PHARMIG
Verband der pharmazeutischen Industrie Österreichs

Vienna, 20 November 2015

PHARMIG response to the European Commission Draft: Commission Delegated Act on Principles and guidelines on good manufacturing practice for investigational medicinal products for human use and inspection procedures, pursuant to the first subparagraph of Article 63(1) of Regulation (EU) No 536/2014

PHARMIG, the association of the Austrian pharmaceutical industry, would like to thank the European Commission for the opportunity to comment on the **Draft Commission Delegated Act on Principles and guidelines on good manufacturing practice for investigational medicinal products for human use and inspection procedures, pursuant to the first subparagraph of Article 63(1) of Regulation (EU) No 536/2014**.

Please find following our comments.

Question 1a: The requirement for a product specification file is not new since it has already been addressed in Annex 13 of the Eudra GMP Guide so far.
Question 1b: Since it has already been a requirement so far in Annex 13 we strongly assume that this file exists for all investigational medicinal products in the EU.

Question 2: From a GMP point of view option (a) is sufficient and there is no need to keep single batch data for a longer period. All basic data regarding an IMP within the clinical master file nevertheless will be kept for 25 years. Single data elements from a certain will not be needed any more after that period of time.

Question 3: Since the QP has to ensure access to all relevant information before releasing the IMP for use, the inclusion of the Certificate of Analysis in every shipment is not necessary from a GMP point of view.

Question 4a: It should be required to retain reference samples only at the manufacturing or testing site (if different), e.g. for the purpose of re-analysing.
Retention samples should be retained at the EU releasing site, these of course can be supported by photos, etc. according to current Annex 13 and the draft detailed guidelines on GMP for IMPs.
Question 4b: Samples of packaging material have to be retained according to current legislation within the batch documentation. Furthermore it is current practise to add photos for documentation.

Question 5a und b: There is no information available to these questions within PHARMIG member companies.
This information should be available within the EU Clinical trials database.