

New drug export regime to ease quality concerns

Aligning local certification with WHO's GMP follows licensing shift

Priyanka Sharma

priyanka.sharma@livemint.com

NEW DELHI: Drugs made in India for global markets will soon have their local certification aligned with global norms, as the central government moves to assure foreign buyers after recent incidents of sub-standard drugs sold abroad.

The drug regulator will upgrade India's Certificate of Pharmaceutical Product (CoPP) to match the World Health Organization's (WHO's) good manufacturing practices (GMP) certification as part of an overhaul of the export-approval process, two officials familiar with the development said.

The CoPP and the WHO's GMP certificates are the preliminary documents required for obtaining product approval and



The move will also help foreign regulators ascertain the authenticity of Indian drugmakers.

authenticity of Indian drugmakers.

"The plan is to put these certificates on the website of the Central Drugs Standard Control Organisation (CDSCO) so that importing countries or regulators can check whether these certificates are issued by CDSCO or not," one of the two people said.

The idea is to bring in transparency in the system, including greater oversight over the num-

The CDSCO is the apex regulatory authority for the pharmaceuticals, medical devices, and cosmetics industries, similar to the US's Food and Drug Administration. The Drugs Controller General of India (DCGI), operates under the CDSCO.

Under the new guidelines, state governments can issue CoPP certificates to pharmaceutical companies only if CDSCO officials are involved in joint inspections.

strictly adhere to the WHO's good manufacturing practices guidelines at their production facilities.

The move to bring uniformity in the CoPP and the WHO's certificates is welcome as it will bring confidence to exporters and overseas regulatory bodies that exports from India are of high quality and under the supervision of the central government, said Sudarshan Jain, secretary general of the Indian Pharmaceutical Alliance.

As part of the overhaul, the Union government recently wrested authority from states to become the sole entity responsible for issuing manufacturing licences for drugs meant for exports.

A health ministry spokesperson did not immediately reply to Mint's queries.

India is the world's largest exporter of generic medicines, which are authorized copies of patented drugs. In 2022-23, India exported pharmaceutical products worth \$25.4 billion to about 210 countries. Around 60% of the