EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

31 December 2011

Submission of comments on 'Commission Guidelines on Good Distribution Practice of Medicinal Products for Human Use (EMA/…/…)

Comments from:

Name of organisation or individual
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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)*
	The intent of the regulation is clear. The main indications and the practical choices they point to are largely followed already, I am sure, by responsible operators. Obviously, the regulation as it is will lead to mountains of additional paperwork, concentration of warehousing and transport operations in the hands of a few entities that are willing and able to keep up the level of paperwork and control on their premises, substantial increases in transport/handling costs which will ultimately impact on the cost of the end product to an extent which is presently hard to foresee. On the other hand, we all know that paper does not necessarily match reality and in the present instance I think that it will be difficult that it will unless some additional measures are taken to make the regulation more flexible and to centralize some of the functions that the regulation assigns to operators, especially in terms of controls on wholesalers, transport, hubs. For instance, hubs: airport secured areas cannot be accessed or inspected by single pharmaceutical producer on request. These are those same areas where goods are downloaded and stored, whenever in transit or waiting for pick-up. So, if the EU wishes to implement specific regulations at the level of airport or sea hubs, for instance, they should first of all address their efforts at working with the hubs, thus laying the basis for the regulation to be practically feasible to start with, without pouring on the	

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	drug manufacturers or dealers undue responsibilities that they cannot fulfil. Similarly on land transport, whomever will accept to be contracted based on this regulation will have to be a carrier specialized in the handling of medicines. If the norm has to be fulfilled to the letter, then availability of transport will be limited (by way of example, drugs will be allowed to be transported by GDP trained drivers only !). Costs will doubtlessly be soaring to the stars and it is still to be seen whether the desired level of control will be attained above a certain level (it is more likely that the regulation will be circumvented in practice, whenever sensible and practical to do so). To my mind this is a clear instance of over-regulation of the single details down to a barely realistic level, whose responsibility, by the way, is loaded onto the shoulders of the manufacturers and wholesalers to an unreasonable extent. There are just a few aspects that look to me more problematic than others; this are highlighted in the following section of this document	

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)*
9.12		Comment: "….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 authorisation. …" Proposed change (if any): 24 hrs are indeed rather tight, especially in case of multimodal transport. Swiss authorities are presently oriented on a 72-hrs moratoria, which is more realistic. Admittedly, the regulation plainly says that - if transit exceeds 24 hrs - The hub will need a wholesale distribution authorization. The following article, 9.13, even states (see next).	
9.13		Comment: "…., these premises should be audited and approved prior to deployment. …" Proposed change (if any): The only way to make these requirements in the least practical is to provide for mandatory authorization and centralized audit of the hubs by the Authorities, not by the manufacturers or wholesalers. In other words, it would be fair, practical and commercially sound that the responsibility for authorization and surveillance stayed with the state, rather than with the single users of the services, who are subject already to a heavy burden of requirements based on this same regulation.	
4th paragraph of the introduction of		Comment: "…. Regardless of the chosen mode, it should be possible to demonstrate that the medicines have not been subjected to conditions during transportation that may	

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chapter 9		compromise their quality….” This would mean data loggers on all shipments, regardless of their sensitiveness to temperature, humidity etc and regardless of seasonal factors. Again, rather impractical and costly, especially considered that the manufacturers/wholesalers are required by the regulation to carry out Quality Risk Assessment by default. Proposed change (if any):	

Please add more rows if needed.