Syllabus subtopic: Statutory, Regulatory and various Quasi-judicial Bodies.

Prelims and Mains focus: about the decision; about drug prices control order; about NPPA and its functions

News: The National Pharmaceutical Pricing Authority (NPPA) has decided to exempt a new stent made by Meril Life Sciences from price control, several months after a patient activist group raised safety concerns about the product.

Background

- The decision comes nearly three years after the drug pricing regulator had capped the prices of these products “in public interest”.

- NPPA, in 2017, had slashed the ceiling prices of stents by up to 85 per cent.

About the decision

- The authority deliberated upon the matter “at length” and observed that establishing significant therapeutic advantage and increased efficacy “is not a pre-requisite for obtaining exemption under para 32(ii) of DPCO 2013.”

- Para 32 of the Drugs (Prices Control) Order, 2013 lists out certain conditions a product has to meet to stay out of the provisions of the regulation.

- This includes new drugs developed through indigenous research and development that are patented under the Indian Patent Act, 1970 and not produced elsewhere as well as new drugs produced in the country by a new process developed indigenously and patented.

Drug Price Control Orders

- The NPPA regularly publishes lists of medicines and their maximum ceiling prices. The latest DPCO was released in 2013 which has a list of 384 drugs.
On 4 December 2017, it was announced that a Multi-disciplinary committee of experts for consultation on matters pertaining to implementation of Drug Price Control Order (DPCO) including technicalities involved in pricing and new launches will be setup and it will have the member secretary of the National Pharmaceutical Pricing authority (NPPA) as its convener.

About NPPA

- The National Pharmaceutical Pricing Authority (NPPA) is a government regulatory agency that controls the prices of pharmaceutical drugs in India.

- NPPA was constituted vide Government of India Resolution dated 29th August, 1997 as an attached office of the Department of Pharmaceuticals (DoP), Ministry of Chemicals & Fertilizers as an independent Regulator for pricing of drugs and to ensure availability and accessibility of medicines at affordable prices.

Functions

1. To implement and enforce the provisions of the Drugs (Prices Control) Order in accordance with the powers delegated to it.

2. To deal with all legal matters arising out of the decisions of the Authority.

3. To monitor the availability of drugs, identify shortages, if any, and to take remedial steps.

4. To collect/ maintain data on production, exports and imports, market share of individual companies, profitability of companies etc, for bulk drugs and formulations.

5. To undertake and/ or sponsor relevant studies in respect of pricing of
drugs/ pharmaceuticals.

6. To **recruit/appoint the officers and other staff members** of the Authority, as per rules and procedures laid down by the Government.

7. To **render advice to the Central Government** on changes/ revisions in the drug policy.

8. To render assistance to the Central Government in the parliamentary matters relating to the drug pricing