SANTE PHARMACEUTICALS D6

From: SANTE PHARMACEUTICALS D6
Subject: FW: Comments on Annex 15

From: Kathleen Cussen
Sent: Tuesday, June 10, 2014 11:56 AM
To: ADM-GMDP@ema.europa.eu; SANCO PHARMACEUTICALS D6
Subject: Comments on Annex 15

Hi,

Apologies for missing the deadline of May 31st.

Comments on the update to Annex 15 include the following:

Section 5.1 states that the material in scope should be transported in accordance with the conditions defined (i) in the Marketing Authorisation, (ii) product specification file or (iii) by the manufacturer. This conflicts with the current GDP requirement that states that the required storage conditions for medicinal products should be maintained during transportation within the defined limits as described by the manufacturers or on the outer packaging. Regulators have recently consistently emphasised the labelled storage conditions and have ultimately disregarded extended limits that may be included in the products' Marketing Authorisations.

Section 5.4 states that continuous monitoring of critical environmental conditions should be performed due to the variable conditions that may be expected during transport. This seems to conflict with recent expectations that the product's storage conditions should be monitored where monitoring is required. It is also considered unnecessary to monitor ambient conditions if an appropriately qualified active transport system is being used, particularly when continuous temperature monitoring of the product's storage conditions is being performed.

Section 9.8 states that where a worst case product approach is taken that the choice of worst cases should consider toxicity and PDE. PDE is a toxicological assessment, so why both?

Regards,
Kathleen Cussen
Gilead Sciences Ltd.
