



European Association of Hospital Pharmacists

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Subject	Response to the public consultation in preparation of a legal proposal to combat counterfeit medicines for human use – key ideas for better protection of patients against the risk of counterfeit medicines.
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To	European Commission, DG ENTER

The European Association of Hospital Pharmacists (EAHP) represents over 21,000 hospital pharmacists and aims to promote and uphold the interest of European hospital pharmacy policies, standards and vision. It is our role to work for the advancement of the position and role of the pharmacists in hospitals and to promote co-operation with other professional bodies.

The EAHP welcomes the initiative from the European Commission to consult the public on how to best combat counterfeit medicines in Europe and agrees with its approach to first consult all stakeholders involved in this fight and then conduct an impact assessment on the feasibility of its proposals.

Although counterfeit medicines have very rarely made their ways into European hospital pharmacies, the EAHP is highly concerned by the growing threat of these drugs and wishes to highlight its strong commitment to combating them, as hospital pharmacists are with other healthcare professionals essential to the detection, monitoring and reporting of any kind of unsafe medicines.

1. Proposed legal actions

- A. EAHP welcomes the proposal to tightening existing measures for the manufacturing, trading and distribution of medicines for human use and active substances and its potential implications on the mentioned guidelines. We also approve the suggestion to submit all parties involved in the distribution chain to the European pharmaceutical legislation, as we see it as the best way to secure the provision of medicines to hospital pharmacies. However, given the complexity of the medicines supply chain¹, this may prove almost impossible to be implemented.
- B. The proposal to perform mandatory audits to assess compliances to GMP/GDP is also supported by EAHP provided that auditing criteria, objectives and outcomes are set up and agreed upon by all pharmacists and not only the marketing authorisation holder.

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- C. Regarding the idea to make the provisions on inspections and supervisions mandatory to third countries, EAHP does not see in the proposal how the European authorities could monitor this obligation made to manufacturers and therefore, questions the feasibility of this suggestion.
- D. EAHP warmly welcomes the proposal to ban repackaging and the obligation to make the outer packaging sealed provided “repackaging” and “relabeling” are clearly defined and banned for anyone but pharmacists. It is normal practise for hospital and community pharmacists to repack medicines (i.e. compounding for instance). Clarity is needed over where pharmacies are exempted or controlled by such new requirements.

Furthermore, EAHP does not support the idea that this measure should be limited to a certain category of products, the rule should be made systematic to all products to avoid any risks of counterfeit and the uncertainty (products evolve) of categorising one type of product as being without any health impact on the citizens or without potential profit for counterfeiters.

In terms of packaging, the EAHP invites the European authorities to go one step further in securing the safety of the medicines by proposing that the medicines are packaged in unit doses to prevent any risks of incidents and of lost of serialisation numbers (see point 2, Proposed technical actions, below).

- E. Increasing transparency concerning authorised wholesalers through a Community database is supported by EAHP.

We would like to also underline the need to use the EudraPharm database (not only the EudraGMP), as a good source of information on medicines; it could contain data on counterfeit medicines.

- F. Insuring medication safety over internal market obligations – additional legal protection needed

EAHP requests that trading of medicines be dealt with using extra caution and while we welcome increased controls on medicines, EAHP is very concerned with the fact that allowing full internal market rules on the freedom to trade may compromise the security of medicines. Importing and exporting of medicines, when tackling the issue of counterfeit medicines, should be the subject of additional legal protection to insure full transparency of the distribution of medicines within EU boundaries.

Regarding the **impact assessment** to be implemented once the consultation on the above mentioned proposals is achieved, the EAHP would like to underline the absolute necessity to put the medication safety processes of which fighting counterfeit medicines is part of, first and not to allow administrative procedures and costs to be an obstacle in the implementation of robust European policies to combat counterfeit medicines. Hospital pharmacists would prefer additional paper work than extra cases of severe adverse drug reactions due to counterfeit drugs! Therefore, the impact assessment planned should clearly prioritise the proposed changes so that economical considerations do not weaken patient safety measures.

