EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 October 2015
EMA/710507/2015

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

GVP Module VIII Addendum I – Requirements for transmission of information on non-interventional post-authorisation safety studies (Rev 2) (EMA/395730/2012)

The draft of this module was released for public consultation between 11 August and 9 October 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

8 October 2015

Submission of comments on GVP Module VIII Addendum I – Requirements for transmission of information on non-interventional post-authorisation safety studies (Rev 2) (EMA/395730/2012)

Comments from:

Name of organisation or individual
ACRO (Association of Clinical Research Organizations)

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	Outcome *(To be completed by the Agency)*
	The Association of Clinical Research Organizations (ACRO) represents the world's leading, global clinical research organizations (CROs). Our member companies provide a wide range of specialized services across the entire spectrum of development for new drugs, biologics and medical devices – from discovery, pre-clinical, proof of concept and first-in-man studies through post-approval and pharmacovigilance research. With more than 110,000 employees engaged in research activities around the world (including 30,000 in Europe), ACRO advances clinical outsourcing to improve the quality, efficiency and safety of biomedical research. Each year, ACRO member companies conduct more than 9,000 clinical trials involving nearly two million research participants in 142 countries. On average, each of our member companies works with more than 500 research sponsors annually. ACRO welcomes this opportunity to comment on the draft Addendum to the Module VIII pharmacovigilance guidance and appreciates that the Addendum clearly summarises the current requirements of the competent authorities in the EU for transmission of information on non-interventional post-authorisation safety studies (PASS). ACRO is concerned, however, that there is an	

Stakeholder number *(To be completed by the Agency)*	General comment	Outcome *(To be completed by the Agency)*
	unnecessary level of complexity in these requirements. ACRO therefore recommends and encourages the EU regulatory network to simplify and harmonise the transmission requirements.	

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')*	Outcome *(To be completed by the Agency)*
Table VIII Add I.1. Studies imposed as an obligation by a competent authority		Comment: ACRO welcomes the clarity on current requirements shown by the table. However, ACRO encourages the competent authorities of the EU regulatory network to simplify requirements by moving to a position where the same requirements apply in all Member States. If this is not possible at this time, ACRO further encourages the EU regulatory network to work towards achieving this position and further revising the guideline in the near future. For instance, ACRO questions why it is considered necessary by all Member States except Denmark that information must be submitted directly to the competent authority as well as via the PRAC. In the interests of simplification of requirements and reducing the administrative burden on organisations conducting PASS imposed by a competent authority, ACRO recommends that all competent authorities accept transmission of information via the PRAC without the need for additional direct submissions. Proposed change (if any): Modify the table to indicate that all competent authorities accept transmission of information via the PRAC without the need for additional direct submissions.	
Table VIII Add I.2. Studies initiated, managed or		Comment: Again, ACRO welcomes the clarity on current requirements shown by the table. However, ACRO encourages the competent authorities of the EU regulatory network to simplify requirements by moving to a position where the same	

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')*	Outcome *(To be completed by the Agency)*
financed voluntarily by marketing authorisation holder		requirements apply in all Member States. If this is not possible at this time, ACRO further encourages the EU regulatory network to work towards achieving this position and further revising the guideline in the near future. Additionally, ACRO notes that the proposed revision of the main Annex VIII guideline on PASS seeks to make a distinction in the text of the guideline between legal requirements and recommendations. ACRO recommends that this should be done also for the Addendum. For instance, while there are benefits to including non-imposed PASS conducted voluntarily by the marketing authorisation holder in the EU PAS Registry (transmission to some Member States via the registry, and the desire to apply the same level of transparency, scientific and quality standards to all PASS), the proposed revisions to the Addendum do not make clear that there is no legal requirement to include voluntary, non-imposed studies in the registry. However, given that all EU competent authorities have access to the EU PAS Registry, ACRO questions why it is also considered necessary to submit the required information directly to the competent authorities of several Member States when information is included in the registry. In the interests of simplification of requirements, reducing the administrative burden on organisations conducting voluntary PASS, and encouraging the inclusion of voluntary PASS in the registry,	

