From: Adolfo Gonzalez [mailto:Adolfo.Gonzalez@chemogroup.net]
Sent: Tuesday, May 14, 2013 2:57 PM
To: SANCO PHARMACEUTICALS D6
Subject: Guidelines on the principles of good distribution practices for active substances for medicinal products for human use

Dear Sirs,

I'm writing as the Corporate Quality Director for the API division of the Chemo Group (http://www.chemogroup.com/). CHEMO operates across the entire pharmaceutical value chain, delivering specialized expertise in scientific research, development, manufacturing, sales and marketing of a wide range of active pharmaceutical ingredients (APIs), finished dosage forms (FDFs) and branded pharmaceuticals, for human and animal care. I assume Chemo would not fit into the EU definition of a small and medium-sized Enterprise.

I've been recently aware of the draft document published for consultation on the topic "good distribution practices for active substances".

Although I've noticed that the consultation period ended by April 30th I'd like to provide my comments, because I believe it may come in contradiction with another guidance document currently official in the EMA: CPMP/QWP/609/96/Rev 2.

Specifically, point 27 (page 5, under chapter Deliveries to Customers) in the draft document seems to indicate that APIs requiring controlled temperature storage should also be transported under controlled temperature conditions.

That statement if understood like that, would be limiting the possibilities offered by the EMA guidance document CPMP/QWP/609/96/Rev 2, which separates storage from transportation conditions.
Please refer to labeling statements (page 3 of 4) for the material to be stored under cold conditions e.g. 5+/-3ºC:

"Store in a refrigerator or Store and transport refrigerated".
"The stability data generated at 25°C/60%RH (acc) should be taken into account when deciding whether or not transport under refrigeration is necessary. The statement should only be used in exceptional cases."

The importance of this differential labeling and consequent management would have a significant impact on the cost of transportation and the API.

As a summary I would request the clarification of point 27 in the draft guidance document so that different storage and transport conditions may be considered based on long term and accelerated stability data.

Thanks in advance for your consideration,
Yours faithfully,

Adolfo Gonzalez

API - Corporate Quality Director

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