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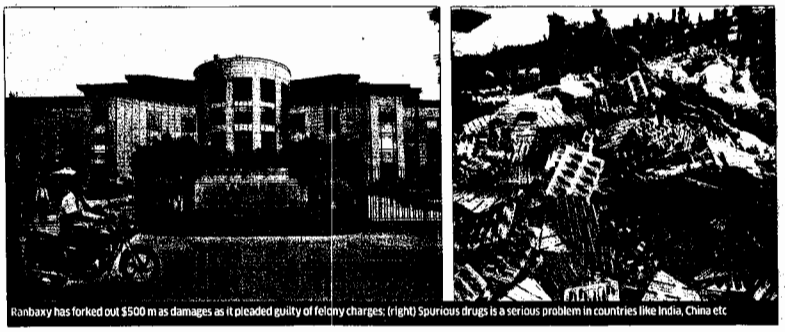
Faking it: India, known as "pharmacy to the world", faces the task of fighting spurious drugs



Ranbaxy has forked out $500 m as damages as it pleaded guilty of felony charges; (right) Spurious drugs is a serious problem in countries like India, China etc

Stamping out spurious drugs

Kalyan Ray

On November 25, 2013, Wockhardt group CEO Habil Khorakiwala received a letter from the US Food and Drugs Administration flagging several shortcomings of the company's two drugs manufacturing units at Chikalthana and Waluj, both in Aurangabad district of Maharashtra. The two units were inspected by an FDA team simultaneously between July 22 and 31, 2013, to prepare the warning letter on the deficiencies of the plants that manufacture drugs, which Wockhardt exports to the USA. The company is expected to comply with the FDA norms to remain in the US market.

The scanner on Wockhardt is relatively new but the production units of Ranbaxy at Paonta Sahib, Mohali, Tonsa and Dewas were under the FDA scrutiny since 2006 when the company consolidated its market in the USA. The US regulator issued several warnings and inspected the facilities before putting Ranbaxy on notice.

In May 2013, Ranbaxy pleaded guilty to felony charges relating to the manufacture and distribution of certain adulterated drugs made at the company's manufacturing facilities in Paonta Sahib and Dewas, and agreed to pay $ 500 million as damages. In September 2013, Ranbaxy's Mohali unit too came under prohibition followed by the January 2014, ban on the Toansa facility, where the FDA inspectors, among other deficiencies, noticed flies too numerous to count in the sample preparation room. The firm is now left only with its Ohm Laboratories in Gloversville, New York, to cater to the US market, which constitutes almost 35 per cent of the Ranbaxy's global sale worth $ 2.3 billion.

"Ranbaxy was given a long rope. How can they be so casual when it involves thousands of crore worth of export market," wonders S Srinivasan of the Vadodara-based non-governmental organisation Low Cost Standard Therapeutics (LOCOST). According to Margaret Hamburg, Commissioner of American drugs regulator USFDA, strong and smart regulation in a clear, predictable and transparent ecosystem creates a level playing field for all players in the market.

But why the Indian drugs regulator – Central Drugs Standard Control Organisation – or even the UK regulators could not pick up these flaws in Ranbaxy units? The difference, officials explain, lies in the inspection process adopted by different regulatory agencies. "For instance, let's assume, there are 30 industrial processes to be followed while making a medicine named "A". Let us also assume the process involves initiating a particular step on the 15th day. Now, if a company does it on the 17th day after ensuring that the chemicals do not degrade in those two days, we will still get the drugs of right quality at the end. It will be all right for CDSCO. But the USFDA will call it an adulterated product because the process was not followed in toto," explains an official of the union health ministry.

Officials and public health specialists hint at how the global pharma industry pick up isolated cases and cleverly mix up separate issues related to spurious drugs, counterfeit or look-alike drugs and not-of-standard drugs to project Indian pharma industry in a bad light. "There are quality issues no doubt, but these should not be used as a non-tariff barrier targeting Indian products," says Aradhana Johri, secretary in the department of pharmaceuticals in the Union Ministry of Chemicals and Fertilizers.

