Bring Out The Main Provisions of the Bill Seeking To Override The Existing Drugs & Cosmetics Act 1940. What Can Be Its Significance ? (150 Words / 10 M) (GS-3 Govt Policies)

Approach:

1. Introduction
2. Mention the key features in the draft Bill.
3. Perceived significance.

The Ministry of Health and Family Welfare has released a draft of the proposed Drugs, Medical Devices and Cosmetics Bill, 2022 . The Bill seeks to ***replace*** the existing ***Drugs and Cosmetics Act, 1940***, and several sets of rules which are currently followed by the industry. The new Bill has been drafted to keep pace with the changing needs, times and technology.

Key Provisions:

- The Bill proposes ***new definitions*** for *clinical trials, over-the-counter drugs, manufacturers, medical devices, new drugs, bioavailability studies, investigational new drugs and imported spurious drugs*, among others e.g., diagnostic equipment, their software, implants, devices for assistance with disabilities, life support, instruments used for disinfection, and reagents come under the ambit of medical devices.
- It seeks to introduce ***regulation*** for ***online pharmacies and medical devices***. Though there is no separate chapter on e-pharmacies, the Bill suggests that the Union government should formulate rules to regulate online pharmacies.
- It proposes to empower the ***Drugs Control Officer*** with ***prior approval*** of the controlling authority to ***enter any premises related to clinical trials*** to inspect the facilities, records, data, documents, books and drugs.
- It proposes ***stringent penalties*** such as imprisonment and compensation in case of injury or death during clinical trials for drugs. It lays the onus of providing medical management for any injury arising due to the trial on the investigators.
- A ***Drugs Technical Advisory Board*** (DTAB) and a ***Medical Devices Technical Advisory Board*** (MDTAB) are planned to submit recommendations to the Government from time to time on policy matters.
- The draft proposes to allow the Union government to waive the requirement of conducting clinical investigations for the manufacture or import of a new medical device in public interest.

Significance:

It is a positive move by the Government to update an over 60-year-old law on drugs. India is third-largest pharmaceutical producer in the world. It is important that the regulatory legislation keeps pace with the changing times.

- A separate Medical Devices Technical Advisory Board (MDTAB) will help in catering to the specific and varied needs of the medical device sector vis-a-vis drugs.
- Online pharmacies are currently working completely outside the law. In case of a violation, drug inspectors are unaware of the provisions of the law or Rule under which they can proceed against the websites. Further, drug inspectors often find that the licenses these websites hold are from another state, over which they have no jurisdiction. Sometimes the websites don't have any licenses at all. This makes it even more difficult to take any action.
- Thus their inclusion in the new bill was a much needed step.
- The Bill prohibits clinical trials or clinical investigations of drugs and medical devices without permission from the central licensing authority. While companies have to seek permission from the regulator to conduct trials even now, this is not specifically mentioned in the existing law.

The current clinical trial Rules have fines, but a fine of few lakh rupees is not enough to deter a big pharma company. However, the provisions for imprisonment under the draft Bill might act as a deterrent.