Safeguarding against substandard medicines

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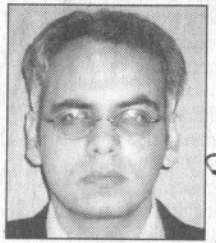

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Despite the impediments hindering effective regulation of medicines, our government could at least allow concerned civil society organisations to help increase pharmaco-vigilance in the country

THE GLOBAL PROFUSION OF SUBSTANDARD medicines is a serious public health concern. Substandard medicines can be deliberate counterfeits or the result of negligence or error. In both cases they lead to therapeutic failure in the best of circumstances. They can even have very adverse effects on the health of users.

The practice of counterfeiting medicines prevails in both industrialised and developing countries. In developed countries, counterfeiters usually target new, expensive 'lifestyle' drugs like steroids or hormones. In developing countries, however, counterfeited medicines include those used to treat life-threatening conditions including malaria, tuberculosis and HIV/AIDS.

A recent study published in the medical journal, *Lancet*, concludes that 40 percent of the medicines for resistant malaria contain no active ingredients and have no therapeutic benefits. A significant fraction of the deaths occurring from malaria every year may be prevented if the medicines available are effective, of good quality and correctly used.

On account of the high demand and low production costs, counterfeiting medicines is a lucrative business. The United States Food and Drug Administration estimates that counterfeits make up more than 10 percent of the global medicine market. Annual earnings from their sales are over $32 billion. Production of counterfeit drugs is easy and does not require elaborate infrastructure or facilities. Trade in substandard medicines flourishes when drug regulation is weak and supply of basic medicines is scarce or erratic.

Developing countries face a challenge in ensuring access to quality medicines. Registration of medicines is the process by which a designated regulatory authority, having considered a medicine's safety, quality and efficacy, approves its use in a particular country. Effective regulation is thus necessary to prevent use of substandard medicines. Yet, under-resourced and poorly equipped to assess increasingly complex data, regulatory authorities in developing countries are often expected to register medicines quickly and cheaply. Moreover, international financial institutions recommend that governments in developing countries should rely on user fees to pay for a cost-effective medicine regulation. But dependence on user fees compels regulating agencies to think of pharmaceutical manufacturers, rather than the public at large, as the constituency to which they are primarily responsible. However in the interest of public safety, it is important for governments to realise their responsibility for funding effective medicine regulation.

Some countries have begun serious efforts to address the counterfeit medicines issue. In China last year, 1,300 illegal factories were closed down and cases involving counterfeit drugs worth $57million were investigated.

Some policymakers consider drug regulation an unnecessary barrier to trade. Where regulatory processes are unwieldy and delay entry of needed medicines in a market, they can create barriers to access, as well as to the growth of the pharmaceutical industry.

But it must be remembered that pharmaceuticals are not like other commodities since most consumers cannot assess the quality of medicines for themselves and because use of substandard medicines has dire consequences. Conversely, the removal of trade barriers between countries has spurred a profusion of counterfeit medicines. Also the extension of a single standard of intellectual property right protection to all inventions, including medicines, by the World Trade Organisation has created new barriers to access to essential medicines, like those needed to treat HIV/AIDS in poorer countries.

To provide access to safe medicines, the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use has sought to improve the efficiency of medicines registration in the US, Europe and Japan by creating common templates and standards under the ambit of the Organisation for Economic Cooperation and Development (OECD). There are moves to try and apply these harmonisation standards and processes to non-harmonised developing countries. Again, this could increase the costs of essential medicines and even hamper access to them. Developing countries are more inclined towards a regional approach in setting standards for the pharmaceutical sector.

They also consider the World Health Organisation a more appropriate intergovernmental organisation to set international standards than OECD. The WHO does endorse the need for regular availability and accessibility of affordable essential medicines of good quality around the world. It could certainly do more to actively support developing countries in strengthening pharmaceutical registration, distribution and quality.

A look at ground realities concerning these issues should prove revealing. Consider, for example, the results of a market-based survey by an NGO to check availability of essential drugs in nine cities and towns across Pakistan. It revealed that 47 out of 478 essential drugs were not available in local markets in 2001. The lethargy of our regulatory authorities is also evident from the time taken to deal with banned medicines, such as the arthritis drug, Vioxx, which caused thousands of heart attacks, strokes and deaths.

Following its global ban, Vioxx was removed virtually overnight from medical outlets in the industrialised world. Even the Indian authorities banned Vioxx in seven days and began removing it from the huge health delivery system. In Pakistan, however, watchdog groups found that Vioxx had not been completely removed from the health system even nine weeks later. While the removal has now taken place, safely discarding the banned drug is still proving problematic.

There are also complaints of other substandard medicines being provided to the basic health units, rural health centres, and even to government hospitals at the *tehsil* level. Substandard medicines are used partly due to contradictory rulings by provincial drug testing laboratories and their appellate body, the National Institute of Health. Despite the impediments hindering effective regulation of medicines, our government could at least allow concerned civil society organisations to help increase pharmaco-vigilance in the country.

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