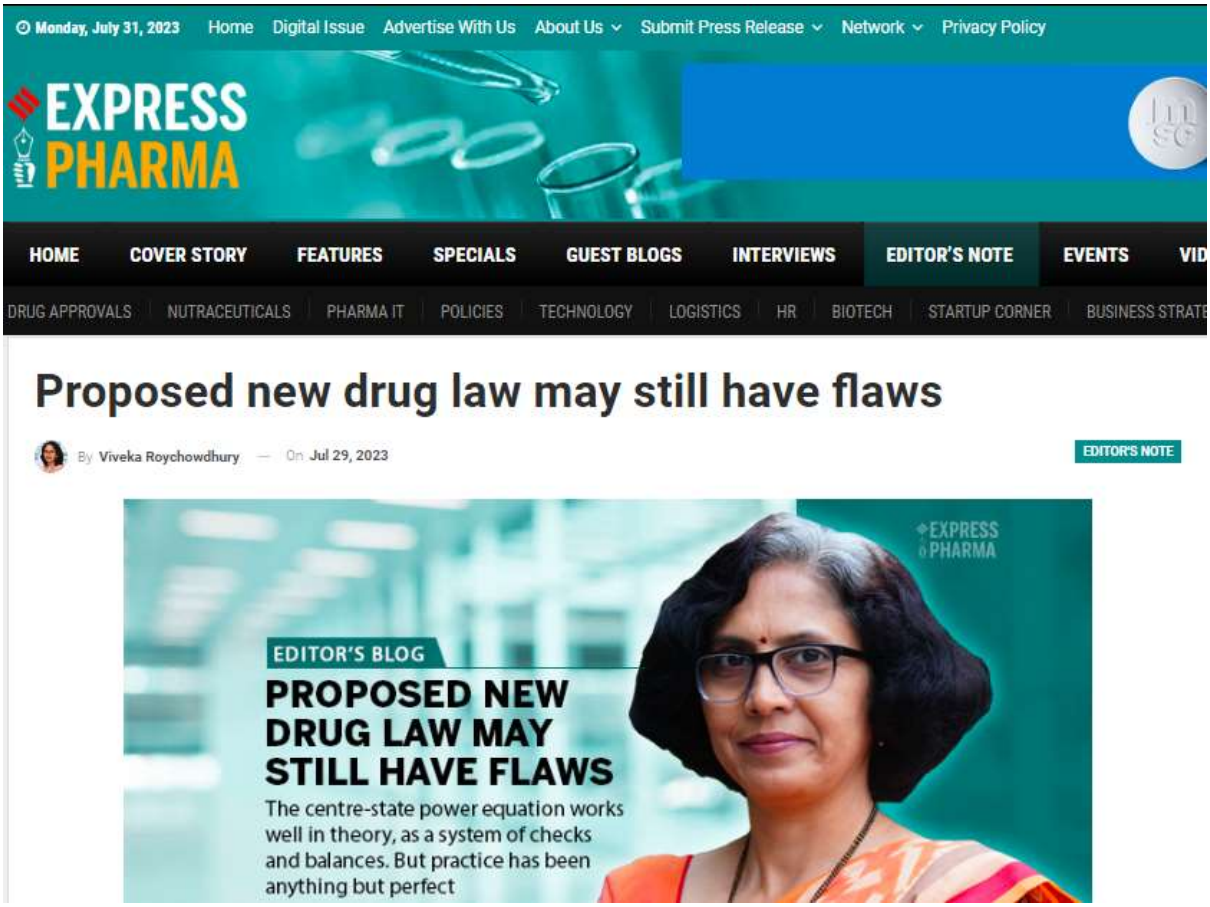
Link: https://www.expresspharma.in/proposed-new-drug-law-may-still-have-flaws/



The centre-state power equation works well in theory, as a system of checks and balances. But practice has been anything but perfect

Of the 32 bills awaiting discussion during the ongoing 2023 Parliament Monsoon Session, the Drugs, Medical Devices and Cosmetics Bill, 2023 is one of 21 new draft legislations. Once passed, this will replace the Drugs and Cosmetics Act, 1940.

However, not everyone is on board with the proposed Bill. Pavan Choudary, Chairman, Medical Technology Association of India (MTaI) says that although the draft of the Bill has not been shared with stakeholders yet, they expect that it will incorporate several thoughtful provisions from the Medical Devices Rules 2017.

He points out that the regulation of Medical Devices currently operates under The Medical Devices Rules (MDR) 2017, a well-considered framework that emerged through extensive consultations between CDSCO and various stakeholders. Choudary further adds, that they strongly recommend that the industry is consulted and given an opportunity to submit their recommendations before the Bill is finalised. His point is that advancing the inclusive approach that the

government has adopted so far, would help it avoid blind spots and enable the supply of quality products to continue uninterrupted.

