EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

<21 November 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:

| Name of organisation or individual |
| --- |
| **Union européenne des Pharmacies sociales (UEPS)**<br>**European Union of the Social Pharmacies (EUSP)**<br>Route de Lennik 900<br>B-1070 Bruxelles<br>T : +32.25 299 242<br>F : +32.25 299 376<br>GSM : +32.479 285 900<br>E-mail : mh_cornely@multipharma.be<br>Website : http://www.eurosocialpharma.org |

*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<br>*(To be completed by the Agency)* | General comment (if any) | Outcome (if applicable)<br>*(To be completed by the Agency)* |
|---|---|---|
| | 1. Those guidelines gives more clarity on risk management and gives more guidance compared to the text from 1994 (94/C 63/03).<br>2. Description of Critical Processes can be added for clarity. Suggestion is to define Critical Processes as the outcome of a risk based approach and add some examples just for information<br>3. Why are Medicines for Animal use not in scope or clearly excluded (Dir. 2001/82)?<br>4. Chapter 10: Specific Provisions for Brokers. The guidance is deviating to much in comparison to regular wholesalers/distributors. Comparable expectations for comparable activities should be established. | |

## 2. Specific comments on text

| Line number(s) of the relevant text<br>*(e.g. Lines 20-23)* | Stakeholder number<br>*(To be completed by the Agency)* | Comment and rationale; proposed changes<br>*(If changes to the wording are suggested, they should be highlighted using 'track changes')* | Outcome<br>*(To be completed by the Agency)* |
|---|---|---|---|
| 1.4 & 1.6 | | Comment: There is overlap in these two paragraphs<br><br>Proposed change (if any): Merge into one paragraph | |
| 1.11 | | Comment: add "documented"<br><br>Proposed change (if any): The outcome of this management review of the quality management system should be timely and effectively communicated and documented. | |
| 2.4 | | Comment: Rephrase the paragraph to reflect the effective content and liability.<br><br>Proposed change (if any): The Responsible Person should carry out his/her activities in such a way to ensure the wholesale distributor can demonstrate GDP compliance and that public service obligations are met. | |
| 2.16 | | Comment: Change "storage" to "presence" to reflect better the intent.<br><br>Proposed change (if any): The presence of food, drink, smoking materials or medication for personal use in the storage areas should be prohibited. | |
| 3.3 & 3.4 | | Comment: These paragraphs should reference to 5.24 where a | |

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|---|---|---|---|
| | | validated Building Management System can be used instead of physical separation<br><br>Proposed change (if any): | |
| 3.23 | | Comment: Not clear what is meant by "Durability", additional clarification would be useful.<br><br>Proposed change (if any): | |
| Chapter 4 principle | | Comment: specify that paper as well as electronic format can be used.<br><br>Proposed change (if any): Instructions, procedures, and records should be free from errors and each employee should have access to such instructions and procedures in paper or electronic format. | |
| 4.6 | | Comment: More specification is needed<br><br>Proposed change (if any): All necessary documentation for the tasks executed should be readily available. | |
| 4.8 | | Comment: text lay out, should be formatted as title<br><br>Proposed change (if any): | |
| 4.10 | | Comment: Add expiry date to the summation. | |

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|---|---|---|---|
| | | Proposed change (if any): Records should include the following information: date; name of the medicinal product; expiry date; quantity received, supplied or brokered; name and address of the supplier, broker or consignee, as appropriate; and batch number where required. | |
| Chapter 5 principle paragraph 3 | | Comment: please revise sentence. It is not clear what exactly is meant. Is parallel import meant?<br><br>Proposed change (if any): | |
| 5.2 & 5.5 | | Comment: Replace "qualification" by "mutual verification of Distribution Licenses"<br><br>Proposed change (if any): | |
| 5.4 | | Comment: replace written by documented so paper based as electronic format can be used<br><br>Proposed change (if any): Purchase of medicinal products should be controlled by documented procedures. The supply chain of medicinal products should be known and documented. | |
| 5.7 | | Comment: "due diligence" is a heavy term. This paragraph is also related to 5.2 & 5.5 | |

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|---|---|---|---|
| | | Proposed change (if any): | |
| 5.17 | | Comment: It is not always possible for wholesalers with a lot of references to store all products "separately". A risk based approach should be used to guarantee the quality, efficacy and safety of the products.<br><br>Proposed change (if any): | |
| 5.18 | | Comment: It is not clear what is the definition of "Containers"<br><br>Proposed change (if any): Add "Containers" to Glossary of Terms | |
| 5.21 | | Comment: Is not always possible. Some medicinal gasses are placed directly on the floor.<br><br>Proposed change (if any): | |
| 5.26 | | Comment: segregation and separation are used throughout the document. Both terms should be added to the Glossary of Terms for clarification.<br><br>Proposed change (if any): | |
| 5.32 | | Comment: Additional clarification needed | |

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|---|---|---|---|
| | | Proposed change (if any): Records (paper based or electronic format that can made visible/printed) should be kept so that the actual physical journey undertaken by the product can be tracked. | |
| 5.32 | | Comment: clarification needed on "at least for products bearing the safety features"<br><br>Proposed change (if any): | |
| 5.33 | | Comment: "operation" change into "operating"<br><br>Proposed change (if any): A person exporting medicinal products must thus hold a wholesale distribution authorization or a manufacturing authorization. This is also the case if the exporting wholesale distributor is operating from a free zone. | |
| 6.9 ii | | Comment: 5 days is very short, as pharmacies don't have wholesale licenses they can be added.<br><br>Proposed change (if any): medicinal products returns from a customer not holding a wholesale distribution Authorization/pharmacy license should only be returned to saleable stock after thorough evaluation | |
| 6.20 | | Comment: "available" can be replaced by "Accessible"<br><br>Proposed change (if any): | |
| 9.12 | | Comment: for consistency use of "2°-8°" instead of | |

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|---|---|---|---|
| | | refrigerated.<br><br>Proposed change (if any): | |
| 9.12 & 9.13 | | Comment: Incorporate Risk Based evaluation in the use of HUB's<br><br>Proposed change (if any): | |
| 9.12 | | Comment: add HUB to the Glossary of Terms<br><br>Proposed change (if any): | |

Please add more rows if needed.