higher profile role and strive to harmonise the documents. Harmonised educational material between Member States is also important in case of on-line publication (internet). Otherwise, confusion may arise especially in bi- and trilingual Member States. The information should be e.g. identical in the German language for the population in AT, DE and BE, which then results in BE, FR and NL needing to be harmonised as well. The same may apply to IE/UK/MT and SE/FI. In case of pack sharing, the educational material could be shared as well.
7	**Harmonisation of educational material across procedures (CP/DCP/MRP)**

Stakeholder number (To be completed by the Agency)	General comment
	To ensure harmonised approach on EU level, it is preferred that educational material is drafted in English for the initial assessment by the CAs, i.e. on a procedural level (at the same time/following assessment of the RMP, since the educational material is an appendix in the RMP). This would encourage more harmonisation across EU and decrease resources, both with regard to preparation and assessment in each Member State. The assessed English version ('core version') would then be translated into official language(s) of each Member State in the procedure and adjustments could be made in line with local practice and requirements. The translations/nationalised versions would finally be assessed by the individual authorities and the need for distribution on a local level decided. This would also simplify version control and content control (reduce the need of back translations) by the MA-holder. More concretely, for products following decentralised procedures (DCP): If Reference Member State (RMS) is of the view that educational material is needed and in order not to delay the access to the generic medicines on the market, the content of educational materials (i.e. key elements) should be agreed already during the DCP procedures, i.e. in Day 70 Assessment Report. In the national phase, translation and additionally required elements (if any) would be incorporated.
7	**Assessment of RMPs including additional risk minimisation measures** Since the RMP for an active substance can include different licences from different regulatory procedures (e.g. DCP and national licences), how can the annexed example of the educational material (usually in English) represent the educational material for all of the different Member States, if the material is not harmonised and CAs might have different opinions? Also, in case of generic products, some CAs of Member States could conclude that the educational material is not needed for the generic product in question, or propose substantial changes. Should this be in any way noted in the appendix of the RMP, or is this appendix only considered to be an example of a version that is perhaps not applicable to all of the Member States included in the RMP? Furthermore, it is not quite clear in cases where e.g. HCP communication is listed in the appendix, and was meant for one-time distribution for the licences included in the RMP. At what point would this educational material be considered as 'known risk' (and already implemented to SmPCs/PLs), and would not need to be distributed in cases where more licences might be added to the RMP sometime later? i.e. is there a procedure proposed for removing or archiving 'historical' educational material from the RMP?
7	**Format**

Stakeholder number *(To be completed by the Agency)*	General comment
	Some more clarification would be helpful as regards the format as well, for example: • There is no reference to use only one colour, e.g. the MHRA insists on this. • No detailed guidance is provided on different formats that would be deemed acceptable in CA opinion. • There are no templates/ examples of an acceptable format provided, e.g. standardised template, font sizes etc. for patent alert cards, brochures...
7	**Timelines and Distribution** • No clear timelines for each step in the life cycle is provided in this guideline, hence expectations are very unclear towards MAHs, especially generics. • The same challenge in case of dissemination time and expected re-dissemination periods (i.e. once before the launch or every 2 years, to remind the HCP) – no details provided. • Concrete examples of distribution methods that would actually guide MAHs would be welcome. • Guidance for cases when generic product is not launched until 2-3 years following MA approval (e.g. due to patent status) would be appreciated, especially in case of HCP communications where information to be included in SmPCs and PLs is announced (i.e. when is the information considered to be 'known risk', hence already distributed by the "first" MAH and implemented in SmPCs/PLs for quite some time, and the distribution of the HCP communication is considered unnecessary). • More clarity or examples how MAHs could properly define the target audience would be needed.

2. Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
Lines 16-20	7	Comment: Paragraph should be phrased more precisely. Proposed change: In this case, draft educational materials with the key elements should be submitted to the competent authorities of Member States for their approval and these educational materials should be implemented upon approval of the MS. Alternatively, the exact content of educational material could be agreed on an EU level. ~~and~~ The information may also become a part of the PI document, such as the summary of product characteristics (SmPC), labelling and/or the package leaflet (PL), as applicable.
Lines 18-20	7	Comment: Proposed change:
Lines 30-55	7	Comment: Additional bullet-point is proposed to be added. Proposed change: • Collaboration of the various MAH should be considered in all applicable cases in order to prepare common materials.
Line 38	7	Comment: Please refer to general comment 'Harmonisation of educational material across procedures (CP/DCP/MRP)' above.

