The Maiden Pharma Episode

Why in news?

The Republic of The Gambia reported deaths of 69 children after the consumption of Indian-made cough syrups.

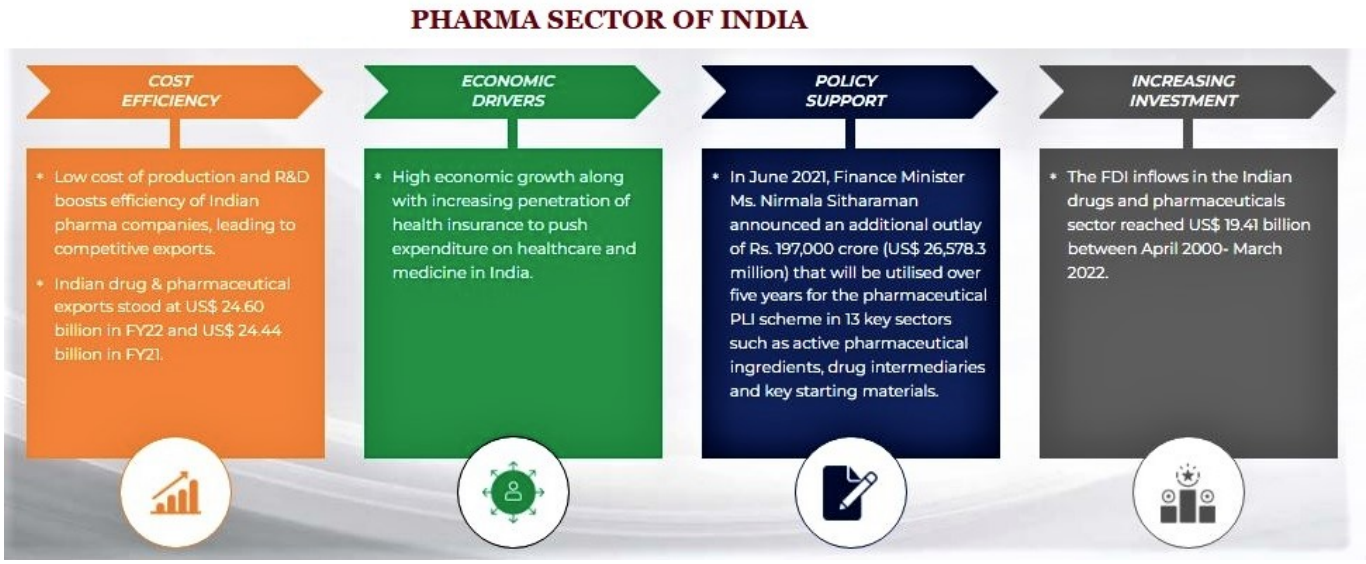
What is the issue?

- The World Health Organization (WHO) issued a global alert over four cough and cold syrups that could be linked to the death of 69 children in the small West African country.
- All the four drugs were produced by an Indian drug maker, Maiden Pharmaceuticals Ltd.
- The syrups have been potentially linked with **Acute Kidney Injury (AKI)**, a sudden decrease in kidney function to complete kidney failure that develops within 7 days.
- The WHO tested the samples to discover unacceptable amounts of diethylene glycol and ethylene glycol, which damage the kidney and liver.
- The products of the firm have been identified by States such as Gujarat, Kerala and Bihar as sub-standard, while Vietnam too has banned its products in 2014.

What about the response?

- **Gambia**- The Gambian President Adama Barrow had ordered the suspension of the license of the suspected pharmacy and importer of the cough syrups.
- He had ordered his foreign minister to take up the matter with the Indian ambassador.
- **Drug maker**- Maiden Pharmaceuticals Ltd. cited that samples were taken by the Central Drugs Standard Control Organization for testing.
- The company cited that it had valid approvals for the export of the products.
- It also said that it had obtained raw materials from certified and reputed companies.
- **India**- The Health Ministry has argued that the connection between the contaminants and the unfortunate deaths in Gambia is yet to be established.
- The current Drugs and Cosmetics Act has provisions for up to 3 years of imprisonment, while the draft bill has increased this upto 10 years.

What lessons should India learn from Maiden Pharma episode?



- For a country that has chosen to position itself as the **pharma factory of the world**, this episode will turn the global spotlight on its regulatory practices.
- **Recall-** India should recall Maiden's products from other markets and the contamination should be traced back to solvent suppliers of propylene glycol.
- **Better regulation-** The regulation all-round needs to be better.
- **Detailed explanation**- The producer needs to spell out every detail of the process.
- **Role of drug inspection authorities**- The drugs inspection authorities should do a follow up on whether the processes are observed.
- The drugs inspection authorities are short staffed which needs to be addressed.
- **Export certification**- At present, exporters are issued an 'import-export code' on the basis of a manufacturing licence.
- It will be good to have separate export certification norms for least developed countries (LDCs), which have weak regulatory systems.
- **Pre-shipment checking**- They must be encouraged to deploy pre-shipment checking systems, as Nigeria has done.

References

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Quick facts

Ethylene Glycol and Diethylene Glycol

- Diethylene glycol and Ethylene glycol are sweet-tasting, colourless, odourless liquids

used in the commercial preparation of antifreeze solutions.
- Ethylene glycol is used in the production of polyester fibres, paints and polyethene terephthalate (PET).
- Diethylene glycol because of its hygroscopic property, is used in brake fluid, cigarettes, treatment of paper and some dyes.
- It is an excellent solvent for many relatively insoluble substances.

Central Drugs Standard Control Organization (CDSCO)

- The CDSCO is the national regulatory body for pharmaceuticals and medical devices in India.
- It works under the **Ministry of Health & Family Welfare**.
- Headquarters- New Delhi
- The Drugs & Cosmetics Act, 1940 and rules 1945 have entrusted various responsibilities to central & state regulators for regulation of drugs & cosmetics.
- Under the Drugs and Cosmetics Act, CDSCO is responsible for
    - Approval of Drugs
    - Conduct of Clinical Trials
    - Laying down the standards for Drugs
    - Control over the quality of imported Drugs in the country
    - Coordination of activities of State Drug Control Organizations by providing expert advice
- Along with state regulators, it 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.
- The **Drug Controller General of India (DCGI)**, which is an organ of the CDSCO, is responsible for approving and licensing of drugs and medical devices.