3 August 2015
EMA/395730/2012 Rev 2* Draft for public consultation

Guideline on good pharmacovigilance practices (GVP)

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

Date for coming into effect of first version	2 July 2012
Date for coming into effect of Revision 1*	25 April 2013
Draft Revision 2* finalised by the Agency in collaboration with Member States	23 June 2015
Draft Revision 2 agreed by the European Risk Management Facilitation Group (ERMS FG)	16 July 2015
Draft Revision 2 adopted by Executive Director	3 August 2015
Release for public consultation	11 August 2015
End of consultation (deadline for comments)	9 October 2015
Anticipated date for coming into effect	Q1 2016

*Note: Revision 2 contains the following:

- Inclusion of notification requirements to the Agency and amendment accordingly of the title of the Addendum;

- Revision of Tables XIII. Add I.1. and XIII. Add I.2. based on updated information provided by Member States;

- Addition of a statement that the statistical analytical plan (SAP) should follow the same requirements as for PASS protocols if it is not included in the protocol.

Comments should be provided using this template. The completed comments form should be sent to gvp@ema.europa.eu.

Note for public consultation:

The public consultation is restricted to the yellow highlighted revised texts (i.e. replaced by new texts with deletions and additions) or deleted texts (i.e. not replaced). However, if revisions or deletions

impact or contradict other existing text, comments on such non-highlighted texts will be processed and taken into account for the finalisation process.

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. 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.

These requirements are based on Directive 2001/83/EC Art 107 m-q ~~and the GVP Module VIII~~. They do not cover the situation of studies conducted in only one Member State that requests the study according to Article 22a of Directive 2001/83/EC, in which case the marketing authorisation holders shall submit the draft protocol and the other study information to the national competent authority of the Member State in which the study is conducted.

These Tables cover the requirements for transmission of information to competent (i.e. regulatory) authorities, not to ethics committees, national review boards or other bodies in place according to national legislation.

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 study. For centrally authorised products, study protocols and reports should always also be sent to the Agency.

Table VIII Add I.1. Studies imposed as an obligation by a competent authority

	Study protocols, updated study protocols following substantial amendments, final study reports [1]		**Progress reports if requested** [1]
	Direct transmission by MAH to MS [2]	*Transmission by MAH to MS via PRAC* [3]	*Direct transmission by MAH to MS* [2]
Member States where the study is conducted	All except DK	All	All except DK
Member States acting as Rapporteur or RMS for the medicinal product *		All	All except DK
Member States where the medicinal product is authorised, but not acting as Rapporteur of RMS for the medicinal product *		All	~~DE~~

[1] *Study information should also be entered and maintained in the EU PAS Register.*
[2] *Final study protocols, substantial amendments to study protocol, any progress reports, abstracts of final study report and final study reports to be transmitted by marketing authorisation holders to Member States according to national procedures.*
[3] *Information to be transmitted by marketing authorisation holders to the Agency and all PRAC members in the context of the oversight of post-authorisation safety studies by the PRAC as described in Directive 2001/83/EC Art 107 n-p.*
** even if study not conducted in the Member State*

Table VIII Add I.2. Studies initiated, managed or financed voluntarily by marketing authorisation holders

	Study protocols, updated study protocols following substantial amendments, progress reports if requested and final study reports	
	Transmission by MAH via registration in the EU PAS Register [4]	*Additional transmission by MAH to the MS* [5]
Member States where the study is conducted	All	AT, BG, CZ, DE, ES, IT, NL, PT, RO, SI,

		HR, LT, SK, FR
Member States acting as Rapporteur or RMS for the medicinal product **	All	DE, ~~DK,~~ NL, PT, RO, CZ, SK, FR
Member States where the medicinal product is authorised but not acting as Rapporteur or RMS for the medicinal product **	All	~~DE, RO~~

[4] *After the study has been registered, a notification message is sent by the Agency to all EU Member States with a link to the study record.*

[5] *Information to be transmitted by marketing authorisation holders to Member States according to national procedures.*

*** even if study not conducted in the Member State*