EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22nd March 2013

Submission of comments on
European Commission Template for the Qualified Person's declaration concerning GMP compliance of investigational medicinal products manufactured in non-EU countries
SANCO/D/6/SF/mg/ddg1.d.6(2013)179167

Comments from:

Name of organisation or individual
UPIP-VAPI Belgium

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received.

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1. General comments

Stakeholder no. *<to be completed by the Agency>*	General comment (if any)	Outcome (if applicable) *<to be completed by the Agency>*
	The QP Working Group of the Belgian professional association of pharmacist working in the industry welcomes the current activities to harmonise the template for the provision of QP declarations of IMPs manufactured in third countries across the EU. Our association contains more than 300 members, pharmacists working at multiple levels in pharmaceutical industry and lots of them working as Qualified Persons. The comment below comes from the QP taskforce recently created within our association.	

2. Specific comments on text

Line No of the first line(s) affected *<e.g. Line 20-23>*	Stakeholder no. *<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>*
First Table : Eudra CT number		Comments : Add some rows if the case of multiple EUDRA CT numbers.	
Part B table (i)		Comments : Chapter 7 of the GMP Guide as well as other chapters have been/are being revised to integrate basic concepts of ICH Q 9, ICH Q10 and anticipating the new regulations of Directive 2011/62. Within the Quality Management System of the Pharmaceutical Manufacturer audits are conducted by a suitably trained and experienced personnel within the organisation of the MIA holder. It is not explicitly required that the QP *in person* conducts each and any audit. Thus, we propose to adapt this section respectively. Proposed change (if any): from "Personal audit" to "Direct audit by or on behalf of the QP of the MIA holder within the Quality Management System"	

Line No of the first line(s) affected *<e.g. Line 20-23>*	Stakeholder no. *<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>*

Please feel free to add more rows if needed.