EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

28 December 2011

Submission of comments on

Guidelines on Good Distribution Practice of Medicinal Products for Human Use

Comments from: The European Express Association (EEA)

Name of organisation or individual

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).

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1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*
	1. Introduction Express Delivery companies are important providers of transportation services to the healthcare sector. The recently published report on the economic impact of the express delivery sector by Oxford Economics indicates that the healthcare sector represents 8% of the customer based on the express delivery sector. More and more manufacturers and distributors of pharmaceutical products look for just in time transport solutions, time and day definite transport and delivery, allowing them to save cost on inventory and storage. This ultimately helps to reduce the cost of pharmaceutical products. **2. Transport is different from Storage** The guidelines seek to tighten the definition of the term "wholesale distribution" (WD) – trading, brokerage and storage of medicinal products – so as to regulate the periphery of this activity that was not previously directly addressed. The draft guidelines use the term storage for medicinal product that was previously considered to be in transit and define any period of refrigerated storage of medicinal products and medicinal products held on a premises for longer than 24 hours as a regulated activity requiring a GDP authorisation on a site by site basis,	

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	subject to full oversight and inspection by regulatory bodies. The draft guidelines moreover do not clarify that "refrigerated product" excludes passive temperature controlled packaging such as isothermic boxes. The draft guidelines also suggest that loading, unloading and reloading should be subject to audit and approval procedures resulting from the new proposed GDP. In practice, it is possible that goods, once handed over to a transportation company, do not continuously move and are temporarily staged in one of the transportation company's sites for more than 24 hrs during the transportation process. However, staging of goods – even if this is done in a controlled environment – is not the objective of the express transportation process. In addition, passive temperature controlled packaging is frequently used. Finally, goods also need to be loaded, unloaded, staged and transported during the process of being moved from origin to destination as defined on the waybill/shipping document. Therefore, without a clarification, the proposed guidelines seem to require the transportation company involved in these steps to convert all its sites into WD compliant facilities. These requirements would significantly increase the cost of the medicinal product supply chains. **3. Solution** To allow the pharmaceutical sector to benefit from cost effective transportation, additional clarification of the draft guidelines is necessary to indicate that temporary	

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	staging – even if this is done in a controlled environment – during a transport service is excluded from warehousing or storage of medicinal products as defined by article 9.12 of the proposed GDP. Furthermore, it should be clarified in 9.12 that passive temperature controlled packaging is excluded from the term “refrigerated products”. We also propose that the guidelines confirm that activities such as loading, reloading and unloading of shipments to move them from one form of transport to another (example: unload from a vehicle to load on an aircraft) are excluded from the provisions listed in 9.13, in particular when it does not involve opening the shipment and repacking of product. The guidelines would also benefit from removing article 9.1 as article 9.4 already provides the necessary clarity on the need to ensure the provision of correct storage conditions as part of the responsibility of the distributor. Given that Article 9.4 sets the leading principle, it should in our view be move to the beginning of the elements listed under transportation.	

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)*
		Comment: Proposed change (if any):	
		Comment: Proposed change (if any):	
		Comment: Proposed change (if any):	

Please add more rows if needed.