2. Proposed technical actions

EAHP strongly supports and advocates for a European traceability system for medicinal products. Traceability is instrumental to insuring medication safety and is essential for fighting counterfeiting. We approve the proposal to include in the tracking system information on ownerships and transactions and to set up a unique and centrally accessible record of all past ownerships and transactions (pedigree) to avoid fragmentation of information.

EAHP supports the use of GS1 standards for quality tracking of medicines and questions the fact that the pharmaceutical industry did not adopt standards that are so common for the tracking of other goods, often the subject of large volume distribution, such as express mail for instance.

EAHP requests the European Commission to engage a dialogue with the pharmaceutical industry so that it agrees on one tracking standard which will benefit both the trade of medicines from one country to the other and patient safety.

However, EAHP does not support the proposal to limit traceability means to medicines packs which can be cut, altered and therefore, create a risk of losing information needed for their traceability.

EAHP recommends and requires for medication safety and combating counterfeit medicines unit dose packaging with two dimensional bar codes (data matrix).

The doses should

- be packed for a single application, preferably in a standardised size (e.g. 3,5x3,5 cm),
- alternatively, they could be perforated multiple dose blister packs that can be easily divided into single dose packing (each of them must contain the whole information),
- ready to use, no further manipulation necessary,
- easy to pack into automatic dispensing systems.

The printing must be easy to read, durable and clear. Each unit dose must contain the trade name, the active substance(s), and the quantity of active substance, i.e. dosage, the manufacturer's name, the batch number and the expiry date, in addition to the data matrix code of the drug.

In addition, EAHP, together with other healthcare professionals supports the creation of a European (and in the long term, international) database containing the data collected on the 2D bar codes to allow healthcare professionals to assess the integrity of the medicines. This database would respect all European rights to privacy and be protected by the most updated and advanced technology to make access by intruders impossible.

3. Additional actions to support the fight against counterfeit: information and prevention

The EAHP underlines the necessity to run European information and prevention campaigns on the risk of counterfeit drugs. Although the hospital pharmacists are not concerned by internet pharmacy given their field of actions, EAHP feels it is of utmost importance to properly and repeatedly inform European citizens of the risks of buying medicines outside of the legitimate supply chain if the European Union wants to commit to reducing the risks of serious adverse drug reactions or fatalities.

These preventing actions would come in addition to the legal and technical measures as proposed above and to bilateral legal agreements with third party countries, often providers of counterfeit medicines.

In terms of prevention, the hospital pharmacists are trained to be constantly vigilant and to report any suspicion of counterfeit medicines. The most important element to prevent access to the hospital shelves of counterfeit medicines is the quality of the supply chain. To avoid any incidents, hospital pharmacists are encouraged to follow the recommendations drafted by the FIP, the MHRA and RPSGB²: medicines should be bought from qualified suppliers with appropriate wholesaler licences; they should treat with extra caution a product that is offered at an unusually cheap price; they must look for signs of a removed or switched product label, for altered expiry dates, for subtle changes in the product's package, and for variation in the size of the container³.

In conclusion, the European Association Hospital Pharmacists wishes to express its support to the legal and technical actions proposed by the European Commission to fight counterfeit medicines provided implementation, policing and information measures are also put in place to turn these

proposals into reality. EAHP highlights the fact that the EU legislation on the supply chain must be harmonised and the fundamental importance of serialisation as the best way forward.

We also request the Commission to support the introduction of mandatory bar coded unit doses to strengthen medication safety.

EAHP, 5 May 2008

¹ See Figure 3 “The complexity of the medicines supply chain”, - Counterfeit Medicines, A Threat to Public Health and Safety, Frank Vanderdonck, Pfizer Belgium, 2007, 126, 9: S138-143

² MHRA and RPSGB: Counterfeit medicines, Guidance for Pharmacists.
<http://www.rpsgb.org.uk/pdfs/counterfeitmedsguid.pdf>

³ Frank M Jung, PhD, Counterfeit Protein Drugs: How To Discover and How to Prevent, EJHP Practice, Volume 13, 2007/3 (61)