



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

21/9/11

## Submission of comments on revised guideline on good distribution practice of medicinal products for human use (2001/83/EC)

### Comments from:

#### Name of organisation or individual

The NHS Pharmaceutical Quality Assurance Committee

The NHS Pharmaceutical Quality Assurance Committee is comprised of the lead specialist Quality Assurance Pharmacists who work for the National Health Service (NHS) in the United Kingdom. Many NHS Hospital Pharmacy Departments hold either a manufacturing licence, a wholesale dealers licence or both and thus must comply with the requirements of EU Good Distribution Practice. We are therefore commenting on these proposed changes with respect to the impact they may have on NHS hospital pharmacy practice.



## 1. General comments

Stakeholder number <i>(To be completed by the Agency)</i>	General comment (if any)	Outcome (if applicable) <i>(To be completed by the Agency)</i>
	In general the NHS Pharmaceutical Quality Assurance Committee is fully supportive of the proposed changes outlined with the exception of some specific points with respect to transportation as detailed below.	

## 2. Specific comments on text

<b>Line number(s) of the relevant text</b> <i>(e.g. Lines 20-23)</i>	<b>Stakeholder number</b> <i>(To be completed by the Agency)</i>	<b>Comment and rationale; proposed changes</b> <i>(If changes to the wording are suggested, they should be highlighted using 'track changes')</i>	<b>Outcome</b> <i>(To be completed by the Agency)</i>
Paragraph 9.4		<p>Comment: NHS hospital pharmacies that hold a wholesale dealers licence may on occasion distribute medicines using general couriers such DHL or send medicines through the postal system or in urgent cases, particularly at night they may send medicines to another hospital or healthcare provider using a taxi service. In such circumstances the dispatching pharmacy will need to ensure that any medicines distributed in this manner are packaged in such a manner that protects them from conditions that could affect their quality and packaging integrity, and to prevent contamination of any kind. However, it would be impossible for the dispatching hospital to ensure that vehicles and equipment used to distribute, store or handle medicinal products are suitable for this purpose.</p> <p>Proposed change (if any): Remove this specific requirement as it is covered by the more general requirement stated in paragraph 9.1 that “the required storage conditions for medicinal products should be maintained during transportation within the defined limits as described on the packaging information” and 9.8 that “dedicated vehicles and equipment should be used, where possible, when handling medicinal products. Where non-dedicated vehicles and equipment are used procedures should be in place to ensure that the quality of the medicinal product will not be compromised”. This activity would also be covered by the provisions given in Chapter 7 Contract Operations. For example if a taxi service is used for urgent local deliveries a contract should be in place with the taxi company which specifies where and how medicines are to be collected, that the taxi takes the item directly to the destination without deviating from the route or</p>	

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		<p>stopping to undertake other work and where and how the medicines are to be handed over.</p>	
<p>Paragraph 9.5</p>		<p>Comment: NHS hospital pharmacies that hold a wholesale dealers licence may on occasion distribute medicines using general couriers such DHL or send medicines through the postal system or in urgent cases, particularly at night they may send medicines to another hospital or healthcare provider using a taxi service. In such circumstances the dispatching pharmacy will need to ensure that any medicines distributed in this manner are packaged in such a manner that protects them from conditions that could affect their quality and packaging integrity, and to prevent contamination of any kind. However, it would be impossible for the dispatching hospital to ensure that the "delivery drivers (including contract drivers) should be trained in the relevant areas of GDP".</p> <p>Proposed change (if any): Remove this specific requirement as it is covered by the more general requirement stated in paragraph 9.1 that "the required storage conditions for medicinal products should be maintained during transportation within the defined limits as described on the packaging information". This activity would also be covered by the provisions given in Chapter 7 Contract Operations as outlined in our comment above.</p>	
<p>Paragraph 9.11</p>		<p>Comment: NHS hospital pharmacies that hold a wholesale dealers licence may on occasion distribute medicines using general couriers such DHL or send medicines through the postal system or in urgent cases, particularly at night they may send medicines to another hospital or healthcare provider using a taxi service. In such circumstances the dispatching pharmacy will need to ensure that any medicines distributed</p>	

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		<p>in this manner are packaged in such a manner that protects them from conditions that could affect their quality and packaging integrity, and to prevent contamination of any kind. However, it would be impossible for the dispatching hospital to ensure that “in addition the contractors should be fully aware of all relevant conditions applicable to the storage and transportation of medicinal products”.</p> <p>Proposed change (if any): Remove this specific requirement as it is covered by the more general requirement stated in paragraph 9.1 that “the required storage conditions for medicinal products should be maintained during transportation within the defined limits as described on the packaging information”. This activity would also be covered by the provisions given in Chapter 7 Contract Operations as outlined in our comment above.</p>	

Please add more rows if needed.