

All patients have a right to expect the medicines they take to be genuine

This is the first of two articles concerning the counterfeit medicines market. In this article the extent of the problem is introduced along with systems for reporting suspect medicines in the UK and internationally. In the second article we will report the findings of investigations, made by the European Alliance for Access to Safe Medicines, into internet pharmacies.

The problem of counterfeit medicines entering the UK legitimate supply chain was highlighted in a *Soapbox* article by Jim Thompson last year.¹ Since that publication Jim has spearheaded the launch of the European Alliance for Access to Safe Medicines (EAASM)² — an independent pan-European patient safety initiative committed to promoting the exclusion of counterfeit and substandard medicines from the supply chain (Box 1). The EAASM promotes the right for all European patients to expect that the medicines he or she takes are genuine. The EAASM is a broad cross-sector alliance of patient groups, health care professionals, inter- and non-governmental organisations and industry members — and it is expanding rapidly.

Since it was founded the EAASM has promoted debate on counterfeit medicines, beginning with commissioning and publishing the in-depth report *European patient safety and parallel pharmaceutical trade — a potential public health disaster?*³ This report examines the available studies on counterfeit medicines and evaluates the

economic issues surrounding parallel pharmaceutical trade.

The extent of the problem

Because there is currently no legal requirement for a medicine to have a full record of its journey from manufacturer to purchaser and because it is possible to purchase medicines in one country and sell them at a higher price in another, there is room for the entry of substandard or counterfeit medicines into the marketplace.

This hypothetical possibility has been borne out in practice. Drug alerts have been issued for Cialis 20mg, Reductil 15mg,

Lipitor 20mg, Zyprexa 10mg, Plavix 75mg, Casodex 50mg and Sensodyne original and Sensodyne mint 50ml tubes — with four of these occurring in May and June of 2007.⁴ At that time counterfeit medicines were estimated to make up between 6% to 10% of the world wide market in medicines with annual sales in the region of \$35 billion.⁵ Since more than 650 million prescriptions are written annually in the UK⁵ this represents a potentially large number of revenue-generating opportunities for the counterfeiter.

Counterfeiting or distributing substandard medicines has the potential for significant social and economic consequences. For example, patients could receive a different medicine from the one they requested (whether this is contained within a seemingly correct or incorrect package), they could get the correct medicine in a dangerously high or too low dosage, or they could get an inactive compound posing as a medicine. Clearly, each of these possibilities gives rise to significant and different risks for the recipient. In terms of economics, at the very least legitimate pharmaceutical manufacturers would suffer from patent and copyright infringement and associated loss of revenue, and the Government would lose taxation revenue.

Parallel imported medicines have to be repackaged and need patient information leaflets (PILs) in the destination country language, which may be different from that of the originator country. When these enter the supply chain illegally PILs are often missing, with further potentially important consequences for the recipients. Counter-



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Box 1. Aims of The European Alliance for Access to Safe Medicines

EAASM aims to:

- raise public awareness of the dangers of counterfeit and substandard medicines
- be proactive in devising and implementing safe medicines initiatives
- input into existing anti-counterfeiting initiatives where appropriate
- build a network of influencers of change charged with establishing a secure supply chain and drive legislative change where necessary
- create a call for action for improved legislation, enforcement and patients' rights to safe medicines
- call for a comprehensive revision of the European pharmaceutical supply chain, including reviewing the practices of 'de-boxing' and re-labelling

Box 2. Why might people purchase medicines online?

Some potential reasons for making online medicines purchases might include:

- Speed of accessing prescription medicines
- Convenience of having medicines delivered
- Embarrassment about approaching the GP with particular symptoms or embarrassment about asking for a particular medicine
- Not wanting the reasons for needing to use a specific medicine to be publically accessible — for example, to employers or authorities
- Concern that the GP would refuse to prescribe a medicine — for example, if this might be deemed inappropriate or excessively costly by the GP
- The possibility of by-passing the medical system and self-medicating, perhaps to experiment with new treatments for a poorly-controlled or self-diagnosed condition

feit medicines, therefore, represent a large public health challenge.⁶

Measures to monitor and report counterfeit medicines availability

After the counterfeit cases of 2007 the Royal Pharmaceutical Society of Great Britain (RPSGB) and the Medicines and Healthcare products Regulatory Agency (MHRA) jointly issued a guidance document for pharmacists on counterfeit medicines.^{4,5} The document offered pharmacists practical advice on the correct



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steps to take when encountering suspected counterfeit medicines, including reporting it to the MHRA.^{4,5} Anyone encountering a suspect medicine should report this either by telephoning the MHRA or by completing an online form at www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=550.⁵

The World Health Organization (WHO) has developed a web-based system

to track counterfeit medicines (available at <http://218.111.249.28/ras/default.asp>). This is designed to help countries disseminate information about sales of fake medicines rapidly. A reporting form asks users to enter the medicine's name, classification, packaging information, dosage form, country where the medicine was identified, and whether the medicine was discovered at a hospital, pharmacy or through other means.^{5,6}

Preventive measures are needed

Reporting instances of discovered counterfeit medicines is a good start, but steps also need to be taken to prevent the distribution of counterfeit or substandard medicines. This requires in-depth knowledge about who the manufacturers are and what the main routes of distribution are. One distribution method for counterfeiters is through internet sales. The scale of this problem, however, is unknown.

EAASM research programme

One of the objectives of EAASM in 2008 is to assess the prevalence of online pharmacies and the dangers posed to customers by purchasing medicines through the internet. At first glance it seems illogical that people with medical complaints would choose to purchase medicines through the internet rather than go to their GP for investigation and an appropriate prescription. However, potential reasons might include the convenience of having medicines delivered rather than having to travel to collect them. Some other possible reasons are listed in Box 2. Whatever the reason it is clear that internet purchasers are unaware of the risks they are taking with their health.

The WHO estimates that more than 50% of websites concealing their physical address are selling counterfeit medicines.⁶ The EAASM project has therefore begun with a survey of internet pharmacies and the products they sell. The findings are currently being analysed and will be reported in June 2008. This research was followed by a two-phase study to ascertain the extent of counterfeit or substandard medicines sold by internet pharmacies. A selection of 'medicines' were purchased from a sample of internet pharmacies. In the first phase of the study the received medicines were evaluated visually by a group of health professionals, including pharmacists. In the second phase, the medicines are undergoing chemical testing. We will



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summarise the findings of all studies after their publication in the EAASM report *The counterfeiting superhighway* later this year. ❖

Declaration of competing interests

The author declares she has no competing interests.

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