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COUNTERFEIT drugs kill and increased international collaboration is essential to defeat this \$200-billion-a-year industry. A global effort is underway to mobilise awareness and action against the scourge. Until now, World Health Organisation (WHO) led concerted efforts with its International Medical Products Anti-Counterfeiting Taskforce (IMPACT) initiative, by engaging with police and customs agencies to address counterfeit and illegal medicines. The American drug regulator US Food and Drug Administration (FDA) has joined the fray and is actively working with multiple agencies—international organisations, enforcement agencies and associations representing pharmaceutical manufacturers and wholesalers—so that eventually the production, trading and selling of fake medicines will cease. Together, they are chalking out strategies for curbing the menace of counterfeit medicines by setting up processes and systems in place.

India, the world's leading maker of generic medicines, is also the hub for counterfeit and substandard medicines. To fire-wall counterfeits, various measures are being undertaken to ensure stringent regulatory control of medicines and enforcement by drug regulatory authorities. These include sprucing up the legislative and regulatory infrastructure, regulatory implementation and enforcement for curbing the menace. Enforcement agencies—both at the Central and state level—are in an overdrive, conducting raids to confiscate counterfeit medicines. Pharmaceutical companies are actively conducting on the spot quick samples of their products to check for quality. Technology tools coming to the rescue and some of the commonly used are RFID, colour shifting, chemical markers, holograms, laser coding, inkjet technology and invisible tags.

Lupin Group president of India region formulations, Shakti Chakraborty says, "It is imperative that regulators and pharmaceutical companies work together to set up systems and processes and adopt technologies that would ensure that authentic drugs reach the consumer. At Lupin, we are focused on ensuring that the right drugs reach the market. There is an anti-counterfeit solution which enables consumers to access entire details of a medicine by sending the code printed on Lupin drug packs through an SMS to a dedicated number. "We have launched this solution for our flagship brands and will eventually extend it to all Lupin products in the market," he adds.

Roger Williams, CEO of the United States Pharmacopoeia (USP) says, "In countries like India and China, which are centres for the manufacture of medicines and ingredients, it is inevitable that some of them are counterfeits. The US market is driven by generics where Indian pharmaceutical companies have been playing a key role. India needs strong drug standards." USP is working closely with the FDA to help ensure the quality of medicines and its role is to set standards for the identity, purity, strength and quality of medicines and FDA participates in this standards-setting process. However, USP plays no role in enforcement of these quality standards, which in the US is the sole responsibility of FDA.

Recently, USP rolled out a new public database listing quality measures on drugs sampled around the world. The resource, launched with backing from the FDA, lists authenticity testing results for 8,700 drug samples to date, including key anti-malarials and anti-tuberculosis medications obtained from pharmacies and clinics worldwide. The database is freely accessible online, and con-



ILLUSTRATION: SHANI

FIGHTING FAKES

Taking a cue from global initiatives, India is adopting stringent measures to fight counterfeit drugs by sprucing up the regulatory infrastructure and putting in technology like RFID, holograms and laser coding

tains critical quality data such as the time and location of drug sampling. With the new database, countries will be able to identify which drugs are being counterfeited in neighbouring countries and be alerted of products of concern. USP and FDA are also developing use of hand-held instruments for law enforcement inspectors to test drug quality in the field.

Generally speaking, all kinds of medicines are counterfeited—branded and generic—ranging from medicines for the treatment of life-threatening conditions to inexpensive generic versions of painkillers and antihistamines. The complexity of the distribution network is the principal point from where counterfeit drugs make their way into the pharmaceutical chain. Once a product leaves the company, a number of players like wholesalers and brokers get their hands on the drugs consignment. The danger snakes its way into the pharmaceutical chain soon after the product leaves the four walls of a company. With a number of wholesalers and brokers getting their hands on the drugs consignment, it is difficult to identify exactly when the process starts to take an ugly turn. The low likelihood of

detection is an added incentive. "The economic motivation to counterfeit certain medicines can be powerful, especially given the low costs and low likelihood of detection or punishment in many countries," Williams explains.

Sample some recent fake drug seizures in India: enforcement agencies carried out raids at central Delhi's medical wholesale market, Bhagirath Place, and subsequently also in Agra, and busted an organised gang selling spurious drugs and those meant for Central Government Health Services (CGHS), Municipal Corporation of Delhi (MCD) and even the Director-General of Armed Forces Medical Services (DGAFFMS). Drugs worth ₹40 lakh were seized in both the cities. Bejon Mishra, founder, Partnership for Safe Medicines India says that the existing laws in India are adequate to deal with counterfeiters. The Drugs and Cosmetics Act has been amended to provide for stricter penalties for offences particularly to those engaged in making of spurious, adulterated, misbranded and substandard drugs. The maximum penalty has gone up to life imprisonment and fine of ₹10 lakh or three times the value of confiscated goods, whichever is

more. "But it is high time all the stakeholders agree to work on this challenge to protect patient's right and public health. While spurious medicine sales are difficult to quantify and track, it would be foolhardy to ignore their trail of damage and death," he laments.

Ranjit Shahani, vice-chairman & managing director, Novartis India, has also strongly canvassed for deterrent legislation against counterfeit drugs. "It is a rather arduous task to estimate the true penetration of counterfeit drugs. Trade in counterfeit drugs is widespread and affects both developing and developed countries. All medicines are subject to counterfeiting, both branded and generic." The pharmaceutical industry has looked at various measures to prevent counterfeiting including innovative packaging, bar coding and RFID. "Product serialisation, that is, a unique ID code attached to each saleable item, combined with consumer verification ability of that code via SMS or internet is the state-of-the-art. Perhaps, this technology can empower consumers themselves to check the authenticity of their medicines," he adds.

From IT companies' perspective, S Suryamohan, head of life sciences solutions,



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Group President, Lupin

Mahindra Satyam feels that lack of ownership and integrity in the pharmaceutical supply chain is leading to dented brand value, adulterated or diverted prescription drugs. This is having a big impact on brand value and cost of recalls. The company has launched its new offering, 'Serial xPress'. When implemented across the supply chain and used effectively, serialisation and electronic pedigree can bring in supply chain optimisation, reduced product recalls in addition to anti-counterfeiting and enhanced brand value.

J Sairamkumar, vice-president, life sciences practice, Cognizant says that counterfeiting of medicines is a concern that affects the end consumer safety as well as the image of the industry. With state governments starting to mandate implementing anti-counterfeiting measures, there is a much stronger commitment now from the industry. The intent to tackle the problem of counterfeiting is high with pharmaceutical companies but they do not necessarily have the technological expertise for developing solutions which lies with the IT companies. Thus, effective partnership between IT and pharmaceutical companies is essential to tackle the problem of counterfeit medicines, says Anjan Sen, director (strategy and operations) Deloitte in India.

While the world has adopted stringent measures to fight counterfeit drugs, it's time India showed some resolve to arrest this menace.