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Pharma firms, regulators step up action on fake drugs

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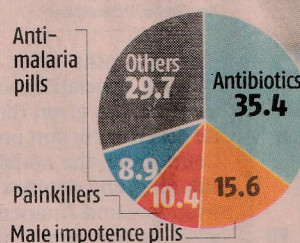
Pharma companies and state drug regulators are intensifying action against spurious and substandard drugs in the country.

Government data shows that in 2019-20, of the 81,329 tested drug samples, 2,497 were found to be of non-standard quality (NSQ), and 199 were declared spurious. In 2020-21, the NSQ count rose to 2,652 in the 84,874 tested samples; 263 were spurious.

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THE SPURIOUS PIE

% share of global value of fake pharmaceutical drugs seized



Source: OECD & EUIPO report

Others include dietary supplements, local anaesthetics, treatment of diabetes, cardiac ailments, allergy, and cancer

the “mastermind”, Mohit Bansal, who were making spurious versions of popular drug brands such as Montair, Atorva, Zerodol, Urispas, etc. Marwaha said he estimated that the value of drugs seized from Trizal Formulation (Bansal’s outfit) is about ₹1.5 crore. Marwaha said these counterfeiting units often have a food manufacturing licence. “The same machines used to make nutraceuticals and several drugs. These units don’t go for drug manufacturing licenses mostly. Therefore, it becomes tough for drug regulators to nab them,” he said.

Firms are also taking action to ensure the consumer can detect a spurious drug from a genuine one. It is becoming more critical as fake-medicine makers are counterfeiting life-saving drugs such as those for cancer. Last month, the Delhi police crime branch nabbed seven people, including a doctor, for allegedly making cancer medicines and supplying them not only in India but also in Nepal, Bangladesh, and China.

A Zydus Lifesciences spokesperson said they introduced a new feature called ZyVerify in its packaging of critical drugs to help patients ensure that the product is not fake. “We have incorporated an IT-enabled scratch code, which shall be printed under a scratchable surface. The patients can check to see if the product is genuine or not by scratching the surface and verifying the code through the app or the website,” the spokesperson said.

“We have implemented this technology in some of the products and is also being extended to other products,” the Zydus spokesperson said,

RECENT INCIDENTS

There has been a 47 per cent surge in incidents involving spurious and sub-standard pharmaceutical products from 2020 to 2021, according to ASPA report

February 2021: Action was initiated against an Agra-based firm for purchasing expired drugs at low cost and re-selling them on real values after new packaging

June 2021: Criminals started encashing on the rise in black fungus cases. More than 3,500 vials of black fungus injections were found during a raid in New Delhi

June 2021: Gujarat FDA busted racket selling fake antiviral drugs Favimax400 and Favimax-200

June 2021: Mumbai police arrested a factory owner in Meerut for allegedly supplying counterfeit Paracetamol and Diclofenac medicines

July 2021: Kanpur crime branch arrested a gang and seized fake medicines worth ₹4 crore. Those arrested accepted that they were producing medicines as per the demand and using UP Transportation Buses for distribution. Code words ‘Parle-G’ and ‘Cadbury’ were used for order bookings

adding they are also in the process of implementing a holographic solution for select products where it is finding higher instances of counterfeits. “It will have hidden features, which can be detected through a special film and will help in immediate confirmation of an authentic product. The QR code, a great initiative by the government, is being adopted for all products mandated by the government,” Zydus said.

Darren Punnen, leader, Pharma & Life Sciences Practice at Nishith Desai Associates, said, “Action can be taken by companies from two angles — one from an IP (primarily trademark) infringement perspective, where the brand owner investigates into the source of the counterfeiting and initiates criminal or civil action for infringement against the offender, and the other is from a quality or regulatory

perspective, where the brand owner informs the drug regulator (CDSCO and/or state drug controller) regarding the counterfeits and requests for their intervention.”

How do these drugs reach the market?

Nakul Pasricha, president, Authentication Solution Providers’ Association (ASPA), said in large-scale pharma distribution markets, such as Agra, some distributors do this mixing of genuine and fake medicines and pass it on to chemists. “The chemists are at times unwitting partners in crime, and sometimes they are also actively involved,” he said.

Pasricha said according to a worldwide study by WHO, one in 10 drugs distributed globally are either spurious or substandard. “In India, the CDSCO has done studies in 2009 and then in 2016 in which they found the

rate of sub-standard drugs was somewhere around 4 per cent. Of this, spurious drugs were about 0.3 per cent,” Pasricha says. The ASPA has done a study where it looked at incidents being reported by the media across India.

In August, the Union Health Minister Mansukh Mandaviya asked the pharma industry to act against firms involved in manufacturing substandard and fake drugs. The Centre has decided to introduce QR codes for ensuring authenticity and traceability for 300 common drug brands. HG Koshia, commissioner, Food and Drug Controller Administration, Gujarat, said they got machines that can scan and check if any consignment is spurious without breaking the seal.

Pharma...

Between 2019 and 2021, 384 were arrested in relation to counterfeit or NSQ drugs.

The state drug controller of Himachal Pradesh, which houses a major pharma manufacturing hub of Baddi, has set up a team of 3-4 members from the department, who are working on generating intelligence on spurious activities in the state. “No spurious drug-making unit will be like a regular one, which has a manufacturing licence. These are clandestinely done. Therefore, we have created a team of officers who are constantly working on generating intelligence about such “underground” activities. It has given results — we have busted three rackets in the last three months,” said Navneet Marwaha, state drug controller of Himachal Pradesh.

Marwaha’s team recently nabbed four people, including