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).

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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 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	

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	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 (knoonan@acrohealth.org or +1 202 464 9340).	

Please add more rows if needed.