British Association of Pharmaceutical Wholesalers

European Commission consultation in preparation of a legal proposal to combat counterfeit medicines for human use

Response by:

British Association of Pharmaceutical Wholesalers

Introduction

The British Association of Pharmaceutical Wholesalers (BAPW) is the trade association for an essential, but often overlooked, part of the medicines supply chain – full-line wholesalers. We have 10 members: AAH Pharmaceuticals Ltd., F.Maltby & Sons Ltd., Mawdsley-Brooks & Co. Ltd., Norchem Ltd., Phoenix Healthcare Distribution Ltd., P.I.F. Medical Supplies Ltd., Sangers (Maidstone) Ltd., Sangers (Northern Ireland) Ltd., Sants Pharmaceutical Distributors Ltd and UniChem Ltd.

The BAPW represents only full-line wholesalers (as opposed to short line operators). This is an important distinction to make since short liners only stock and supply products where they can make the biggest profit margins. Full-line wholesalers, on the other hand, offer a full range of products to their customers, even those lines where there is little or no profit mark up. Wholesalers are a vital part of the supply chain which sees medicines delivered quickly and safely to patients. In some countries, elements of full-line pharmaceutical wholesaling are viewed as a public service and receive state subsidies, although in the UK this is not the case. Wholesalers buy most of the medicines they supply direct from manufacturers to meet the demands of the customer - the NHS. In essence, the industry carries all the risk and investment involved in the distribution of medicines with no specific investment or subsidy from, or cost to, the NHS or the taxpayer.

The BAPW welcomes the European Commission's public consultation on key ideas for better protection of patients against the risk of counterfeit medicines. The public consultation comes at the right time, following the extensive debate on how to address the increasing threat to public health and safety of counterfeit medicines penetrating the market and reaching patients.

Full-line pharmaceutical wholesalers – ensuring patient safety

As Full-line wholesalers we take our responsibilities to patients very seriously. In the UK, medicines wholesalers are rigorously and regularly inspected by the Medicines and Healthcare products Regulatory Agency (MHRA) and were the only stakeholder group praised for our operating procedures in the Shipman Inquiry into controlled drugs. Full-line wholesalers place the highest premium on patient safety and we go to great lengths to ensure that the medicines we supply are in perfect condition and are safe for patients. Full-line wholesalers work with suppliers, customers and regulators to co-ordinate action to prevent counterfeit medicines entering the supply chain. For example, the MHRA has established an ongoing "Watch List" of products most likely to be counterfeited, and BAPW members monitor these medicines more rigorously.

As well as this liaison, the full-line wholesale industry has reviewed every area of its Standard Operating Procedure to increase the opportunities for staff to detect counterfeit products among the medicines purchased from licensed suppliers. The BAPW has produced a training leaflet for its members to re-inforce this. Furthermore, the BAPW has developed a Gold Standard of Pharmaceutical Wholesaling Practice – which was launched by a UK Government Minister in 2006 - to explain and enforce the rigorous procedures upheld by full-line wholesalers. We take our role as guardians of the supply chain seriously and we are keen to extend our Gold Standard across the entire industry. We believe all types of wholesaler should be subject to the same rigorous licence application tests, standards of distribution and inspection regimes in order to protect the integrity of the supply chain and patient safety.

90 Long Acre, London, WC2E 9RA • Telephone: 0207 031 0590 • Fax: 0207 031 0591
Email: info@bapw.net • www.bapw.net

In addition, the BAPW has also instituted its own "Responsible Persons Committee", to be chaired by the MHRA. This committee will uphold and self-regulate the highest standards in UK pharmaceutical wholesaling, whilst creating a permanent dialogue with the statutory regulator. Perhaps in the longer term, there will be a BAPW Code of Practice established on a formal basis.

We also implement the most stringent operating practices, necessitated in particular by the specific storage and distribution needs of the entire range of medicines we supply for patients. We believe that our regular MHRA inspections, which can take up to two days, are more rigorous than inspections on other types of wholesaler.

Wholesale Dealers Licences (WDLs)
Full-line wholesalers have been concerned for many years about the total number of wholesale dealer licenses (WDLs) issued by the MHRA in the UK, and about the resources available to the Agency for its regulatory activities in this area. In the UK around 1,700 wholesalers' dealers' licenses have been issued, however only 10 full-lines wholesalers are active on the UK market. The licensing regime needs addressing urgently in order that the supply chain partners can be more confident about security of supply.

