

## **Drugs (Prices Control) Amendment Order, 2019**

### **Why in news?**

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The Ministry of Chemicals and Fertilizers has recently released the Drugs (Prices Control) Amendment Order, 2019.

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### **What is it for?**

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- Drug price control is all about striking the right balance between consumer and producer interests.

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- The DPCO (Drugs Prices Control Order) fixes the prices of scheduled drug formulations.

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- It also monitors maximum retail prices of all drugs, including the non-scheduled formulations.

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### **What are the key provisions in the recent order?**

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- A drugmaker who has brought in an innovative patented drug will be exempt from the price control regulations for 5 years from the date of marketing.

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- The Drug Price Control Order (DPCO), 2013, has been amended to this effect.

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- The amendments were made on the basis of the NITI Aayog's recommendations to the Department of Pharmaceuticals (DoP).

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- Drugs for treating rare or "orphan" diseases too will be exempt from price control, with a view to encouraging their production.

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- Under the amended DPCO, the Centre will continue fixing prices in line with market-based data available on drugs.
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- The source of market-based data shall be the data available with the pharmaceutical market data specialising company as decided by the government.
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- If the government deems it necessary, it may validate such data by appropriate survey or evaluation.
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- [Alternatively, cost-based pricing model takes into account the actual money that went into developing the drug, sourcing the raw material and so on].
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### **What are the concerns?**

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- The changes are aimed at lifting foreign investor sentiment, particularly of US companies.
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- But not bringing orphan drugs into price control will significantly impact patients.
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- Only MNCs are manufacturing orphan drugs at the moment; so lack of price control will have a detrimental effect on affordability.
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- Also, cancer drugs are increasingly patented with no generic competition, putting them out of the reach of poor patients.
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### **What should be done?**

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- Medicines account for over half the costs of inpatient care and 80% in the case of out-patient care.
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- So, there must be a way of ensuring that their prices remain accessible without producers feeling disincentivised in the process.
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- The Competition Commission of India's recent report identifies retailers' margins as a major cause of high prices.  
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- This can best be addressed by investing in wholesale public procurement, as Tamil Nadu and Rajasthan have shown.  
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- A combination of State-led insurance, such as Arogyashree in Andhra Pradesh, and public procurement can help keep health costs down.  
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- All these essentially require increasing the budget allocation for the health sector.  
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**Source: Financial Express, BusinessLine**

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