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'MNCs and lobbyists campaign against Indian drugs industry'

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How serious is the problem of sub-standard medicine in India?
The term substandard is a catch-all phrase that captures any deviation from regulatory requirements. But not all sub-standard or spurious drugs pose a threat to life. From a public health perspective, only the drugs of 'non standard quality' pose the major threat. According to a 2009, CDSCO study, the extent of spurious drugs in retail outlets was only 0.046 per cent and the percentage of drugs failing chemical analysis was only 0.1 per cent (3 out of 2976 samples). In addition, sub-standard drugs accounted for 6-7 per cent of overall tested drugs (state drugs controller estimates). The problem of spurious drugs is nowhere as dire as has been claimed by unverified reports in media.

Is there an underlying Western campaign to malign the Indian pharmaceutical industry, which is a major player in global drugs export market?
There is certainly a campaign by multinational companies and their lobbies to undermine confidence in Indian generics. The chief tactic is to conflate the issue of 'counterfeit' which refers strictly to an intellectual property violation (an egregious trademark violation) with poor quality. The last few years have seen the emergence of an anti-counterfeiting agenda that focuses on misguided global enforcement mechanisms that have nothing to do with real health concerns.

What is the size of the small and medium scale enterprise in the Indian pharmaceutical industry?
The Indian pharmaceutical industry is characterised as 'long-tailed' with approximately 5000 manufacturing units producing drugs, of which only around 250 and large scale units.

Do you think implementation of strict regulatory measures will be an expensive proposition for the SME unit?
Schedule M (good manufacturing practices-GMP) of the Drugs and Cosmetics Act has been implemented since July 2005. Firms were required to come into compliance and during this period several small and medium scale entities were impacted and had to shut down, particularly those producing bulk drugs. MNCs are engaged in attempts to leverage quality as a barrier to trade.

The main objective should be to aim for appropriate quality and regulatory standards and not only the highest standards.

Why Indian chemist shops don't have qualified pharmacists?
Under current rules, only qualified pharmacists are allowed and provided licences for setting up pharmacies. The lack of enforcement is certainly a challenge.

What are the flaws with the Indian drugs regulatory system? Why the Drugs Controller-General of India could not see these faults which American Food and Drugs Authority discovered with Ranbaxy?
Some of the current challenges facing the regulatory system include inadequate financing, lack of technical workforce and poor infrastructure and capacity for testing of drugs. But inadequate financial resources coupled with poor augmentation of testing laboratories and infrastructure, hiring of skilled personnel has crippled the CDSCO and state authorities' effective functioning. In the case of Ranbaxy, the complaints were related to violations of Standard Operating Procedures and not because of product quality defaults. India has the maximum number of FDA approved plants outside US. Over 300 plus Indian pharmaceutical manufacturing units have EU mandated GMP certificates, while the largest number of DMFs (Drugs Master Files) approved in US are from Indian Generic firms. A large segment of our drugs manufacturing units are already qualified with Indian GMP.