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
Lines 48-51	7	Comment: It is mentioned in the draft guidelines that when the need for educational material is agreed at EU level, the dissemination of the educational material is "mandatory". In many cases, CA authorities conclude that dissemination of educational material is not necessary for generic products since the innovator is already distributing the material. According to current practice, this paragraph does therefore not entirely apply to generic products and is recommended to be revised/explained further.
Lines 52-53	7	Comment: Please rephrase the sentence. Proposed change: The marketing authorisation holder should provide a proposal of the target population ~~of the material~~ to whom the materials will be distributed.
Line 62	7	Comment: Please clarify what exactly is meant by 'the route of authorisation', i.e. type of procedure or procedure number. An example would be welcome.
Line 69	7	Comment: Besides "intended dissemination time", re-dissemination periods should be provided in GVP as well. Examples should be given about intended dissemination time and expected re-dissemination periods i.e. once before the launch or every 2 years (to remind the doctors). Please see also general comments.
Line 75	7	Comment 1: Guidance needs to be more detailed and include instruction about when updated educational material needs to be

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
		submitted to the CAs, e.g. only in case of update of the key safety elements OR also following amendments to supplementary information initially included in the material (e.g. paragraphs from SmPC) or even company name change, contact detail changes etc. Comment 2: The RMM is an appendix to the RMP. Clarifications on when RMPs need to be submitted due to RMM updates would be appreciated, and then in which scenarios.
Lines 78-106	7	Comment: Is the described format required in case the educational material is included in the pack, e.g. as an alert card (and thereby a part of the product information document). This is unclear here and should be defined more specifically.
Lines 79-84	7	Comment: This paragraph might be explained further for clarity whether the guideline is referring to consortium of certain MAHs that agree to publish/distribute in a joint venture. Moreover, this might be feasible for physician's educational material and not for the patient, who might not recognise the link between the material and the medication, since patients are not usually familiar with active substances.
Lines 87-88	7	Comment: The proposed title line is very user unfriendly and could be confusing and not appropriate for patients. If this standard sentence is only a recommendation, i.e. not mandatory, it should be stated that this is the *preferred* title line and that other may apply in specific circumstances. In case of a mandatory use the standard translation to all official EU/EEA languages would be appreciated. Moreover, in the past the MHRA has informed one of EGA member companies not to refer to this as educational material – and in no part does the guidance ask to refer to the document as Educational Material. To avoid being

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
		misleading consider amending the title of this guidance from Addendum I - "Educational Material" to either Addendum Educational Programmes or Addendum I - "Important Risk Minimisation Information for <HCPs/Patients>".
Lines 89-90	7	Comment: It is preferred that this sentence includes that the additional title line is *recommended*, i.e. in case it is not mandatory, since different approaches might apply in specific circumstances.
Lines 94-96	7	Comment: Is it deemed necessary to include the black symbol and the explanatory standard sentence in all cases of educational material for these products? The explanatory standard sentence would already be included in the SmPC/PL and according to lines 120-122 in the draft guidelines, repetitions of information already presented in SmPC/PL should be avoided.
Lines 100-101	7	Comment: A clear definition of the date of agreement would be needed, i.e. is this date of agreement of the educational material in the Word version of the material or in the final printed version? Also, it might look strange in cases such as booklets, where a random date is printed on each page without further explanations. In these cases, it would be preferred to have a standard sentence on the *last page* (such as in Package Leaflets), that the material was last revised in <month><year>.
Lines 104-106	7	Comment: Contradictory sentence, since e.g. MHRA prefers no use of Company Logo at all. Cleary state that use of logo should be avoided or at least define in which cases (countries) can be used.
Lines 130-131	7	Comment: Instead of mandatory it would be preferred that this is *recommended* to be included, depending on the size of the

