<Date of submission>

Submission of comments on '**Good Distribution Practice of Medicinal Products for Human Use**'

Comments from:

Name of organisation or individual
Conseil National de l'Ordre des Pharmaciens (French National Council of the Order of Pharmacists)

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)*
	"Wholesale distributor" should be used in all parts of the document, not only "distributor".	

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 (p4)		Comment: Returns should be prohibited except in case of delivery error. Proposed change (if any):	
Chapter 1 Quality Management (p6)		Comment: Proposed change (if any): 1.9- It should be specified that "Outsourced activities" means "**Pharmaceutical outsourced activities**".	
Chapter 2 Personnel (p8)		Comment: Being "permanently available" does not mean "being permanently present". Proposed change (if any): 2.1- The wholesale distributor must designate a person as Responsible Person. The Responsible Person should fulfil his/her responsibilities personally, **can delegate some of his/her tasks and can be reached at any time**. The Responsible Person should meet the conditions provided for by the legislation of the Member State concerned.	
Chapter 3 Premises and Equipment (p11)		Comment: Proposed change (if any): 3.5- Where specific storage conditions are required, **monitoring** should be adequate to maintain all parts of the relevant storage area within defined temperature, humidity or light parameters.	

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Chapter 4 Documentation (p14)		Comment: The numbering is not correct. Proposed change (if any): Numbering should be corrected as follows: 4.8- Records **4.8.1**- Records must be kept… **4.8.2**- Records should include… **4.8.3**- Records should be made…	
Chapter 5 Operations (p16)		Comment: Proposed change (if any): 5.12- The purpose of the receiving function is to ensure that the arriving consignment is **in compliance with the delivery slip**, the medicinal products originate from approved suppliers and that they have not been damaged or altered ~~during transportation~~.	
Chapter 5 Operations (p17)		Comment: Proposed change (if any): 5.17- Medicinal products should be stored separately from other products **likely to alter them** and protected from harmful effect of light, temperature, moisture or other external factors. Particular attention should be paid to products where specific storage conditions are required.	

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Chapter 5 Operations (p18)		Comment: Proposed change (if any): 5.32- For all supplies to a person authorised or entitled to supply medicinal product to the public, a document must be enclosed to ascertain the date; name and pharmaceutical form of the medicinal product, batch number at least for products bearing the safety features, where required; quantity supplied; name and address of the supplier, name and delivery address of the consignee (actual physical storage premises, if different) ~~and applicable transport and storage conditions. Records should be kept so that the actual physical journey undertaken by the product can be tracked~~.	
Chapter 6 Complaints, Returns, suspected falsified Medicinal Products and Medicinal Product Recalls (p20-21)		Comment: Proposed change (if any): 6.9- Medicinal products which have left the premises of the distributor should only be returned to saleable stock if: i) the medicinal products are in their **original** unopened, **sealed if need be** and undamaged ~~**secondary**~~ packaging and in good condition; … iii) it is demonstrated **by the consignee** that the medicinal products have been transported, stored and handled under proper specified/predefined conditions; …	

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Chapter 6 Complaints, Returns, suspected falsified Medicinal Products and Medicinal Product Recalls (p21)		Comment: Proposed change (if any): 6.10- Medicinal products requiring low temperature storage conditions **cannot** 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 authorised 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 site refrigerator	
Chapter 6 Complaints, Returns, suspected falsified Medicinal Products and Medicinal Product Recalls (p21)		Comment: Proposed change (if any): 6.11- All handling of returned medicinal products including their return to saleable stock or disposal **(which is the case of the products requiring low temperature storage conditions)** should be **made by an authorized person under the authority of** the Responsible Person **defined in § 2.1** ~~and recorded~~.	

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Chapter 6 Complaints, Returns, suspected falsified Medicinal Products and Medicinal Product Recalls (p22)		Comment: Proposed change (if any): 6.20- The distribution records should be readily available to the person(s) responsible for the recall, and should contain sufficient information on distributors and directly supplied customers (with addresses, phone and/or fax numbers inside and outside working hours, batches and quantities delivered), including those for exported products and medicinal product samples, **according to the legislation of the Member State concerned**.	
Chapter 7 Contract Operations (p23)		Comment: Proposed change (if any): Principle - When outsourcing activities a written contract should be drawn up. Both the contract giver and the contract acceptor **must hold an authorisation according to the legislation of the Member State concerned**. The written and signed contract should cover all wholesale distribution activities and clearly establish the duties and responsibilities of each party. Written contracts should be established for any activity likely to impact on GDP related activities.	
Chapter 7 Contract Operations (p23)		Comment: Proposed change (if any): 7.1- The Contract Giver **should set up a quality system** ~~is responsible~~ for the activities contracted out.	

