29 September 2017
EMA/646647/2017

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

Module XV – Safety communication (EMA/118465/2012 Rev 1*)

The draft of this module was released for public consultation between 15 December 2015 and 29 February 2016. 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.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
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< February 25, 2016>

Guideline on good pharmacovigilance practices (GVP)

Module XV – Safety communication (Rev 1)

Comments from:

Name of organisation or individual
Asociación Española de Farmacéuticos de la Industria (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

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')*
519-523		Comment: In order to arrange for one marketing authorization holder to act on behalf of all concerned marketing authorization holders as the contact point for the national competent authority, it could be necessary to mention the role of the competent authority in this process or to provide more detail about how this process should be performed. Proposed change (if any):
623-624		Comment: Could it be possible to include some information about the potential role of the competent authority in the coordination or collaboration between different MAHs involved to be in agreement with a single consistent message to be sent to healthcare professionals in each EU Member State? Proposed change (if any):
		Comment: Proposed change (if any):

Please add more rows if needed.

29 February 2016

Submission of comments on 'Guideline on good pharmacovigilance practices (GVP) – Module XV (Rev 1)' – EMA/118465/2012

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).

7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

1. General comments

Stakeholder number ***(To be completed by the Agency)***	General comment (if any)
General Key Point 1 XV.C.2.1. 510 -518	**Processing of DHPCs:** The concept of a "core EU DHPC" is considered very helpful. It is proposed to keep differences across the EEA to a minimum in order to ensure a single message to patients and healthcare professionals; to reduce individual NCA time and to increase efficiency and speed of communication. It is helpful to have a Core message and it is proposed for an additional template be provided for the Core DHPC to ensure consistency of core message. In addition, any follow-up discussions by national HAs of messages agreed at EU level should be avoided, therefore it is suggested guidance is provided in order to be able to adapt DHPCs and stronger wording is suggested: *Although there will be national tailoring of such DHPCs, any core messages agreed at EU level ~~should~~ need to be preserved (i.e.* tailoring should not conflict with these core messages).
519 -530	It is noted that MAHs are strongly encouraged to arrange for a single contact point to the NCA(s) to ensure that a single DHPC is sent. This would be considered difficult to achieve as well as impractical to manage, particularly with some of the rapid timeframes typically associated with these types of communications. Although this seems to make sense, the MAHs have concerns as to how this would work in practice and the legal implications of one MAH acting on behalf of other MAHs. It is unclear how this can be achieved unless other steps are taken, e.g. • A single point of contact is also established at the level of the NCA(s), • The extra tasks required for the lead MAH to be able to act on behalf of others MAHs (e.g. legal agreements, cost sharing) are acknowledged, • Some/all timelines are adjusted in case a lead MAH is involved. It is strongly suggested that such a scheme is better described in the GVP, and that EMA/NCAs put in place some steps that can enable such a coordination role.

Stakeholder number ***(To be completed by the Agency)***	General comment (if any)
	An alternative would be for the NCA(s) to take on some of the tasks that could be allocated to the lead MAH, e.g. translation of DHPC, dissemination of the DHPC on behalf of all MAHs. There is no appropriate platform amongst MAHs (originators / generics) to discuss and coordinate these activities. Therefore, another alternative is that the EMA or NCA is requested to act as a facilitator of an ad-hoc (virtual) platform meeting, e.g. teleconference/Adobe Connect. In this way identified MAHs can join and decide how to coordinate appropriate efforts, including appointment of/to volunteer as lead MAH. Another proposal is to choose the coordinator for a common DHPC based on a volunteer basis or based on market share
General Key Point 2 **XV.C.2.2.** 551-555	"The draft translations should be submitted to the Member States for a language review within a reasonable timeframe (no more than ~~two~~ 4-5 working days)." This change is helpful. However, this time can be too short, especially if a lead MAH needs to reconcile and obtain agreement on translations from other MAHs. It is recommended that the time remains flexible and appropriate according to the urgency of the proposed change and safety issue. Conversely NCAs should also follow a strict time for their review, especially as DHPCs are a key tool for patient's safety. **Proposed change:** 'The draft translations should be submitted to the Member States for a language review within a reasonable timeframe (ideally no more than 4-5 working days). The review of the translations by the NCAs will also be carried out within a reasonable timeframe (within 48 hours).'
General Key Point 3	**Removal of references to GVP Modules that will not been developed** It is noted that the update to the GVP contains the removal of references that were previously in the text to other GVP

