ConnectIN Health

MDR in India: Rules Demystified

Dr Surbhi Gupta,
Non-Executive Director, ConnectIN Health Ltd

Investigation

Medical Device regulatory rules in India

In January 2017, India's Ministry of Health and Family Welfare released the long-awaited Medical Device Rules of 2017 (MDR 2017 or the Act), which took effect on Jan. 1, 2018. Upon implementation, this regulation replaced the existing Drugs and Cosmetics Act (DCA)
Before this Act, the medical device industry in India was largely unregulated, except for a few devices covered specifically by the DCA. The list of covered devices was limited (only 15 medical devices were included), and the DCA treated these devices as drugs.
The implementation of MDR 2017 attempts to establish a uniform regime for Indian medical device manufacturing and marketing. The structure of this regulatory paradigm appears to be on par with international standards, including the EU's Medical Device Regulation, although the extent of these similarities will depend upon India's implementation of the Act.

Central Government and State Government bodies are responsible for implementation and enforcement of MDR 2017. Medical device approvals are now conducted by the Drugs Controller General of India (DCGI) who are also responsible for overseeing clinical trials, import licenses, and device classifications.

Under these new rules, clinical investigation framework has been added.

- The licensing agency has 90 days from the time it receives an application to conduct a clinical investigation to either approve or grant permission to conduct the study.
- No approval is required for academic clinical studies on licensed medical devices where the Ethics Committee approves such a study and the data generated during the study is not used for a marketing application.
- The rule has conditions that must be met once a clinical study protocol has been approved.
- The clinical investigation must be initiated within a period of one year from the date of approval.
- The clinical investigation must be registered with the Clinical Trial Registry of India before enrolling the first participant.
- Annual status reports must be submitted to the licensing authority, including notification of termination of the study, and the reporting of suspected or unexpected serious adverse events occurring during the clinical investigation within 14 days of knowledge of its occurrence.

investigation

Clinical investigation framework

The Medical Device Rules have added a new regulatory framework for clinical investigations.The government requires that clinical investigations in humans be approved prior to initiation. Further, permission must be obtained to import or manufacture investigational medical devices to conduct clinical investigations.

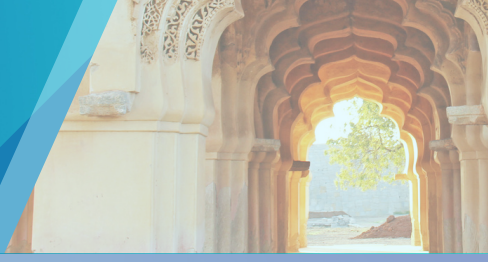
For “**Regulated Devices**” (listed in Annexe) a test license for import into India for clinical investigation is required under the MDR Rules.
For "**Unregulated Devices**", currently no license is required for import into India for clinical investigation.

However, given some lack of clarity in the regulations on Unregulated Devices, further recommendations from Central Drugs Standard Control Organization suggests that even though no specific license is required under the MDR Rules, the regulator requires Unregulated Devices to obtain a no-objection certificate ("NOC") from the regulator for their import into India for conducting clinical investigations.

The import (including for the purposes of clinical investigations) of medical devices into India is governed by the MDR Rules. The MDR Rules regulate only those devices that have been specifically notified by the Government (as listed in the Annexe).

With effect from 1 April 2020, the Government has notified all medical devices which are covered in the following definition as medical devices to be regulated under the MDR Rules:

"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; and
(vi) control of conception."

Amendment to MDR rules

Also, with effect from 1 April 2020, the Government has amended the MDR Rules ("Amendment") to provide that all medical devices (except those listed in the Annexe) will be exempted (for a period of 30 to 42 months) from the provisions of the MDR Rules (i.e. will be Unregulated Devices) if they register under Chapter IIIA of the MDR Rules. No such exemption is available for the Regulated Devices.