Controlled Drugs Regulations
The BAPW's other main concern is focused on the recent relaxation of regulations covering the storage and distribution of Controlled Drugs in the UK. The BAPW cannot understand why the Home Office's regular inspections of controlled drug procedures were replaced by self-supervision.

Changes to the regulations came into effect in 2007 as a result of a Cabinet Office "Better Regulation" initiative. These changes seemed to the BAPW to suggest procedures that contrast poorly with what the Shipman Committee follow-up report, chaired by the Department of Health, had implemented only the previous year in 2006. For example, in 2006, BAPW members had to have new Controlled Drug Stores, which were built to more exacting specifications; Home Office inspectors could visit wholesalers without notice and there was a complete audit trail from manufacturer to dispensing – this latter point had enabled the Home Office to monitor dispensing doctors prescribing, for example.

All this improvement in monitoring and traceability of CDs has, we believe, been put in jeopardy by the relaxing of standards and regulations put in place in 2007. Currently, Controlled Drugs in the UK are now subject to self-regulation and the licences are free and not time limited any more.

Detailed Comments on the Proposals

In terms of our response to this consultation, we will be concentrating on section 4 of the consultation.

4.1. Tightening requirements for manufacture, placing on the market of medicinal products and inspections

4.1.1. Subject all actors of the distribution chain to pharmaceutical legislation

The BAPW concurs with the European Commission that only a concert of various measures designed to change and improve the current regulatory framework can help to minimise the risk of counterfeit medicines entering the legal supply chain. We also agree with the European Commission's three areas of regulation of medicinal products and believe that these areas of medicinal products legislation need to complement and support each other, thus contributing as a whole to better protection against counterfeit medicinal products existing within the EU.

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4.1.2. Tightening rules on inspections
The BAPW agrees that effective enforcement through inspection and supervision is crucial, while continuous cooperation with third countries on the basis of bilateral arrangements should ensure international synergies in performing inspections.

4.1.3. Improving product integrity through a unique seal from the manufacturer to the retailer or wholesaler, using a risk-based approach, supported by a ban on repackaging
The BAPW believes that maintaining product integrity on medicinal products is an important focus - members have developed a number of processes which provide reassurance to wholesalers or retailers that product comes via a legitimate supply chain source. Increased requirements, for example a unique seal on packaging would present an opportunity to improve the robustness of these measures, however these would only be of value if adopted on an industry-wide basis. The large number of WDL's across the UK mean that this would in practice be difficult to enforce, however, we intend to review opportunities and solutions in this regard in planned meetings with the MHRA.

4.1.4. Centrally accessible record to facilitate traceability of batches throughout the distribution chain
We agree that an efficient traceability system for medical products is crucial to tackling the issue of counterfeit products. Our members employ state-of-the-art information technology systems in order to undertake their services with the current demands of intensity, sophistication, quality and efficiency. These quality systems ensure proper handling conditions for medicinal products are maintained throughout the journey from manufacturer to patient. Nevertheless, we would query if an accessible record to facilitate traceability of batches is an achievable and cost-effective measure.

4.1.5. Mass serialisation for pack-tracing and authenticity checks on a case-by-case basis
We feel that there would be practical and patient issues if authenticity checks at the delivery point in the supply chain were implemented. We are also concerned about the cost-effectiveness of such an initiative, particularly as such technology still needs to be developed.

4.1.6. Increasing transparency concerning authorised wholesalers through a Community database
The BAPW strongly supports the idea of a community database of wholesalers documenting GDP compliance, which would be achieved via extension of the EudraGMP database.

4.2. Tightening requirements for the import/export/transit (transhipment) of medicinal products
The BAPW concurs that it is vital that the requirements for the import/export/transit (transhipment) of medicinal products is tightened.

4.3. Tightening requirements for manufacture, placing on the market of active substances and inspections
We agree that a comprehensive strategy to combat counterfeit medicinal products also requires a reassessment of the rules for active ingredients of medicinal products. Tightening the requirements for manufacturers would contribute to better security around medicinal products.

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4.3.1. Requirement of a mandatory notification procedure for manufacturers/importers of active substances
The BAPW supports the idea of a mandatory notification procedure for manufacturers/importers of active substances. In addition, a notification regime for manufacturers as well as importers of active substances placed on the EU market, either on their own or in preparations, would ensure greater transparency and facilitate supervision of all parties involved in the supply chain.

4.3.2. Enhancing audit and enforceability of GMP
This section is not relevant to our organisation.

4.3.3. Enhancing GMP inspections
This section is not relevant to our organisation.

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