GHP Guild of Healthcare Pharmacists

unite the UNION

European Commission
Enterprise and Industry Directorate General
Consumer Goods: Pharmaceuticals

7th May 2008

Dear Sir/Madam

Public Consultation in Preparation of a Legal Proposal to Combat Counterfeit Medicines for Human Use

Response from the Guild of Healthcare Pharmacists UK

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 Primary Care Trusts (PCTs) and pharmacists employed by other public bodies such as the Commission for Social Care Inspection and the Healthcare Commission. The Guild is part of the health sector of the union Unite-Amicus section.

General points

We welcome the proposal to introduce legislation to combat counterfeit medicines for human use in Europe as;

This is becoming an increasing threat to public health
Life-saving drugs are now being targeted
The classical supply chain is being targeted making traditional supplies less reliable
Some products may be just substandard but still pose a risk to health

We consider that medicines imported into Europe should be manufactured to the same standards as those manufactured within Europe and manufacturing premises inspected to ensure this.

We also consider that the whole of the supply chain should be subject to inspection to similar standards as wholesalers.

President: Richard Cattell
Professional Secretary: Jean Curtis, 6, The Sycamores, Bishops Stortford, Herts CM23 5JR
Tel / fax: 01279 831685 Mobile: 07979 245346 Email: Jeancm23@aol.com ***Website:*** www.ghp.org.uk

However, we do have some concerns about costs and beaurocracy of some of the proposals, and in particular, on the definition of "end user" for the purposes of opening packs (section 4.11.3).

Responses to "Key Ideas".

Our responses to the specific "Key ideas for changes to EC legislation" are shown below. The "key ideas" are shown in italics.

4.1.1.
a) Clarify that the obligations for wholesalers apply to all parties in the distribution chain, except for those directly distributing or administering to the patient. Brokers, traders and agents would be considered as wholesalers, with the respective obligations stemming from the pharmaceutical legislation

b) Make regular audits of GMP/GDP compliance mandatory by qualified auditors:
- of (contract) manufacturers by manufacturers;
- between suppliers (wholesalers, manufacturers) at least in cases of suspicion of non-compliance with GMP and/or GDP.

We support these proposals in principle, provided they will not be excessively costly.

If the organisation is already inspected by, for example, a licensing authority, there should be no need to have separate audits of manufacturers by manufacturers and between suppliers, provided inspections and audits are to the same standards.

It would be necessary for third party audits by accredited companies to be acceptable. Not every organisation, including UK NHS organisations, would have the necessary expertise to carry out the tasks noted in b) above, themselves.

4.1.2
Strengthen provisions on inspections and supervisions, in particular regarding inspections in third countries. For example make application of the Community procedures on inspections and supervision ("Compilation of Community Procedures on Inspections and Exchange of Information") mandatory.

Include specific harmonised provisions for inspections by competent authorities of parties in the distribution chain (e.g. wholesalers, brokers, traders, agents, business-to-business platforms).

We support these proposals.

4.1.3.
Require the outer packaging of medicinal products to be sealed. This would reveal any subsequent opening of the packs.

Such a requirement could be applied to certain categories of products chosen on a risk-based approach, i.e. by taking into account the public health impact of the appearance of a counterfeit product and the profit strategies of counterfeiters.

The right to opening the outer packaging would be restricted to the market authorisation holder and end-user (hospital, health care professional, or patient).

Sealing of outer packaging of medicinal products: we are not convinced that the benefit would be significant: seals would be easy to copy, although the breaking of the seal might deter some less sophisticated counterfeiting organisations.

The definition of "end user" needs to be carefully formulated to avoid creating unsafe situations. It is **essential for pharmacists to retain the right to open packs for reasons of patient safety.** This may be when dispensing certain medicines or pre-packing them under controlled conditions, ready for issue to such patients. The pharmaceutical industry is unlikely ever to be able to produce the number and range of packs required for specialist work.

