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Drug Safety News: Counterfeit Medicines and Adulteration

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*"Counterfeit: made in imitation of something else with intent to deceive: forged.
Adulterate: to corrupt, debase, or make impure by the addition of a foreign or inferior substance or element; especially: to prepare for sale by replacing more valuable with less valuable or inert ingredient"¹*

In simplest terms, adverse drug reactions can arise from three main mechanisms: medication errors, impurities in the product, and the inherent chemical toxicity of the drug itself. The first two types of adverse drug reaction are, theoretically, highly preventable.

The second type, impurity in drug products, has been a concern for many centuries, as summarised by D.M. Davies, in his *Textbook of Adverse Drug Reactions*.² In 9th century Arabia an official, the Mutsahib, was given authority to supervise the makers of drug products: "make them fearful, try them, and warn them against imprisonment." Penalties in olden times were quite harsh. In Salerno, Italy in the 10th century, the penalty for adulteration of a drug included "whoever shall have or sell any noxious drug or poison not useful or necessary to his art, let him be hanged." Concerns over quality control continued and eventually led to the creation of pharmacopoeias in the 19th century with their defined standards for drug purity. The first statute to control the quality of drugs in the U.S. was passed in 1848, following an incident in which quinine, imported for use by the army, was found to be adulterated. Yet problems with drug quality continued, and in 1937 an elixir of sulphanilamide fatally poisoned 107 people because of the presence of diethylene glycol, a known toxin. Despite this tragedy, similar poisoning has occurred in Argentina, Haiti and India, and as recently as 2009 in Nigeria, due to the use of diethylene glycol as a solvent in place of the harmless but more expensive ingredient glycerine.³

A Global Problem

Impurities in counterfeit drugs are increasingly a global problem. In response, the World Health Organization (WHO) created a taskforce in 2006.⁴ As noted on the WHO website, the main public health concern with counterfeit medicines is that the content is not reliable. These products are illegal, dangerous, and often sold over the internet. As stated by the Head of Enforcement for the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK: "illegal suppliers do not care about quality control or standards, and people who purchase their medicine from these websites will never know where the product has originated from or what it might contain. People running these websites are not healthcare professionals; in fact, they are not professional in any way shape or form. They're simply financially motivated criminals making a living at the expense of people's health."⁵

The four main problems are:

- The presence of a totally different active drug from the one on the label:
 - Singapore, 2008: Four drug products labelled as Cialis or as herbal products for erectile dysfunction were found to actually contain up to 100 mg of glyburide. Severe hypoglycaemia developed in 150 patients and four died.⁶
 - China, 2009: A traditional medicine used to treat diabetes contained six times the normal dose of glyburide. Two people died, and nine were hospitalized.⁴
 - United States, 2010: A product sold over the internet as "generic Tamiflu" was found to contain cloxacillin, not oseltamivir. Patients who are allergic to penicillin would be at risk.⁷
- The product contains the correct active ingredient but also a toxin:
 - United States, 2008: heparin imported from an uninspected plant in China led to four deaths and numerous adverse reactions.⁸ The U.S. now imports about 27 per cent of its drugs, and it is recognized that increasing globalization has created difficulties in insuring the safety of the drug supply.⁹ In this case, the product was contaminated with over-sulfated chondroitin sulphate (OSCS), which had similar biological activity but caused hypersensitivity reactions.¹⁰
- The product contains no active ingredient:
 - Tanzania, 2009: An antimalarial drug in 40 pharmacies contained no active ingredient.⁴
 - Cambodia, 2010: Antimalarials sold by 60 percent of street vendors have been labelled as mefloquine but contained the ineffective and cheaper sulphadoxine-pyrimethamine.¹¹ This has led both to ineffective patient treatment and a misperception of the incidence of drug resistance. With a weak public health system and poorly regulated private sector, Cambodia's unlicensed pharmacies are being targeted by the authorities in an effort to reduce fake and substandard antimalarial drugs.¹²
- The product contains the correct ingredient but comes from an illegal source:
 - Montreal, 2009: The RCMP seized illegal erectile dysfunction pills being sold in various establishments including sex shops. In this case of intellectual property crime, the pills did contain the correct active ingredient, but the suspects were charged with fraud.¹³

How do these products reach patients? Often over the internet, but in the UK authorities have documented the movement of counterfeit drugs through licensed wholesalers to pharmacies.¹⁴ While the incidence of counterfeit drugs is considered relatively low in Canada, estimated at less than 1 per cent,³ Canadian patients can acquire drugs from other countries and from

the internet. In 2005, two pharmacies in Ontario were charged with knowingly selling counterfeit drugs.¹⁵ Pharmacists should be suspicious of unusual adverse effects in a patient using drugs from outside sources, which might suggest adulteration. Pharmacists should also be proactive in their efforts to educate patients about counterfeit drugs.

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