29/12/2011

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

Stowarzyszenie Importerów Równoległych Produktów Leczniczych

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- parallel importers organisation

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)*
	References to GMP should be removed. If there are some GMP supporting documents that are applicable to GDP, they should have separate GDP supporting version.	

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)*
1.5		Comment:*A quality manual orequivalent documentation approach should be established.* – what is quality manual in this sense? Proposed change (if any): define what quality manual is	
1.8 iii)		Comment: only the part that deliveries should reach "right recipients" fits within GDP, time to deliver ("satisfactory") is a business part and should not be regulated Proposed change (if any): delete "within a satisfactory time period"	
1.8 iv)		Comment: point too general, not all activities need to be recorded at the time they are performed Proposed change (if any): activities necessary to be recorded should be listed	
1.9		Comment:*The quality management system should extend to the control and review of any outsourced activities* – not every outsourced activity (eg. accounting) needs to be implemented in the GDP QMS	

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		Proposed change (if any): list of outsourced activities connected to distribution, necessary to be implemented in the QMS should be made (eg. transport)	
1.11		Comment: there should be stated to whom the outcome of review should be communicated Proposed change (if any): The outcome of this management review of the quality management system should betimely and effectively communicated **within the company**	
1.13		Comment: QRM should be aimed for the protection of the product, not patient, because wholesaler has no contact with patient and therefore QRM should be not as complicated as for pharmaceutical production purposes Proposed change (if any): replace "patient" with "product" and erase references to GMP guidelines	
2.1		Comment: Responsible Person is not able to be "permanently available" while fulfilling the responsibilities personally Proposed change (if any): specify in which situations RP is should be available; add possibility to appoint duties to other employees	
2.5 vi)		Comment: those duties should be also possible to be	

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		delegated Proposed change (if any): add possibility to delegate qualification of suppliers and customers	
2.5 x)		Comment: delegating duties should be possible whenever necessary, not only during the absence of RP; there is also contradiction with 2.1 where the RP should fulfil the responsibilities personally and be permanently available Proposed change (if any): change to "x) delegating her/his duties **whenever necessary** and keeping appropriate records to any delegation"	
2.11		Comment: training about product identification and avoidance of falsified medicines should be only mandatory for employees working with the product (e.g. telemarketing does not have to be included in the training) Proposed change (if any): add "where appropriate" at the end of the sentence	
3.4		Comment: we do not see the point in this, because "intention of sale" can change or can be not specified, because wholesaler will not know if he is going to sale product within EU or export it at the moment of storage	

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		Proposed change (if any): erase this point	
3.5		Comment: light-sensitive products should be protected appropriately by the manufacturer, GMP guarantees the quality of the product at the manufacturer level, therefore no additional control is needed at wholesale level Proposed change (if any): delete "or light"	
3.9		Comment: appropriate access control will be sufficient Proposed change (if any): delete "a monitored intruder alarm system and"	
3.14		Comment: what do "significant modifications" mean? Proposed change (if any): define what is treated as "significant modification"	
3.20 – 3.25		Comment: unnecessary complication and burden for wholesalers Proposed change (if any): erase this chapter	
3.26 – 3.29		Comment: unnecessary complication and burden for wholesalers	

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		Proposed change (if any): erase this chapter	
4.8		Comment: typing mistake Proposed change (if any): delete "4.8" and mark "Records" as sub-chapter title	
4.11		Comment: too wide point which gives impression that everything should be recorded in real time Proposed change (if any): change to "Records should be made in such a way that allsignificant activities or events are traceable."	
5.7		Comment: does it mean that due-diligence should be performed "on site" of every supplier? Proposed change (if any): if so, the point should be modified because it would engage too much wholesaler resources to perform due-diligence with every supplier	
5.8		Comment: the point does not include clinics and hospitals; is it necessary to quality every single pharmacy? Proposed change (if any): add hospitals and clinics and "other authorised entities" to the approved wholesaler customers category	