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Chapter 7 Contract Operations (p23)		Comment: Proposed change (if any): 7.2- The Contract Giver is responsible, **regarding the critical pharmaceutical activities**, for assessing the competence of the Contract Acceptor to carry out successfully the work required and for ensuring by means of the contract and through audits that the principles and guidelines of GDP are followed. An audit of the Contract Acceptor should be performed before the beginning of the outsourced activities and afterwards audits should be done periodically.	
Chapter 8 Self-Inspections (p25)		Comment: Proposed change (if any): 8.3- Audit of subcontracted **critical pharmaceutical** activities should be a part of the self-inspection programme.	

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Chapter 9 Transportation (p26)		Comment: Proposed change (if any): Principle - **It is the responsibility of the wholesale distributor that, during the supply of medicinal products until delivery, the quality of the product be maintained, and breakage, adulteration and theft be prevented.** ~~It is the responsibility of the wholesale distributor that, during the supply of medicinal products, the transport conditions are such as to maintain the quality of the product, to protect against breakage, adulteration and theft, and to ensure appropriate environmental conditions are maintained during transport.~~ ~~Adequate precautions should be taken to this effect.~~ ~~Medicinal products should be transported in accordance with the storage conditions indicated on the packaging information.~~ ~~Appropriate transport methods should be employed which may include transport by air, road, sea, rail or a combination of the above. Regardless of the chosen mode, it should be possible to demonstrate that the medicines have not been subjected to conditions during transportation that may compromise their quality. A risk based approach should be utilised when planning transportation routes.~~	
Chapter 9 Transportation (p26)		Comment: Proposed change (if any): 9.1- The required ~~**storage**~~ **preservation** conditions **during transportation** for medicinal products should be **compatible** ~~**maintained during transportation**~~ within the defined limits as described on the packaging information **and should take into account the product criticity and the transportation duration**.	

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Chapter 9 Transportation (p26)		Comment: Proposed change (if any): 9.2- If a **temperature** deviation has occurred during transportation, this should be reported to **all parties: the contract giver,** the distributor and recipient of the affected medicinal products.	
Chapter 9 Transportation (p26)		Comment: Proposed change (if any): 9.4- It is the responsibility of the distributor to **make sure** ~~ensure~~ that vehicles and equipment used ~~to distribute, store or handle medicinal products~~ are suitable ~~for their use and appropriately equipped~~ to prevent exposure of the products to conditions that could affect their quality and packaging integrity, and to prevent contamination of any kind.	
Chapter 9 Transportation (p26)		Comment: Proposed change (if any): 9.8- **Suitable** ~~Dedicated~~ vehicles and equipment should be used, where possible, when handling medicinal products. Where non-**suitable** ~~dedicated~~ vehicles and equipment are used procedures should be in place to ensure that the quality of the medicinal product will not be compromised.	
Chapter 9 Transportation (p27)		Comment: Proposed change (if any): 9.11- If transportation is sub-contracted to a third party then the contract should encompass the requirements contained within Chapter 7. In addition the contractors should be fully aware of all relevant conditions applicable to the ~~storage and~~ transportation of medicinal products.	

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Chapter 9 Transportation (p27)		Comment: Proposed change (if any): **The order of 9.12 and 9.13 should be reversed.**	
Chapter 9 Transportation (p27)		Comment: Proposed change (if any): 9.12- In the event that the transportation of medicinal products requires unloading and reloading e.g. at terminals and hubs, the~~se~~ **concerned organisations** ~~premises~~ should be audited and approved prior to deployment. Whenever any changes are made to the approved premises or **organisation** ~~functions~~, attention should be paid to the continued suitability of the changed premises or **organisation** ~~functions~~ for their intended use. Particular attention should be paid to temperature monitoring, cleanliness and the security ~~of unguarded intermediate storage facilities~~.	
Chapter 9 Transportation (p27)		Comment: Proposed change (if any): 9.13- Where transportation hubs are utilised in the supply chain, **the transit duration should be set in common with the contract giver** ~~a maximum time limit of normally 24 hours should be set to await the next stage of the transportation route~~. **Particular attention should be paid to the transit of refrigerated products.** ~~Where medicinal products are held on the premises for longer than this defined time limit, 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 a transportation hub for any period of time would require that premises to hold a wholesalers distribution authorisation.~~	

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Chapter 9 Transportation (p27)		Comment: Proposed change (if any): 9.16- Containers should bear ~~labels providing~~ sufficient information on handling and storage requirements and precautions to ensure that the products are properly handled and secured at all times. The containers should enable identification of the contents of the containers and the source.	
Chapter 10 Specific Provisions for Brokers (29-30)		Comment: Brokers are not wholesale distributors. Guidelines on Good Distribution Practice do not apply to brokers. Including brokers activities in the present guidelines could lead to a risk of considering them as wholesale distributors. Proposed change (if any): **This chapter should be removed from the guidelines.**	

Please add more rows if needed.