17 April 2012

Submission of comments on 'GVP Module VIII – Post-authorisation safety studies' (EMA/813938/2011)

Comments from:

Name of organisation or individual
Drug Commission of the German Medical Association; D-10623 Berlin, Herbert-Lewin-Platz 1, Germany

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 Drug Commission of the German Medical Association (DCGMA) thanks for having given the opportunity to comment on the Guideline on good pharmacovigilance practice. The DCGMA is taking the opportunity to make some general comments to 'Module VIII – Post authorisation safety studies' followed by detailed proposed changes of the text and will also propose changes to the Module V and Module VI. First of all, it is greeted that specific rules have been set up for the post-authorisation safety studies. Having said this, we nevertheless have to criticise that final study reports (VIII.B.5.3.2.) of PASS voluntary initiated by the marketing authorisation holder are differently handled compared to PASS initiated by the marketing authorisation holder pursuant to an obligation imposed in accordance with Articles 10 or 10a of Regulation (EC) No 726/2004 or with Articles 21a or 22a of Directive 2001/83/EC. We are of the opinion that at least the abstract must be made public and be available in an English translation to ensure that the medical professionals have access to this very important information related to patient safety and necessary to perform an appropriate risk-benefit analysis before prescribing a drug.	

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)*
Line 369		Comment: This information must be available for public information. Proposed change (Line 369): Change "…is also encouraged to transmit the final study report to the national competent authority…" to "…is also **requested** to transmit the final study report to the national competent authority…"	
Line 371		Comment: This information must be available for public information. Proposed change (Lines 371 – 372): Please add after the last sentence: "The study report should include a public abstract and the authorisation holder should ensure that an English translation of the abstract is submitted."	
Line 499		Comment (Line 499): We are of the opinion that it is indispensable that scientist can independently prepare publications from the work they have performed. Proposed change: Please change "It is recommended that this strategy allows…" to "**It is indispensable** that this strategy allows…".	

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)*
Line 532		Comment: From our point of view this information must be available. Proposed change (Line 532): Please change ”The marketing authorisation holder is encouraged to have information on the study…” to “The marketing authorisation holder **should** have information on the study…”.	

Please add more rows if needed.