From the pharma sector, Sudarshan Jain, Secretary General, Indian Pharmaceutical Alliance (IPA) reiterates that quality is fundamental, and this (the proposed Bill) will help to strengthen quality management systems in the country and take our industry to the next level.

Echoing these sentiments, Suresh Pattathil, President, OPPI comments, "…we find confidence in the thoughtful integration of provisions of the acclaimed New Drugs and Clinical Trials Rules, 2019 (NDCT), Medical Devices Rules 2017 (MDR) and the Cosmetics Rules, 2020. All these framed rules stand as a testament to the power of collaboration, arising from extensive consultations between CDSCO and diverse stakeholders. In nurturing this progressive legacy, the government's inclusive approach fosters a horizon of transparency and foresight. By removing blind spots, we pave the way for an uninterrupted flow of quality products, enriching the lives of those we serve. Together, we aim to uphold the highest standards of safety, efficacy, and accessibility, empowering healthcare for all.

In contrast, sources from the pharma MSME segment allege that while the stated purpose is quality and to replace the archaic Drugs and Cosmetics Act 1940, the real purpose of the proposed Bill is to 'strangulate 8000-10000 small units and facilitate Big Pharma'. They allege that the proposed Bill is an attempt to unconstitutionally divest state drug regulators of powers, and aver that such changes cannot be made as long as medicines are on the concurrent List.

If this sounds familiar, that's because it is. MSME players in any sector are bound to play the underdog card. Secondly, the centre-state power equation works well in theory, as a system of checks and balances. But practice has been anything but perfect. As drugs/medicines are on the concurrent list of the Constitution, the centre legislates and states implement the regulated manufacture and sale of medicines.

Supporting their argument, pharma MSMEs experts single out the relevant sections in the new Bill like Section 41(5) of the proposed Bill which creates a Central Licensing Approving Authority, meaning that no unit can be licensed without its approval. Section 41 (6) of the proposed Bill empowers the Central Government to assume control of manufacture and sale of medicines by issuing a Notification. Similarly, Section 68(2) enables the Central Government to cancel any license.

They point out that this is the third attempt to centralise (pharma regulation), alluding to previous attempts in 2007 and 2013, which were stymied when the Parliament Standing Committees rejected the Bills. The 79th Report of the Standing Committee on Health and Family Welfare also reprimanded the Central

Government for misleading the Parliament. Given past censure, these sources note that the new bill is not being sent to the Standing Committee this time.

It's easy to understand why pharma MSMEs are on the backfoot. Starting with cases in Gambia, the past year has thrown up multiple instances of MSME pharma exporters cutting corners on GMP, resulting in tragic deaths due to medicines containing non-pharma grade solvents. State drug authorities gave these companies a clean chit, even though some were multiple offenders.

Conceding that these incidents could be the trigger for this latest attempt to centralise pharma regulatory powers, pharma MSMEs claim bad policies force them to cut corners. They argue that the Central Government should own up responsibility as 'the manufacturer alone is not the culprit'.

Blaming policies like tax holidays to hill states, followed by increasing excise burden to 30 per cent by levy of MRP excise, pharma MSMEs say they had to cut corners on quality to survive, 'resulting in Gambia and Uzbekistan.'

They also allege that no more than 10 per cent MSMEs can comply with the inspection format and more stringent GMP norms which came into effect post 2005.

Pointing out that while India currently is fortunate to have a grid of skilled workers and technology to qualify as the Pharmacy of the World, they warn that if pharma MSMEs are closed down, the capacity to produce affordable drugs will be lost forever. In addition, the country loses employment to crores who make and sell drugs as part of the pharma MSME sector.

Referring to multiple instances when FIRs have been registered against officials in CDSCO, sources in pharma MSMEs wonder how the proposed Bill seeks to make the same body and officials more powerful. Their contention is that while state inspectors are answerable to multiple tiers of state government which are accessible, CDSCO inspectors are not subject to such oversight, which raises their corruption levels.

Ironically, while India's medicines watchdog the CDSCO is facing flak here, its US counterpart is in the same boat. A recent letter from the US House Energy and Commerce Committee to the FDA Commissioner, expressed concern regarding the effectiveness of the FDA's foreign drug inspection programme, stating 'we are worried that the United States is overly reliant on sourcing from foreign manufacturers with a demonstrated pattern of repeatedly violating FDA safety regulations.'

It is true that medical expenses push more Indian citizens below the poverty line each year, and pharma MSMEs create competition which keeps prices more affordable. However, maintaining quality standards is equally important.

While the blame game between centre and state regulators, as well as large and MSME pharma companies continues, let’s hope that legislators get a fair chance to debate the proposed bill and if not satisfied, ask for changes or defer it pending further discussion.