

The role of hospital pharmacists in counterfeit medicines



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Pharmacists are the key to patient safety with regard to medication. Hospital pharmacists can play a major role in the fight against counterfeit medicines not only by ensuring the safety of medicines but by reporting suspicious cases and raising the awareness of the general public.

Why could hospital pharmacists be facing counterfeit medicines?

In the last few years, several cases of counterfeit medicines have been discovered in the legal pharmaceutical distribution chain, both in Europe and North America. Consequently, counterfeit medicines should not be considered as an issue solely for developing countries.

This threat to public health is now spreading to the developed world: the latest figures from European Union customs [1] showed that in 2006, there was an increase of 384% in seizures of counterfeit medicines, representing up to 2,711,410 units of counterfeit products! Although not all of these counterfeit medicines were intended for the European Market, there is a tendency for counterfeiters to consider developed countries as a more profitable market. Over the years, they have developed industrial methods of manufacturing counterfeit medicines, thus creating a perfect looking copy of the original medicines. However, the composition of counterfeit medicines can vary a lot from the original ones!

It should also be emphasised that the cost of production of counterfeit medicines is very low, especially if they do not contain any active principle ingredient. So, for similar production prices, it is often more profitable to produce counterfeits of expensive original medicines. Since hospitals often use more expensive medicines than ambulatory care settings, they may be at a higher risk of being affected by counterfeit medicines.

Moreover, through their activities, hospitals may have to treat patients suffering from the side effects of counterfeit medicines or unexplained medicines treatment failure caused by counterfeit medicines. Therefore, hospital pharmacists could experience the effects of counterfeit medicines either from their



own purchasing activities or through hospital care activities to patients.

What can hospital pharmacists do?

Hospital pharmacists can play a major role in the fight against counterfeit medicines. Some of our colleagues have already taken initiatives in response to this issue.

Ensuring the safety of medicines provided to patients - be aware of the problem

Being aware of a problem is a major step in tackling it. In several countries, pharmacist associations in collaboration with their national drug regulatory authorities have developed some useful continuing education tools to inform pharmacists of this issue.

In May 2006, the Royal Pharmaceutical Society of Great Britain (RPSGB) and the Medicines and Health products Regulatory Authority (MHRA) launched a 6-page document entitled *Counterfeit medicines: Guidance for pharmacists* where key information on counterfeit medicines and how to deal with a possible case was provided. This document was produced after the UK experienced several cases of counterfeit medicines which were detected in the legal pharmaceutical chain. This document is available at www.rpsgb.org and at www.mhra.gov.uk [cited 2008 April 15].

In May 2007, the *Ordre national des Pharmaciens* and the *Agence Française de Sécurité Sanitaire des Produits de Santé* (Afsaps), the French counterparts of the RPSGB and the MHRA issued a 12-page document in French on the same issues. It provides a more extensive view of the issue and offers a standard rule of procedure to report any suspicious case. This document was issued, although France was not experiencing any counterfeit medicines in its legal pharmaceutical distribution chain, as a proactive action to strengthen pharmacists' awareness of this issue. This document can be downloaded at www.ordre.pharmacien.fr [cited 2008 April 15] then click on *Documents de référence* or at agmed.sante.gouv.fr/htm/10/contre_facon/sommaire.htm [cited 2008 April 15].

In other countries, such as Lebanon or Hungary [2], an immense effort has been made by local pharmacist associations to raise awareness among their members

on this issue, by means of conferences and press articles.

Finally, through this issue of EJHP, we can consider that your awareness has been raised. Now you are aware of the issue, how can you contribute to the fight against counterfeit medicines and thus to the safety of your patients?

Reliable sources of medicines

First of all, always buy your medicines from a reliable source, which is authorised by your drug regulatory authority and has a solid reputation. If you have any doubt as to whether a supplier is authorised, ask your drug regulatory authority.

The reliability of your sources of medicines should also apply to bulk materials used in making your compounding medicines. In 2007, an article published in the *New York Times* [3] reported the deaths of hundreds of Panamanian people after the intake of cough syrup and

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antihistamine syrup produced by the government health programme, using a counterfeit glycerin which originated from China. The counterfeit “99.5% pure glycerin” was in fact a mixture made from diethylene glycol. The similar use of fake glycerin in a syrup led, in the 1990s, to the death of 89 children in Haiti and 30 children in India [4]. It is therefore important not only to have a reliable source for your bulk materials but also to test them with methods described in the monographies of your national pharmacopoeia. To facilitate the detection of a possible counterfeit medicine, a tool for visual inspection of medicines was jointly developed by the International Pharmaceutical Federation (FIP), the International Council of Nurses (ICN) and the United States Pharmacopoeia (USP). This tool can be downloaded on the FIP website: www.pharmacistscombatcounterfeiting.org [cited 2008 April 15].

These requirements for reliable sources

should also apply to any other kind of medical products, including medical devices, since counterfeit medical products have also been reported, e.g. contact lenses in France in 2004 [5], blood glucose test strips in the USA in 2006 [6], condoms in the UK and Ireland [7-9].

Ensure traceability

In the case of the discovery of a counterfeit health product, it is imperative to be able to quickly retrieve the suspected products from the hospital pharmacy stock or at patient levels. Consequently, the traceability of healthcare products up to patient level in procedures established by hospital pharmacists will improve their ability to act in a way which ensures patient safety.

Reporting suspected cases of counterfeit medicines

As described in the article by Marcel Moester, patients can be a source of information on possible counterfeit medicines case, when they report

changes, for instance, in tastes, in the package, or when an unusual side effect or an unexplained treatment failure occurs. Moreover, through your own activities (at the receipt of an order or during the dispensing process), you may notice some changes in the packaging. It is important to report these cases to your national drug regulatory authority and to keep the suspected counterfeit medicines, in order to facilitate its investigation. It is of interest to know where the suspected counterfeit medicine was bought: from a legal community pharmacy, from a hospital pharmacy or from an illegal source (black market, e.g. gym clubs or over the Internet).

Health education at patient levels

The hospital pharmacist can play a major role in educating patients on the risks of buying their medicines from illegal sources. In many countries, medicines may not be bought over the Internet. Even in the countries where it

is allowed, a special focus should be made on the importance for patients to check if the offer is made by an authorised pharmacy. Moreover, in developing countries, pharmacists have played a major role in raising awareness campaigns targeting politicians or patients, such as in Cote d'Ivoire or Lebanon, where a wide range of actions have been launched including communication with journalists, patients and other key players.

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