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Guideline on good pharmacovigilance practices (GVP)

Module VIII Addendum I – Member States' requirements for transmission of information on non-interventional post-authorisation safety studies (Rev 1)

Date for coming into effect of first version	2 July 2012
Date for coming into effect of Revision 1*	25 April 2013

*Note: Revision 1 contains the following:

- Specification in explanatory note no 4 that the notification to all Member States is made by the Agency;

- Renaming of the document as Module VIII Addendum I (instead of Annex to Module VIII) in order to avoid confusion with GVP Annexes which are applicable to all GVP Modules.

This version is not valid anymore, but kept on the Agency's website for the purpose of public access to historical documents. For the valid version, please refer to the Agency's GVP webpage for the latest revision of this GVP Module.

The tables below specify Member States' (MS) requirements for the transmission of information on post-authorisation safety studies initiated, managed or financed by marketing authorisation holders (MAHs) voluntarily or pursuant to an obligation.

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, in which case the MAH 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 national regulatory authorities, not to ethics committees, national review boards or other bodies in place according to national legislation.

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		All
Member States acting as Rapporteur or RMS for the medicinal product **		All	All
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 MAHs

	Study protocols, updated study protocols following substantial amendments, progress reports if requested and final study reports	
	Transmission by MAH via notification from EU PAS Register [4]	*Additional transmission by MAH to MS* [5]
Member States where the study is conducted	All	AT, BG, CZ, DE, ES, IT, NL, PT, RO
Member States acting as Rapporteur or RMS for the medicinal product **	All	DE, DK, NL, PT, RO
Member States where the medicinal product is authorised but not acting as Rapporteur or RMS for the medicinal product **	All	DE, RO

[4] *Notification message sent by the European Medicines 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*