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
		material and the information given (e.g. in the case of patient alert cards included in the package which are considered to be additional risk minimisation measures). Additionally, this statement is already included in the SmPC/PL and, as also defined in this guideline in lines 120-122, repetitions of information already presented in SmPC/PIL should be avoided. Proposed change: A statement encouraging the reporting of any suspected adverse reaction and the modalities to report in the competent authority of the Member State could be included.
Lines 134-136	7	Comment: (1) We propose indicating in the guideline, if not already fixed timelines, at least maximum allowed time for the review of educational material by the NCA – e.g. 30 days, which is also duration of the national phase after the MRP/DCP. (2) Since the educational material normally includes the most important safety information for safe use of products, which is communicated immediately or for a longer periods of time, the wording 'the current work priorities of the authority' seem to lessen the importance of these activities. Especially in the context of compliance requirements for MAHs of submitting safety variations and RMPs the approval and implementation of educational material can be a very important outcome of the whole assessment. All involved stakeholders should follow defined timelines and there should not be any excuses for delaying the approval of the material. Hence, this part should be deleted. Proposed change: Although 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 submitted drafts, the maximum assessment time should not exceed 30 days.

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
Lines 137-139	7	Comment: Further clarification would be needed whether this means that: (a) English common version/core version of the educational material will be assessed only, accompanied with further assessment of translated national version, following the finalisation of the assessment procedure or (b) Each Member State will assess individually proposals in their own official language during the referral/single PSUR assessment procedure?
Line 140	7	Comment: 'The final version of the educational material' refers to the artwork for the educational material, presented as a pdf? This might be explained further.
Line 142	7	Comment: We would strongly encourage commitment of NCAs to do all efforts to publish agreed educational materials, in terms of transparency to patients. We believe that words 'may' and 'as applicable' reduce the authorities' responsibility. Proposal: Competent Authorities of Member States should publish agreed educational materials on their websites.
Lines 146-148	7	Comment: Please clarify whether publishing educational materials on a website is meant instead of distributing the paper version or in addition to the paper version distribution.
Lines 152-153	7	Comment: This request is clearly far from pragmatic and typical use patterns, as well and not patient/HCP friendly – no target audience is willing to endure numerous click-through attempts etc. The main electronic entry for all participants in the market for a specific company's product is the company's website.

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
		It is feasible to have a separate page with approved educational materials, SmPC and PIL only, but this is in domain of the company and no restrictions from the NCAs should be applicable as such, especially given the fact that NCA can/should publish the agreed educational material. Such a requirement in the world wide web is beyond the web realities/social media and electronic communication. Possible option would be NCAs establishing URLs by INN with a suitable top-level domain. Proposal: This bullet point should be deleted or at least rephrased to reflect the above comment.
Line 154	7	Comment: When the official language is the same in more than one Member State, it is even more important that the educational material is harmonised on an EU level, as discussed above in the general comments. Patients/HCPs/caregivers search the internet for information and different information found in the same language may cause confusion. *Example to clarify further:* A product approved in all EU via a single DCP procedure and the name of the product is the same in all Member States. In the package leaflet, a list of the product name in all Member States is included (in line with QRD-template). Educational material may be found on-line for Irish and UK patients, but the CAs in these Member States did not come to the same conclusion so that the information is not harmonised, although it is the same product. The same may apply for SE/FI and BE/NL/FR/DE/AT (partly).
Lines 157-158	7	Comment: This request is not very clear and might be hard to avoid in scenarios where the product name is frequently the same in different Member States and the official language might be the same (or partly the same, e.g. FR/BE). Some further clarification would be welcome.

Please add more rows if needed.

June 22, 2015

Submission of comments on GVP Module XVI Addendum I – Educational materials (EMA/61341/2015)

Comments from:

Name of organisation or individual
IFAPP (International Federation of Associations of Pharmaceutical Physicians & Pharmaceutical Medicine

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received (please see privacy statements: http://www.ema.europa.eu/ema/index.jsp?curl=pages/home/general/general_content_000516.jsp&mid *and* http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/02/WC500123144.pdf*).*

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF) (see Introductory cover note for the public consultation of GVP under Practical advice for the public consultation: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/02/WC500123145.pdf).

