<16 December 2011>

Submission of comments on '< Commission Guidelines on Good Distribution Practice of Medicinal Products for Human Use >' (SANCO/C8/AM/an D(2010) 380358)

Comments from:

Name of organisation or individual
LinkedIn Vital Logistics group.

(http://www.linkedin.com/groups?home=&gid=4109829&trk=anet_ug_hm)

For the group:
Claude Ammann
Claude Ammann Consulting
www.claudeammann.com

Thierry Moreno
NV Logistics & Vital Logistics Group responsible
www.healthcare-logistics.com

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received.

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF).

1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*
	The group welcomes the modifications of the EU GDP documents. The content goes in the right direction and is adapted to the European industry development. Some points need to be improved and our proposals are described hereunder. We have some general comments: - wholesalers are regularly mentioned, but logistic service providers are key partners and are not looked at or mentioned - focus is too much on road transport and national supply and distribution - no difference is made between primary vs. secondary supply (International vs. local supply). - other transport modes (airfreight, ocean freight) used regularly for overseas distribution are not mentioned - complex supply chains with different actors (forwarding companies, transporters, airlines, shipping lines, customs brokers, customs authorities etc…) are not taken into enough consideration - term validation is often used – distribution process can't be validated – at most qualified	

2. Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Agency)*
The second paragraph states "All distribution activities should be clearly defined and systematically reviewed and all critical steps of distribution processes and significant changes should be validated."		Comment: *The distribution itself is a critical step and according to this paragraph, it should be validated. Validation is not possible when an event such as weather conditions is coming into the validation parameters. Therefore this statement should be modified in the following sense* Proposed change (if any): **All distribution activities should be clearly defined and systematically reviewed and all critical steps of distribution processes and significant changes should be maintained under control.**	
Responsible Person 2.5 His/her responsibilities include, but are not limited to:		Comment: *Add :* Proposed change (if any): **xiii) Authorizing the storage of incoming products;** **xiv) Authorizing the dispatch of products** **xv) Ensuring quality agreements between wholesaler and service providers such as calibration laboratories, cleaning companies etc.**	
Point 6.9 "medicinal products returned from a customer not holding a wholesale distribution		Comment: *Knowing the difficulties linked to customs clearance and shipping turnaround time, the proposed time limit is hardly feasible. It should be left to the qualified judgment of the responsible person to define if a product can be returned to*	

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Agency)*
authorization should only be returned to saleable stock if they were returned within five days of original dispatch".		*the saleable stock and not to an arbitrary lapse of time* Proposed change (if any): **"medicinal products returned from a customer not holding a wholesale distribution authorization should only be returned to saleable stock only if it is accepted by the responsible person**".	
Chapter 9 Transportation ***Principle*** "Medicinal products should be transported in accordance with the storage conditions indicated on the packaging information."		Comments: *This requirements is not justified if the manufacturer has stability data and relevant scientific justification that demonstrate that product quality is maintained using transport conditions that are different of storage conditions* Proposed changes (if any): *(see 1079 Good Storage and Shipping Practices, USP 34 page 595 revision proposal in Pharmacopoeial Forum 36(1) (Jan-Feb. 2010.):* **Drug products can be transported at temperatures outside of their labelled storage temperatures if stability data and relevant scientific justification demonstrate that product quality is maintained.**	
9.1 The required storage conditions for medicinal products should be maintained during transportation within the defined limits as described on the packaging		Comments: *This requirements is not justified if the manufacturer has stability data and relevant scientific justification that demonstrate that product quality is maintained using transport conditions that are different of storage conditions* Proposed changes (if any): *(see 1079 Good Storage and Shipping Practices, USP 34 page 595 revision proposal in Pharmacopoeial Forum 36(1) (Jan-Feb. 2010.):*	

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Agency)*
information." 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		**Drug products can be transported at temperatures outside of their labelled storage temperatures if stability data and relevant scientific justification demonstrate that product quality is maintained.** Comments: *This requirement is not justified. Why to fix these requirements for hubs and not for the transport organizations ? All distribution partners should have the same quality standards. Implementing this guideline would make most of the current transport of medicinal products GDP non-compliant. It is still much safer and easier to focus on* - *the control of the distribution chain by the pharmaceutical manufacturer and* - *adequate packaging that protects the medication from negative effects of inappropriate handling* *than trying to fully certify the whole transport chain.* Proposed changes (if any):	

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Agency)*
transportation hub for any period of time would require that premises to hold a wholesalers distribution authorization.			
Point 9.19 - Validated temperature control systems should be used to ensure correct transport conditions are maintained between the distributor and the customer. Customers should be provided with a temperature data to demonstrate that products remained within the required temperature storage conditions during transit, if requested		Comments: *Comment 1 : "control" .means: when it is too cold it must be heated and when it is too hot, it must be cooled. This would be applicable using refrigerated shipping containers. And what about room temperature shipping? Depending on the season, and transit locations, temperature can easily vary from near 0°C to above 45°C.* Proposed changes (if any): Please consider modifying the wording in Point 9.19 to **«Validated temperature monitoring devices...".** *Comment 2 - "Customers should be provided with a temperature data to demonstrate that products remained within the required temperature storage conditions during transit, if requested."* *This should be made if the manufacturer doesn't have sufficient data to demonstrate that product can support short time excursions outside the defined temperature range, especially for small distances e.g. journey time of less than 2 hours.*	

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Agency)*
		Comment 3 - "If requested" - Does this means that record of temperature during transit has not to be recorded and archived if not requested by the customer ?	
Point 9.20 "If refrigerated vehicles are used, the temperature monitoring equipment used during transport should be maintained and calibrated at regular intervals or at a minimum of once a year. This includes thermal mapping .		Comments: *According to this requirement thermal mapping is to be performed each year. Thermal mapping is not time dependent, but depend on the maintenance of the vehicles parts.* Proposed changes (if any): If refrigerated vehicles are used, the temperature monitoring equipment used during transport should be maintained and calibrated at regular intervals or at a minimum of once a year. **Initial thermal mapping should be performed and then the vehicle should be kept in a qualified status. Further thermal mapping might be necessary if significant changes are performed to the installation. This should be documented in the vehicle maintenance log**	

Please add more rows if needed.