Drugs, Medical Devices and Cosmetics Bill, 2022

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In news-The Union Health Ministry has recently released the draft 'Drug, Medical Devices, and Cosmetics Bill-2022' that seeks for the first time to regulate e-pharmacies.

Key features of the bill-

- **The health ministry plans to replace the Drugs and Cosmetics Act of 1940** with an updated law laying down strict regulatory guidelines to keep pace with changing needs and technology.
- Given the need to have comprehensive legislation, a committee was constituted for framing the drugs, medical devices and cosmetics bill, 2022.
- **The bill proposes new definitions for clinical trial, over-the-counter drugs**, manufacturers, medical devices, new drugs, bioavailability study, investigational new drug and imported spurious drugs, among others.
- **It seeks to bring in regulation for online pharmacies and medical devices** and penalties such as imprisonment and compensation in case of injury or death during clinical trials for drugs.
- The draft proposes that **no clinical trial can be carried out without permission,** medical management and compensation for injury or death, the draft proposes.
- It says that **no person shall himself or by any other person on his behalf sell, or stock or exhibit or offer for sale or distribute any drug by online mode** (e-pharmacy) **except under and in accordance with a licence or permission** issued in such manner as may be prescribed.
- The government has **proposed empowering the Drugs Control Officer** with prior approval of the controlling authority

to enter into any premises related to clinical trial to inspect the facilities, record, data, documents, books and drugs.

- The Centre has proposed **a separate Drugs Technical Advisory Board (DTAB) and Medical Devices Technical Advisory Board (MDTAB)** to give suggestions to the government from time to time.
- **MDTAB will not only include medical professionals, but also people with technical knowledge** of the devices.
- Other than officials from the Health ministry, the board will also **include people from the department of atomic energy, department of science and technology, ministry of Electronics, DRDO,** and experts in the field of biomedical technology, biomaterials, and polymer technology.
- The draft **proposes to allow the Centre to waive the requirement of conducting clinical investigation** for manufacture or import of **a new medical device in public interest.**
- It proposes **medical device testing centres** on the lines of drug laboratories in states and at the central level.
- It states **medical management and compensation** has to be provided to persons who are injured while participating in such trials. And, in case of death, the legal heir of the participant should be awarded the compensation.
- The Bill also touches upon the **contentious issue of e-pharmacies**, which drug store owners say are hard to regulate.
- It specifically states that the C**entral government must come up with rules to regulate online sale of drugs and for online pharmacies to operate** "in accordance with a licence or permission issued".
- **The Bill aslo includes a chapter on Ayurveda, Siddha, Sowa-Rigpa, Unani** and **Homeopathy**, and their respective Drug Technical Advisory Boards.