<Date of submission>

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

Comments from:

Name of organisation or individual
Spanish Agency of Medicinal Products and Medical Devices

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).

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1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*
	Overall, we welcome the drafting of this guideline. It provides detailed requirements that will have a final positive impact on ensuring safety throughout the distribution chain.	

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 (new paragraph 2)		Comment: A definition of GDP is needed; the Proposed change (if any): GDP is that part of the quality assurance which ensures that the quality of medicinal products is maintained at all stages of the activities from the site of the manufacturer to the pharmacy or person authorised or entitled to supply medicinal products to the public.	
Introduction Line 23 (paragraph 6 page 4)		Comment: The supply of medicinal products is not included in the mentioned activities of wholesale distributors. We consider it would be better to include "supplying", which is one of the four activities included in the definition of wholesale of medicinal products in Directive 2001/83. Proposed change (if any): "….to wholesale distribution activities (such as exporting, holding storing or supplying)".	
Introduction Line 27 (paragraph 8 page 4)		Comment: It could be convenient to change the wording related to the requirement to comply with GDP for manufacturers in order to clarify their need to comply with GDP when performing distribution activities.	

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		Proposed change (if any): "…Manufacturers performing any distribution activities with their own products should also comply with GDP."	
Introduction Line 29 (paragraph 8 page 4)		Comment: Spelling mistake Proposed change (if any): "…shall be subject to certain provisions applicable…"	
Point 1.1 (page 5)		Comment: It seems that the only objective is to ensure confidence that the product delivered is not adulterated during storage and/or transportation Proposed change (if any): "…that the product delivered maintains its quality and safety during storage and/or transportation."	
Point 1.4 and 1.6 (page 5)		Comment: Points 1.4 and 1.6 could be integrated in the same bullet. Proposed change(if any): 1.4 The size and complexity of distributor's activities should be taken into consideration when developing the quality management system or modifying an existing one. This should be reflected in the organisation of the quality system . "	
Point 1.5 (page 5)		Comment: We propose a change of wording Proposed change (if any): The quality system should be defined, agreed, approved, and fully documented and its effectiveness monitored.. A quality	

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		manual or equivalent documentation approach should be established.	
Point 1.9 (page 5)		Comment: We propose to delete the word 'management' for consistency with the wording of this chapter Proposed change (if any): The quality system should extend…	
Point 1.11 (page 6)		Comment: the outcome of the management review should as well be documented, e.g. in a report, and should be available for inspection. Proposed change: The outcome of this management review of the quality management system should be documented and timely and effectively communicated.	
Point 3.8. (page 11)		Comment: Receiving areas should be equipped with materials to clean containers before storage, in consistency with GMP requirements (GMP point 3.20). Proposed change: addition of the following sentence at the end of point 3.8: Reception areas should be designed and equipped to allow containers of incoming materials to be cleaned where necessary before storage.	
Point 4.8 (page 14)		Comment: Delete	
Chapter 5		Comment: We propose to delete last paragraph that is already	

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Principle		included in Directive 2001/83 article 76.3, except the last sentence. We think it is not needed and the mention of the 'importation' by a wholesaler, even when related to medicinal products received from another Member State and in the same way that is included in the directive, might be confusing for other actors. Proposed change (if any): .All key operations should be fully described in the quality management system in appropriate standard operating procedures.	
Point 5.6 (page 16)		Comment: Brokers must also comply with the other requirements included in Directive 2001/83 that would be transposed into national regulations Proposed change (if any): If the medicinal product is obtained through brokering, the wholesale distributor must verify that the broker is registered and complies with the requirements set out in national regulations and those included in Chapter 10[14]	
Point 5.8 (page 16)		Comment: the qualification of customers should be perfomed on all of them. Proposed change (if any): It is the responsibility of the distributor to ensure the customers are appropriately authorised or entitled to receive a	

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		particular medicinal product at the appropriate address from the distributor	
Title of point 5.11 (page 16)		Comment: The title does not correspond with its content Proposed change (if any): ***Distribution in other Member States***	
Point 5.11 (page 16)		Comment: In relation with the sentence *"Where appropriate the competent authorities will inform the wholesale distributor of any public services obligation imposed on wholesale distributions operating on their territory",* we consider that if the obligation is included in the national regulations there is no additional need for the authorities to inform the wholesalers about it because distributors have to be informed and have an appropriate knowledge of national laws, prior to begin their operations in that territory. Proposed change (if any): Where appropriate, the wholesale distributor should comply with any public service obligation imposed on wholesale distributors on national regulations .	
Point 5.22 (page 17)		Comment: Regarding the sentence "Medicinal products beyond their expiry date or shelf life should be withdrawn…". According to Spanish regulations medicinal products cannot be supplied to pharmacies if they have passed 6 months before its expiry date, unless exceptionally authorised. A reference to national regulations may be needed.	

