Pharma & Healthcare Update

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DRAFT DRUGS, MEDICAL DEVICES AND COSMETICS BILL, 2022: DAWN OF A NEW ERA?

The Ministry of Health and Family Welfare, Government of India has released a draft of the Drugs, Medical Devices and Cosmetics Bill, 2022 ("**Draft Bill**")[1] for public consultation on July 8, 2022. The Draft Bill is intended to be a comprehensive legislation with provisions to regulate drugs, medical devices, cosmetics, clinical trials and online pharmacies, among others. Once enacted, the Draft Bill will replace the Drugs and Cosmetics Act, 1940 ("**D&C Act**") - India's primary drug regulation at the present. Public comments to the Draft Bill are invited until August 22, 2022.

A revamp of the D&C Act has been in the works for a while now. A Committee was constituted by the Central Government for review of the existing laws and framing a new law in order to keep pace with changing needs, times and technology. Considering the recommendations of the said committee, the Draft Bill has been proposed. Basis the public comments on the Draft Bill, the present draft may undergo further changes before being introduced in the Parliament for deliberation. Subsequently, it may be passed as a new law, effectively repealing the D&C Act.

We have discussed some key aspects of the Draft Bill below.

REGULATION OF MEDICAL DEVICES

The Draft Bill seeks to regulate all medical devices independently from drugs. Currently, under the D&C Act only notified medical devices are regulated as 'drugs'. In 2020, a new broad definition for medical devices was notified,[2] effectively bringing all medical devices under the ambit of the Medical Device Rules, 2017 ("**MDR**"). The Draft Bill imports the notified definition and creates a separate definition for 'medical devices'[3]. All medical devices falling within the ambit of this definition will be regulated.

The Draft Bill also significantly broadens the regulations pertaining to quality of medical devices. Specifically, the manufacture and import of medical devices which do not conform to the prescribed standards,[4] or which are misbranded,[5] adulterated[6] and spurious[7] are prohibited.[8]

For obtaining a marketing approval, a clinical investigation[9] is required to be conducted for investigational medical devices (including in-vitro diagnostic medical devices), unless this requirement is waived by the Central Licensing Authority. Unlike the MDR, which distinguishes between medical devices and in-vitro diagnostic devices for the purpose of safety and efficacy studies, the Draft Bill seeks to regulate studies for all classes of medical devices uniformly. Requirements to obtain permission prior to conduct clinical investigation[10] and provide medical management and compensation for study related injury and death[11] is also provided. Specific penalties have been proposed for violation of these provisions.[12]

The Draft Bill also creates a parallel regime for regulation of all medical devices. Unlike the D&C Act where drug authorities regulate medical devices, the Draft Bill proposes the creation of independent authorities and boards to take decisions on regulation of medical devices. The Medical Devices Technical Advisory Board ("**MDTAB**") is proposed to be constituted by people who have technical knowledge of medical devices and members of the industry including- officials from Ministry of Health and Family Welfare, Department of Atomic Energy, Department of Science and Technology, Ministry of Electronics and Information Technology, Defence Research and Development Organisation; experts from the fields of biomedical technology, biomaterials, and polymer technology; experts from the field of medical, surgical or dentistry practices nominated by the Central Government.[13]

For the enforcement of regulations, Medical Devices Officers shall be appointed and vested with powers of inspection, search and seizure.[14] The Draft Bill also proposes the creation of Central and State Medical Devices Testing Centres[15] (at Central and state levels) for testing and evaluation of medical devices. The functions of these centres are likely to be similar to the Central Medical Devices Testing Laboratory and authorized Medical Device Testing Laboratories under the MDR.

REGULATION OF DRUGS

The provisions for the regulation of drugs under the Draft Bill does not substantially deviate from the existing regime. However, the penalties for violation under Draft Bill are enhanced in comparison to the current regime. The new penalties range between imprisonment for a period of one to ten years; and fines up to fifteen lakhs.

Notably, the Draft Bill establishes the procedure for improvement notices.[16] The licensing authorities may issue an improvement notice specifying measures for compliance or directing remedy of an existing contravention. It enables

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the licensee to rectify any violations as opposed to the licensing authority directly instituting proceedings for violation of license conditions.

REGULATION OF AYUSH PRODUCTS

Under the Draft Bill AYUSH includes- Ayurveda, Siddha, Sowa-Rigpa, Unani and Homeopathy. Additionally, traditional medicine (indigenous systems of medicines legally recognized in the countries of their origin other than Allopathy or western medicine) will also be regulated as AYUSH products in India.[17] The Draft Bill contains provisions to regulate AYUSH drugs, medical devices and cosmetics. This is unlike the D&C Act, which does not specifically recognize AYUSH medical devices and cosmetics as an independent class of products for the purpose of regulation. While there are no new compliance measures laid down for AYUSH medical devices and drugs under the present draft of the Draft Bill, subsequent rules and guidelines may elaborate upon these aspects.