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5.14		Comment: "any suspicion" is very wide and can trigger false alarms, what then happens with the segregated batch, how long do we have to wait until it is again put in the saleable stock? Proposed change (if any): specify what fits within "suspicion of falsified medicinal product" and how the procedure is organised	
5.17		Comment:what does it mean "stored separately"? Proposed change (if any): specify the requirements – is marked area in the warehouse enough? delete reference to light (see comment to point 3.5)	
5.20		Comment: it is a business of wholesaler how he wants the stock to rotate, the only rule is that he cannot supply recipients with expired product Proposed change (if any): erase this point	
5.29		Comment: it is a business of wholesaler how to handle the stock Proposed change (if any): erase "It should be picked on a "firstexpired first out" (FEFO) basis."	

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5.32		Comment: this would mean real-time monitoring of transport trucks – unnecessary burden Proposed change (if any): erase this point	
6.1		Comment: in case of complaint authorities, not MAH/manufacturershould be notified by wholesaler Proposed change (if any):change to "In the case of a complaint about the quality of amedicinal product, the **relevant authorities** should beinformed without delay."	
6.9 ii)		Comment: why 5 days? the products are handled by authorised recipient (pharmacy) therefore they are stored in proper conditions Proposed change (if any): change to "medicinal productsreturns from a customer not holding a wholesale distribution authorisation should only be returned to saleable stock if they are not expired and they were stored in proper conditions;"	
6.9 iv)		Comment:what does "sufficiently trained and competent person authorised to do so" mean? Proposed change (if any):specify what training, competences	

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		and/or authorisations this person needs	
6.9 v)		Comment: typing errors Proposed change (if any):evidence that **th** the product was **upplied**	
6.10		Comment:see comment to point 6.9 ii) Proposed change (if any): this evidence should include only a statement from the customer, that he has stored the goods in proper, required conditions	
6.11		Comment: RP should be able to delegate the duties of handling/approving the returned medicinal products Proposed change (if any):add "the Responsible Person**or deputy person**"	
6.12		Comment: it is a business of wholesaler how he handles his stock, the only rule is that he can not sell expired medicinal product, GDP should not impose FEFO rule Proposed change (if any): erase this point	
6.14		Comment: see comment to point 5.14 and 6.1	

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		Proposed change (if any): change to "Distributors mustimmediately inform the competent authority about the medicinal products they identify as falsified orsuspect to be falsified. A procedure should be in place to this effect."; please specify how the procedure and handling of the goods should be processed (see comment to point 5.14)	
6.16		Comment: sudden recall procedure test could cause confusion on the market (if the recall is a real one or a test) Proposed change (if any): specify how the "periodical testing of recall procedure" should look like and what steps need to be taken	
6.17		Comment: "at any time" far too wide Proposed change (if any): change to "Recall operations should be capable of being initiated promptly and at any time **within working days/working hours of the distributor performing the recall procedure**"	
6.20		Comment: Proposed change (if any): add "e-mail address" to the list of "sufficient information" in the brackets	
7.1		Comment: contract giver cannot be responsible for the	

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		activities of other company Proposed change (if any): erase this point	
Chapter 9		Comment: Proposed change (if any): all requirements for distributor related to transport (like 9.4, 9.5, 9.6, 9.7, 9.8, 9.9, 9.10, 9.14, 9.15, 9.17, 9.23 etc.) should be clearly noted as possible to be outsourced and therefore the responsibility lies on transport company not on the distributor	
9.12		Comment:transportation hubs should have authorisation no matter how long (or short) the products is stored in the hub Proposed change (if any):change to "Where transportation hubs are utilised in the supply chain, 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 atransportation hub for any period of time would require that premises to hold awholesalers distribution authorisation."	
9.16		Comment: this point would impose on printing the storage conditions on collective package, which is an unnecessary burden, because storage conditions are clearly described in the invoice and in the transport documents	

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		Proposed change (if any): change to "Containers should bear labels providing sufficient information to enable identification of the contents of the containers and the source.	

Please add more rows if needed.