Tackling the booming trade in counterfeit drugs

The black market in counterfeit drugs is worth billions, but it does untold damage to the health of the poorest populations. Nayanah Siva reports on international efforts to tackle the problem.

Last month 45 countries took part in the internet-based campaign Operation Pangea III to tackle online counterfeit drug crime. As a result, regulators recovered thousands of illicit and counterfeit drugs valued at US$2.6 million, 76 people were arrested across the globe, 694 website investigations were opened, and 290 illegal websites have already been shut down. The operation involved several international organisations, including police, customs, national drug regulators, and internet service providers working together.

Operation Pangea III is the third of its kind, and over the past 2 years has aimed to raise awareness about the international black market of counterfeit medication. The head of INTERPOL, who coordinated the operation, lauded the fact that 20 more countries took part in the operation than in 2009, signifying a step towards greater international cooperation against counterfeit drug crime.

The problem of counterfeit drugs was first addressed at a conference in Nairobi, Kenya, in 1985. However, since then the counterfeit market has rapidly expanded, largely as a result of the widespread use of the internet to market counterfeit products. Counterfeit drug rackets are most common in regions where regulatory and policing systems for drugs are at their weakest, thus one of the key battlegrounds in the fight against organised counterfeit crime is Africa, where drugs are counterfeited on a huge scale. In June, 2009, a member of the Pharmacy Board of Sierra Leone reported that more than $150 million worth of counterfeit drugs are brought into Sierra Leone alone every year. Ashley How, European Director of the Pharmaceutical Security Institute, believes that counterfeit drugs further endanger the health of already vulnerable populations across the continent.

One of the biggest problems when tackling counterfeit drugs is understanding the true scale of the issue. Surveillance of the problem is difficult, particularly in rural areas. “There are many reports of counterfeit medicines in Africa, especially antimalarials”, says Paul Newton, who is part of the Wellcome Trust-Mahost Hospital-Oxford Tropical Medicine Research Collaboration, “but there have always been very few studies that allow one to estimate what proportion of the pharmaceutical market is counterfeit, and certainly none that allow a reliable estimate for the whole of Africa.”

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But if there were more studies on counterfeiting, would it make a difference? WHO are of the opinion that “studies can only give snapshots of the immediate situation. Counterfeiteers are extremely flexible in the methods they use to mimic products and prevent their detection. They can change these methods from day to day, so when the results of a study are released, they may already be outdated.” How adds that it is very difficult to get detailed information from parties involved in combating counterfeiting. “In many cases where successful actions against counterfeit, illegal and substandard drugs were undertaken by authorities, little public information is forthcoming about the case...As a consequence it is difficult for the stakeholders to understand the nature and extent of the problem, let alone to develop strategies to combat illegal medicines.”

Drug companies are trying their best to intervene, but there are many difficulties. Steve Allen, Senior Director of Pfizer Global Security told The Lancet “I saw [counterfeiting] first hand in Tanzania last year, where we had antimalarial products being counterfeited, to the degree that they were using identical batch numbers, identical expiry dates, the packaging, to all intents and purposes, seemed to be absolutely genuine, the blisters looked genuine, the tablets looked as if they were genuine, you would not be able to tell the difference, I can promise you, I’ve seen them myself.” It was only after these tablets were tested in a laboratory in the UK that it was discovered they had no active ingredients at all. “I can’t think of many more worst-case scenarios, you have a counterfeiter somewhere in the world manufacturing a medicine for someone [pregnant women], she believes she might die anyway from malaria but it also impacts the unborn child, it is one of the most despicable of crimes.”

Allen has 11 people working throughout Europe, the Middle East, and Africa trying to understand the issues they are encountering; all
Counterfeit drugs often look indistinguishable from the genuine article. The printed journal includes an image merely for illustration.

Counterfeit drugs are sold alongside vegetables in local markets. “Illegal internet pharmacies or marketing of products through the internet adds an additional dimension to the problem”, Ghodse explains.

Newton is deeply concerned about the substantial detrimental effects counterfeit medicines have on African populations. “The main consequences...are increased mortality and morbidity, endangering drug resistance and loss of medicine efficacy, loss of confidence in health systems and health workers, economic loss for patients, their families, health systems, and the producers and traders in good-quality medicines, adverse effects from incorrect active ingredients, a waste of enormous human efforts and financial outlay in the development and manufacture of medicines...”

But Ghodse does see promise in the movement against counterfeit drugs. “Recently, African Ministers responsible for drug control and crime prevention met in Addis Ababa at a conference organised by the African Union to address the drug problems facing the region and to review the [older version of the] African Union Plan of Action for Drug Control, which is already being implemented. This meeting was a critical juncture in ensuring cooperation in the region in drug control efforts.”

And there have been some notable success stories in tackling counterfeiters in Africa. For example, in Nigeria, the National Agency for Food, Drug Administration and Control (NAFDAC) was set up in 1993. Between 2001 and 2008 the Director General Professor Dora Akunyili led NAFDAC in 123 interception events during which they destroyed counterfeit and substandard drugs valued at more than $16.25 billion. New testing equipment is also being developed by NAFDAC, called the “True Scan Machine”, which has the capacity to detect the quality of commonly used drugs in 3 minutes.

The Tanzania Food and Drugs Authority is in the middle of a 5-year strategic plan to combat both locally manufactured and imported counterfeit drugs. And in 2008, Kenya introduced a new law, the Anti-Counterfeit Act, which will allow for the prosecution of counterfeiters. Kenya is also working very closely with INTERPOL and other international organisations to combat counterfeiting. In 2009, the World Custom Organization organised a seminar for operational customs officers working at seaports or airports in 22 countries in east and southern Africa, which involved training customs officers in the identification and seizure of counterfeit medicines.

Allen emphasises the importance of international collaboration among regulators, the pharmaceutical industry and political representatives, and thinks this strategy will have the best chances of tackling counterfeiting. “This is not just an issue for one company, it is not an issue for one country, it is an issue for all of us.”

However, not only is it important to tackle the network of criminal organisations involved in counterfeit drugs, it is also essential to increase the availability of genuine drugs in developing countries that are appropriately priced for local people. Counterfeit drug crime is a complex issue requiring international and regional initiatives among industry, government, charities, and law enforcement. “Numerous parallel interventions are required”, says Newton. “Strengthening medicine regulatory authorities to police the drug supply and facilitating the availability of relatively inexpensive, good-quality anti-infectives are likely to be the key factors in improving drug quality. More political will and collaboration between medicine regulatory authorities, police and customs is essential.”

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