PHARMIG
Verband der pharmazeutischen Industrie Österreichs

Vienna, 31 May 2012

SANCO/D6/(2012)ddg1.d6.517666

PHARMIG response to the European Commission Draft: Template for the Written Confirmation for Active Substances Imported into the European Union for Medicinal Products for Human Use

PHARMIG, the association of the Austrian pharmaceutical industry, would like to thank the European Commission for the opportunity to comment on the Draft Template for the Written Confirmation for Active Substances Imported into the European Union for Medicinal Products for Human Use.

Please find following our comments.

PHARMIG supports the need for adequate oversight and control of the importation of active substances into the European Union. We therefore welcome the installation of a list of third countries whose GMP requirements and enforcement procedures for active substances have been judged by the Commission to be equivalent to EU GMP standards for APIs. It would be worthwhile if this list consisted of a high number of third countries.
In our opinion the European authorities should encourage third countries to seek getting listed as an "EU-GMP-equivalent country" instead of preferring the alternative option for exporting active substances: a written confirmation from the competent authority of the exporting third country that the standards of GMP are at least equivalent to those laid down by the Union.
Relating to this written confirmation a lot of issues arise which can neither be clarified by directive 2011/62/EU nor by the concept papers on the "Implementing Act on the Requirements for the Assessment of the Regulatory Framework Applicable to the

Manufacturing of Active Substances of Medicinal Products for Human Use" and the "Delegated Act on the Principles and Guidelines of Good Manufacturing Practice for Active Substances in Medicinal Products for Human Use":

- *It is not made clear yet if or how the self-conformation of the competent authority of the exporting third country will be evaluated and against which criteria the self-confirmation will be performed.*
- *Third countries, especially those which are large active substance exporting countries, typically have their own regulatory environment. Even ICH Guidelines, such as ICH Q7, are not officially applicable in those countries.*
- *Are the responsible competent authorities of third countries already informed by the European Union that these requirements will occur in 2013? Otherwise there are serious doubts that these authorities are ready and willing to sign the document. Apart from that, the relevant competent authorities in those countries will have to be addressed what might be difficult since the governmental structures might be quite different in some countries than those we are used to in the European Union.*
- *Some large third countries have a quite decentralised system regarding monitoring and inspections of their local pharmaceutical industry. Would the European Union accept a confirmation by the local competent authority of the state / province or is it mandatory that the national competent authority of the country acts as the issuing regulatory authority? It has to be considered that the national competent authority might not even have the required information to sign the confirmation.*
- *Is the written confirmation only required for active substances used in the manufacture of medicinal products only or will it be required as well for active substances which are used in further API manufacture, e.g. undergo further purification, sterilization or synthesis steps?*
- *In the draft for the written confirmation it says "In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU." It has to be addressed to which authority or office within the EU the information on such findings should be supplied.*