October 10th 2011

Submission of comments on 'Commission Guidelines on Good Distribution Practice of Medicial products for Human Use'

Comments from:

Name of organisation or individual
LifeConEx, David BANG and Nina HEINZ

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).

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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 introduction of the document as well as the main body of this guideline makes reference primarily to wholesale distribution and wholesalers. It is however not fully clear as to whom this guideline applies. Does it apply only to the wholesaler or does it also apply to the manufacturer (sometimes also acting as his own wholesaler). It is also mentioned on page 4 that "all parties involved in any aspect of distribution of medicinal products" should consider these guidelines for implementation. This thus opens some room for interpretation as to whether or not logistics providers and/or transportation hubs are also concerned.	
	Additional clarification may be required to clearly stipulate for what substances this guideline applies: APIs? Bulk? Finished Product? Others?	

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)*
Section 3.4		Comment: The reference to "segregated areas" implies that goods should be kept in separated areas. It is unclear if this storage must be physically separate or if the locations can be identified and controlled in an IT system and thus "virtually" separated. Proposed change (if any):	
Section 9		Comment: Again the "Principle" statements only mention about the wholesalers. Transporting of medicinal products involve many parties. Is this document only applicable to the wholesalers?	
Section 9.1		Comment: Reference is made to the "transportation within the defined limits as described on the packaging information". It appears unclear as to how the use of stability data may be applied in cases where stability data allows for transportation under a broader temperature range as the temperature range indicated in the packaging information. Proposed change (if any):	
Section 9.12		Comment: "For refrigerated product any storage at a transportation hub for any period of time would require that premises hold a wholesales distribution authorisation". Taking airfreight shipments as an example, storage periods at	

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)*
		airport warehouses may for many reasons extend over periods of time exceeding 24hours. This could be triggered by customs delays, weekend closures, connecting flights, etc. Such a statement would imply that a shipment at an airport warehouse would thus require the airport warehouse or logistics providers' in-transit warehouses to obtain a wholesale distribution authorization. This case does not seem to be feasible not does it appear to be reasonable. Proposed change (if any):	
Section 9.16		These labels should be more standardized in transportation industry. For an example, there has been a substantial effort made at IATA (International Air Transportation Association) along with pharmaceutical manufacturers. It is according to IATA Chapter 17 of Perishable Regulations.	

Please add more rows if needed.