Examples are:

- Supply of medicines in small instalments to suicidal patients to avoid them taking an overdose. These may be dispensed directly to the patient, or the hospital may prepare pre-packs to avoid unnecessary repetitive work at busy times.
- Supply of types of preparations such as eye drops, creams and ointments, where the container which the patient uses are inside a carton. It is accepted good practice to label a dispensed medicine on the inner container which the patient uses so that they cannot throw away the instructions for use.
- Under certain circumstances the pharmacist may wish to check the contents of a medicines container to assure him/herself that the product appears to be in order, for the protection of the patient.
-

A pharmacist **must** be able to open packs.

4.1.4
Require the possibility of tracing ownership and transactions of a specific batch. This should be achieved by making a specific record (pedigree) obligatory.

The record should be accessible by all actors in the distribution chain.

We support the principle of being able to trace ownership and transactions of a specific batch. However, the proposals for a central record would seem to be costly and liable to error, and we expect it would be relatively easy to forge entries.

4.1.5
Require the possibility to trace each pack and perform authenticity checks. This could be attained by a mass serialisation feature on the outer packaging. Technical details would be further defined in implementing legislation and/or by standardisation organisations.

Mass serialisation would need to be demonstrated to be cost effective, eg if the number of serious counterfeiting incidents increased steeply this proposal might become more cost effective.

4.1.6
Require GDP certificates to be issued after each inspection of a wholesaler.

Establish a Community database of wholesalers (including distributing manufacturers) documenting GDP compliance. This could be achieved via extension of the EudraGMP database.

We support these proposals.

4.2
Directive 2001/83/EC would be clarified to the effect that imported medicinal products intended for export (i.e. not necessarily subject to marketing authorisation) are subject to the rules for imports of medicinal products. The following provisions would apply:

- *The obligatory importation authorisation under the conditions set out under Article 41 Directive 2001/83/EC, e.g. relating to premises and the qualified person;*
- *The relevant obligations for the importation authorisation holders set out under*
- *Articles 46 and 48 Directive 2001/83/EC, e.g. relating to staff and access for inspection;*
- *The obligations stemming from Article 51(1)(b) and (2) Directive 2001/83/EC, relating to qualitative and quantitative analysis of the imported medicinal product; and*
- *The relevant obligations stemming from Directive 2003/94/EC on good manufacturing practice.*

The corresponding rules on inspections would apply.

We support these proposals.

4.3.1
Submit the manufacturing/import of active ingredients to a mandatory notification procedure.

- *Render information on notified parties available in a Community database. This could be achieved via extension of the EudraGMP database.*

We support this proposal.

4.3.2

- *Make regular audits of active substance suppliers on GMP compliance by manufacturers and importers of medicinal products mandatory. Auditors should be sufficiently qualified.*
- *Require, where scientifically feasible, control of active substances via sufficiently discriminating analytical techniques, such as fingerprint technologies, Near Infrared Spectroscopy (NIR), as a mandatory method for identification by the manufacturer of the medicinal product. Such a testing is meant to identify deviations of the manufacturing process and manufacturing site for each batch.*
- *Turn principles of good manufacturing practice for active substances placed on the Community market into a legal act of Community law (e.g. a Commission Directive) in order to enhance enforceability.*

We support these proposals.

4.3.3.
The competent authority may carry out announced or unannounced inspections of active substance manufacturers in order to verify compliance with the principles of good manufacturing practice for active substances placed on the Community market. The competent authority shall carry out these inspections if there is suspected noncompliance with GMP.

The competent authority shall carry out repeated inspections in the exporting country if the third country applies standards of good manufacturing practice not at least equivalent to those laid down by the Community or if mechanisms for supervision and inspections are not at least equivalent to those applied in the Community. To this end, a Member State, the Commission or the Agency shall require a manufacturer established in a third country to undergo an inspection.

We support these proposals.

We hope these comments are of assistance

Our reply may be made freely available.

Yours sincerely

Jean Curtis

Jean Curtis
Professional Secretary