

FINANCIAL TIMES

MAY 14, 2007

COMMENT AND ANALYSIS: Bitter pills: the fast-growing, deadly industry in fake drugs

By Andrew Jack, Financial Times
Published: May 14, 2007

Sherif Olagunju, deputy head of the Lagos Central Drug and Vaccine Laboratory, sighs as he spreads out a gruesome collection of counterfeit medicines on his desk. Despite tough efforts in Nigeria to clamp down on fakes, recent hauls by his agency highlight the challenge they face.

He points to a bottle of Coflin cough mixture with a corroded cap and congealed contents; a packet of the antibiotic Septrin with no manufacturer's details; and a box of Ephedrine, a stimulant, that his analysis reveals to have less than three-quarters of the "active ingredient" needed to make it work effectively.

With fakes - often indistinguishable from genuine medicines - accounting for about 10 per cent of the developing world's drugs, unwitting patients are each year being killed by neglect at best and poison at worst.

But if some of the worst-hit countries such as Nigeria have lobbied with little success over several years for tougher international action, the growing commercial stakes are encouraging a fresh willingness to tackle the problem globally - and to develop new tools that may help.

The World Health Organisation last year helped create a new International Medical Products Anti-counterfeiting Taskforce (Impact). The Council of Europe last month called for tougher new laws. And today European Commission officials and politicians meet in Brussels to assess the problem and how best to respond.

"We have made incredible progress in the past year," says Howard Zucker, the WHO's assistant director-general who has co-ordinated Impact meetings bringing together regulators, police, drug companies and health specialists in efforts that he hopes will culminate in important measures to be launched this autumn.

One explanation for the renewed efforts to fight counterfeiting is its expansion into the developed world, where it is affecting the large pharmaceutical companies, notably through fast-growing unregulated internet sales. While difficult to measure and still modest in scale, Impact estimates that the proportion of fake medicines circulating in industrial countries is 1 per cent - and rising.

Since it introduced tough new security measures in 2001, for example, Boehringer Ingelheim of Germany has identified more than 100 incidents of counterfeits of its products, which range from respiratory treatments to cardio-vascular and arthritis medicines.

If regulators are responding because of the threat to public safety, pharmaceutical companies, struggling to improve their image, are keen to be seen to be supportive. They are also motivated by the risk to their businesses - including the danger that patients might sue over defective copies of their branded medicines, even if the companies themselves are not responsible.

In 2006, for example, Pfizer felt obliged to bear the cost of withdrawing 120,000 treatments of a fake version of Lipitor, its best-selling anti-cholesterol drug, from pharmacies across the UK. That helped trigger a much more tightly-controlled system of drug distribution it launched across the country in March 2007.

As their traditional markets in the US, Europe and Japan wane, many of the western pharmaceutical groups are seeking to boost sales in fast-growing emerging economies where faking is more widespread and poses a threat to their expansion.

That includes countries such as India, Brazil and China with a significant middle class and growing demand for innovative products to treat diseases such as diabetes. It also involves Russia and other former Soviet bloc states where weak enforcement and the past absence of strong patent protection has allowed faking to reach up to 30 per cent.

However, the broad coalition of interests that have assembled to tackle counterfeiting has been beset by tension due to differing motivations and the varied methods that need to be employed, along with other issues.

Dora Akunyili, the head of Nafdac, Nigeria's medicines agency, says that most of the fake drugs in her country are made abroad, notably in India and China. She wants an international convention enforced by UN sanctions to impose heavy criminal sanctions on counterfeiters who today often face only modest fines.

She argues that many from the developed world are too focused on controlling internet sales of "lifestyle" drugs such as Viagra for impotence. "This is not a problem that can be compared with what we are going through," she says. "They worry about the internet when we don't even have electricity."

There are also divisions within industry. Some pharmaceutical companies draw the definitions of counterfeiting too broadly. They risk conflating criminal groups with other legal activities which threaten their business: off-patent generic drug companies; "parallel importers" who arbitrage the price differences of drugs between different countries; and developing world manufacturers who need assistance to improve their products.

Furthermore, while many stress the importance of communication to alert regulators and patients alike to fakes, the drug companies remain secretive, partly out of fear of provoking panic and damaging their brand reputation.

Finally, there are ideological conflicts in the battle against counterfeits. "Radical price cuts and the support of public health systems could abolish the major part of the counterfeit problem," argued Buko Pharma, a German health campaigning group, in a recent document. Industry retorts that many fakes are instead low-price, high-volume, less conspicuous generic drugs.

Despite the divisions, Mr Zucker at the WHO argues that the common ground is now far greater than in the past.

He points to measures currently being developed by Impact that could soon begin to bite. These include efforts to strengthen domestic and cross-border laws, and tougher police and regulatory action, to ensure that medicine counterfeiters are tracked down and receive tough criminal sanctions on conviction.

As the pharmaceutical flows between richer and poorer countries intensify, so will the drive for progress to tackle counterfeiting. But as long as price differences exist alongside inconsistent regulatory regimes and weak enforcement, so will the temptation to counterfeit.

<http://search.ft.com/ftArticle?id=070514000828>