The multinationals, say industry sources, mix up intellectual property issues (trade mark violations), tax violations (inter-state movements) and technical issues (storage problems can make drugs sub-standard) with spurious drugs manufacturing to propagate a campaign which is seriously threatening the existence and credibility of Indian small-scale drugs manufacturing sector. "Simply speaking, counterfeit refers to unlawful use of brand names that hurt commercial interests of a company while fake refers to products that do not contain any medicine or substandard ingredients and hence are harmful to public health," explains C M Gulhati, a former consultant to the World Health Organisation and the editor of a pharmaceutical industry journal. In a 2009 survey, CDSCO found only 0.046 per cent (11 samples out of 24,136) of drugs in retail pharmacy as spurious. These 11 samples were not accepted by the manufacturers as their genuine products. The government's own past estimates suggest 8-10 per cent substandard medicine that can happen for a variety of reasons including storage problem.

Storage problems

Improper transportation and storage of medicines is a serious problem in the country. Many quality products turn substandard by the time they reach consumers. "In the semi-urban areas, many retail chemists do not have functioning refrigerators. Most chemist shops sell chocolates and find it more profitable to stock them in refrigerators rather than medicines. Others switch them off on weekly holidays to save on electricity expenses. In many places power load shedding for 8 hours or more a day is a routine. Temperature sensitive drugs are bound to degenerate in such an environment," says Gulhati.

Under the current regulations, manufacturers are hauled up for sub standard drugs while the actual responsibility lies with either distributors or retailers or both. "There is a need to revisit the law," he said.

The false propaganda leads to tightening of rules, which eventually come as an obstacle for small and medium scale industry. In the last decade, almost 40 per cent SSI units had been closed and setting up a new pharma unit now costs 10 times more than what was needed before these legislations. "From the government, we have launched the cluster schemes in which Rs 20 crore would be provided to set up common facilities needed for quality control like effluent treatment plant," says Johri. "Had we been so bad, we would not have exported medicine worth $ 15 billion to over 150 countries. As many as 360 manufacturing facilities are FDA approved, which is the largest outside the USA," says the health ministry official.

In the presence of Hamburg, India and USA signed a statement of intent with the underlying purpose of improving the Indian drugs regulation standards using the US expertise.

One of the components of the agreement is FDA intimation to respective regulatory authorities before undertaking inspections, so that host-country inspectors may join inspections as observers.

"We are not here to tell the Indian regulator how to do their job. But for companies that want to sell their products in the US marketplace, they do need to comply with our standards and practices and expectations, and we think that through greater collaboration we can enhance understanding about what our standards and expectations are," says the FDA commissioner.

Fact file of illegal drugs

Extent of spurious/sub-standard drugs in India

Indian drugs regulator Central Drugs Standards Control Organisation's (CDSCO) nationwide survey 2009-12

1.37 lakh — 345 spurious

- In 2009-10, CDSCO tested 39,248 medicine samples, of which 1,942 found to be substandard, 117 or 0.29 per cent found to be spurious.
- In 2010-11 and 2011-12, 49,682 and 48,082 samples were tested. Out of these, 2,372 and 2,186 found to be substandard.

Indian pharma industry & USA

- India's pharmaceutical industry supplies 40 per cent of over-the-counter and generic prescription drugs consumed in the United States
- FDA inspected 160 Indian drugs plants last year, three times as many as in 2009. Increased scrutiny has led to a flood of new penalties on drugs makers.
- Ranbaxy, one of India's biggest drugs manufacturers, pleaded guilty to felony charges and paid a $500 million fine last year, the largest ever levied against a generic company.
- A recent FDA Operation in four US airports revealed several drugs promoted as "Canadian" products originated from other countries including India.

FLAWS IN THE SYSTEM	STEPS TAKEN BY THE GOVERNMENT
CDSCO understaffed. Till April 2013, only 327 sanctioned posts, out of which 124 were occupied	Sanctioned posts went up to 327, 200 posts still vacant
Earlier, drugs prohibited for sale in the USA, UK, EU, Australia, Japan and Canada for safety reasons were allowed to be sold in India	Now, such drugs are immediately suspended for sale in India till the safety of the drugs is examined and established
No effective system to deal with sub-standard and adulterated medicine.	Guidelines formed on recall of drugs; drugs alert system initiated
Ill-equipped drugs testing laboratories at Central and state levels	Rs 3000 cr outlay in 12the Plan to spruce up Central and state drugs authorities
Much of the drugs inspection and licensing at the state level, with little oversight	Little action on ground, primarily because of the complicated Centre-State relations
No system to monitor adverse side-effects of drugs once launched in market	No action initiated
Extent of corruption in drugs regulatory system brazen, as highlighted by the Parliamentary Standing Committee on Health	Several steps taken by CDSCO and Health Ministry to make drugs regulation organised and transparent system; more needs to be done

Regulatory