Stakeholder number ***(To be completed by the Agency)***	General comment (if any)
	modules, as these modules will not be developed. For GVP Module XI or XIV: this has now been replaced by the Agency's webpage on Partners & Networks. It is not clear on this page with which partners the EMA will exchange information in the context of the activities described in C.1.2. It is recommended that a specific section is developed on the website that identifies clearly which authorities outside the EU the EMA collaborates with pro-actively on the exchange of safety information.
General Point	Consider the use of stakeholders rather than parties, audiences etc e.g. lines 91 – 93; 125; 164.

2. Specific comments on text

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes
XV.A 71/72		The objective of the following statement does not provide clear purpose of the document: "coordinate safety information... in particular to support achieving quality objectives of pharmacovigilance". **Proposed change:** "…communicate and coordinate safety information concerning medicinal products authorised in the EU, to support the pharmacovigilance objectives. Both standalone risk communication and risk communication as a risk minimisation method are in scope for this document."
77		"Safety communication is a broad term covering different types of information …" **Proposed change:** (which is accordance with CIOMS IX): Safety communication is a risk minimisation strategy covering different types of information…
81		"The module itself focuses on the communication of 'new or emerging safety information" **Proposed change:** "The module itself focuses on the communication of important new or emerging safety information." This therefore would align with 91: "Communication of important new safety information on medicinal products should take into account the views and expectations of concerned parties including patients and healthcare professionals."
95		"some aspects" Further clarity on what this document includes and excludes, and the rationale why would be helpful. **Proposed change:** This Module…..with concerned parties including XX. XX is excluded from this module because…."
XV.B.1. 119		"supporting risk minimisation behaviour." Suggest the following text: supporting risk minimisation measures (since safety communication spearheads risk minimisation planning and may target more than just behaviour modification as indicated in 117-118 is probably redundant).
132 – 133		The sentence as it is written is confusing. **Proposed change:** 'should be part of ~~the~~ considering the options for safety-related action'
143		"Information on risks should be presented in the context of the benefits of the medicine…" This implies the use of a benefit risk profile structure ("*presented* in the *context…*). Can the Agency provide guidance on

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes
		this (and also the use of tools noted in line 154) as relevant for this Module in order to ensure consistency across companies in presentation of the BR, (and BRB), and thus the resulting consistency for all stakeholders?
156-157		"Patients and healthcare professionals should, where possible, be consulted and messages pre- tested early in the preparation of safety communication, particularly on complex safety concerns." Although the adjective "possible" is used here, it is not realistic to be able to pre-test safety communication in the Module context of "new or emerging safety information" as that might cause delay, which should not occur. Furthermore, will there be any guidance in the Module now or in the future on "patient" involvement?
160		"The effectiveness of safety communication should be evaluated where appropriate and possible." This statement has significant impact since per GVP legislation, "measurement of effectiveness" is a PASS (given that "Safety Communication" in the context of this Module is a risk minimisation tool, i.e., DHCP. (See 223). Please clarify what parameters of effectiveness need to be measured, i.e., process and or outcome indicators especially since DHPCs would spearhead a risk minimisation plan including the use of other risk minimisation strategies such as removal of a medicinal product from market, or restriction, which by default would need to be measured for effectiveness as a PASS. Please provide clear additional guidance here and similarly for the information in lines 339 - 343.
165; 173		For the Agency to be clear and recommend to uniformly indicate what the target audience is for this module, for example is it: "Patients, carers or consumers, and healthcare professional(s) (organisations)."
XV.B.4. 189-192		It is assumed that this section refers to any change in the product information relevant for the issue in scope of the communication **Proposed change:** information on any proposed change to the product information… relevant for the issue in scope of the communication. And A list of literature reference….. be found, relevant for the issue in scope of the communication.
193-194		Suggest including a reference to reporting trade name and batch number. This is useful for all AE/ADR reports, but particularly for those biologics with a specific safety concern where a DHPC is required. "where relevant, a reminder of the need to report suspected adverse reactions in accordance with national spontaneous reporting systems, including product name and batch information"

