Syllabus subtopic:

- Government Policies and Interventions for Development in various sectors and Issues arising out of their Design and Implementation

Prelims and Mains focus: about the move and its significance; about Coronavirus outbreak and its impact on India-China trade; about CDSCO

News: The government is planning to revive old drug manufacturing units that produced key ingredients for crucial medicines in the past, but are now being imported from China.

Background

- The move is significant in the backdrop of the novel coronavirus (COVID-19) outbreak in China, and disruption of global supply chains.
- China contributes to almost 70 per cent of India’s imports of key ingredients for medicines.

About the move

- In response to the novel coronavirus outbreak, the Department of Pharmaceuticals constituted a committee under the chairmanship of Central Drugs Standard Control Organisation (CDSCO) Joint Drug Controller to assess and “closely monitor” the situation.
- The committee has identified 58 active pharmaceutical ingredients (APIs), intermediates and key starting materials (KSMs) where India needs to build self-reliance. Considering the long gestation period to start a new plant, the government is considering whether upgrading older facilities with newer technology would help expedite the process.
- Over the last three decades, most of the 7-8 manufacturing plants producing
as many as 20 ingredients such as penicillin G, erythromycin, rifamycin, tetracycline, citric acid and vitamin B12, were shut down due to “cheaper alternatives from China”. The possibility of upgrading and restarting these plants is under consideration of the Department of Pharmaceuticals.

- The idea is looking to wean away the Indian pharmaceutical industry from its heavy dependence on Chinese imports and strengthen its self-reliance. While India had the capability to manufacture most key ingredients, there was no domestic manufacturer currently for fermentation-based ingredients. Fermentation-based ingredients are used in most antibiotics and vitamins.

**Why is government’s support necessary?**

- Unless the pharmaceutical industry is incentivised at least for a few years the way China incentivised its own pharmaceutical industry, there is little chance of private investment in this sector.

- Three decades back, China wasn’t even in the picture in API production. But then, with full government support, they scaled up and sold to India at 20-25 percent less than domestic companies producing bulk drugs. Even with import duties, their products were cheaper, so Indian formulators began picking them over Indian manufacturers.

- China was able to build its cost-effective active pharmaceutical ingredients (API) capabilities due to various incentives like cheap land and electricity. India may have to consider similar incentives to ensure domestic manufacturers build scale and compete with lower Chinese prices.

- Niti Aayog, in a meeting on India’s dependence on imports of “critical” APIs, with the government had given some suggestions on environmental concerns and financial incentives like subsidies, which will be examined by the government.

About CDSCO:
The Central Drugs Standard Control Organisation (CDSCO) under Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India is the National Regulatory Authority (NRA) of India.

**Functions:** Under the Drugs and Cosmetics Act, CDSCO is responsible for approval of New Drugs, Conduct of Clinical Trials, laying down the standards for Drugs, control over the quality of imported Drugs in the country and coordination of the activities of State Drug Control Organizations by providing expert advice with a view to bring about the uniformity in the enforcement of the Drugs and Cosmetics Act.

CDSCO along with state regulators, is jointly responsible for grant of licenses of certain specialized categories of critical Drugs such as blood and blood products, I. V. Fluids, Vaccine and Sera.