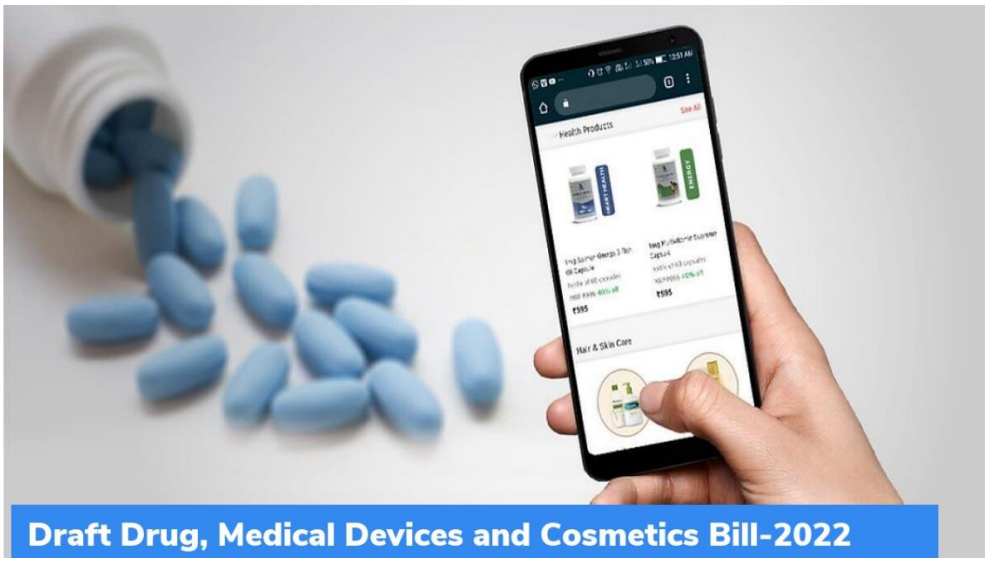
Draft 'Drug, Medical Devices and Cosmetics Bill-2022



Draft "Drug, Medical Devices & Cosmetics Bill-2022" was released recently by Union Health Ministry.

Highlights

- This draft bill 2022 will replace the Drugs and Cosmetics Act, 1940, and other sets of Rules through which industry is currently run.
- It seeks to regulate medical devices as a separate entity, comprises of provision for fines & imprisonment in case of injury and death related to clinical trials or investigations. The bill also aims to regulate e-pharmacies.

What is the need of regulating e-pharmacies?

- In India, e-pharmacies or online-pharmacies are completely outside the law currently. They are not regulated 1940 law or any other Rules. Online websites have got licence for a physical shop or storage unit perhaps. Thus, if there is violation of rule, drug inspectors do not know under which law or Rule proceedings can be done against the websites.
- Thus, a law or change in current rules was needed to regulate online-pharmacies.
- Apart from that, drug inspectors often find that these websites are holding licences from another state, which is outside the jurisdiction of drug inspectors.
- Furthermore, these websites sell medicine even without a prescription. If a person places order, in-house doctors from websites write a prescription. This prescription is uploaded to their database so that they can provide explanation over medicines they dispense, if there is an audit.

Important Provisions of the Draft Bill

1. The draft Bill 2022 provides for compensation to participants or their legal heirs in case of injury or death the patient suffered in clinical trials and investigations of drugs or medical devices. In case compensation is not paid, there is a provision of imprisonment and double fine.
2. It prohibits clinical trials or clinical investigations related to drugs and medical devices, if central licensing authority has not permitted. Though, Companies are required to take permission from the regulator for conducting trials under current rules as well. But this provision is not mentioned in 1940 act.
3. Under the definition of Medical Device, the draft Bill includes diagnostic equipment & related software, devices for assistance with disabilities, implants, instruments used for disinfection, life support, and reagents or kits. On the other hand, 1940 Act categorises "medical devices" as one among the four categories of "drugs".