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes
XV.B.5. 201/202		"various means" **Proposed change:** " Relevant communication tools and channels"
XV.B.5.1. 208		The GVP acknowledges that a DHPC can be delivered directly to individual HCPs **by a competent authority**. However, chapters relating to the handling of DHPCs, in particular regarding measuring their effectiveness (B.6) or their processing (C.2.1), all activities are described as applying to MAHs. It is recommended that clarification is added to highlight that these also apply to DHPCs delivered by NCAs. **Proposed change**: amend text in B.6 and C.2.1. to reflect obligations of NCAs when they are the actors in the delivery of DHPCs.
210-211		It is unclear why the statement "nor are they meant as educational material for routine risk minimisation activities" has been removed, and it is suggested that it is reinstated.
217-218		Propose that additional guidance is provided here. Ideally the HA(s)/agency would take on the coordination role for a unified message affecting products of multiple MAHs in cooperation with the MAHs. Only then one message for one issue would be provided once to the target audience. Propose adding a cross reference to line 521. Proposed change(s): Where there are……normally be delivered. Refer to XV.C.2.1 for further details when a DHPC covers several products, and therefore, requires collaboration between multiple MAHs.
224-225		"A DHPC may be an additional risk minimisation measure as part of a risk management plan (see GVP Modules V and XV)." Suggest adding Module XVI as well.
236		New evidence in itself should not be a reason for considering a DHPC. The assessment of the new evidence in relation to existing evidence and the existing risk–benefit balance may change that risk benefit balance and only in that case should a DHPC be considered. Proposed change (if any): "new credible evidence that the medicinal product is not as effective as previously considered and which changes the risk-benefit balance for the product;"
XV.B.5.2. 249-251		"Communication should be in lay language" - it would be helpful if the guidance specifically mentioned that materials should be developed consistent with principles of health literacy and numeracy.
XV.B.5.6.		"~~Adequate~~ Where possible, mechanisms should be introduced in order to measure the effectiveness of the communication

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes
331-332		~~based on clear objectives~~." Suggest that greater clarification be provided to sponsors as to when and how they should evaluate the impact of a DHCP. Implementation of mechanisms to measure the effectiveness of the communication should be considered only when possible and when truly proportionate to the risk to implement, to prevent over-usage of these mechanisms and disproportionate workload and costs. **Proposed change**: "~~Adequate~~ Where possible and appropriate, mechanisms should be introduced in order to measure the effectiveness of the communication ~~based on clear objectives~~.."
364-369		The two sentences are redundant and theparagraph could be optimized. **Proposed change**: "Only safety announcements that relate to topics of major health relevance and that pertain to active substances contained in medicinal products authorised in more than one Member State require exchange and coordination within the EU regulatory network:
XV.C.1.1. 404-409		Should the safety announcement and possible other communications e.g. DHPC, not be coordinated and cross-referenced? Consider addition of this sentence to 406 "For situations where a DHPC is also required, this should be coordinated and cross referenced with the DHPC".
420-421		Consider giving the detail of the international partners with whom safety announcements will systematically be shared, as this is not easy to identify when looking at the alternative source of information for GVP XIV. (http://www.ema.europa.eu/ema/index.jsp?curl=pages/partners_and_networks/general/general_content_000212.jsp&mid) It is important for companies to know who these international partners are, so that companies can be pro-active communication with these while the procedure in the EU is ongoing.
488 / 546 / 553		Referral has been deleted and replaced by "EU procedure for safety reasons". This implies that procedures other than referral are relevant here while it not clear enough to which procedure the text refers to. **Proposed change:** " EU procedure**s** for safety reasons, such as referral, … " to be completed with other examples to better define the scope.
XV.C.2.1. 510-518		While it is agreed that in certain situations (such as differences in available therapeutic alternatives) there may be differences between member states, which would warrant different DHPCs (based on a core DHPC), the differences

