



31st December 2011

**EUROPEAN COMMISSION**  
HEALTH AND CONSUMERS DIRECTORATE-GENERAL  
Public Health and Risk Assessment  
**Pharmaceuticals**

## **Consultation on Guidelines on Good Distribution Practice of Medicinal Products for Human Use**

### **Response from the Guild of Healthcare Pharmacists**

Thank you for the opportunity to respond to this consultation. The Guild of Healthcare Pharmacists represents UK wide around 4,000 pharmacists including the majority of hospital pharmacists, pharmacists employed by NHS Primary Care organisations and pharmacists employed by other public bodies such as Prisons and the Care Quality Commission. The Guild is part of the health sector of the union Unite.

Our comments and suggestions on specific areas of the guidelines are set out below but we firstly wish to make the following general comments:

The document is very readable and comprehensive and we welcome the additional emphasis on risk management, management of outsourced activities, and review and monitoring requirements.

In terms of the NHS Hospital service in the UK, a great deal of the focus is upon two areas:

(a) Prevention of suspected falsified Medicinal Products entering the supply chain -

This is now less of a problem for UK hospitals as there is almost total adherence to Generic contracts from reputable suppliers with QA testing. Branded medicines tend to be purchased either direct or through their nominated distributor.

(b) Development of Good Distribution Practices (to improve what we do and to manage suspected falsified medicinal products entering the supply chain). We believe that the proposed new guidelines build on previous GDP publications by emphasising quality systems and how they should be developed and managed. In order to do this effectively as described there may be a requirement for additional resources. We would urge all NHS Hospital Trusts to adhere to these guidelines irrespective of whether they have/need a Wholesale Dealers Authorisation. We would recommend that a copy of the document be circulated (at the earliest opportunity) to all those involved in procurement and distribution as well as to Chief Pharmacists so that they can start working towards completing the expectations.

In terms of registered pharmacies, there is a need for an exemption from the requirement of a wholesaler distribution authorisation when a product is sold to a purchaser, out-with the legal entity, who intends to sell, supply or administer the product to another person. This should be an inconsiderable part of the

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business otherwise a formal authorisation should be obtained. This is to ensure that minimal supplies of medications are available to small organisations and their patients. The requirements for a quality system to be in place should be a condition of registration set by the national regulator.

We wish to comment on the following specific areas of the guidelines:

## **Chapter 2 Personnel –**

*Responsible person:* Whilst the details in this section should provide for a higher quality management system we feel that (a) the a degree in Pharmacy is essential rather than desirable within statement 2.3, and (b) a statement is needed to actually specify that the responsible person must fulfil his/her responsibilities personally (even though this is implied by statement 2.5 x).

## **Chapter 3 Premises and Equipment –**

*Premises:*

We feel that there should be an additional statement to take adequate precautions against spillage or breakage, attack by micro-organisms, and cross contamination.

*Temperature and Environment Control:*

3.13 – “Suitable equipment and procedures should be in place to ensure adequate control of the environment of medicinal products during storage”: We propose that written procedures should state that recorded deviations in temperature from the required ranges must be reported to a senior person within the quality system and acted on immediately.

## **Chapter 4 Documentation –**

*4.7 General* – “Attention should be paid to maintaining the SOP system so as to ensure the use of valid and approved procedures”: We feel that documents should be approved, signed and dated by the person responsible for the quality system.

*4.8 Records* – There is no text following this heading! This is either an omission or the following sub-sections 4.9, 4.10, and 4.11 should be sub-sections (or bullet points) under 4.8.

## **Chapter 5 Operations –**

*Delivery:*

This section does not mention emergency situations and we therefore propose that suppliers should be in a position to supply immediately the medicinal products that they regularly supply to the persons entitled to supply the products to the public.

## **Chapter 6 Complaints, Returns, suspected falsified Medicinal Products and Medicinal Product Recalls –**

*Principle:* “All complaints and other information concerning potentially defective medicinal products must be collected and reviewed carefully according to written procedures”: We feel that procedures should be approved, signed and dated by the person responsible for the quality system.

*Returned Medicinal Products:*

6.9 v – there are two typos in the first line: ‘th’ and ‘applied’

## **Chapter 9 Transportation –**

*Transportation of Products requiring special conditions:*

9.17 “In relation to deliveries containing medicinal products requiring special conditions such as narcotics or psychotropic substances”: We propose that the ‘psychotropic substances’ should be changed to ‘medicines of potential misuse or abuse’.

There are certain areas of the guidelines that are of particular importance and which we feel they require greater emphasis. We therefore suggest replacing the word ‘should’ with ‘must’ in the following sections:

Chapter 2 Personnel: 2.3, 2.4, 2.6, 2.8, 2.10 to 2.16 inclusive.

Chapter 3 Premises and Equipment: 3.1 to 3.12 inclusive.

Chapter 4 Documentation: 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.10, 4.11

Chapter 5 Operations: 5.13, 5.17, 5.19 to 5.27, and 5.31.

Chapter 6: 6.8, 6.11, 6.19, 6.20, and 6.21

Chapter: 7: 7.4, 7.6 and 7.7.

Chapter 9: Principle - 3<sup>rd</sup> line, and at 9.1, 9.2, 9.3, 9.14, and 9.16 to 9.19 inclusive.

Our reply may be made freely available.

Yours faithfully

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