<21.12.2011>

Submission of comments on '2011-07_gdpguidline_publicconsultation' (EMA/…/…)

Comments from:

Name of organisation or individual
DB Schenker

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)*
	<u>Section 9.12</u> Due to the fact that the allowed time for storage is now down to 24 hours (compared to 48 hours before the new update) it will be almost impossible setting up weekend operations without having a fully licensed facility. 1. Maximum of 24 hours at a hub. That will make it difficult for a transport setup. Especially if sea-, air- or train is used. For domestic distribution that would be a problem for deliveries at Mondays. That would require pick up at Sundays with special setups and extra costs for the manufacturer. 2. For refrigerated products no time at a hub is allowed without wholesalers authorisation. That is not feasible at all, and will make it impossible to transport and distribute refrigerated products. Every hub (airports, sea terminals, distribution hubs etc) would need authorization. We believe that the current wording / regulation is strict enough to secure the temperature control without this authorisation.	

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.