

Medical Device Regulation in India



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Introduction

India is a nation that constitutes approximately 17% of the World's population. People from around the world flock to India for surgeries and advanced treatment as the facilities are top-notch yet affordable. Prior to 2005, India did not have a regulatory policy for Medical Devices, while Drugs and Cosmetics were brought under the ambit of Regulation. In 2017, the Indian government issued a set of guidelines for the Regulation of Medical Devices. This guideline will be taking effect in 2018. This paper aims to explain the regulatory process in India and offer a perspective on the same.

Overview of the regulatory framework in India

The Medical Devices are to be classified into four classes namely A, B, C and D. Class A devices are typically low risk devices and the risk factor involves increases progressively. Class D, refers to High risk devices. This classification applies to all medical devices excepting in-vitro diagnostic aids which are classified separately [1].

- a) CLASS A: Class A typically represents low risk medical devices which do not have a direct bearing on the wellness of the patient. These devices do not Require Regulatory Approval in India. The manufacturer is required to follow Good Manufacturing Processes in Accordance with set standards. Some of the examples of Class A devices include dishes to store fluids, thermometer etc. The primary requirement for classification as a type a device is that the device should only come in contact with the skin or other tissues such as the ear and should not be absorbed by the mucous membrane.
- b) CLASS B: Medical devices that present a low to medium risk are grouped under Class B. This includes devices used for disinfection and sterilization as well as devices that provide energy for other implantable devices in the body. Implants and other invasive devices that are intended for short term use are grouped under class B.
- c) CLASS C: Medium to High risk devices are grouped under Class C. Devices that are used to treat skin injuries that have breached the dermis are classified under class C. Devices

intended for the exchange or modification of blood composition (Such as Dialysis) are classified under Class C.

- d) CLASS D: High Risk Devices come under the Classification of Class D. This includes devices that are used in treating circulatory and nervous disorders and are in contact with sensitive tissues such as the heart, spine and brain.

Perspective on the New Regulatory Policy

The new regulatory policy has paved a way for an expedited regulatory process in India. Prior to the new policy, Medical Device Manufacturers either obtained Regulatory Approval from other nations such as USA, Australia, Japan etc. or did not obtain Regulatory Approval at all. This trend is set to change with the implementation of the new regulatory policy. In order to obtain licenses for devices manufactured abroad, the Central Drugs Standard Control Organization (CDSCO) has provided for a provision in which Regulatory Approval from Nations such as USA may be used to accelerate the Regulation Process in India and aid in the dealer or distributor obtaining an import license instead of a manufacturing license for the same. Additionally, the CDSCO has also allowed for exemption in the case of Custom Devices which are not intended for Mass Production. Such devices may be manufactured under the instructions of a doctor and may be used in scenarios where there is either insufficient time to obtain regulatory approval or in cases where the population affected by the said condition is so small that it would not be necessary to mass produce the device. The CDSCO has also exempted Class A devices and mechanical contraceptives such as condoms and other low risk devices which possess exceptionally low risk. Class A and B devices, manufactured by companies manufacturing Class C and D devices, need to obtain approval for the Class C and D devices, when the Class A and B devices are to be used in conjunction with the class C and D devices. This will aid in manufacturing the device with all its constituents.

The Grey Area

In several nations Stem Cells and other biologically derived materials are classified as 'Biologics'. However, in India, such a classification does not exist yet. As a result, such biologically

derived materials are classified as drugs [3].As the Regulatory System in India is still in its nascent stages, only high-risk devices are now being subject to regulation. It is speculated that the ambit of the CDSCO will extend to cover other medical devices. The regulatory process may make healthcare more expensive as the costs associated with regulatory paperwork will be passed on to the patient.

Conclusion

By implementing a pathway for Regulation, the world's second most populous country has paved way for improved quality in healthcare. Setting up a framework aids Local Device Manufacturing

Units in obtaining Regulatory approval within the country itself. This in turn is expected to lower the cost of medical treatment while improving the quality as indigenous companies will have a chance to obtain regulatory approval within the nation.The quality of the medical devices is set to improve as Devices will need to match up to standards in order to obtain the green signal from CDSCO.

References

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