1. Not in Good Health

Context:

- The recent Covid-19 Outbreak has exposed the medical industry's fault-lines by bringing India's heavy reliance on imports to the forefront.

Brief Background:

- The medical device industry grown at a CAGR of 15% over the past few years
- As per industry estimates, the Indian medical devices market will grow to a $50 billion industry by 2025, contributing approximately 4-5% to the Indian healthcare industry
- The Indian medical devices market has been dominated by imported products, which comprise around 70% of the total sales
- In this backdrop that the government has decided to give a push to domestic manufacturing of medical devices to reduce India's dependence on imports
- Medical devices in India have hitherto been largely unregulated. The act and rules are only applicable to such devices which have been specifically notified by the government.
- Until April this year, only thirty seven devices were notified by the government while the medical devices market consists of an estimated five thousand devices.

All Medical Devices to be treated as 'Drugs':

- Recent development has been the extension of the applicability of the Medical Devices Rules, 2017 to all medical devices.
- The government has achieved this by bringing all medical devices and software under the ambit of the principal legislation, the 'Drugs and Cosmetics Act, 1940' with effect from April 1.
- Apart from expanding the scope of regulation to ensure safety and efficacy, the move may pave the way for regulation of prices under the Drugs Price Control Order (DPCO).
- It will also make companies, in case of violations, liable to be penalised in a court of law.
- Companies will now have to seek approval from the drug controller to manufacture, import and sell any medical device in the country.
- Medical devices shall be registered with the Central Licensing Authority through an identified online portal established by the Central Drugs Standard Control Organisation (CDSCO).
- Such registration is voluntary for a period of 18 months, after which it will be mandatory.

- The manufacturer of a medical device shall upload the information relating to that medical device for registration on the "Online System for Medical Devices" established by the CDSCO. Importers too will be required to do the same.
- Simultaneous with the government's decision to regulate all medical devices under the act, the NPPA has also stated that all medical devices would be governed under the Drugs (Prices Control) Order, 2013, with effect from April.
- As a result, any increase in prices of medical devices, including software, can now only be to the extent of 10% of the prevailing rate in any year.
- This order is in addition to the NPPA's powers to provide a cap or ceiling on the prices of medical devices.

Industry's Concerns:

- Currently, the manufacturing, import and distribution of medical devices falls under the regulatory supervision of the CDSCO, India's apex drug regulator.
- However, the policy inaction on following the Niti Aayog's recommendations of introducing a new act for the regulation of medical devices separate from that of pharmaceutical/ drugs industry shows ignorance of industry's demands.
- Besides, NPPA's capping of rates has only resulted in a paucity of innovation, with both domestic and foreign stent manufacturers choosing not to introduce the latest devices in the Indian market.

Conclusion:

- India is already a leader in generic drug manufacturing, and Indian pharma companies have made their presence felt across the globe.
- With rising threats of protectionism, internal initiatives to control healthcare cost and trade barriers signalled by western countries, it is crucial for India to take right steps to ensure that it remains an attractive destination for global majors.