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes
		between the DHPCs across Europe should be kept to a minimum and should not lead to the addition of local information and requirements on top of the core DHPC. The more information that's included in a DHPC and the more different DHPCs are across Europe, the more the actual message will be diluted. Also, the possibility of tailoring DHPCs on a national level will result in additional authority review time (i.e. not only review of translation, but also review of country-specific information to be added) and potential resulting delays in finalisation and publication of the DHPCs across Europe. It is proposed to strictly limit and specifically describe the additional information in local DHPCs. **Proposed change**: "The core EU DHPC can then be complemented at national level only with additional information to address the different national situations ~~(for example~~ in relation to availability and choice of alternative treatments~~)~~. It would be useful to develop a template for the core DHPC, alongside the template already listed in Annex II to highlight which sections of the DHPC are more likely to contain the messages that should be preserved across the EU. It is not clear how marketing authorisation holders will be able to identify all other marketing authorisation holders that have products to which a DHPC applies in a given Member State (or the extent to which national trade associations might play a role in helping identify relevant marketing authorisation holders). It would be helpful if the guide provided additional information about how affected marketing authorisation holders might identify each other and work together as contemplated in the proposal.
519-530		Regarding the request for MAH to coordinate DHPC for same active substance. This may work well for same active substance and the same safety issue. However, for products of the same therapeutic class (but different active substances) it is considered that this could be confusing to healthcare professionals since not all active substances of the same therapeutic area may be affected. We would ask the Agency to consider this and provide additional clarity on expectations. **Proposed change:** "(i.e. when the DHPC covers several products with the same active substance and the same safety issue ~~or products of the same therapeutic class~~)" *"Where generics are involved, the contact point should normally be the marketing authorisation holder of the originator product."* In the context of safety communication, it is not considered relevant to distinguish between the MAH role of an originator

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes
		and generic product. It is more appropriate to have a shared responsibility of the significant workload independent of the MAH role. This relates to the comment on lines 521-523 regarding multiple MAHs: all concerned MAHs should be able to volunteer, as this will also depend on the specific case. **Proposed Change:** Where generics are involved the contact point should normally be ~~the marketing authorisation holder of the originator product~~ be chosen based on a volunteer basis or based on market share in the concerned country.
545		The flow chart does not illustrate the steps added in this revision of the GVP Module, in particular: • when and how the decision will be made on a core EU DHPC, • when and how the decision will be made to appoint a lead MAH, and on the activities needed for this appointment.
XV.C.2.2. 554-556		It is unclear with the "core DHPC" concept why and how the EMA is expected to receive the complete set of all final EU official language versions. Further clarity on this point could be helpful.
XV.C.2.3. 557		It would be appreciated, if the affected MAH(s) is informed about the publication prior to release. Proposed change(s): "The competent authorities may publish the final DHPC and notify the MAH of the intent to publish."
561 (Figure VX.1)		Left rhombe-shaped box "Issue concerns CAPs or products subject to EU procedures" Unclear what is meant by "products subject to EU procedures". **Proposed change:** Please write "Issue concerns CAPs or products subject to EU procedures <u>for safety reasons</u>" to be in with terminology of line 546.
562		**Editorial comment:** Correct typo in figure title from VX to **XV**.
562-565		Figure VX.1: Flow chart for the processing of Direct Healthcare Professional Communications (DHPCs) in the EU does not include reference to the Core EU DHPC nor the process for preparation, approval and translations of local versions, which would be helpful. **Proposed change:** Figure VX.1 be updated to include reference to the Core EU DHPC and preparation, approval and translations of local versions of the DHPC.
Annex II DHPC template		Suggest to include reference to reporting product name and batch details here. Proposed change: "<A reminder…….national spontaneous system. <u>For biological medicinal products, also include a reminder to report the product name and batch details.</u>

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes
607		

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25th February 2016

Submission of comments on Guideline on good pharmacovigilance practices (GVP) Module XV – Safety communication (Rev 1) (EMA/118465/2012)

Comments from:

Name of organisation or individual
Gilead Sciences International Ltd

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30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
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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')*
73-77		Comment: Removal of detailed text and reference to communicating safety information to meet quality objectives. Proposed change (if any): It would be helpful to add the text from Module I section I B 4.
261-263		Comment: Clarity sought on whom exactly involves patients and HCPs in the preparation of lay language documents as there is still some confusion regarding the expectation of dissemination of the safety communication as an MAH. Proposed change (if any):
511-518		Comment: With both a core EU DHPC and nationally-implemented DHPC, does this mean that a physician gets two letters or that across Europe you could get different letters depending on the member State? Also clarity is sought on how the national tailoring of DHPCs would be policed. Proposed change (if any):
519-531		Comment: When the DHPC covers the same active substance of drugs of the same class and one MAH is strongly encouraged to work on behalf of all of the others, the reality of how this would happen commercially is difficult and this concept is a significant change from previous guidance. Proposed change (if any):
624		Comment: Clarification sought on the level of information required for the 'DHCP recipients' section. Would

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')*
		this be as shown in the template e.g. GPs, nurses or actual names of the recipients? If specific names are needed, this would be a huge undertaking and may possibly raise a question in some of the countries regarding data privacy. Proposed change (if any):

Please add more rows if needed.

