The New Drugs, Medical Devices and Cosmetics Bill

Why in news?

The Union Health Ministry recently published a new draft Bill to replace the antiquated Drugs and Cosmetics Act, of 1940.

What are the provisions of the draft bill?

- The draft focuses on regulating medical devices as a separate entity, makes provision for fines and imprisonment for injury and death related to clinical trials or investigations, and seeks to regulate e-pharmacies.
- **Online Pharmacies:** No provisions to regulate online pharmacies exist in the 1940 law or any of the Rules.
- Online pharmacies are currently working completely outside the law.
- Most of these websites have perhaps a license for a physical shop or storage unit.
- In case of a violation, drug inspectors do not know under which provision of the law or Rule they can proceed against the websites.
- The draft Bill states: 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 except under and in accordance with a license or permission issued in such manner as may be prescribed.
- It also states that the central government can formulate Rules to regulate aspects of the industry for which the old law has no provisions.
- **Clinical trials and investigations:** The draft Bill makes provisions for compensation to participants or their legal heirs for injury or death suffered in clinical trials and investigations for drugs and medical devices.
- The draft also lays the onus on providing medical management for any injury arising due to the trial of the investigators.
- There is a new provision for imprisonment, and fines amounting to double the compensation amount if the compensation is not paid.
- If the draft Bill becomes law, these provisions will be part of it, and will not be restricted to just clinical trial Rules.

- The draft 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 draft provides for debarring the investigators and sponsors of a trial or investigation if the laid-down provisions are not followed.
- However, the draft bill completely misses is post-marketing surveillance, especially for medical devices, because implants can remain within a patient's body for years.
- There should also be provisions for recalling medicines or devices if any issues are detected.
- The Bill has to be for the protection of the people.
- Medical devices: Under the ambit of medical devices defined by the draft Bill are diagnostic equipment, their software, implants, devices for assistance with disabilities, life support, instruments used for disinfection, and reagents or kits.
- The 1940 Act has medical devices as one of four categories of drugs.
- To make decisions on regulating medical devices, the draft Bill creates a Medical Devices Technical Advisory Board on the lines of the existing drugs technical advisory board, with people who have technical knowledge of the engineering of these devices, and members of the industry.
- Other than officials of the Health Ministry, the board will have officials from
    - the Department of Atomic Energy
    - the Department of Science and Technology
    - the Ministry of Electronics and Information Technology
    - the Defense Research and Development Organization
    - the experts from the fields of biomedical technology, biomaterials, and polymer technology.
- Drawing on the existing law on drugs, the draft Bill defines provisions for imprisonment or fines for "adulterated" or "spurious" medical devices.
- The draft states that a medical device will be considered to be adulterated if it is rusted, corroded, filthy, putrid, decomposed, packed, or stored in unsanitary conditions, and contains harmful or toxic substances, or has any component or software removed making it unsafe.
- The draft Bill deems a medical device to be spurious if it carries the label of a fictitious company or is purported to be of a manufacturer that has not manufactured it.

What is the regulatory theory behind the draft bill?

- The original Act was enacted when the Indian pharmaceutical industry was in its infancy.
- At the time, the guiding theory of this law was based on testing manufactured drugs purchased by drug inspectors from the open market.
- If a drug failed quality testing, the manufacturer could be jailed.
- This was not the most efficient system of regulation because it depended entirely on luck or fate, only if a drug inspector picked a certain drug on a certain day and it failed testing would the manufacturer face legal action.
- Much of the world has shifted to a more rigorous system of regulation centered around the compliance of manufacturing units with good manufacturing practices (GMPs).
- In theory, a drug manufactured in compliance with GMPs is subject to so many checks that it is unlikely that it would fail quality tests once shipped to the market.
- In 1988, India incorporated a system of GMPs via rules framed by the government rather than Parliament.
- But even then, the government did not make GMPs the centerpiece of its regulatory strategy.
- In the U.S., the regulator's focus is on ensuring that manufacturing units comply with GMPs.
- American law presumes that any drug that is manufactured in a facility that fails to comply with GMPs is adulterated.
- Given this focus on GMP compliance, U.S. law mandates the publication of reports of inspections conducted by its drug inspectors.
- Indian law, on the other hand, contains no such criminal penalties for pharmaceutical companies failing to comply with GMPs.
- At the most, licenses may be canceled, but since inspection reports are never published, citizens have no idea if drug inspectors are conducting GMP compliance-related inspections.
- There is ample evidence to suggest that such inspections are not carried out.
- The Bill does nothing to change this system.
- In fact, it does not mention the phrase GMP even once.