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')*	Outcome *(To be completed by the Agency)*
		ACRO recommends that all competent authorities accept transmission of information via the registry without the need for additional direct submissions. Proposed change (if any): Modify the table to indicate that use of the EU PAS Registry is recommended but not a legal requirement for voluntary PASS and that, if the registry is used, all competent authorities will accept transmission of information via the registry without the need for additional direct submissions ACRO thanks the EMA for the opportunity to submit comments on this consultation. Please do not hesitate to contact us if we can provide additional information [redacted]	

Please add more rows if needed.

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

9 Oct 2015

Submission of comments on Guideline on good pharmacovigilance practices (GVP) – Module VIII Addendum I – Requirements for transmission of information on non-interventional post-authorisation safety studies (Rev. 2) – EMA/395730/2012 Rev. 2

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)	Outcome (if applicable) *(To be completed by the Agency)*
	The format of this addendum could be further improved to clarify the MAH requirements, i.e. to whom and how to send what, as it is currently very difficult to follow, which has a potential to create a risk of misunderstanding requirements and even worse regulators may not be receiving the right documents. EFPIA's current understanding is that the addendum seems to require that the same document is sent via different routes to the same recipients. EFPIA strongly recommends that efforts are made to reduce this redundancy.	
	To provide comprehensive information on requirements for the transmission of information, it would be welcomed if expected timelines for transmission of information could be specified in this addendum in line with recommendation provided in the Module VIII revision 2, lines 218-220.	

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')***	Outcome ***(To be completed by the Agency)***
Addendum I (1st paragraph) – Statistical analytical plan		*Where the full statistical analytical plan is not included in the protocol, it should be reported following the same requirements as for the study protocol.* **Comment:** The use of the word "reported" is unclear: it could be interpreted as "transmitted" (as in "sent" or "communicated") rather than "reported" since the term "reported" is not consistently used elsewhere. It should also be clarified whether amended statistical analytical plans following substantial amendments need to be transmitted as per the protocol. Especially how much detail is required in the SAP beyond what is currently already provided as part of the protocol itself. **Proposed change:** *This Addendum specifies requirements for the transmission of study protocols, updated protocols following substantial amendments, statistical analysis plans, updated statistical analysis plans following substantial statistical analysis plan amendments, final study reports and progress reports if requested on post authorisation safety studies initiated, managed or financed by marketing authorisation holders voluntarily or pursuant to an obligation. Where the full statistical plan is not included in the protocol, it should be ~~reported~~ transmitted following the same requirements as for the study protocol."*	
First paragraph		**Comment**: It is recommended to mention the scope of this addendum in order to clarify that it applies to non-interventional studies. **Proposed change**: • *This Addendum specifies requirements for the transmission of study*	

<table>
<tr><th>Line number(s) of the relevant text

(e.g. Lines 20-23)</th><th>Stakeholder number

(To be completed by the Agency)</th><th>Comment and rationale; proposed changes

(If changes to the wording are suggested, they should be highlighted using 'track changes')</th><th>Outcome

(To be completed by the Agency)</th></tr>
<tr><td></td><td></td><td>protocols, updated protocols following substantial amendments, final study reports and progress reports if requested on non-interventional post-authorisation safety studies initiated, managed or financed by marketing voluntary or pursuant to an obligation.
• Table VIII Add I.1. Non Interventional PASS Studies imposed as an obligation by a competent authority
• Table VIII Add I.2. Non Interventional PASS Studies initiated, managed or financed voluntarily by marketing authorisation holders</td><td></td></tr>
<tr><td></td><td></td><td>Comment:
It should be clarified, and explicitly stated, if the requirements outlined in this addendum apply to PASS studies, which have been imposed or required by EU competent authorities only or, if it applies to PASS studies which have been imposed or required by EU and non-EU competent authorities. This should be aligned with guidance provided in Module VIII revision 2.

