Medical Devices (including software used for disease prevention) to be regulated as Drugs

20 April 2020

This update covers:

1 Background

For over a decade, software technologies have been bringing innovative changes and advancements in the healthcare sector, be it in monitoring, diagnosis, prevention or treatment of diseases or drug manufacturing. On 11 February 2020, the Ministry of Health and Family Welfare issued a notification (**Notification**) to broaden the scope of medical devices that are to be regulated under the Drugs and Cosmetics Act, 1940 (**DCA**) and Medical Devices Rules, 2017 (**MDR**). Under this Notification, any medical device, including software, will be regulated as a 'drug' under the DCA, effective from 1 April 2020, if they are used for any of the following:

The Government has broadened the scope of medical devices which are regulated as a 'drug' under the Drugs and Cosmetics Act, 1940. Notably, any software or app used for prevention or monitoring diseases has been classified as a medical device and consequently will be regulated as a 'drug'.

a. diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;

b. diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability;

c. investigation, replacement or modification or support of the anatomy or of a physiological process;

d. supporting or sustaining life;

e. disinfection of medical devices; and

f. control of conception.

Previously, under the DCA, the definition of a 'drug' included devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals as notified from time to time by the Central Government. MDR accordingly defined 'medical device' to mean:

a. substances such as those used for in vitro diagnosis and surgical dressings, surgical bandages, surgical staples, surgical sutures, ligatures, blood and blood component collection bag with or without anticoagulant;

b. substances including mechanical contraceptives (condoms, intrauterine devices, tubal rings), disinfectants and insecticides etc.; and

c. devices notified from time to time under DCA.

The Government of India has notified and regulated only 37 categories of medical devices so far.

Therefore, prior to this Notification, 'software' was not included in the definition of medical device either under the MDR or DCA (except in a limited context of clinical investigation and in relation to in-vitro devices). With this inclusion, any software or app, that is part of or used in conjunction with a device, that is capable of or assists in the investigation of a physiological process or in the diagnosis, prevention or monitoring of any disease or disorder would be treated as a medical device and consequently would be regulated as a 'drug' under DCA.

If a medical device is regulated as a drug under the DCA, it needs to be registered in accordance with the provisions of DCA for it to be imported, manufactured, sold or distributed in India. Such registrations are done by drug regulatory agency- Central Drug Standards Control Organisation, after appropriate quality checks. Further, an entity that imports, manufactures, sells and distributes these regulated medical devices in India must obtain a license to do so.

2 Amendment of MDR - Exemption to New Devices

Along with this Notification, the Ministry amended the MDR on 11 February 2020. It introduced a new chapter for registration of medical devices which fall under the new definition provided in the Notification. This registration allows new medical devices to be exempted from the provisions of MDR, including the requirement of getting a license. Manufacturers, importers or sellers of any medical devices that fall under this new definition are required to register their medical devices with the Drugs Controller General of India. This registration is on a voluntary basis for a period of 18 months from the effective date of the Notification. After 1 October 2021, all medical devices that fall under this definition will need to be compulsorily registered. In order to get a registration, a manufacturer will need to provide certificate of ISO compliance for Medical Devices category.

The amendment also exempts the already regulated 37 categories of medical devices from the requirement of registration under this new chapter. However, this registration-based exemption from licensing requirement is also time bound. Medical devices classified as low risk and low-moderate risk as per the provisions of DCA and MDR will cease to have this exemption after a period of 30 months from the date of issuance of this amendment notification, i.e. 11 August 2022 and those classified as moderate-high risk and high risk devices will cease to have this exemption after a period of 42 months, i.e. 11 August 2023.

3 Conclusion

It appears that the intention behind broadening the definition is to further hold medical device companies accountable for the quality and safety of their product given the sophisticated functions that these devices are able to perform. This is largely in line with international norms and practices with respect to the regulation of medical devices. In fact, this definition is in accordance with what has been recommended by the Global

Harmonisation Task Force (GHTF) framework of the World Health Organisation. However, the GHTF also suggested that certain medical products may not fit comfortably within the definition of medical devices and placed a responsibility on authorities to clarify the nature of regulatory requirements applying to such products. Unlike United States Food and Drug Administration that puts in a clear mechanism of determination on whether a product may be classified as a medical device, at this stage there is not much clarity on the scope of the definition under this Notification.

Given the broad nature of the definition, the functioning of digital health products and wearables with their new and advanced features would need to be closely assessed to determine whether they would fall within the definition of a medical device and consequently be regulated as a drug. Further, given the extensive regulatory requirements associated with this classification, it remains to be seen whether this move will impact innovation and the entry of such products in the Indian market.