From:
Sent: 25 November 2015 23:02
To: SANTE-D6-DA-GMP-IMP
Subject: DA on GMP for IMP, DKMA position to the consultation document: Principles
and guidelines of Good Manufacturing Practice for Investigational Medicinal
Products for Human Use

Please publish the contribution as B

position to the consultation document
. Principles and guidelines of Good Manufacturing Practice for Investigational Medicinal Products
for Human Use

Questions given in the consultation document "Principles and guidelines of Good Manufacturing Practice
for Investigational Medicinal Products for Human Use"

Question 1a: Yes as mentioned in the current annex 13

Question 1b: has fully implemented the current annex 13

Question 2 a): Not preferred

Question 2 b): Preferred at least 25 five years storage of IMP documentation, from a consumer safety
perspective we consider five years as not adequate for storage of documentation.

Question 3: Yes a Certificate of Analysis should accompany each shipment of imported IMP. The same
CofA can accompany different sub lots of packaged IMP.

Question 4a: finds that, yes, the retention samples should be present in EU. Material for at least
two QC testings should be present in EU.

Question 4b: finds that if retention samples are not required, thus a minimum of sample material
must be at least a photo.

Question 5a: is not able to provide any data for 5a.

Question 5b: is not able to provide any data for 5b.

First subparagraph of Article 63(1) of Regulation (EU) No. 536/2014 -

acknowledge the necessity (section 3.1) of EU inspectorates to perform GMP inspections of IMP
manufacturers in third countries

Kind regards