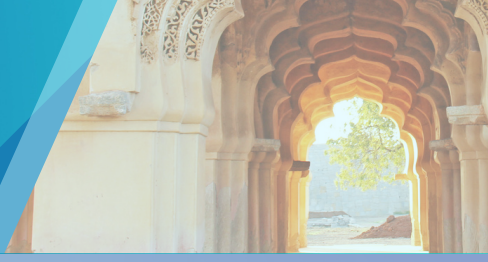
The Amendment also states that the registration under Chapter IIIA of the MDR Rules is voluntary for a period of 18 months (from 1 April 2020) and thereafter it will be mandatory.
For Unregulated Devices, the restrictions and detailed provisions of MDR Rules relating to clinical investigation will not apply.

Ethics Guidelines

As per the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, any medical practitioner undertaking clinical investigations in India is required to comply with the Ethical Guidelines for Biomedical Research on Human Subjects issued by Indian Council of Medical Research, Good Clinical Practice Guidelines issued by Central Drugs Standard Control Organization and the Declaration of Helsinki (collectively, "Ethics Guidelines").

The Ethics Guidelines provide general requirements for undertaking clinical investigations in India. These, amongst others, include requirement of approval of clinical investigation plan by the Ethics Committee, registration of clinical trials with the Clinical Trial Registry of India, informed consents to be obtained from the participants/ patients and requirement for maintenance of the privacy of the participants/ patients.

Study in India



First time pilot study in India

For Regulated Devices, the restrictions and detailed provisions of MDR Rules relating to clinical investigation apply. In the first instance, the clinical investigation will require a prior approval from the authority. However, for medical devices developed and studied in a country other than India, the data from the pilot clinical investigation or relevant clinical study is required to be submitted along with the application for conducting clinical investigations in India. The permission may be granted for a repeat pilot study or to conduct pivotal clinical investigation only. In other words, a first time pilot study only in India may not be allowed. However, an application could be made as a part of multi-national clinical development of medical device in which case the details of the number of sites and the patients as well as justification to conduct such clinical investigation in India will have to be provided.

Other key requirements under the MDR Rules for clinical investigations include:

- approval of clinical investigation plan by the registered Ethics Committee;
- registration with the Clinical Trial Registry of India;
- the premises of the sponsor including its employees, subsidiaries and branches, its agents, contractors and sub-contractors and clinical investigation sites should be open for inspection by officers of the authority;
- compliance with Ethics Guidelines.

Clinical trials

Conditions for conducting clinical trials in India

- DCGI Aproval
- Ethics committee Approval
- Clinical trial registration
- Import license to import the medical device from Manufacturer
- Compliance to Protocol & Good Clinical Practices
- SAE reporting – within 14 days
- Maintain Data Integrity

Annexe

S. No.	Name of the device
1.	Disposable Hypodermic Syringes
2.	Disposable Hypodermic Needles
3.	Disposable Perfusion Sets
4.	Substances used for in vitro diagnosis including Blood Grouping Sera
5.	Cardiac Stents
6.	Drug Eluting Stents
7.	Catheters
8.	Intra Ocular Lenses
9.	ICannulae
10.	Bone Cements
11.	Heart Valves
12.	Scalp Vein Set
13.	Orthopedic Implants
14.	Internal Prosthetic Replacements
15.	Ablation Devices
16.	Ligatures, Sutures and Staplers
17.	Intra Uterine Devices (Cu-T)
18.	Condoms
19.	Tubal Rings
20.	Surgical Dressings
21.	Umbilical Tapes
22.	Blood / Blood Component Bags
23.	Organ Preservative Solution
24.	Nebulizer (effective from 1 January 2021)
25.	Blood Pressure Monitoring Device (effective from 1 January 2021)
26.	Glucometer (effective from 1 January 2021)
27.	Digital Thermometer (effective from 1 January 2021)
28.	All Implantable Medical Devices Equipment (effective from 1 January 2021)
29.	CT Scan Equipment (effective from 1 April 2021)
30.	MRI Equipment (effective from 1 April, 2021)
31.	Defibrillators (effective from 1 April 2021)
32.	PET Equipment (effective from 1 April 2021)
33.	X - Ray Machine (effective from 1 April 2021)
34.	Dialysis Machine (effective from 1 April 2021)
35.	Bone Marrow Cell Separator (effective from 1 April 2021)
36.	Disinfectants and Insecticide (specified in Medical Devices Rules, 2017)
37.	Ultrasound Equipment (effective from 1 November 2021)