In addition, as for GVP VIII, the clarity of this document would be enhanced with the use of a table listing the actual provisions of the legislation in a tabular form for each type of PASS by category. This should make clear what is imposed by law for each category, vs. what is recommended or may be imposed at NCA's level.

Proposed change:
Insert table
<table><tr><td></td><td>Category 1</td><td>Category 2</td><td>Category 3</td><td>Category 4</td></tr><tr><td>Provisions of Art 107m</td><td></td><td></td><td></td><td></td></tr><tr><td>Provisions of Art 107n</td><td></td><td></td><td></td><td></td></tr><tr><td>Provisions of Art 107o</td><td></td><td></td><td></td><td></td></tr><tr><td>Provisions of Art 107p</td><td></td><td></td><td></td><td></td></tr><tr><td>Provisions of Art 107q</td><td></td><td></td><td></td><td></td></tr></table></td><td></td></tr>
<tr><td>14-17</td><td></td><td>Comment:
For centrally authorised products and nationally authorised products, study protocols and reports should be reported to Member States according to Table VIII Add I.1. or Table VIII Add I.2., depending on the regulatory status of the</td><td></td></tr>
</table>

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')*	Outcome *(To be completed by the Agency)*
		study. For centrally authorised products, study protocols and reports should always also be sent to the Agency. This sentence would benefit from further clarity; It could be interpreted as if an additional submission to the EMA is requested whilst this would lead into duplication: • EMA would receive protocols/results of imposed NI-PASS as the MAH submits them to the PRAC following the Dossier requirements for Centrally Authorised Products (CAPs) (EMA/497021/2012). • For voluntary NI-PASS, the EMA would receive them via the EU PAS register. In addition, the pharmacovigilance legislation does not foresee that applicants should send all non-interventional PASS protocol/report to the EMA/PRAC, only for the imposed NI-PASS. The wording should therefore be changed as follows. **Proposed change (if any):** *"As a reminder, for centrally authorised products, study protocols and reports ~~should always also be sent to the Agency~~ will be received by the EMA:* - *for Studies initiated, managed or financed voluntarily by marketing authorisation holders: automatically following their submission on the EU PAS register by the MAH.* - *For Studies imposed as an obligation: as part of the submission of the protocol/results to the PRAC following the Dossier requirements for Centrally Authorised Products (CAPs) (EMA/497021/2012)."*	
Footnote 4 of Table VIII Add I.2		**Comment:** This footnote states that a message is sent at the end of registration in the EU PAS register by the Agency to all EU MSs with a link to the study record. EFPIA requests the EMA to clarify this process, as it is not described in the ENCePP register or on the EMA 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')*	Outcome *(To be completed by the Agency)*
		Comment: Table VIII Add I.2. indicate that next to the provision via EU PAS register, reports/protocols should also be provided to member states, according to national procedures, in case the study is conducted in that member state (applicable to AT, BG, CZ, DE, ES, IT, NL, PT, RO, SI, HR, LT, SK, FR). EFPIA interprets this to imply that the provision to EU PAS register of protocols and reports for voluntary studies is not enough, but local submissions also need to be done. **Proposed change:** Additional clarification should be added to the Guideline highlighting whether all protocols and reports for voluntary studies need to be submitted to EU PAS register as well as submitted directly to NCAs.	

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

<Date of submission>

Submission of comments on GVP Module VIII Addendum I – Requirements for transmission of information on non-interventional post-authorisation safety studies (Rev 2) (EMA/395730/2012)

Comments from:

Name of organisation or individual
EGA – European Generic and Biosimilar medicines Association [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*).*

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1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment	Outcome *(To be completed by the Agency)*
	The EGA welcomes this opportunity to comment the new revision of the *GVP Module VIII – Post-authorisation safety studies – Addendum I.* We don't have any specific comment, just one general comment regarding study information: Study information must be submitted to the EU PAS Registry but also to the Member State (MS) where the study is to be conducted and all PRAC members. We believe that the EU PAS Registry should be used as a single submission portal which allows the study documents to then be disseminated to the relevant MS and PRAC members.	

