EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

October 5th 2011

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

Comments from:

Name of organisation or individual
EALTH : European Association for Logistics and Transportation in Healthcare

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).

7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom

An agency of the European Union

Telephone +44 (0)20 7418 8400 Facsimile +44 (0)20 7418 8416
E-mail info@ema.europa.eu Website www.ema.europa.eu

1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*
	1) Having analyzed in detail the GDP guideline proposition document, we found that, in the light of the responsibilities and actions that are requested to the different actors of the pharmaceutical supply chain, we would prefer the use of sharper terms than wholesale, wholesaling, wholesale distributor, distributors and wholesaler in the different paragraphs. At this day, both volumes handled and missions accomplished show that we are playing an important role as Pharmaceutical Logistics Service Providers acting as Pre-wholesalers and Healthcare Transport Providers. Thus, more precision and clearer attribution of roles and responsibilities among the different actors would lead to a better understanding and efficient implementation. 2) As rightly emphasized in the document, security in the supply chain is fundamental and risk management is a necessary approach to deploy and apply these Good Distribution Practices. We are already using this approach. Moreover our best practices take especially into account the GMP	

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	Pharma Validation Process which includes not only Process Design and Process Qualification but also a Continued Process Verification. This is in particular the case when selecting critical suppliers /providers or means.	

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)*
Chap 1, §1.8 iii)		Comment: NA Proposed change (if any): " iii) products are delivered to the designated recipients within a satisfactory time period;"	
Chap 1, § 1.11		Comment: NA Proposed change (if any): The outcome of this management review of the quality management system should be timely and effectively communicated at least once a year.	
Chap 2, § 2.5 vii		Comment: NA Proposed change (if any): vii) authorizing or executing the authorization of the return to saleable stock of any returned medicines;	
Chap 2, § 2.5 v		Comment: Does effectively mean efficiently in this context, if so could you replace effectively by efficiently. Proposed change (if any): v) ensuring that relevant customer complaints are efficiently dealt with ;	
Chap 2, § 2.5 xi		Comment: According to the pharmaceutical definition of	

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		quarantine the word "decision" is not appropriate for all wholesaling actors. Proposed change (if any): xi) being involved in any decision to quarantine or dispose of returned, rejected, recalled or falsified products; Pharmaceutical Supply Chain service providers shall guarantee the good execution of such decisions.	
Chap 3, 3.26		Comment: we propose to replace "plan" by "protocol" (EUDRALEX vol. 4 ap. 15) Proposed change (if any): The protocol should specify acceptance criteria.	
Chap 4, 4.8		Comment: An error has occurred in the sub numbers. Proposed change: 4.9, 4.10 and 4.11 replaced by i), ii) et iii).	
Chap 5 Principle		Comment: Could you explain the use of the word "distributor" in this chapter? Proposed change: All actions taken by all actors involved in the distribution operations should ensure that the identity of the medicinal product is not lost and that wholesale distribution of medicinal products is handled according to the specifications given on the packaging information	

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Chap 5, § 5.1 to 5.11		Comment: Qualification of suppliers and customers, marketing authorization should only concern wholesale distributors, when owner of the products. Proposed change: NA	
Chap 5, § 5.17		Comment: Medicinal products could be stored separately with other Healthcare products and ensure that they are managed under the required pharmaceutical processes. Proposed change: 5.17 Medicinal products should be stored separately from other products except the case of Healthcare products treated under the same pharmaceutical processes. They should be protected from harmful effects of light, temperature, moisture or other external factors. Particular attention should be paid to products where specific storage conditions are required	
Chap 5, § 5.33		Comment: We understand that export is considered being outside the EU. Could you clarify? Proposed change: NA	
Chap 6, § 6.9 ii		Comment: NA Proposed change: ii) medicinal products returns from a customer not holding a wholesale distribution authorization should only be returned to saleable stock if they were returned within ten to fifteen working days of original dispatch;	
Chap 6, § 6.10		Comment: We propose these words. Proposed change: 6.10 Medicinal products requiring controlled	

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		temperature storage conditions can be returned to saleable stock only if the batch number of the dispatched product is known and there is evidence that the product has been stored within the authorized storage conditions throughout the entire time. This evidence should include but is not limited to the following: - delivery to customer - opening of the packaging - examination of the product - returning of the product to the packaging and sealing of the packaging - collection and return to the distributor - return to the distribution in the appropriate temperature conditions	
Chap 7, §7.6		Comment: NA Proposed change: The Contract Acceptor should not pass to a third party any of the work entrusted to him under the contract without having had previously evaluated and audited the third party as well as informed the Contract Giver. Arrangements made between the Contract Acceptor and any third party should ensure that the wholesale distribution information is made available in the same way as between the original Contract Giver and Contract Acceptor.	
Chap 9, §9.19		Comment: Comment: We must consider cooling and heating, the second change is based on the thermal packaging and temperature controlled containers validation.	

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		Proposed change: 9.19 Validated temperature-control systems (e.g. thermal packaging, temperature-controlled containers, and temperature controlled vehicles) should be used to ensure correct transport conditions are maintained between the distributor and customer. Customers should be provided with a temperature data to demonstrate that products remained within the required temperature storage conditions during transit, if requested.	
Chap 9,§9.20		Comment: We must consider cooling and heating, the second change is based on the same assessment than in §9.7 Proposed change: 9.20 If temperature controlled vehicles are used, the temperature monitoring equipment used during transport should be maintained and calibrated at regular intervals or at a minimum of once a years. This includes temperature mapping and vehicle type-validation under representative conditions and should take into account seasonal variations. Customers should be provided with data to demonstrate that products remained within the required temperature storage conditions during transportation, if requested.	
Chap 10, Principle		Comment: could you please tell us who are targeted under the definition of brokers? Do you confirm that the Broker own (buy and sell) without any physical contact with the Medicinal product and their different packaging?	

Please add more rows if needed.