From: Koen VINCENT (DHL EUHQ) [koen.vincent@dhl.com]
Sent: lundi 24 octobre 2011 15:08
To: SANCO GMP; ADM-GMDP@ema.europa.eu!
Subject: Draft GDP Guidelines - comments

Good afternoon,

I'm working for DHL Express Europe, focusing on customers from the Lifesciences and Healthcare Industry. I'm aware of the new GDP guideline published on the Internet and have some requests for clarification on this, especially on section 9 related to Transportation. I was wondering if you could help me clarifying these points or direct me to the right person(s) for further discussion.

The way we typically work is that our customers are shipping their product in validated Temperature Controlled Packaging, with or without a temperature logger. As an Express provider, we move these shipments through our network as fast as possible from shipper to final consignee without any temporary storage.. Within Europe, this typically means an overnight service to the main business areas i.e. pick up Monday, delivery Tuesday. We work with the customer to define the capabilities on transit time on the lanes he wishes to ship to, we give insights as to what routings the shipments will follow so the customer has a clear idea on what Temperature Controlled packaging he should use.

In the draft guidelines, I noticed a few points that I would like to see further clarified. It concerns the following:

* **Section 9.2**: **If a deviation has occurred during transportation, this should be reported to the distributor and recipient of the affected medicinal products**

- Is this any deviation or only deviation as to the temperature?
- If the latter, doesn't that imply all shipments should be shipped with a temperature logger?

* **Section 9.12**: **Where transportation hubs are utilized in the supply chain, a maximum time limit of normally 24 hours should be set to await the next stage of the transportation route. Where medicinal products are held on the premises for longer than this defined time limit, the hub will be deemed to be acting as a storage site and required to obtain a wholesale distribution authorization. For refrigerated product any storage at a transportation hub for any period of time would require that premises to hold a wholesalers distribution authorization**

- As mentioned above, we move our shipments as fast as possible from shipper to final consignee and don't store. However, when shipped on Friday, it may be that a shipment is physically present at one and the same HUB for >24hrs during the weekend before it is lifted on the network to its next destination. That's inherent to our way of operating. My view is that you can not consider our integrator HUBS as storage sites (even in the weekend) so we do not need any wholesale distribution license. Can you confirm?

- for refrigerated product..: as mentioned, we only transport product inside temperature controlled packaging and as such I don't believe we need wholesale distribution license. Can you confirm?

* **Section 9.13**: **In the event that the transportation of medicinal products requires unloading and reloading e.g. at terminals and hubs, these premises should be audited and approved prior to deployment. Whenever any changes are made to the approved premises or functions, attention should be paid to the continued suitability of the changed premises or functions for their intended use. Particular attention should be paid to temperature monitoring, cleanliness and the security of unguarded intermediate storage facilities**

- we operate thousands of facilities worldwide and all perform loading and unloading to some degree. I can not imagine these would all need to be audited and approved. How do I need to read this paragraph?

I thank you for your attention and I'm looking forward to your feedback.

Regards,

Koen

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