14/12/2011

Submission of comments on ' Commission Guidelines on Good Distribution Practice of Medicinal Products for Human Use'

Comments from:

Name of organisation or individual
Fresenius Medical Care (Schweiz) AG Medical-Scientific Department Aawasserstrasse 2 CH-6370 Stans

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)*

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)*
Chapter 9 Transportation: Transportation, 9.1		Comment: The added guidelines of chapter 9 "Transportation" are stipulated in detail and will ensue comprehensive investments into transport control activities. In practice transportation duration can range between few hours to many weeks. In order not to impose the unreasonable, rigid specification to transport at storage conditions for short duration transports, transport specifications should be defined by the manufacturer or distributor based on stability data. E.g. if a medicinal product fulfills the release specifications under accelerated conditions (40°C, 6 months), it should be allowed to be transported for a total of 36 hours transportation time at temp. <40°C. Proposed change (if any): 9.1 The transport conditions for medicinal products during transportation should be defined on the basis of their stability data.	
		Comment: Proposed change (if any):	

Please add more rows if needed.