PHARMIG
Verband der pharmazeutischen Industrie Österreichs

Vienna, 05 November 2013

PHARMIG response to the European Commission Draft:
EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use
Annex 16: Certification by a Qualified Person and Batch Release

PHARMIG, the association of the Austrian pharmaceutical industry, would like to thank the European Commission for the opportunity to comment on the Draft Annex 16 of the EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use.

Please find following our comments.

2.2. However, the responsibility for ensuring that a particular batch has been manufactured in accordance with its marketing authorisation for the destination country of the medicinal product, with EU Good Manufacturing Practice (GMP), or equivalent, and that it is in compliance with the laws in force in the Member State where certification takes place ~~and of the destination country of the medicinal product~~, lies with the QP certifying that batch as being suitable for release.

Comment: It is not possible for the QP to be aware of all specific national legislations, especially of those of third countries which might be available only in the third country's language. It can be assumed that a medicinal product which is in accordance with its marketing authorisation complies also with the corresponding national legislation. We therefore propose the amendment above which is also consistent with point 2.3.2 "The certification of the finished product batch performed by a Qualified Person signifying that the batch is in compliance with EU GMP and the requirements of its marketing authorisation."