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Send a question via our website www.ema.europa.eu/contact

1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment
8	It is a good and concise guideline, but we raise your attention to 3 issues as follows.

2. Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
Line 68	8	Comment: at present the dissemination method is left to the decisions of the National Authorities Proposed change (if any): we suggest that this guideline suggests more modern dissemination methods (email, website, social media, patients associations). Usually National Authorities are asking for a paper distribution, which is very expensive and time consuming, and possibly not so efficient as an electronic distribution.
Lines 79-84	8	Comment: ……. 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** Proposed change (if any): in several cases, the disclosure of the invented name is very important to better address the safety message. We propose to delete this sentence or, at least, to delete the words in **bold.**
Lines 134-136	8	Comment: 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…** Proposed change (if any): the approval times may vary significantly among different National Authorities, which is not in the spirit of harmonization. We propose to specify a maximum deadline for the approval time.

Please add more rows if needed.

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

2 July 2015

Submission of comments on Draft Addendum to GVP Module XVI guidance for marketing authorisation holders on the submission of draft education materials to the competent authorities (EMA/61341/2015 Draft)

Comments from:

Name of organisation or individual
International Plasma Fractional Association (IPFA)

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received.

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF).

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Send a question via our website www.ema.europa.eu/contact

1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)

2. Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
141	9	Comment: When does the pdf-format of the agreed material should be provided to the CA ? Proposed change (if any):
144-145	9	Comment: The title is not understandable Proposed change (if any) : Publication of educational materials on marketing authorisation holders ~~on~~ specific websites
150-151	9	Comment: To whom and when should the statement be submitted? Proposed change (if any):
152-153 And 157-158	9	Comment: About information on line 157-158: does this means 1) that the website should only be accessible in the member State (and not in member states where the product is not marketed) or 2) that the specific website should not mention any other not marketed products ? if this is the case, this give the feeling that other marketed products can be mentioned. Proposed change (if any): Clarify ; if the response is 2) remove sentence in lines 157158 and modify line 152-153 as follows : The specific website should not include any reference to documents or to other websites/pages or other products (marketed or not) or weblinks not agreed with the competent authority of the Member State;

Please add more rows if needed.

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 June 2015

Submission of comments on GVP Module XVI Addendum I – Educational materials (EMA/61341/2015)

Comments from:

Name of organisation or individual
International Patient Organisation for Primary Immunodeficiencies (IPOPI)

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received (please see privacy statements: http://www.ema.europa.eu/ema/index.jsp?curl=pages/home/general/general_content_000516.jsp&mid *and* http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/02/WC500123144.pdf*).*

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1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment

2. Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
15-16	10	Comment: key elements agreed at EU level, Have these key elements been set down? Proposed change (if any):
17-18	10	Comment: shall implement the key elements Proposed change (if any):have to include the agreed key elements
23	10	Comment: competent authorities Proposed change (if any):enter after this: to assist with the assessment etc
28-29	10	Comment: if the educational material could be part of the package leaflet and of the summary of the product characteristics, the Agency should have already received the draft educational materials for its incorporation in such documents. Proposed change (if any): only in the case that the educational material shall not be part of the package leaflet or of the summary of the product characteristics of a centrally approved medicinal product, the Agency shall not be required to receive the draft of such material.
32	10	Comment: at the moment of Proposed change(if any): at the time of

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
42	10	Comment: Should there be a timeline?
53	10	Comment: Should this not be agreed between the MA and the MS?
103	10	Comment: should be exception, not exceptions, unless this was meant to be " appropriate exceptions"
122	10	Comment: hence effectiveness Propose changes : to strengthen the effectiveness etc

Please add more rows if needed.

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

3 July 2015

Submission of comments on GVP Module XVI Addendum I – Educational materials (EMA/61341/2015)

Comments from:

Name of organisation or individual
Medicine Evaluation Board NL

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received (please see privacy statements: http://www.ema.europa.eu/ema/index.jsp?curl=pages/home/general/general_content_000516.jsp&mid *and* http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/02/WC500123144.pdf*).*

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF) (see Introductory cover note for the public consultation of GVP under Practical advice for the public consultation: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/02/WC500123145.pdf).