Like the D&C Act, authorities for governing AYUSH products are distinct from drug authorities and the AYUSH Technical Advisory Board will continue to remain in force.[18] In addition to the existing authorities, the Draft Bill introduces new boards to act in advisory capacities constituted by members with domain knowledge- the Drugs, Medical Devices and Cosmetics Consultative Committee for AYUSH Drugs[19]; Scientific Research Board and the plant boards (at national and state level)[20]. The creation of these boards is aligned with the recent approach of the Government to promote the AYUSH industry.

CLINICAL TRIALS

Some key aspects of clinical trials under the New Drug and Clinical Trial Rules, 2019 ("**CT Rules**") have been imported into the Draft Bill. This is substantial since provisions requiring sponsors to obtain mandatory permission prior to conduct of clinical trial[21] and provide medical management and compensation for trial related injury and death[22] will fall within the parent legislation. Further, specific penalties have been proposed for violation of these provisions.[23]

However, one of the prime areas of concern with respect to clinical trials is that the Draft Bill fails to clarify whether academic trials and biomedical research is exempted from its ambit. Presently, the CT Rules specifically excludes these studies from compliance.[24]

ONLINE PHARMACIES

Although, sale of medicine over the internet is rampant in India, at the present, there are no direct rules for selling medicines online. It may be recalled that the government had published draft E-pharmacy Rules in 2018[25], however these were not enacted.

The Draft Bill intends to remedy this gap in regulation by mandating license requirements for sale of drugs and medical devices through online mode.[26] Although there are no compliances contained in the Draft Bill for online pharmacies, the Central Government may formulate rules to regulate aspects of this industry.[27]

REGULATORY BODIES

For the purpose of enforcement, the authorities governing drugs, medical devices and AYUSH products are independent. While this is laudable, there is no prohibition on the Central/state governments from notifying the existing drug inspectors to perform functions in respect of medical devices and AYUSH products. This impairs the intent behind the Draft Bill to regulate these classes independently taking into account the nuances of each industry.

Separately, the Draft Bill also introduces a new body for drugs and medical devices- the Drugs, Medical Devices and Cosmetics Consultative Committee[28] ("**DMDCCC**") headed by the Drugs Controller General of India to advise the Central and state governments, DTAB and MDTAB on matters tending to secure uniformity in the country in the administration of drugs/medical devices.

OFFENCES AND PENALTIES

All offences under the D&C Act have been retained, however, higher penalties are proposed. Additionally, the Draft Bill also prescribes specific penalties for conduct of clinical trial/clinical investigation without permission[29], failure to provide compensation,[30] failure to pay financial penalty imposed by adjudicating officer[31] and for furnishing misleading information.[32]

Interestingly, the Draft Bill enables police officers to assist the authorized officer appointed under the Draft Bill for the purpose of investigation into violations.[33] While its appreciated that police may now assist the authorized officers for investigation into offences, in some instances, the powers of investigation may be extended to arrest persons. There are no controls prescribed under the Draft Bill for exercise of excessive powers.

CONTINUANCE OF CURRENT REGULATIONS

The Draft Bill contains transitory provisions[34] enabling the continuance of rules, regulations and notifications introduced under the D&C Act. Hence, the rules issued under the D&C Act - the Drugs and Cosmetics Rules, 1945, MDR, CT Rules and the Cosmetics Rules, 2020 may continue to supplement the Draft Bill, unless new rules are introduced in succession.

The Draft Bill also preserves the operation of the D&C Act to the limited extent of:

- Any right, privilege, obligation or liability acquired, accrued or incurred under the D&C Act;
- Any penalty, forfeiture or punishment incurred in respect of any offences committed against the enactment and orders under the D&C Act;
- Any investigation or remedy in respect of any such penalty, forfeiture or punishment, and any such investigation,

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legal proceedings or remedy may be instituted, continued or enforced and any such penalty, forfeiture or punishment may be imposed as per the D&C Act;

- Licenses issued under the D&C Act will continue to be in force till the date of their as if they had been issued under the provisions of Draft Bill;
- Cognizance of the offence under the D&C Act may be taken by Courts for up to three years from the date of commencement of the Draft Bill.

DRAFT BILL: HITS AND MISSES

The revamp of D&C Act is a welcome move and has been long overdue. The distinction between regulation of allopathic drugs and cosmetics, AYUSH products and medical devices clears the obscurity and ambiguity faced by the industry under the current regime.