29 February 2016

Submission of comments on GVP Module XV – Safety Communication (Rev 1) (EMA/118465/2012)

Comments from:

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

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1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment
	PHARMIG, the association of the Austrian pharmaceutical industry welcomes the opportunity to comment on the draft GVP Module XV – Safety Communication (Rev 1).

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')*
524-525		If no originator product is marketed in a Member State, it is encouraged that one generic company acts as the contact point. Comment: The wording is different from the wording in the Annex II – Templates: Communication Plan: If no originator product is marketed in the Member State, it is encouraged that the concerned generic companies acts as contact point for the competent authority. Proposed change (if any): We suggest to align the wording in the two documents and change the sentence in the communication plan to "one generic company".
		Comment: Proposed change (if any):
		Comment: Proposed change (if any):

Please add more rows if needed.

<29/02/2016>

Submission of comments on 'Guideline on good pharmacovigilance practices (GVP)

Module XV – Safety communication (Rev 1)'

(EMA/118465/2012 Rev 1)

Comments from:

Name of organisation or individual
[redacted] and [redacted] on behalf of the REGenableMED consortium

Please find below the answer to the 'Guideline on good pharmacovigilance practices (GVP) Module XV – Safety communication (Rev 1)' by the REGenableMED consortium.

REGenableMED - REGenableMED is a United Kingdom Economic and Social Research Council (ESRC)-funded project (N°ES/L002779/1: http://www.york.ac.uk/satsu/regenablemed/). It brings together research team builds on work by social science experts based in Birmingham, Edinburgh, Sussex and York in the UK. It is coordinated by [redacted], Science and Technology Studies Unit at the University of York, UK. The project aims to examine the dynamics of innovation within the field of regenerative medicine. Using a mixed-methods social science approach, the project will undertake a detailed analysis of the interplay between business models, measures of clinical utility, patterns of regulatory oversight and clinical workflows within healthcare settings. The results of the research will inform strategies aimed at facilitating the responsible development of effective and useful regenerative medicine products and services.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
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All work packages of the project consider what we call the ‘institutional readiness’, i. e. the capacity and willingness of key pre-existing organisations and inter-organisational structures to adopt, respond to and utilise novel technologies, such as advanced therapy medicinal products as part of regenerative medicine. One work package led by [redacted], Centre for Global Health Policy, School of Global Studies, University of Sussex, the UK is dealing with the role of a range of intermediary agencies, patient groups and health insurance companies, in determining what can be called 'healthcare readiness' for the field, that is, how the field aligns with and can be embedded in existing practice and how far changes need to be made. As part of this work a regular survey of regulatory tools (including relevant linked public consultations) that influence the pathways through which the field develops is performed. The draft response has been prepared by [redacted], academic lawyer, with [redacted], sociologist. A discussion between persons interested was then organised and the attached answer circulated to all project participants before submission.

The REGenableMED consortium is grateful to the European Medicines Agency to have been given the opportunity to contribute to this consultation.

1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)
	All the partners of the REGenableMED project are aware of the existence of this draft Guidance. We welcome the opportunity to review this 'Guideline on good pharmacovigilance practices (GVP) Module XV – Safety communication (Rev 1)'. Apart from one specific comment, the revisions in the text are highly relevant and well provided.

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 73- 76		Comment: Why would this text be deleted? The deletion of this text has no link with the purposes of Revision 1 as they have been detailed from lines 6 to 20. This text should be kept as the public health objective is highlighted. It is even more relevant since the explicit extension of EU competency in public health for medicinal products. Proposed change (if any):
		Comment: Proposed change (if any):
		Comment: Proposed change (if any):
		Comment: Proposed change (if any):
		Comment: Proposed change (if any):

Please add more rows if needed.