EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 December 2011

Submission of comments on 'the revised Commission guidelines on Good Distribution Practice of Medicinal Products for Human Use (SANCO/C8/AM/anD(2010)380358)

Comments from:

Name of organisation or individual
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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)*
	Comment: As a general comment, the analysis of the guideline has highlighted a serious concern related to the early implementation of the revised GDP guideline even before the entry into force of Directive 2011/62 and delegated acts. The risk it could arise is a non-coordinated legislation impacting the supply chain with different timing and approaches.	

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)*
1.1		**Comment:** The use of the term "adulterated" it could create misunderstanding as it is not in line with the term "falsified" as it is reported in the Directive 2011/62 **Proposed change**: Replace the term "adulterated" with "falsified"	
1.3		**Comment:** the guideline speaks about "senior management". It would be helpful to understand what is meant exactly: how many years of experience should have a person to be considered as "senior"? What kind of experience? To whom he/she should (or should not) hierarchically report the "Person Responsible"? In other words, these aspects should be clarified as they have been for the Qualified Person in the industrial side of the supply chain.	
2.10 e 2.11		**Comment:** When the text refers to training, it is intended for initial training or continuing education? how often and at what minimum level? The guidelines should clarify the obligations for the distributors regarding this theme.	
3.4		**Comment:** The physical segregation of medicinal products intended for	

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		the EU from those that are not intended for the EU poses tremendous practical feasibility questions. This is particularly critical for supply chain operators such as international manufacturers who carry out distribution. **Proposed change:** remove section 3.4 from the final guidance text or to change the text as follow Medicinal products not intended for the Union market should **either** be kept in segregated areas **or controlled by an approved and validated computer system.**"	
3.9		**Comment:** The requirement to install an alarm system appears very detailed for the purpose of a general guideline on GDP. Additionally, various valid ways may be considered to prevent unauthorized access depending on the situation at stake. **Proposed change:** Accordingly, we would propose the following change in the proposed text **"**Prevention measures would usually include, but not be limited to, a monitored intruder alarm system and**/or** appropriate access control."	
3.13		**Comment :** The parameter of humidity should be set up only for those areas where sensitive products are handled. Keeping this parameter within the limits established for the entire storage	

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		area, with no differentiation, would be enormously expensive as storage areas for pharmaceuticals are generally large and bulky.	
3.15		**Comment:** The current wording lacks specificity to indicate that only the relevant equipment used and having an impact on the medicinal product quality must fulfil this requirement. **Proposed change:** We therefore propose the following change to the draft text **"**All equipment used **and impacting on** the ~~storage~~ quality and distribution of medicinal products …"	
4.8		**Comment:** Editorial comment: This seems to be a title and not a numbered item. **Proposed change:** Remove art. 4.8	
5.8		**Comment:** A clarification is needed in relation to what is meant by documentation to "qualify customers".	
5.14		**Comment:** The disclosure of a suspected falsified medicinal products should be given not only to the competent authority, but always also to the MA Holder. **Proposed change:** Delete "where applicable"	
9.6		**Comment:** the guideline should clarify whether written	

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		standard operation procedures are needed and at what level of detail	
9.12		**Comment:** The guideline requires hubs who handle medicinal products for storage for more than 24 hours to have a wholesale distribution authorization. The particular geography of the Italian territory poses serious concerns regarding the feasibility of such provision. The distributors and carriers network in Italy will suffer enormous problems. In order to fulfill with this requirement some carriers/distributors might have to raise prices to recoup from huge investment, with direct effects on the drugs costs that can be easily imagined. **Proposed change:** Remove article 9.12	
9.13		**Comment:** **"***In the event that the transportation of medicinal products requires* ***unloading and reloading e.g. at terminals and hubs, these premises should be audited and approved prior to deployment****. Whenever any changes are made to the approved premises or functions, attention should be paid to the continued suitability of the changed premises or functions for their intended use. Particular attention should be paid to temperature monitoring, cleanliness and the security of unguarded intermediate storage facilities."* We foresee major challenges and critical feasibility issues with the implementation of the above requirement. It is in our opinion not realistic to expect manufacturing authorisation holders and / or MAH to audit all terminals at	

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		airports and all harbours where medicines transit. Additionally, it appears equally unlikely that airports and harbours representatives will accept such audits to be carried out and moreover, in the event a company would suggest changes and improvements based on findings during their audit, there are no guarantees that these would be taken into account. **Proposed change:** The EMA and European Commission should clarify whether EU GDP inspectors will initiate dialogue with customs authorities in airport and harbour storage facilities in view of future authority inspections.	

Please add more rows if needed.