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		Proposed change (if any): "Medicinal products beyond their expiry date, shelf life, or too close to it, should be withdrawn immediately from saleable stock either physically or through other equivalent electronic segregation. Requirements imposed in this regard by national should be adhered to	
Point 5.33 (page 18)		Comment: Spelling mistake Proposed change (if any): This is also the case if the exporting wholesale distributor is operating n from a free zone.	
Point 5.34 (page 19)		Comment: points b and c It is stated that there is no obligation to verify the authorisation status or GDP compliance of customers/suppliers in third countries. The current approach could pose risks to public health not only for the third countries but also for EU countries. It would also set a different level of warranties when the products are intended for the EU market or third countries and this could be against EU trade interests. It is clear that the legal requirements will be different from those in the EU but the customer/supplier should fulfil them, otherwise we would be allowing the operations between our	

[1] Article 85a of Directive 2001/83/EC
[2] Article 85a of Directive 2001/83/EC

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		wholesalers and companies in third countries who do not fulfil legal requirement in those countries. The need of these checks is already included in WHO last guidelines (WHO Tech. Report Series,No 957,2010: *5.5 Holders of an authorization to distribute pharmaceutical products should obtain their supplies of pharmaceutical products only from persons or entities which are in possession of the applicable authorization to sell or supply such products to a distributor.* *5.6 Distributors or their agents should supply pharmaceutical products only to persons or entities which are themselves authorized to acquire such products either in terms of an authorization to act as a distributor or to sell or supply products directly to a patient or to his or her agent.* Proposed change: 5.34. The rules for wholesale distribution [1] apply in their entirety in the case of export of medicinal products, with the following exceptions[2]: a. The medicinal product does not have to be covered by a marketing authorisation of the EU or a Member State. b. The shipment of medicinal products has to be in accordance with the legislation related to medicinal products in the country of destination. i.e. the medicinal product must have a marketing authorization or an importation authorization, and	

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		the receptor customer of the shipment must posses the appropriate permits as importer or distributor, whatever it is required in the country where it is located. c. Distributors operating in free trade zones should ensure, when exporting medicinal products received directly from third countries, that their suppliers are appropriately authorised according to local regulations.	
Chapter 6 Principle		Comments: The need of a procedure for recalls is already in 6.16. The concept of 'similar situations' is unclear so we propose to delete the last sentence Proposed change:	
Point 8.1 (page 25)		Comments: The last sentence "….whilst individual self inspections may be limited in scope" is not clear. Proposed change: "….However, every self inspection scope or activity could be limited."	
Point 9.19 (page 28)		Comments: "Customers should be provided with data to demonstrate that products….". There is not always data to provide it is common to use pass/no pass indicators that only provide information if the temperature during transport was OK or not.	

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		Proposed change: "…Customers should be provided with evidence or records to demonstrate that products remained within the required temperature storage conditions during transit, if requested".	
Chapter 10 Principle (paragraph 2)		Comments: We proposed to insert the mention of wholesaler distributor for clarification. Proposed change: Thus a person that procures, holds, supplies or exports medicinal products is never a broker but a wholesale distributor.	
Chapter 10 Principle (paragraph 5)		Comments: We proposed to insert the mention of 'export' also included wholesale distribution definition and repeat the activities in the order they are in the directive as well as in paragraph 2 of this principle. Also in the same paragraph the word management should be deleted in order to align with the name of the system in Chapter 1. Proposed change: By definition, brokers do not procure, hold, supply or export medicines… brokers must maintain a quality system that ensures applicable records are kept, efficient emergency plans for supporting recalls…	

Please add more rows if needed.