EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 April 2012

Submission of comments on 'GVP Module VI – Management and reporting of adverse reactions to medicinal products' (EMA/873138/2011)

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).

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.	

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)*
Lines 311-321		Comment: The question arises here – and should be addressed – whether or not a company is obliged to run its own website as a "receptor" for direct ICSR reports (from healthcare professionals or consumers).	
Line 362		Comment: The list of information characterising a patient seems unclear and hence inappropriate: The word "or" implies that any single one of the characteristics could suffice. This means that e.g. "a female patient" would be considered sufficient. This is too little information to allow reasonably accurate identification of the patient and to avoid or detect duplicates.	
Lines 400-411		Comment: We strongly agree that follow-up methods should be conducted in ways that encourage health care professionals to submit additional information and that motivate them to report adverse drug reactions again in the future. However, in our experience extensive questionnaires without any pre-populated data fields are common practice by some MAH to obtain follow-up information. In some cases, these questionnaires are sent to the primary source only in English language.	

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		Proposed change (Lines 406-407) In follow-up report forms information already provided in the initial report should be pre-populated in the corresponding data fields to make their completion by the primary source less burdensome. Follow-up report forms have to be provided in the national language of the primary source.	
Lines 525 and 1236-1259		Comment: In both sections, ADR reports originating from situations of medication error, other kinds of inappropriate medication, or of medically well justified off-label use should be given special attention. In addition to judgement about relatedness between medication and adverse event (creating a reportable ICSR) it is always crucial whether just the fact that the medicine was used other than officially recommended/authorised created the adverse event, and if so, what might have been the cause of the deviation from what is recommended/authorised (root-cause-analysis). It should be kept in mind that some kind of deviation from “standard” underlies about every second ICSR and is worth analysing.	
Lines 533-535		Comment: Expedited reporting does not seem appropriate in all cases included here. Reports of medication errors should contain additional information on the context the error occurred to enable a valid case assessment. Proposed change (Lines 533-535): The case report should contain a detailed description of the	

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		incident including information on prescription, administration, transcription or dispensing. Additional information about the type of medication error (wrong prescription, dosage error, sound- or look-alike, wrong transcription…) as well as the context should be reported according to the MedDRA terms.	

Please add more rows if needed.