December 2011

Submission of comments on 'Commission Guidelines on Good Distribution Practice of Medicinal Products for Human Use (SANCO/C8/AM/an (2010) 380358)

Comments from:

Name of organisation or individual
BRISTOL-MYERS SQUIBB

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received.

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)*
Introduction The relevant sections of these guidelines should also be considered for implementation by, among others, governments, regulatory bodies, international procurement organisations and donor agencies, as well as all parties involved in any aspect of distribution of medicinal products. This Guideline is presented as a set of basic requirements in different Chapters providing details about specific areas of activity.		**Comment:** Clarify if this Guideline is intended to apply to IMP products **Proposed change (if any):** N/A	
3.4 Medicinal products not intended for the Union market should be kept in segregated areas.		**Comment:** For Supply Chain efficiency, many companies ship their goods together. For example, products for Norway, Iceland, Switzerland and Russia, are stored with EU. The differentiation is done only when dispatching. It will be very difficult to apply this requirement. **Proposed change (if any):**N/A	
4.8 Records		**Comment:** To be deleted as empty **Proposed change (if any)**: N/A	

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5.4 Purchase of medicinal products should be controlled by written procedures. The supply chain of medicinal products should be known and documented.		**Comment:** Clarify if this requirement includes all the Supply Chain steps including routing. **Proposed change (if any):** N/A	
Segregation of Goods 5.24 If required, medicinal products should be stored in segregated areas, which are clearly marked and their access restricted to authorised personnel. Any system replacing physical segregation such as electronic segregation based on a computerised system shall provide equivalent security and should be validated.		**Comment:** Clarification should be provided for the meaning of "if required". **Proposed change (if any):** N/A	
6.3 Any complaint concerning a potential product defect or a potential falsified product should be recorded with all the original details and investigated. The national competent authority should be notified without delay.		**Comment:** Competent authority is notified of confirmed product defect if serious only and not potential (EU GMP). Regarding falsified product, the notification to Authority should be made after the investigation confirms the falsified product. **Proposed change (if any):** The national competent authority should be notified without delay of any serious product defect or any falsified product.	
6.9 Medicinal products which have left the premises of the distributor should only be returned to saleable stock if: i) the medicinal products are in their unopened and undamaged secondary packaging and in good condition; ii) medicinal products returns from a customer not holding a wholesale distribution authorisation should only be returned to saleable stock if they were returned within five days of original dispatch;		**Comment:** Five days is not enough for the products returned from pharmacists due to the transportation time for delivery and shipment back organization. Also clarify if it working days or calendar days.	

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iii) it is demonstrated that the medicinal products have been transported, stored and handled under proper specified/predefined conditions; iv) they have been examined and assessed by a sufficiently trained and competent person authorised to do so; v) the distributor has reasonable evidence that the product was supplied to that customer and the batch number of the dispatched product is known, that a copy of the original delivery note is attached and that there is no reason to believe that the product has been falsified.		**Proposed change (if any):** N/A	
6.10 Medicinal products requiring low temperature storage conditions can be returned to saleable stock only if the batch number of the dispatched product is known and there is evidence that the product has been stored within the authorised storage conditions throughout the entire time. This evidence should include but is not limited to the following: - delivery to customer - opening of the packaging - examination of the product - returning of the product to the packaging and sealing of the packaging - collection and return to the distributor - return to the distribution site refrigerator		**Comment:** **Proposed change:** - returning of the product to the packaging of the product and sealing of the packaging	
Chapter 9 Transportation ***Principle*** It is the responsibility of the wholesale distributor that, during the supply of medicinal products, the transport conditions are such as to maintain the quality of the product, to protect against breakage, adulteration and theft, and to ensure appropriate environmental conditions are maintained during transport. Adequate precautions should be taken to this effect.		**Comment:** Clarification needed for "adulteration" meaning. **Proposed change (if any):** N/A	

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Medicinal products should be transported in accordance with the storage conditions indicated on the packaging information.		**Comment:** 1. Proposed wording: "Labelled storage conditions". 2. There will be issues in some markets regarding the Logistics means that are available. The controlled temperature trucks fleet is not enough in several EU countries to ship all pharmaceutical products in controlled temperature conditions. **Proposed change:** 1. "Labelled storage conditions". 2. N/A	
Transportation 9.1 The required storage conditions for medicinal products should be maintained during transportation within the defined limits as described on the packaging information.		**Comment:** Same comment as above: There will be issues in some markets regarding the Logistics means offer. The controlled temperature trucks fleet is not enough in several EU countries to ship all pharmaceutical products in controlled temperature conditions. **Proposed change (if any):** N/A	
9.8 Dedicated vehicles and equipment should be used, where possible, when handling medicinal products. Where non-dedicated vehicles and equipment are used procedures should be in place to ensure that the quality of the medicinal product will not be compromised.	.	**Comment:** Clarify if "Dedicated" mean dedicated to Pharmaceutical products or pharmaceutical products of the Company **Proposed change (if any):** N/A	

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9.12 Where transportation hubs are utilised in the supply chain, a maximum time limit of normally 24 hours should be set to await the next stage of the transportation route. 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. For refrigerated product any storage at a transportation hub for any period of time would require that premises to hold a wholesalers distribution authorisation.		**Comment:** The limit of 24 hours is not enough. The products may stay in a hub for more than 48 hours, 72 hours, even 7 days. It will take time to get a wholesaler authorization for a hub. Consequently, a transition period has to be accepted so that carriers that are currently used by the wholesalers can continue to be used without interruption pending the new status granting. There is a risk that the carriers refuse to request the Wholesale status and therefore less carriers are available for the pharmaceutical products shipments. **Proposed change (if any):** N/A	
9.18 Transportation of medicinal products comprising highly active and radioactive materials should be transported in safe, dedicated and secure containers and vehicles. In addition, these safety measures should be in accordance with international agreements and national legislation.		**Comment:** Need clarification about ”active”. Do these active materials include Cytotoxics? **Proposed change (if any):** N/A	
Temperature Control during Transport 9.19 Validated temperature-control systems (e.g. thermal packaging, temperature-controlled containers, and refrigerated vehicles) should be used to ensure correct transport conditions are maintained between the distributor and customer. Customers should be provided with a temperature data to demonstrate that products remained within the required temperature storage conditions during transit, if requested.		**Comment:** See above comment 9.1. Clarification is needed regarding a possible risk based approach without temperature monitoring if a transportation solution (active or passive) is validated. Customers can be provided with the information that the validation has been performed. **Proposed change (if any)**: N/A	