Uniform Drugs Standards For All State Regulators (UPSC Notes)

The Government of India is currently developing a digital platform with the aim of overhauling the country's drug regulatory system. This is an important topic for the IAS exam.

Govt plans common drugs standards for all state regulators:

- The Ministry of Health is contemplating the creation of uniform regulations for drug regulators across both central and state levels, as well as establishing a centralized database to enhance oversight of the production, sale, and distribution of pharmaceuticals.
- Efforts are underway to promote consistency in the evaluation and approval of drugs by harmonizing regulatory requirements, procedures, and databases across all states.

Existing system:

- In the present system, both central as well as the state governments have roles to play in issuing manufacturing licenses and regulating the drug sector.
- We have a fragmented system, consisting of 38 regulators and each with their own database.

Recent issues:

- There have been many incidents involving the death of some children consuming drugs manufactured by Indian pharmaceutical firms.
- A medical product alert was issued by the World Health Organization (WHO) regarding four cough syrups produced and exported by Maiden Pharma, a company based in Haryana. It is believed that the consumption of these cough syrups may have caused the deaths of at least 70 children in The Gambia.

Need for a new system:-

- India currently lacks a consolidated public database that records the transgressions of each company licensed under the Drugs And Cosmetics Act.
- While India has 38 drug regulators, only three states - Gujarat, Maharashtra, and Kerala - make their laboratory results available in a consolidated database.
- Currently, if a drug company violates regulations in one state, the information may not be shared with other regional or federal regulatory bodies, such as the Central Drugs Standard Control Organization (CDSCO).

- In the light of recent issues (mentioned above) emerged, it is necessary to ensure that all manufacturing taking place within the country, regardless of whether it is being carried out by MSMEs or larger drug manufacturers based in India, conforms to Good Manufacturing Practices (GMP).

Proposed System

- Recently, the Ministry of Health and family welfare, organized a two-day "Chintan Shivir", with a focus on improving drug quality, regulation, and enforcement. The session helped to identify concerns of the pharma industry and other stakeholders and prepare a roadmap for a more efficient regulatory system.
- India is working on a single window portal, which will serve as a unifying hub for all key players involved in the process, including regulators, manufacturers, distributors, state-run entities, and procurement agencies.
- The integration of various stakeholders such as Central Drug Laboratories, state drug controllers, manufacturers, and others will be achieved through the integration of the Sugam portal (existing IT portal of the Central Drugs Standard Control Organisation (CDSCO)) with the new portal.

Benefits:

- It will bring in a common set of standards and regulations for the whole nation.
- It will enable drug regulators throughout India to easily access information about the credentials of pharmaceutical companies and drugs.

Challenges:

- This idea may face challenges due to India's federal structure and the fact that healthcare is a state subject. For the idea to be successful, all stakeholders involved, including both the Central and state governments must willingly cooperate.
- Maintaining a central database could be difficult if states do not provide accurate data in a timely manner. Generating awareness and encouraging active participation from all states will take time and effort.
- However, attempting to implement the idea is worth it as it would improve the regulatory system.