“Murder by fake drugs: Time for international action”

Until recently the most infamous internationally known example of fake drug dealing was Graham Greene’s fictional account of a British fake penicillin peddler who was eliminated in the sewers of postwar Vienna in The Third Man. Unfortunately, malevolent dealings in counterfeit drugs are very much a contemporary reality. Notorious recent real examples include neomycin eye drops and meningoococcal vaccine made of tap water; paracetamol syrup made of industrial solvent; ampicillin consisting of turmeric; contraceptive pills made of wheat flour; and antimalarials, antibiotics, and snake antivenom containing no active ingredients.

In a recent survey of pharmacies in the Philippines, 8% of drugs bought were fake (quoted by Wondemagegnehu). A countrywide survey in Cambodia in 1999 showed that 60% of 133 drug vendors sampled sold, as the antimalarial mefloquine, tablets that contained the ineffective but much cheaper sulphadoxine-pyrimethamine, obtained from stocks that should have been destroyed, or fakes that contained no drug at all. In another recent survey, 38% of tablets sold in five countries in mainland South East Asia as the new antimalarial artesunate were fake. Artesunate is an extremely important antimalarial drug, and its rapid action and lack of side effects have created significant demand in endemic areas. These characteristics, along with a relatively high cost, make artesunate particularly attractive to counterfeiters, who have gone to great lengths to deceive patients, using small amounts of ineffectual bitter chloroquine, copying the blister pack design, and even providing fake holograms on the package. Some counterfeit drugs contain actively harmful ingredients, not just bogus placebos. For example, aspirin, thought to be an important contributor to acidosis in children with malaria and a cause of Reye’s syndrome, has been used in the manufacture of fake chloroquine in Africa.

These pernicious deceptions have been reported mostly in local newspapers. There is little published medical research assessing their prevalence, public health impact, or possible countermeasures. The accumulated evidence, such as it is, suggests that mortality and morbidity arising from this murderous trade are considerable, especially in developing countries. They have also given rise to misperceptions of drug resistance as patients "fail" their ineffectual treatments. For example, artesunate resistance reported from Cambodia turned out to be due to unwitting use of fake drugs. The World Health Organization estimates that 10% of global pharmaceutical commerce is in fakes. In the past, drug companies have tended to avoid publicising the problem for fear of “damaging public confidence in medicines.” Some countries, well aware of the scale of their problem, have preferred to ignore it.

In the face of this substantial criminal mortality and morbidity there has been little international action. The appearance of fake anticancer drugs in the United States led to local action by the pharmaceutical industry. Much more needs to be done in the developing world. Guidelines have been produced, but most developing countries do not have the infrastructure and financial resources to implement them. Paradoxically, the most accessible testing service for fake drugs is the free, anonymous service allowing people to check the authenticity of their illegal ecstasy (MDMA) tablets (www.harmreduction.net). We hope that the global forum on pharmaceutical anticounterfeiting organised by Reconnaissance International and the World Health Organization to be held in September 2002 will address these issues.
International technical, logistical, and financial support, possibly through a specialised non-governmental organisation, is needed to allow impoverished countries to protect their drug supplies. Measures would include supporting drug regulatory authorities; providing simple, easily interpretable and cheap markers of authenticity; coordinating international surveillance for fake and substandard drugs; improving the availability of quality assured essential drugs; and educating patients, healthcare workers, and pharmacists.

All measures that reduce the profit margins for manufacturing fakes, such as reducing the price and increasing the availability of genuine, quality assured drugs, will make counterfeiting a less attractive criminal activity. Uncompromising international police action against the factories and distribution networks needs the same vigour as that associated with the pursuit of narcotic peddling.

Information on fake drug identity and distribution needs to be shared nationally and internationally between government drug regulatory authorities, customs and police organisations, pharmaceutical companies, non-governmental organisations, and consumer groups. In most tropical countries, however, the only check on the authenticity of the tablets will be the patient or relative buying the medicine, and considerable publicity will be needed to allow them to discriminate the potentially curative from the cryptically lethal. The effectiveness of different strategies allowing patients to reject fake drugs must be assessed. A social marketing campaign of quality assured, pre-packaged drugs can offer patients an easily recognisable and affordable alternative. The two edged strategy of improving the availability of quality assured drugs and public warnings describing fakes has been very effective in Cambodia, where a poster and radio education campaign has educated patients to distinguish fake tablets and has driven the sale of counterfeit antimalarials further underground.

Sophisticated techniques, which are hard to copy, such as holograms and fluorescent markers, can be used to brand the genuine product as real, but they are often too expensive. Simple, inexpensive and low tech methods to identify fakes should be pursued. For example, simple colorimetric assays developed for the artemisinins have been used successfully to identify fake artesunate tablets. The German Pharma Health Fund (www.gphf.org) has developed the Minilab for analysing the authenticity of a wide range of essential drugs relatively simply and inexpensively.

Much of the counterfeit drug trade is probably linked to organised crime, corruption, the narcotics trade, unregulated pharmaceutical companies, and the business interests of unscrupulous politicians. Much greater international political will to eliminate the problem is required.

Source: http://bmj.com/cgi/content/full/324/734/800