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')*	Outcome *(To be completed by the Agency)*
		No further comments.	

Please add more rows if needed.

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

5th October 2015

Submission of comments on GVP Module VIII Addendum I – Requirements for transmission of information on non-interventional post-authorisation safety studies (Rev 2) (EMA/395730/2012)

Comments from:

Name of organisation or individual
Gilead Sciences International Ltd.

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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	Outcome *(To be completed by the Agency)*

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')*	Outcome *(To be completed by the Agency)*
Page 3, Line 4-5		Comment: text 'Where the full statistical analytical plan is not included in the protocol, it should be reported following the same requirements as for the study protocol' Most SAPs are operational and detailed documents expanding on the detailed analytical approaches of those statistical analyses described in the study protocol. Making the full SAP subject to the same submission and review requirements as the protocol may significantly impact study timelines and is considered redundant effort. The planned statistical analyses should be reviewed as part of the protocol, where they have to have sufficient detail to judge the appropriateness for the study protocol objectives, aims and design. Proposed change (if any): remove the reference to the SAP as a separate document and rather make it clear in Module VIII that the protocol needs to have sufficient detail to judge the appropriateness of the statistical analyses planned.	
		Comment: Proposed change (if any):	
		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')*	Outcome *(To be completed by the Agency)*
		Proposed change (if any):	

Please add more rows if needed.

<Date of submission>

Submission of comments on 'GVP Module VIII Addendum I – Requirements for transmission of information on non-interventional post-authorisation safety studies (Rev 2)'

Comments from:

Name of organisation or individual
Pfizer

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

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1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*
	This Addendum I (rev 2) to GVP Module VIII (rev 2) provides additional guidance on the requirements for transmission of information on non-interventional post-authorisation safety studies. We thank the Agency for efforts to provide clear and comprehensive guidance. Further, we appreciate the opportunity to review this document and provide the following comments with the goal of improving, and thereby strengthening the guidance provided. We provide separate comments on GVP Module VIII (rev 2).	
	The expectations and rationale regarding the proposed requirement in draft GVP Module VIII (rev 2) to register certain ex-EU PASS in the EU PAS Register are not clear. The proposed requirement would require registration of non-interventional studies requested by non-EU regulatory authorities and conducted outside the EU. Clarification is needed on whether the requirements in Addendum I (rev 2) for EU non-interventional studies would also apply to non-EU studies.	

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')*	Outcome *(To be completed by the Agency)*
Page 3, 1st paragraph		Comment: We assume that the reference to "if requested" refers to progress reports, and not the other documents (e.g., protocols, amendments) as these other documents must be transmitted; if correct, this should be clarified. Proposed change: " … updated protocols following substantial amendments, final study reports and, if requested, progress reports ~~if requested~~ on post-authorisation safety studies …"	
Page 3, 1st paragraph		Comment: The new text states that separate statistical analysis plans should be submitted. Is this a new requirement? If so, is PRAC endorsement required and before what milestone (for obligated PASS)? Proposed change: Clarify the requirements for statistical analysis plans. If there are any new requirements for statistical analysis plans, this should also be clearly described in GVP Module VIII (rev 2). Please note that in most cases, PRAC endorsement of separate SAPs will most likely delay study start.	

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')*	Outcome *(To be completed by the Agency)*
Tables VIII Add I.1 and I.2		Comment: We suggest providing definitions of country abbreviations. Proposed change: Add a list of country codes and decodes or refer the reader to the appropriate ISO code sets, e.g., those used for ICSRs per GVP Module VI.	
Table VIII Add I.1		Comment: The clarity and utility of Table VIII could be improved with minor adjustments. Proposed change: We suggest that for progress reports, a column referring to “Transmission to by MAH to MS via PRAC” be added so that it is parallel to the study protocols, etc. column. Additionally, in the “Transmission to by MAH to MS via PRAC” column, should “DK” instead of “All” be listed for Member States where the study is conducted? Thus, the MAH should directly transmit the study protocol, etc., to the participating MS except DK, which will receive these documents by PRAC. Finally, it should be noted whether there are any differences in requirements between centrally and nationally	

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')*	Outcome *(To be completed by the Agency)*
		authorized products.	

