Link: https://www.moneycontrol.com/news/health-and-fitness/is-uniform-implementation-of-drug-approval-system-a-possibility-in-india-10042211.html

Is uniform implementation of drug approval system a possibility in India?

In 2003, the RA Mashelkar Committee said that a strong, well-equipped, empowered, independent and professionally-managed CDSCO, which could be given the status of Central Drug Administration, reporting directly to the Ministry of Health would be the most appropriate solution.

AYUSHMAN KUMAR | FEBRUARY 09, 2023 / 05:34 PM IST

Stakeholders in the pharmaceutical industry want the Union government to form a clear framework to ensure uniform implementation of the drug approval system. This follows alleged adulteration in drugs manufactured in India being blamed for deaths abroad.

However, the Centre has said that the state drug control authorities primarily regulate the manufacture, sale and distribution of drugs in the country, while the central government, through the Central Drugs Standard Control Organisation (CDSCO), exercises control over drugs imported into the country.

“As per information received from CDSCO, the number of drug manufacturing units in the country is 10,706 as of December 31. The Department of Pharmaceuticals does not maintain the details of company-wise quantum of drugs manufactured,” said Bhagwant Khuba, MoS, Ministry of Chemicals and Fertilisers, when asked whether the government has any mechanism to regulate and monitor the manufacturing and marketing of drugs by pharma companies.

Last week, **Krishna Ella, the chairman of Bharat Biotech**, said all the state drug regulatory bodies should be merged into the CDSCO to ensure "one quality, one standard".

Responding to a question by Moneycontrol on a growing list of foreign countries flagging the adulteration of Indian drugs, Ella said that a single regulatory framework in India will be helpful.

Ella’s views were echoed by GN Singh, former Drugs Controller General of India (DCGI), who said he had proposed a uniform drug approval mechanism during his tenure but it wasn’t taken ahead due to ‘unknown reasons’.

“During my tenure as DCGI, I had initiated a proposal for bringing uniformity in the implementation of drug rules. It is very important for quality assurance that all the state and central regulators should be on one page,” Singh said.

Singh added that political will was needed to strengthen the state-level regulatory apparatus with complementary roles of the Centre and the states, while at the same time ensuring uniform and effective implementation.

Vivek Sehgal, Director General, Organisation of Pharmaceutical Producers of India (OPPI), representing research-based pharmaceutical companies, said his organisation was in favour of creating a simplified single-window drug approval and regulatory system for the pharmaceutical industry in India.