What is the federalism question behind the bill?

- The one issue that has come up in every review of the drug regulatory system since 1947 has been the uneven enforcement of the Drugs and Cosmetics Act across India.

- This is because, unlike the U.S. which has a single federal agency tasked with enforcing drug regulation across the country, India has 37 agencies for the same job: one in each State and Union Territory along with the Central Drugs Standard Control Organization (CDSCO), which is under the control of the Union Health Ministry.
- State drug controllers are expected to license drug manufacturing and also conduct enforcement actions such as sampling, testing, and prosecution for substandard drugs.
- The CDSCO's role is limited to regulating imports and to deciding whether new drugs have adequate clinical evidence before they can be sold.
- Over the years, even the CDSCO has started drawing samples for testing and prosecuting erring manufacturers.
- In addition, the Health Ministry is in charge of laying down rules and regulations and banning drugs that do not have to support clinical evidence.
- A problem with this setup is that States such as Himachal Pradesh, which account for a bulk of pharmaceutical manufacturing on account of a tax holiday, do a poor job of enforcing the Drugs and Cosmetics Act.
- This is not just because of poor state capacity; the fear of scaring away investments by the pharmaceutical industry likely plays a key role in the State's decision to not enforce the law.
- Since India is a single market, drugs manufactured in Himachal Pradesh are sold across the country and even States with relatively more competent drug regulators, such as Tamil Nadu, Karnataka, and Gujarat, can do little to stop the flood of these substandard drugs.
- It is only the drug controller in Himachal Pradesh who can cancel manufacturing licenses of facilities located in that State.
- This is the reason that the Mashelkar Committee in 2003 recommended centralizing drug licensing with the central regulator.
- The present Bill is silent on the issue.
- And since the Ministry never released a white paper explaining its position, we don't why this issue was never tackled.

How can the regulations be democratized?

- Drug regulation by its very nature vests vast discretionary powers in unelected bureaucrats to take decisions.
- Approving a new drug or a new manufacturing facility, of which can have huge implications for public health and the profits of the pharmaceutical industry.
- These decisions are often based on scientific data, inspections, reports,

etc.

- In such circumstances, the only safeguard to ensure bureaucratic accountability is transparency.
- As citizens, we should not be required to run after the regulator begging for information under the Right to Information Act, 2005.
- Rather, the law should be written in a way to guarantee proactive disclosure of all crucial documentation related to regulatory decisions.
- If a new drug is being approved, the regulator should be required to disclose all the data, including clinical trial data.
- Every time a drug is tested in a government laboratory, the test report should be published on a publicly accessible database.
- Each inspection for GMP compliance should conclude with an inspection report accessible to the general public.
- This is the only way to ensure accountability and build public confidence in the regulator.
- The new law is silent on this critical issue of transparency because it is structured largely on the basis of the original colonial-era legislation.
- The government must consider rewriting this law in a way that guarantees transparency by design.
- Modern regulation delegates an incredible amount of power to unelected bureaucrats and technocrats.
- From a perspective of efficiency, such delegation is required, but from the perspective of accountability, it leads to a democratic deficit.

What is the way forward?

- While the efforts of the Ministry need to be saluted for recognizing the need for new legislation, there is much to disagree with the new Bill.
- Although the Ministry has described it as being consistent with the government's move to review obsolete pre-Independence legislation, most of it is a copy of the old law.
- There is nothing new in this Bill regarding drug regulation.
- And the Bill does nothing to address burning issues thrown up over the last decade since the Ranbaxy scandal.
- A law needs to be simple, reasonable, and implementable, and must not become a barrier to Make in India or Innovate in India.
- A modern regulatory system should be designed to guarantee citizens a right to participate in decision-making.
- Making information available to citizens is only the first step in this process.
- The next step is to create legal pathways, such as public hearings or

citizen’s petitions which will enable citizens to participate in the regulatory process and register their objections.

Reference

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