Newsletter

November 2007

The counterfeit problem in Europe

More and more counterfeit and substandard medicines and medical products are arriving to the European market. In some parts of Europe experts believe that 20% of all medicines are fake, containing no active ingredients, reduced active ingredients or active ingredients totally different from those in the original product. These can have health-damaging and even fatal effects on patients. Manufacturers of counterfeit medicines are criminals, who deliberately expose the sick – a particularly vulnerable group – to serious dangers.

The potential for disaster was highlighted when a heart drug seized by European Union customs last year was found to contain brick dust coated with yellow paint, and covered with furniture polish to give a glossy finish. If counterfeits of this nature reach patients the consequences could be grave.

Over the past 5 years, 170 counterfeit medicines were identified in illegal distribution channels in the EU Member States. In 2006 alone, the EU customs authorities seized 2.7 million counterfeit drugs at European borders.

When counterfeit medicines penetrate the legitimate supply chain there is a direct risk to the public. Fortunately, in the incidents detected so far no patients have suffered detectable harm. However, it is surely only a matter of time before a serious incident happens. This could lead to a loss of public confidence in prescription medicines, and possibly affect patient compliance.

About the EAASM

The European Alliance for Access to Safe Medicines (EAASM) is a new pan-European patient safety initiative campaigning for the exclusion of counterfeit and substandard medicines from the supply chain – to ensure better patient safety. The EAASM is an independent, cross-sector voice representing all interested parties – patient-groups, health professionals, academics, non-governmental organisations, pharmaceutical industry and policy makers.

Objectives

To increase awareness of the dangers of counterfeit and substandard medicines, to successfully campaign for improved legislation, enforcement and patients' rights to safe medicines.

Alliance Key Issues

The Alliance is taking action to increase access to safe medicines by:

- ★ involvement in the ongoing anti-counterfeiting activities of the European Commission, European Parliament, WHO and the Council of Europe – enhancing patient safety through policy and legislation
- ★ participating in the wider debate on counterfeit and substandard medicines through our website, conferences and the media
- ★ raising public awareness and reducing consumer exposure to the risks of purchasing medicines online.

European Alliance for
Access to Safe Medicines

Counterfeit supply chain

We have seen a recent escalation in government and press awareness of the counterfeiting issue. In a recent Pharmaceutical Technology Europe article 'Drug counterfeiters target NHS' (February 2007), the Medicines and Healthcare products Regulatory Agency (MHRA), the UK Government's drug safety watchdog, warned health officials that patients are being put at risk by counterfeiters targeting the NHS supply chain. The trade is believed to be growing because of demand for blockbuster and lifestyle drugs such as Viagra or those to treat obesity, indicating a shift in focus for counterfeiters.

Instead of selling small quantities of counterfeit medicines to individuals over the internet, the traditional target, the counterfeiters are switching their attention to pharmaceutical wholesalers who supply hospitals, pharmacies and doctors across Europe. Medicines worth thousands of Euros are traded in a single transaction. Five incidents have been detected in the past 2 years in which counterfeit medicines have reached patients through high-street pharmacies after the UK supply chain was penetrated. The illegal medicines trade carries lower risks and higher profits than smuggling hard drugs and is putting NHS patients at risk, the MHRA says.

Naem Ahmed, the head of intelligence at the MHRA states that "by trading over the internet the risk of detection is low but counterfeiters only sell small quantities of fake medicines. By penetrating the legitimate supply chain there is a higher risk, but you can make a lot of money". The MHRA are currently investigating 25 cases of medicines counterfeiting, twice as many as 5 years ago.

WHO definition of substandard and counterfeit medicines

Substandard medicines are products whose composition and ingredients do not meet the correct scientific specifications and which are consequently ineffective and often dangerous to the patient. Substandard products may occur as a result of negligence, human error, insufficient human and financial resources or counterfeiting.

Counterfeit medicines are part of the broader phenomenon of substandard pharmaceuticals. The difference is that they are deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit medicines may include products with the correct ingredients but fake packaging, with the wrong ingredients, without active ingredients or with insufficient active ingredients.

Counterfeit and substandard medicine is threatening patient safety

WHO estimates that counterfeit medicine sales range from around 1% in developed countries to over 10% in developing countries and that medicines purchased over the internet from sites that conceal their physical address are counterfeit in over 50% of cases.

Spot the difference!

Counterfeit and substandard medicines are a very real and increasing threat to patient safety that needs to be addressed by all stakeholders. For example, 1647 million packs of medicine were sold in Germany in 2002 – if, as WHO estimates, 1% of these medicines were counterfeit then a staggering 16.4 million packs of counterfeit medicines were sold in Germany in that year.

> "The US based Centre for Medicines in the Public Interest predicts that counterfeit drug sales will reach $75 billion globally in 2010, an increase of more than 90% from 2005."

Not surprisingly there has been a noteworthy and necessary increase in the attention being paid to the threat of counterfeit and substandard medicines. The public sector in particular is examining the problem more actively. For example, the Council of Europe has made an extended investigation into the problem and is determined to provoke action in its member countries. The European Parliament is also calling for action and counterfeit medicines are seen as an increasing threat by MEPs.

Most notably, WHO's IMPACT initiative will further raise the profile of counterfeit medicines and look to work with patient safety organisations world wide.

The pharmaceutical industry is also responding to the increasing threat to patients, with the safemedicines.org initiative in the US and EFPIA in Europe.

However, further action must be taken to raise the profile of safe medicines and campaign for more effective measures to protect patients.

Drugs most commonly counterfeited

REDUCTIL®
Manufactured by Knoll/Abbot, weight loss. About €177 for 28 tablets

CIALIS®
Manufactured by Eli Lilly, for erectile dysfunction. About €7.40 a pill

VIAGRA®
Manufactured by Pfizer, erectile dysfunction. Internet price is around €30 for four tablets. The most widely sold prescription drug on the net

PROZAC®
Manufactured by Eli Lilly, anti-depressant. About €30 for 30 tablets

LIPITOR®
Manufactured by Pfizer, cholesterol lowering. About €60 for 30 tablets

VALIUM®
Manufactured by Roche, anxiety disorders. About €74 for 30 tablets

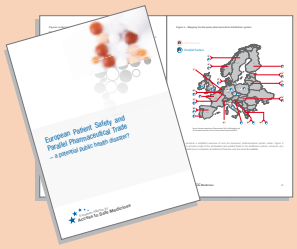
The EAASM website has been launched!

The EAASM website **www.eaasm.eu** was successfully launched in August 2007. The website provides quick access to information about counterfeit and substandard medicines. With this in mind, the website makes it easy for visitors to learn more about the dangers of counterfeit medicines, how patients can stay safe when buying medicines, and read news which is updated weekly.

Website visitors can also find information about the Alliance, its objectives and activities, and how to contact the Alliance to receive more information or become a supporter.

The Harper report

The Harper report provides a critical examination of European Patient Safety and Parallel Pharmaceutical Trade (PPT) in the European Union. To date, the main academic and policy arguments have focused on the economic issues of PPT, but Dr Harper's report provides analysis of the topic in a broader context, which involves a number of factors in addition to pure health economics.



The report states that the European pharmaceutical market could be heading towards a public health disaster with respect to distribution chain regulation and supply chain security.

In the context of ultimate patient safety, a number of recommendations have been made by Dr Harper both in terms of general pharmaceutical market functioning, as well as specific recommendations that address the potential problems of European PPT in the context of pharmaceutical supply chain security.

All Alliance members and supporters can access the report for free by contacting enquiries@eaasm.eu

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