



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1st December 2011

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

(SANCO/C8/AM/an D(2010) 380358)

Comments from:

Celgene Europe Ltd / Celgene International SARL

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 <i>(To be completed by the Agency)</i>	General comment (if any)	Outcome (if applicable) <i>(To be completed by the Agency)</i>
	Are the expectations for storage and distribution of products without any special storage conditions considered?	
	Chapter 7 is ambiguous. Outsourcing activities are only defined in point 7.5; furthermore they are specified as activities falling under the definition of wholesale definition. This means that contracted activities like pest/vermin control or cleaning are not in the scope of this paragraph. Is there a possibility to make this clearer in the introduction of this chapter?	
	Clarification is required on acceptable criteria for procedure for investigating and handling temperature excursions	

2. Specific comments on text

Line number(s) of the relevant text <i>(e.g. Lines 20-23)</i>	Stakeholder number <i>(To be completed by the Agency)</i>	Comment and rationale; proposed changes <i>(If changes to the wording are suggested, they should be highlighted using 'track changes')</i>	Outcome <i>(To be completed by the Agency)</i>
Chapter 9: Transportation 'Principle'		<p>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 compromise their quality. A risk based approach should be utilized when planning transportation routes.</p> <p>Proposed change (if any): Regardless of the chosen mode, it should be possible to demonstrate by a risk analysis that the medicines have not been subjected to conditions during transportation that may compromise their quality. A risk based approach should be utilized when planning transportation routes.</p>	