

# Business Standard

## Drug regulators, pharma firms step up action on fake and substandard drugs

Detection of spurious and substandard drugs was up by 47% from 2020 to 2021, according to an ASPA Report

Sohini Das | Mumbai December 11, 2022 Last Updated at 17:00 IST



Pharma

*Photo: Shutterstock*

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.

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 persons 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,” Navneet Marwaha, state drug controller of Himachal Pradesh, told Business Standard.

Marwaha’s team recently nabbed four persons, including the “mastermind”, Mohit Bansal, who were making spurious versions of popular drug brands such as Montair, Atorva, Zerodol, Urispas, etc. “These people used to come from Agra at night, manufacture these drugs here (Himachal), and then take them back to Agra,” Marwaha said, adding that he estimated that the value of drugs seized from Trizal Formulation (Bansal’s outfit) is about Rs 1.5 crore. This apart, his team has busted two more rackets in recent months — Arya Pharma, and Aclime Formulations.

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 difficult for state drug regulators to nab them,” he said.

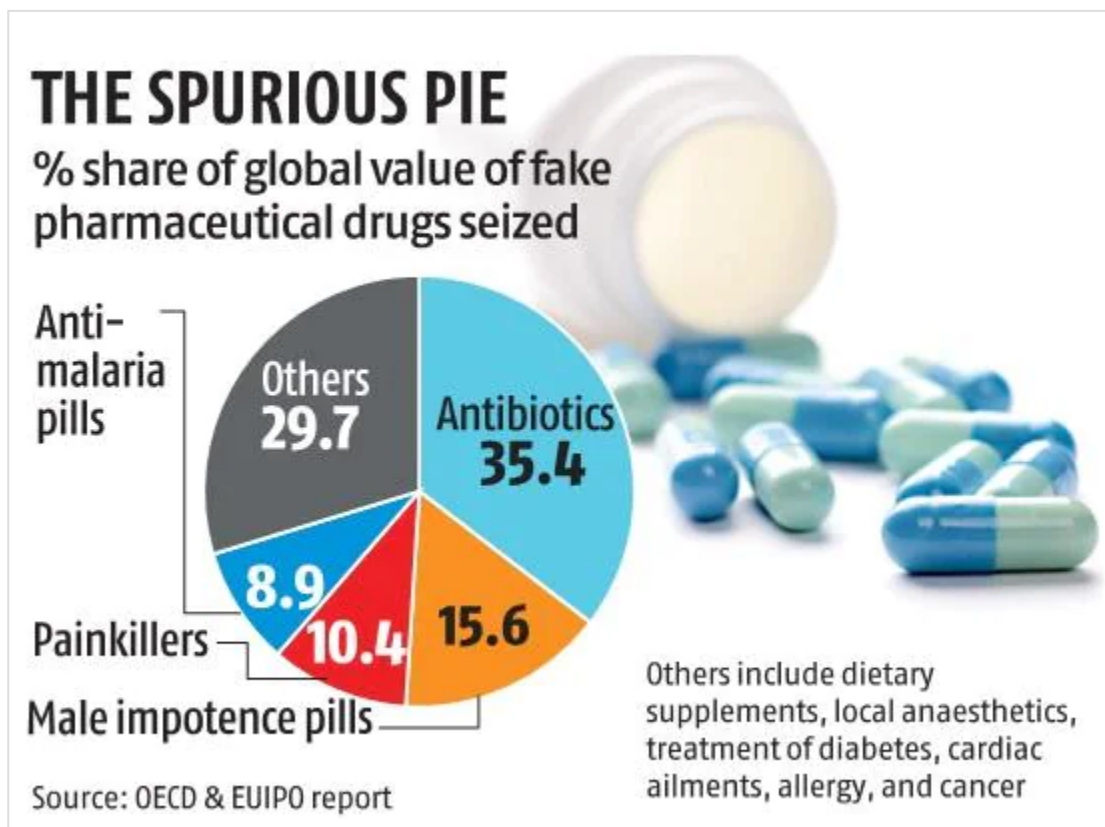
Companies are also taking action to ensure the consumer can detect a spurious drug from a genuine one. It is becoming more critical as fake-medicine makers are also counterfeiting life-saving drugs such as those for cancer.

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 told Business Standard that 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 a new IT-enabled scratch code, which shall be printed under a scratchable surface. The patients can check to see if the product purchased by them is genuine or not by scratching the surface and verifying the code through the app or the website. This security feature developed by Hyperlink Infosystem enables patients and institutions to detect counterfeits,” the spokesperson said.

“We have already implemented this technology in some of the products and is also being extended to other products,” the Zydus spokesperson said, adding that 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. We will continue to expand the scope of the QR code printing,” Zydus said.

Marwaha said it was important for companies to strictly act against each

individual caught counterfeiting.

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 typically 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.”

“Once the regulator is informed, an investigation (typically with the assistance of police) is conducted and criminal prosecution for the import, manufacture or sale of spurious drugs is initiated before the relevant court by the regulator itself,” Punnen said.

### **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 the World Health Organisation (WHO), one in ten 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 the country. “During Covid-19, we found that there was a 47 per cent increase in the number of incidents being reported,” he said.

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, including analgesics, vitamins, diabetes, and hypertension medicines, etc. The draft notification was finalised in November. Popular brands such as Dolo, Allegra, Asthalin, Augmentin, Saridon, Limcee, Calpol, Corex, Thyronorm, Unwanted 72, etc, were identified. These high-selling brands have been shortlisted based on their moving annual turnover (MAT) value.

While the pharma industry starts work on QR codes, the state drug regulators too are getting tech savvy.

HG Koshia, commissioner, Food and Drug Controller Administration (FDCA), Gujarat, said they have got machines that can scan and check if any consignment is spurious without breaking the seal. The Gujarat FDCA has already initiated mobile drug testing labs to reduce response time.

### **Some recent incidents in India:**

- February 2021: A firm engaged in buying expired drugs cheap and reselling them at market prices after repackaging them, was raided in Agra and the drugs seized
- June 2021: Post Covid-19, as soon as black fungus cases started getting reported in Hospitals, criminals began taking advantage. More than 3,500 vials of black fungus injections were found in a raid in New Delhi.
- June 2021: Gujarat FDA busted a racket selling fake antiviral drugs Favimax400 and Favimax-200
- June 2021: Mumbai police arrested a factory owner in Meerut, Uttar Pradesh for allegedly supplying counterfeit Paracetamol and Diclofenac formulations
- July 2021: Kanpur crime branch arrested a gang and seized fake medicine worth Rs 4 crore. The criminals admitted they were producing medicines and using UP State

Transport buses to distribute them. The code words Parle-G and Cadbury were used for order bookings

*Source: ASPA Report of March 2022*