The Draft Bill primarily focuses on regulating medical devices as a separate category. It also recognizes the role of independent governing authorities with technical knowledge of medical devices. To this extent, the Draft Bill is ideal for the industry. On the other hand, the MDR may have to be updated to be aligned with the Draft Bill. The medical device industry has been on the brink of achieving stability in regulation since the revamp in 2020.[35] The passage of the Draft Bill, without appropriate transitory provisions providing clarity on alignment with the MDR may create uncertainty.

It was anticipated by the industry that that the Draft Bill may provide clarity on regulation of software as a medical device, refurbished medical devices and compensation for medical devices. However, the Draft Bill remains silent on these aspects.

The inclusion of clinical trials and clinical investigations within the Draft Bill is beneficial and legitimizes the provisions contained in the CT Rules and MDR. However, there is no clarity on whether Academic studies conducted for the purposes other than seeking a marketing approval is exempted from the regulation. Furthermore, the Draft Bill does not touch upon post-marketing surveillance and recall of drugs/devices.

WAY FORWARD

The Draft Bill is a stepping-stone towards revamping the current approach to regulation of drugs and cosmetics in India. Although it is intended to overhaul the D&C Act, most of it is a replication of the current law. Despite the reiteration of the old law, the additions, omissions and intent behind the Draft Bill is anticipated to boost quality, consumer confidence and expectations of the stakeholders. We hope this Draft Bill brings in the dawn of a new era in regulation of the pharmaceutical and medical device industry in India.

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You can direct your queries or comments to the author

[1] Draft of the Drugs, Medical Devices and Cosmetics Bill, 2022, available at:

https://main.mohfw.gov.in/newshighlights-97 (last accessed on August 17, 2022).

[2] Under the current regime, the scope of D&C Act is restricted to only those medical devices which are notified by the Government from time to time as "drugs." On February 11, 2020, a broad definition of medical devices was notified, effectively bringing all medical devices in India within the ambit of D&C Act. The Central Drugs and Standards Control Organisation has issued a series of classification notices from July 2021 to notify specific medical devices and assign risk classification. The Medical Device Rules, 2017 supplement the D&C Act, and elaborate on the safety and quality standards, and prescribes the licensing regime for medical devices in India.

[3] Clause 3(zd) of the Draft Bill defines 'medical device' as "*(a) all devices including an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may assist in its intended function by such means for one or more of the specific purposes of- (i) diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder; (ii) diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability; (iii) investigation, replacement or modification or support of the anatomy or of a physiological process; (iv) supporting or sustaining life; (v) disinfection of medical devices; (vi) control of conception; (b) in-vitro diagnostic device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination thereof intended to be used for examination and providing information for medical or diagnostic purposes by means of examination of specimens derived from the human bodies or animals.*"

[4] Clause 126, Draft Bill.

[5] Clause 127, Draft Bill.

[6] Clause 128, Draft Bill.

[7] Clause 129, Draft Bill.

[8] Previously, the definitions and provision applicable to misbranded, adulterated and spurious drugs was applicable to medical devices as well by virtue of medical devices being drugs for the purpose of regulation. The Draft Bill provisions specific conditions with respect to medical devices.

[9] Clause 139, Draft Bill.

[10] Clause 139, Draft Bill.

[11] Clause 142, Draft Bill.

[12] Clauses 144, 145 and 146, Draft Bill.

[13] Clause 6, Draft Bill.

[14] Clause 134, Draft Bill.

[15] Clauses 10 and 91, Draft Bill.

[16] Clause 67, Draft Bill.

[17] Clause 86(x), Draft Bill.

[18] Clause 87, Draft Bill.

[19] Clause 88, Draft Bill.

[20] Clause 89, Draft Bill.

[21] Clause 72, Draft Bill.

[22] Clause 73, Draft Bill.

[23] Clauses 79,80 and 81, Draft Bill.

[24] Academic trials and biomedical research are not governed under the CT Rules and instead have to comply with the Guidelines for Biomedical and Health Research involving Human Participants, 2017 issued by the Indian Council for Medical Research.

[25] The draft amendment to the Drugs and Cosmetic Rules, 1945 published by Ministry of Health and Family Welfare on August 28, 2018.

[26] Clauses 41, 102 and 140, Draft Bill.

[27] Clauses 83 and 159, Draft Bill.

[28] Clause 11, Draft Bill.

[29] Clauses 79 and 144, Draft Bill.

[30] Clauses 81 and 146, Draft Bill.

[31] Clause 156, Draft Bill.

[32] Clause 169, Draft Bill.

[33] Clauses 50 and 135, Draft Bill.

[34] Clause 184 and 185, Draft Bill.

[35] On February 11, 2020, the Ministry of Health and Family Welfare published two notifications. The cumulative effect of these two notifications is that all medical devices were brought under the fold of quality and safety regulation from April 1, 2020. Available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTU0OA== ;

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