

Umbrella scheme to boost production of bulk drugs and medical devices

March 31, 2020

Source: *PIB & Economic Times*

Background:

The Indian pharmaceutical industry is the 3rd largest in the world by volume. However, despite this achievement, India is significantly dependent on the import of basic raw materials, viz., Bulk Drugs that are used to produce medicines. In some specific bulk drugs the **import dependence is 80 to 100%.**

Continuous supply of drugs is necessary to ensure the delivery of affordable healthcare to the citizens. Any disruption in supplies can have significant adverse impact on Drug Security, which is also linked to the overall economy of the country. Self-sufficiency in manufacturing of bulk drugs is highly required.

Schemes

Promoting Bulk Drug Parks Scheme:

- The scheme intends to boost domestic manufacturing of critical KSMs/Drug Intermediates and APIs by attracting large investments in the sector to ensure their sustainable domestic supply and thereby reduce India's import dependence on other countries for critical KSMs/Drug Intermediates and APIs.
- It will lead to expected incremental sales of Rs. 46,400 crore and significant additional employment generation over 8 years.
- The scheme is expected to reduce manufacturing cost of

bulk drugs in the country and dependency on other countries for bulk drugs.

- **Decision is to develop 3 mega Bulk Drug parks in India in partnership with States.**
- Government of India will give Grants-in-Aid to States with a maximum limit of Rs. 1000 Crore per Bulk Drug Park.
- Parks will have common facilities such as solvent recovery plant, distillation plant, power & steam units, common effluent treatment plant etc.
- **Implementation:** The scheme will be implemented by State Implementing Agencies (SIA) to be set up by the respective State Governments and the target is to set up 3 mega Bulk Drug Parks.

Production Linked Incentive Scheme:

- The scheme intends **to boost domestic manufacturing of critical KSMs/Drug Intermediates and APIs by attracting large investments in the sector** to ensure their sustainable domestic supply and thereby reduce India's import dependence on other countries for critical KSMs/Drug Intermediates and APIs.
- Financial incentive will be given to eligible manufacturers of identified 53 critical bulk drugs on their incremental sales over the base year (2019-20) for a period of 6 years.
- Out of 53 identified bulk drugs, 26 are fermentation-based bulk drugs and 27 are chemical synthesis based bulk drugs.
- Rate of incentive will be 20 % (of incremental sales value) for fermentation based bulk drugs and 10% for chemical synthesis based bulk drugs.
- **Implementation:** The scheme will be implemented through a Project Management Agency (PMA) to be nominated by the Department of Pharmaceuticals. The Scheme will be applicable only for the manufacturing of 53 identified

critical bulk drugs (KSMs/Drug Intermediates and APIs).

Promoting domestic manufacturing of medical devices

- The scheme focuses on promoting domestic manufacturing of medical devices. It proposes grant-in-aid to state governments for establishing four medical device parks, at a cost of Rs 100 crore each.
- The parks will have common facilities like testing centre, electro-magnetic interference laboratory, medical grade low vacuum moduling, sterilisation and electricity testing centre.

Helping Manufacturers of medicinal devices

- This scheme is to help manufacturers of medical devices.
- A production linked incentive scheme has been formulated to provide incentive at 5% for six years to manufacturers of medical devices of four categories – cancer care/radiotherapy, aesthetic and cardiorespiratory, radiology and nuclear medicine – and all implants like cochlear and pacemakers.
- During these years, Rs 3,420 crore will be distributed as incentives to the manufacturers under the scheme.