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ASIA EDITION

# Indian Government to enhance quality and safety of drugs in the region

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**From March 2021 onwards Indian pharmaceutical companies that market drugs will be accountable for the quality and other regulatory compliances along with the manufacturers says GlobalData**


Following the recent official gazette notification from the Ministry of Health & Family Welfare (MOHFW) of India that from March 2021 onwards Indian pharmaceutical companies that market drugs will be accountable for the quality and other regulatory compliances along with the manufacturers. Here are the reviews from GlobalData, a leading data and analytics company.

Indian pharma regulators have finally acknowledged the flaws existing in the pharma environment and are looking to fix unethical marketing via Uniform Code of Pharmaceutical Marketing Practices (UCPMP). They have also brought pharma marketing firms under the ambit of the Drugs and Cosmetics Act (DCA). The amendment in DCA act would enhance the focus on the quality and safety of drugs and will force pharma marketers to ensure that their manufacturing facilities and processes are as per Good Manufacturing Practices (GMP) standards.

“According to GlobalData, the Indian pharmaceutical market is expected to increase from nearly US$34.3bn in 2020 to more than US$45bn by 2025. Reportedly, non-compliance to quality standards is one of the biggest challenges faced by the Indian pharmaceutical sector.

“Indian pharma companies often delegate domestic manufacturing to third parties under contract manufacturing agreements. Post manufacturing, pharma firms lend their drug brand names and affix their names on the packages for sales and distribution. The drug packaging also contains information regarding local manufacturers. At present, only the manufacturers are held responsible for the sub-standard quality or spurious drugs.

“Notably, in 2019 Indian pharma companies had received 19 warning letters, of which 46% were issued by the Office of Manufacturing Quality of the US Food and Drug Administration (USFDA). These instances have created significant mistrust on Indian pharma manufacturing standards in the international markets. The Government’s direct intervention to enhance the quality and safety of drugs can be seen as silver lining that should bring about high-quality manufacturing/quality standards in

the Indian pharmaceutical sector over the years to come" says Anupama, Pharma Analyst at GlobalData.