**From:** Terracciano Maria [m.terracciano@sanita.it]
**Sent:** lundi 2 janvier 2012 17:52
**To:** SANCO GMP
**Cc:** ADM-GMDP@ema.europa.eu
**Subject:** WC500004016terCommission Guidelines on Good Distribution Practice of Medicinal Products for Human Use
We apologize for the delay of this trasmission for internet problems
yours sincerely
Maria Terracciano

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<Date of submission>
30 December 2011

Submission of comments on '<document title>' (EMA/…/…) Commission Guidelines on Good Distribution Practice of Medicinal Products for Human Use

## Comments from:

**Name of organisation or individual**

**Italian Ministry of Health – Department of Planning and Organization of the National Health Service – Directorate General for Medical Devices**

**Sender : Maria Terracciano**

**Medicines Wholesale Distribution expert**

**On Behalf of**

**Marcella Marletta**

**Director General**

*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 | General comment (if any) | Outcome (if applicable) |
|---|---|---|

| *(To be completed by the Agency)* | | *(To be completed by the Agency)* |
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# 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:** It is necessary to exercise control over the entire chain of distribution objectives by observing good manufacturing practice of medicinal products. This policy ensures that products manufactured in, or imported into the European Union are of the appropriate quality. This level of quality should be maintained throughout the distribution network without any alteration. | | Comment:<br>to exercise control over the entire chain of<br>distribution objectives can be performed by observing<br>good distribution Practice and not manufacturing practice<br>of medicinal products.<br>A correct Good Distribution Practice has to preserve a medicinal product level of quality throughout the distribution network without any alteration.<br><br>Proposed change (if any):<br>to exercise control over the entire chain of<br>distribution objectives can be performed<br>by observing ***Good distribution Practice of medicinal products.***<br>A correct Good Distribution Practice has to preserve a medicinal product level of quality throughout the distribution network without any alteration. | |
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| **CHAPTER 1 Quality Manager** 1.2 A responsible person should be appointed by the management for each distribution site,<br>who should have defined authority and responsibility for ensuring that a quality system is implemented and maintained | | Comment:<br>**This provision should be moved to chapter 2**<br>Proposed change (if any): Delete this point and move it to the point 2 | |
| 1.4 The size and complexity of distributor's activities should be taken into | | Comment: **GDP have to ensure the same standards and the same independent quality of the size and complexity of the activities as risk is not related to the size** | |

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| consideration when developing the quality management system or modifying an existing one | | Proposed change (if any):<br>**1.4 Independent of the size and complexity of a distributor's activities a quality management system should be implemented** | |
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| 1.8<br>**V**)deviations from established procedures are documented and investigated;<br>vi) appropriate corrective and preventive actions (CAPA) are taken to correct | | Comment: **Principles of the risk management are not defined in the relevant GDP**<br>**Proposed change delete point vi and create a single point v**<br>deviations from established procedures are documented and investigated ***and further actions decided to correct deviations and avoid their reoccurrence***<br><br>Proposed change (if any):<br>deviations from established procedures are documented and investigated ***and further actions decided to correct deviations and avoid their reoccurrence***<br>vi) appropriate corrective and preventive actions (CAPA) are taken to correct<br>deviations and prevent them in line with the principles of quality risk management. ***DELETE all point VI*** | |
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| | | Comment:<br><br>Proposed change (if any): | |
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Please add more rows if needed.

<Date of submission>
30 December 2011

Submission of comments on '<document title>' (EMA/…/…) Commission Guidelines on Good Distribution Practice of Medicinal Products for Human Use

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| **Marcella Marletta** |
| **Director General** |
| |

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## 3. 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)* |
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# 4. 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)* |
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Please add more rows if needed.