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1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment

2. Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
Lines 48-51	11	Comment: If the educational material has been already disseminated in a particular MS for another product containing the same active substance, then a repetitive dissemination of the same material to the same group of HCPs is not desirable and should be avoided. Therefore, it is correct to state that the need for dissemination of any educational material should lie with a competent authority in each of the MSs. Proposed change (if any): We suggest to remove the statement that the dissemination of the material is mandatory if agreed at EU level
Line 57	11	We suggest to add 'updated educational material' in addition to the 'draft educational material' (Line 57) to keep consistency in the submission of initial and updated educational material to the competent authorities.
Line 80	11	It would be helpful for MAHs and competent authorities to provide guidance on the situations when an update of the educational is required. We suggest to add "An updated version of the educational material should be submitted for assessment to the competent authorities in case important changes to the risk or risk minimisation measures are identified and agreed i.e. resulting in changes in the key elements.
Lines 79-83		Comment: We propose to rephrase the statement on the need to mention the invented names to make it clear that in all cases where different products containing the same active substance share the same risk(s) being addressed by an educational material, the active substance only should be mentioned on the material and a list of the invented names in the Member State should be annexed. Proposed change (if any): Invented name of the medicinal product followed by 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

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
		only and a list of the invented names in the Member State should be annexed.
Line 74	11	Comment: complement the list of requirements for submission of educational materials. Proposed change (if any): we suggest to add that competent authorities in Mss may have additional requirements regarding the submission of educational materials for assessment.
Line 138	11	Comment: We do not agree with the statement “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.” Material still needs to be submitted on a national level. There may be English wordings that have been agreed. Proposed change (if any): “If the request for implementation of educational materials follows a referral or a single PSUR assessment procedure, it may be possible that English wordings will be agreed as part on the procedure outcome. In this case translations can be agreed during the national implementation”.

Please add more rows if needed.

30 June 2015

Submission of comments on GVP Module XVI Addendum I – Educational materials (EMA/61341/2015)

Comments from:

Name of organisation or individual
PHARMIG – Association of the Austrian pharmaceutical industry

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received (please see privacy statements: http://www.ema.europa.eu/ema/index.jsp?curl=pages/home/general/general_content_000516.jsp&mid *and* http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/02/WC500123144.pdf*).*

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF) (see Introductory cover note for the public consultation of GVP under Practical advice for the public consultation: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/02/WC500123145.pdf).

1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment
12	PHARMIG welcomes the opportunity to comment on the draft GVP Module XVI Addendum I – Educational materials.
12	In our opinion the draft is very unspecific and provides too much room for interpretation and negotiation with NCAs, e.g. the timelines for the assessment of draft educational materials by the different competent authorities of the Member States.

2. Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
18 to 19	12	Comment: Currently it is stated that “Alternatively, the exact content of the 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.” However, if the exact content of the educational materials become part of the SmPC and/or PL this means that there are no longer any additional risk minimisation measures as they become with such a possibility routine risk minimisation measures. In such a situation the additional risk minimisation measures become a routine risk minimisation measure. **Is this intended?** Proposed change (if any): “Alternatively, the exact content of the 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**. In such a situation the additional risk minimisation measures become a routine risk minimisation measure**”.
28 to 29	12	Comment: It is mentioned that “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.” However, it should be clarified that in accordance with GVP Module V Annex 11 a provision of “mock-ups” is still required. Proposed change (if any): Please add after line 29: “**However, it is required to provide finally approved mock ups in English (or the national language if the product is only authorised in a single Member State) of the material provided to healthcare professionals and patients as a requirement of Annex II of the commission decision or as a requirement of national authorisations including those using the mutual recognition or decentralised procedure as applicable as Annex 11 to the RMP”.**
100 to 103	12	Comment:

