

Missed targets in Pharma Sector

What is NPPA's mandate?

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- At present, the National Pharmaceutical Pricing Authority (NPPA) monitors drugs that are part of **National List of Essential Medicines (NLEM)** and identifies players that overcharge. Issues on overcharging and price cap have been areas of tension between the pharmaceutical industry and the NPPA.

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- Not agreeing with various drug price orders, the players have appealed to the Department of Pharmaceuticals for several cases in the past.

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- Further, the NPPA has been issuing show-cause notices to drug manufacturers for not registering with the **Integrated Pharmaceutical Database Management System**, where the companies would declare their products to the drug price regulator.

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- NPPA's mandate is to fix or revise the prices of controlled bulk drugs, formulations and to enforce prices and availability of the medicines in the country.

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- It has been entrusted with fixation of prices of scheduled drugs under the **Drug (Price Control) Order, 1995 (DPCO) 1995 and DPCO 2013.**

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- The National Pharmaceutical Pricing Authority (NPPA)'s mandate will no longer be limited to fixing the prices of drugs mentioned in the National List of Essential Medicines (NLEM), according to the recommendations of an expert committee on restructuring NPPA.

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- NPPA is waiting for the Department of Pharmaceuticals to amend the DPCO 2013 and give it direction to fix prices of those drugs for which the regulator doesn't possess details like in the case of stents.

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Whether the DPCO, 2013 is amended?

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- There is no sign of an amendment to the Drug Price Control Order (DPCO), even as the National Pharmaceutical Pricing Authority (NPPA) struggles to fix prices of drugs in the absence of market data.

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- On the 29 August 2016, the Minister for Chemicals and Fertilisers, under which the Department of Pharmaceuticals falls, had mentioned that DPCO 2013 would be amended to facilitate fixing prices of drugs.

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- However the NPPA, which has been entrusted with the task, is **not equipped with adequate data to do so.**

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- While the NPPA can exercise emergency powers under DPCO 2013, it has refrained from doing so until now.

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What is the need to amend?

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- There are around 140 formulations in the list of essential medicines for which the NPPA does not have market data.

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- In a recent letter to the pharma industry, it had asked retailers of these drugs to furnish their prices, stating that the companies have not been providing the requisite data despite several requests.

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- The letter also states, "Failing to get the market data, the NPPA will have no option but to proceed for price fixation of these formulations exercising extraordinary options under the DPCO 2013."

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- This isn't the only target the department hasn't met.

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What else have been missed?

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- The Jan Aushadhi Scheme was initiated by the UPA government and then revamped by the NDA government.

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- **The purpose of the scheme was to make generics available at affordable prices.**

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- The government is also planning to make medical devices available at these stores.

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- The flagship programme Jan Aushadi Scheme is nowhere near reaching its target.

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- The government had planned to get 3,000 stores up and run by the end of March 2017. It has been successful in opening 600-plus stores on the ground.

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- However, the Centre has been signing memoranda of understanding with various state governments and is also trying to involve NGOs to make the scheme a success.

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- Meanwhile, the government's attempt to give domestic manufacturing a push through clusters has not succeeded so far.

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- The Department of Pharmaceuticals had recently, for the fourth time, invited companies to set up clusters in various parts of the country.

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- Till now, only one cluster is fully operational. Also pending are mandatory rules for marketing by pharma and medical devices companies.

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- The department of pharmaceuticals has been consulting the industry for the same. At the moment, these rules continue to be voluntary.

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