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

8 Oct 2015

Submission of comments on GVP Module VIII Addendum I – Requirements for transmission of information on non-interventional post-authorisation safety studies (Rev 2) (EMA/395730/2012)

Comments from:

Name of organisation or individual
SEC Associates, Inc.

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	Outcome *(To be completed by the Agency)*
	Thank you for the opportunity to address these changes. Please read these comments in conjunction with GVP VIII 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')*	Outcome *(To be completed by the Agency)*
This Addendum specifies **requirements** for the transmission of study protocols, updated protocols following substantial amendments, final study reports and progress reports if requested on post-authorisation safety studies initiated, managed or financed by marketing authorisation holders voluntarily or pursuant to an obligation.		Comment: This is inaccurate in combination with the statement “These requirements are based on Directive 2001/83/EC Art 107 m-q”. Registration and public posting of information in the EU PAS Register by the MAH is not mandated, although the EMA will publish the protocol and public results abstract of PASS imposed as an obligation in the EU PAS Register if not posted by the MAH. The draft GVP VIII does state that MAHs should register (as opposed to legally required to do so), but then it says the “requirements” for submission are in this Annex. In line with the “should register, not required” aspect, in correspondence with the EMA several years ago, we were told ”…registration of PASS information in the EU PAS register is not a legal obligation…”, “As a matter of principle, for all PASS, registration will facilitate the implementation of the new pharmacovigilance legislation and is also recommended for PASS voluntarily conducted by marketing authorisation holders.”, and the EMA will publish the protocols and public abstracts of results of PASS imposed as an obligation in the EU PAS register, unless this has already been done by the MAH. Proposed change (if any): This Addendum specifies requirements for the transmission of study protocols, updated	

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')*	Outcome *(To be completed by the Agency)*
		protocols following substantial amendments, final study reports and progress reports ~~if requested on post-authorisation safety studies initiated, managed or financed by marketing authorisation holders voluntarily or~~ pursuant to an obligation <insert>, and recommendations on transmission of the same, if requested, on post-authorisation safety studies initiated, managed or financed by marketing authorisation holders voluntarily. (or similar; I realize final study reports are required to be submitted directly to NCA for voluntary PASS)	
These requirements are based on Directive 2001/83/EC Art 107 m-q		According to the legislation: The Agency shall, in collaboration with the Member States and the Commission, set up and maintain a European medicines web-portal for the dissemination of information on medicinal products authorised in the Union. **By means of that portal, the Agency shall make public at least the following**: (h) protocols and public abstracts of results of the post-authorisation safety studies referred to in Articles **107n and 107p of Directive 2001/83/EC**; 107m (voluntary studies) is not addressed as required for being made public via the portal – only the obligatory studies. Proposed change (if any): These requirements are based on Directive 2001/83/EC Art 107 n-q	

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')*	Outcome *(To be completed by the Agency)*
Table VIII Add I.2. Studies initiated, managed or financed voluntarily by marketing authorisation holders: specific text: Transmission by MAH via registration in the EU PAS Register - All Member States under several situations		Comment: First, GVP VIII as amended in draft already states that registration via the EU PAS Register is “should”, not required, so the table should reflect the voluntary nature of submission to the EU PAS Register. Second, the table makes no mention of “if requested”. In context with everything else, it implies submission of all these documents is a legal requirement for any voluntary study, whether or not requested by the NCA. Third, since the Directive says “if requested”, then Member States would have to legislate, apart from the Directive, that it wasn’t an “if requested” but always required condition, wouldn’t they? Proposed change (if any): column header to read as follows: **Voluntary** Transmission by MAH via registration in the EU PAS Register	
		Comment: Proposed change (if any):	

Please add more rows if needed.