196 Drug Samples Fail CDSCO Quality Test; One Deca-Durabolin Sample Flagged as Sample Flagged as Spurious

A spurious sample picked from Bihar is of "Deca-Durabolin" and is stated to have been manufactured by an unauthorized entity using a brand name owned by another company.

New Delhi: Drug regulators, during their monthly quality review, have identified around 196 drug samples as "Not of Standard Quality" (NSQ) and one sample as "spurious."

The drug alert issued by the Central Drugs Standard Control Organization (CDSCO) states that out of the 196 NSQ samples, 60 were identified by central drug laboratories, while the remaining 136 were flagged by state laboratories.

In addition, one drug sample identified as spurious is a "Nandrolone Decanoate Injection," marketed as Deca-Durabolin—an anabolic steroid used for various medical conditions, including osteoporosis and anemia.

According to a note from the Union Health Ministry, the spurious sample was picked from Bihar and "is manufactured by an unauthorized manufacturer using the brand name owned by another company."

In its alert, the CDSCO specified that the tested sample failed due to issues with the "Identification and Assay of Nandrolone Decanoate."

In India, “Deca-Durabolin 50 mg” is marketed by Ahmedabad-based Zydus Healthcare, following its acquisition of the brand from MSD (Merck Sharp & Dohme) in December 2016.

The matter is currently under investigation, and the purported spurious drug is subject to the outcome of the inquiry.

A drug is deemed spurious if it resembles another drug in a manner likely to deceive, or if it bears upon its label or container the name of another drug—among several other conditions detailed under Section 17-B of the Drugs and Cosmetics Act, 1940.

Among the 60 NSQ samples flagged by central laboratories are Nimesulide and Paracetamol tablets manufactured by Pro-Pharma Care; Cefpodoxime Proxetil tablets by Sunvij Drugs; Ciprofloxacin tablets by Cadila Pharmaceuticals; and 57 other samples.

The 136 NSQ samples identified by state laboratories include Glimepiride 1 mg and Metformin HCl 500 mg tablets manufactured by Surge Pharmaceuticals; Albendazole tablets by Samkem; and Oxfendazole and Ivermectin Bolus by Argon Remedies, among 133 other samples.

The identification of drug samples as NSQ is based on the failure of the sample to meet one or more specified quality parameters. The term NSQ is defined under Section 16(1)(a) of the Drugs and Cosmetics Act, 1940.

However, according to the Health Ministry, “the failure is specific to the drug products of the batch tested by the Government Laboratory and does not warrant concerns about other drug products available in the market.”

The ministry added that the identification of NSQ and spurious medicines is undertaken regularly (monthly), in collaboration with state regulators, to ensure such drugs are detected and removed from the market.

News Source:

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