2. Non-Scheduled Drugs- Polity

'Need policy to make non-scheduled drugs affordable'- House panel.

A Parliamentary Standing Committee has flagged excessive profiteering (with margins up to 1800%) in non-scheduled drugs due to regulatory gaps, urging the urgent implementation of a statutory Trade Margin Rationalisation (TMR) policy. The report emphasizes that without real-time data transparency and price caps on trade margins, basic healthcare remains unaffordable for many.

Context- The Parliamentary Report

The Warning- A report by the Parliamentary Standing Committee on Chemicals and Fertilisers has flagged serious concerns regarding the pricing of medicines in India.

Core Issue- The lack of regulation on non-scheduled drugs is facilitating excessive profiteering, thereby harming ordinary citizens.

Urgency- The committee has urged the Department of Pharmaceuticals (DoP) and the National Pharmaceutical Pricing Authority (NPPA) to frame a new policy urgently to curb these practices.

Understanding the Drug Categories

To understand the issue, it is essential to differentiate between Scheduled and Non-Scheduled drugs.

Feature	Scheduled Drugs	Non-Scheduled Drugs
Definition	Drugs listed in the National List of Essential Medicines (NLEM).	Drugs not listed in the NLEM or under specific schedules of the Drugs and Cosmetics Act.
Price Control	Strictly regulated. The government fixes the ceiling price.	Not subject to direct price control. Manufacturers set the price.
NPPA Approval	Required for pricing.	Not required to take price approvals from NPPA.
Monitoring	Prices are fixed/revised by NPPA.	NPPA monitors prices and can intervene if price hikes are abnormal (though initial pricing is free).

Key Findings of the Committee

The report highlighted several gaps in the current mechanism-

Excessive Markups (Profiteering)- The committee discovered massive disparities between the Price to Stockist (PTS) and the Maximum Retail Price (MRP).

Scale- Margins were found to be as high as 600%, 1200%, and even 1800% in some cases.

Impact- This renders basic treatments unaffordable for a large section of the population.

Lack of Pricing Transparency- There is a "black box" in the supply chain. Neither the Government nor the NPPA has access to essential data like the Price to Stockist (PTS). Without this data, there is no full visibility of the profit margins being enjoyed by intermediaries.

Limited Scope of Regulation- Current price regulation is largely limited to the NLEM (Scheduled Drugs).Since non-scheduled medicines are not regulated at the initial pricing stage, companies are free to set disproportionately high MRPs from the start.

Delayed Reform (TMR)- Trade Margin Rationalisation (TMR) had previously shown success in reducing cancer drug prices during a pilot phase. However, despite prolonged discussions, this has not yet been formalised into a permanent policy.

Concept- Trade Margin Rationalisation (TMR)

Definition- TMR is a policy aimed at capping and regulating the difference (margin) between the selling price of a drug (to the stockist/distributor) and its MRP (price to consumer).

Objective- To prevent excessive mark-ups across the supply chain (distributors, wholesalers, retailers) and ensure affordability without necessarily fixing the manufacturer's selling price.

Key Recommendations by the Committee

Universal TMR Policy- The government should draft a TMR policy for all non-scheduled drugs, moving beyond just emergency medicines.

Statutory Mechanism- Make TMR a statutory and permanent mechanism rather than an ad-hoc

measure, ensuring long-term prevention of unjustified inflation.

Real-Time Data Collection- Establish a robust mechanism to collect real-time pricing data from all stakeholders (manufacturers, distributors, hospitals) to fix the transparency gap.

Oversight of Online Sales- Implement strict oversight on online pharmacies selling cancer drugs or offering steep discounts to ensure drug authenticity and fair pricing.

Review of Medical Devices- The NPPA and DOP must specifically examine the pricing trends of high-cost devices like stents and intervene to ensure affordability.

Institutional & Regulatory Framework

A breakdown of the bodies involved in drug regulation in India-

Pricing & Policy Bodies

Body	Mandate & Function
Department of Pharmaceuticals (DOP)	Functions under the Ministry of Chemicals and Fertilizers. It oversees the overall pharmaceutical policy and pricing regime.
National Pharmaceutical Pricing Authority (NPPA)	An independent authority under the DOP. Responsible for implementing the Drugs (Prices Control) Order (DPCO). It fixes/revises prices of scheduled drugs and monitors non-scheduled drugs.
NITI Aayog	Plays an advisory role. Through its *Standing Committee on Affordable Medicines and Health Products (SCAMHP)*, it advises NPPA but does not directly participate in price fixation.

Quality & Safety Bodies

Body	Mandate & Function
Central Drugs Standard Control Organisation (CDSCO)	India's National Drug Regulatory Authority (under Ministry of Health). It regulates safety, efficacy, and quality of drugs, vaccines, and devices (unlike NPPA which handles *price*).
Drugs Controller General of India (DCGI)	The Chief Regulatory Officer within CDSCO. Responsible for approving new drugs/devices, authorising clinical trials, and issuing manufacturing licences for specific categories.

Key Acts & Orders

Essential Commodities Act, 1955- The parent act under which the government issues orders to regulate essential items.

Drug (Prices Control) Order (DPCO), 2013- Issued under the Essential Commodities Act. It uses the National List of Essential Medicines (NLEM) as the basis for fixing ceiling prices.

National Pharmaceutical Pricing Policy (NPPP), 2012- The policy framework aiming to guarantee the availability of essential medicines at reasonable prices.

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