29 September 2017
EMA/647372/2017

Comments received from public consultation on good pharmacovigilance practices (GVP)

Annex II – Templates: Communication Plan for Direct Healthcare Professional Communication (CP DHPC)

The draft of this module was released for public consultation between 15 December 2015 and 29 February 2016. The module has been revised, taking the comments received into account.

Those who participated in the public consultation were asked to submit comments using a specific template.

The comments received are published, identifying the sender's organisation (but not name). Where a sender has submitted comments as an individual, the sender's name is published.

The European Medicines Agency thanks all those who participated in the public consultation for their contributions.

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29 February 2016

Submission of comments on GVP Annex II – Templates: Communication Plan for Direct Healthcare Professional Communication (CP DHPC) (EMA/334164/2015)

Comments from:

Name of organisation or individual
PHARMIG – Association of the Austrian pharmaceutical industry

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
	PHARMIG, the association of the Austrian pharmaceutical industry welcomes the opportunity to comment on the draft GVP Annex II – Templates: Communication Plan for Direct Healthcare Professional Communication (CP DHPC).

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')*
Page 2		If no originator product is marketed in the Member State, it is encouraged that the concerned generic companies acts as contact point for the competent authority. Comment: The wording is different from the wording in GVP Module XV – Safety Communication (Rev 1), lines 524-525: If no originator product is marketed in a Member State, it is encouraged that one generic company acts as the contact point. Proposed change (if any): We suggest to align the wording in the two documents and change the sentence in the communication plan to "one generic company".
		Comment: Proposed change (if any):
		Comment: Proposed change (if any):

Please add more rows if needed.