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
		Currently it is mentioned “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).” According to long experiences with educational materials this is not recommended as for example implemented different educational materials i.e. as part of a whole healthcare professional kit may not be always updated on the same time due to different impact of a variation for example. If in such a situation a whole healthcare professional kit will be provided i.e. to a new prescriber the versioning of the educational materials as well as the “<month> <year>” on each sheet may differ and will lead to confusion or even rejection of receipt of such a kit. Proposed change (if any): “for version control, **an unique document identifier should be used on each sheet of the educational material and the date of last revision of the text as the agreement** date of the material by the competent authority(ies) of Member State(s) in the format of “<month> <year>” **should be provided on the first and last page**, unless the type of educational material requires an appropriate exceptions (e.g. a video should have this information appearing at its beginning and end).” Additionally this allows for internal coding and version control at the MAH.
110	12	Comment: Currently it is mentioned that “...conditions of the marketing authorisation, the so-called Annex IIB for centrally authorised products and...”. However, the key elements of educational materials are captured in Annex IID (conditions or restrictions with regard to the safe and effective use of the medicinal product). Proposed change (if any): “...conditions of the marketing authorisation, the so-called Annex II**D** for centrally authorised products and...”.
125 to 126	12	Comment: Currently it is stated that “The scope of the information in the educational material should be limited to the key

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
		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, sometimes it is an Annex IID requirement to have a patient organisation review of the educational materials. To bring the risk into context it may be sometimes beneficial and even recommended by patient organisation to include some efficacy data to enhance adherence of medicinal product intake. Further, the text should be also in line with the provided mock-up educational materials as Annex 11 to the RMP as the mock-ups are approved together with the RMP. Proposed change (if any): "The scope of the information in the **draft** educational material should be limited to **the text of the mock-up educational materials as provided in Annex 11 to the approved RMP** as well as 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 inclusion of efficacy data may be possible.**
134 to 136	12	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. Comment: The timelines for safety related matters with impact on public health should be defined by the Agency and not be dependent on current work priorities of the NCA. Proposed change (if any): The timelines for the assessment of draft educational materials by the different competent authorities of Member States are to be defined by the Agency (e.g. 90 days).

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
142 to 143	12	Comment: It is mentioned that “Competent authorities of Member States may publish agreed educational materials on their websites as applicable.” In such a situation it should be clarified that the Competent authorities of Member States are responsible for updating and maintaining the website with the latest agreed versions. Further, only the latest versions and not also outdated versions should be made available to reduce confusion on information for patients as well as healthcare professionals. Proposed change (if any): Competent authorities of Member States may publish agreed educational materials on their websites as applicable. **In such a situation the Competent authorities of the Member States are responsible for the solely provision of the latest agreed versions of the educational materials.**
144 to 145	12	Comment: There seems to be a typo in “XVI. Add I.7. Publication of educational materials on marketing authorisation holders **on** specific websites” Proposed change (if any): “XVI. Add I.7. Publication of educational materials on specific websites owned by marketing authorisation holders”

Please add more rows if needed.

<16 June 2015>

Submission of comments on GVP Module XVI Addendum I – Educational materials (EMA/61341/2015)

Comments from:

Name of organisation or individual
Pierre Fabre

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received (please see privacy statements: http://www.ema.europa.eu/ema/index.jsp?curl=pages/home/general/general_content_000516.jsp&mid *and* http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/02/WC500123144.pdf*).*

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF) (see Introductory cover note for the public consultation of GVP under Practical advice for the public consultation: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/02/WC500123145.pdf).

1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment
13	1) There is no information on what to do when a document becomes obsolete: modalities of recall, destructions of obsolete version. Is there any guidance to follow? 2) There is no information for generic products and the requirement to have the same documents for all MAH (princeps and generics) 3) If our medicinal product is a combination of more than 5 active substances, do we have the opportunity to mention the invented name more than once instead of repeating the long combination of the multitude of active substance. 4) It will be very helpful for MAH to have an equivalent to the document published by CMDh *on Requirements on Submissions for Periodic safety update reports (PSUR) to National Competent Authorities (NCAs) for products authorised via National Procedures, MRP and DCP* (NAPs) with the local requirements for modalities for dissemination of Educational material. Example: word version, mock-up…

2. Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
52	13	Comment: add the opportunity given to MAH to provide a proposal of deadline for dissemination of the educational material Proposed change (if any): The marketing authorisation holder should provide a proposal of the target population and of deadline for dissemination the material.

Please add more rows if needed.