Editorial

Fake and counterfeit drugs: An emerging scourge or an established blight?

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In any part of the world, whatever precautions one takes, it is impossible to avoid many diseases. Some have been there from time immemorial. Many communicable diseases are the bane of the developing world and non-communicable illnesses assume major importance in the developed world. Drugs used to treat human diseases are very special as they are essential for the well-being of a community. This is particularly relevant to paediatrics. The potency and effectiveness of medicines used to treat human diseases are generally taken for granted as they are supposed to have been rigorously tried, tested and occupy a hallowed position in standardised treatment schedules.

Against this backdrop, the often subtle and sometimes rampant menace of fake or counterfeit drugs is causing major concerns all over the world. A counterfeit drug or a fake medicine is a medication which is produced and sold with the intent to deceptively represent its origin, authenticity or effectiveness. A counterfeit drug may be one which does not contain active ingredients, contains an insufficient quantity of active ingredients, or contains entirely incorrect active ingredients (which may or may not be harmful), and which is typically sold with inaccurate, incorrect, or fake packaging. Fake medicines and generic drugs which are deliberately mislabelled in order to deceive consumers are therefore counterfeit[1]. The British Medical Journal, in an editorial, called it "Murder by fake drugs"[2]. It goes on to postulate that 8% of drugs bought in the Philippines were fake. Major problems were also found in the antimalarial drug mefloquine in Cambodia and artesunate in five countries of South-East Asia. In a study of shop-bought samples of artesunate in Cambodia, Laos, Myanmar, Thailand and Vietnam, 38% did not contain artesunate[3]. However, characteristics such as cost and physical appearance of the tablets and packaging reliably predicted authenticity. The authors concluded that the illicit trade in counterfeit antimalarials is a great threat to the lives of patients with malaria.

The World Health Organisation estimates that up to 25% of medicines consumed in developing nations are counterfeit or sub-standard[4]. In a specific study on chloroquine and selected antibacterials in Nigeria and Thailand, 36.5% of the samples were substandard with respect to pharmacopoeial limits[5]. There is mounting evidence that malevolent dealings in counterfeit drugs are very much a thing of the present world. Notorious recent real examples include neomycin eye drops and meningococcal 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[2].

There is good evidence that the plague of fake medicines has spread even to the developed countries such as the UK and the USA. In the UK in November 2004, Allan Valentine was imprisoned for manufacturing fake diazepam and viagra in his Wembley warehouse where Indian tablet presses and chemicals were found[6]. Even in a country like the USA, there are numerous instances where the problems of substandard and fake drugs have surfaced. Some of these have involved such diverse compounds as epogen, neupogen, anti-cancer drugs, anti-psychotic drugs, anti-cholesterol drugs and even sildenafil[7]. The US Food and Drug Administration estimates that fake drugs alone comprise more than 10% of the global medicine market, generating annual sales of more than 32 billion US dollars. The general position of the blight has now been augmented and facilitated by the availability of all kinds of drugs without a prescription over the internet. There is no control whatsoever on this phenomenon and there is evidence that counterfeit drugs are being made available by unscrupulous agencies through this route.

In point of fact, counterfeiting pills, labels and packages is relatively simple. Most of the tools needed to produce authentic-looking but counterfeit drugs and packaging can be bought over the Internet. 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[8]. Much greater international political will to eliminate the problem is required. Globally, technical, logistical and financial support, possibly through specialised non-governmental organisations, is needed to allow impoverished countries to protect their drug supplies. 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. 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.

There is little published medical research assessing the prevalence, public health impact or possible countermeasures, of and on, these malicious deceptions. 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[9]. In the past, drug companies have tended to avoid publicising these problems for fear of damaging public confidence in medicines. Most unfortunately, some countries, well aware of the scale of their problem, have even chosen to ignore it.

There is a growing voice in Sri Lanka, fuelled by public interest groups, patient rights organisations, politicians and even the government, to compel doctors to prescribe by the generic names of drugs. The often quoted reason is that some doctors have been “bought over” by multinational drug companies to prescribe by trade names. Sri Lanka does not possess the sophisticated machinery which enables regular testing of drugs for physical properties, potency and biological availability in humans. It is also quite impossible to test the vast array of different drugs available for treating a multitude of illnesses. If such facilities are in place and just a few properly tested generic version of a given drug are made available, there is no excuse for doctors to prescribe by trade name. In the absence of such amenities, one has to at least go by the data available from testing in other countries. The so called free market economy in Sri Lanka has gone berserk in the pharmaceutical trade. Our own authorities, on the one hand, allow large numbers of branded products of the same drug to be registered, imported and made available in the pharmacies and then cry foul saying that the doctors are prescribing by trade names. Many doctors do so, especially for children, simply because the branded drugs are of assured quality and not because they are carrying a brief for the multi-national drug companies.

It is high time that the general population and the pressure groups realise that one cannot have the cake and eat it as well. It should be a sobering thought to the authorities that even in the UK, where prescribing is only by generic names, there have been well documented instances of fake and counterfeit drugs causing major problems.

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