EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 April 2012

Submission of comments on 'GVP Module V – Risk management systems' (EMA/838713/2011)

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.	

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 469-470		Comment: The patient time exposed to the medicinal product is not as informative as the number of patients treated for different periods (see also lines 477-478). Proposed change (lines 469-470): "…should be detailed both numbers of patients…" skip the reminder of the sentence and insert "…exposed to the medicinal product and duration of treatment. Patient time (patient-years, patient-months) may also be given…".	
Line 517		Comment: Multimorbidity is often an exclusion criterion for the selection of patients. Hence, interactions because of co-medication might remain not detected. Proposed change (line 517): Please insert the term "4. co-medication;".	

Please add more rows if needed.