India's New Medical Device Rules: Impact and Outlook for Medical Device Industry

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A. Medical Device Rules, 2017

- New Medical Device Rules, 2017 have been published by Government of India via Gazette Notification GSR 78(E) on 31st January 2017.

- These rules shall, unless specified otherwise, come into force with effect from 1st day of January, 2018.

- These rules shall be applicable to:

    - substances 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;
    - substances including mechanical contraceptives (condoms, intrauterine devices, tubal rings), disinfectants and insecticides
    - devices notified from time to time by Government of India

B. Critical Comments on the Medical Device Rules, 2017

S. No.	Section & sub-section	Issue as per rule	Interpretation	Immediate solution for industry
1.	Chapter VI - Labelling of Medical Devices - Shelf life of the medical devices - 47	The shelf life of the medical devices, shall ordinarily not exceed sixty months from the date of manufacture	The manufacturer/ importer of the devices having shelf life greater than sixty months would require to produce supporting documents subject to CDSCO's satisfaction.	Discussion with regulator may help on what document they expect when shelf life is more than 60 months
2.	Fourth Schedule – Documents required for grant of manufacturing or import license - Part III - Appendix II - 7.0 (7.8)	if real-time data is not available, accelerated stability data shall be submitted to support the claimed shelf life. Such a provisional claimed shelf life may be approved provided that the manufacturer immediately initiates real-time stability testing to validate the proposed shelf life. After completion of the real time stability analysis, real-time stability data shall be submitted in support of the claimed shelf life.	The manufacturers would additionally require to conduct the real time stability studies for new devices and submit it later if not there at the time of registration. Till that time the registration certificate will be provisional.	The manufacturers should conduct real time stability studies for the devices to be introduced in India and submit the data to CDSCO as soon as studies are completed.

B. Critical Comments on the Medical Device Rules, 2017

S. No.	Section & sub-section	Issue as per rule	Interpretation	Immediate solution for industry
3.	Chapter II - Regulation of Medical Device – Product standards for medical device – 7 (1)	The medical device shall conform to the standards laid down by the Bureau of Indian Standards …… or as may be notified by the Ministry of Health and Family Welfare, Government of India from time to time… In absence of BIS standards International standards will be OK	This would cause duplication of work and additional time for the companies who already have some international standards in case they need to additionally obtain BIS certification	Participated in BIS work group meeting and advised to harmonize with global standards. BIS officials agreed
4.	Chapter IV – Manufacture of Medical Devices for Sale or for Distribution – Conditions for manufacturing licence or loan licence – 26 (v)	The license holder shall carry out test of each batch of product manufactured prior to its release for compliance with specifications either in his own laboratory or in any other laboratory and shall maintain records of such tests for a period of one year after expiry date of the medical device	Whenever a new batch is produced in the manufacturing facility, complete testing should be performed on each batch before release. This would involve huge cost and time.	Need to negotiate with regulators for brief testing not all tests

B. Critical Comments on the Medical Device Rules, 2017

S. No.	Section & sub-section	Issue as per rule	Interpretation	Immediate solution for industry
5.	Chapter IV – Manufacture of Medical Devices for Sale or for Distribution – Manufacturing of medical devices for clinical investigation, etc. – 31 (1 and 2)	R&D to be removed from Manufacturing of medical devices in small quantities for sale or for distribution for clinical investigation	In case Test License is required for import of small quantity of devices for Research and development purpose still there is a risk that confidential information of the innovators can be circulated and it might limit the R&D to be done in India.	Apply for Test License for the devices and the site should not be opened for inspection and a confidentiality clause should be introduced in the test license granted by CDSCO.
6.	Chapter XI - Sale of Medical Devices – Recall of medical device - 89 (1)	Recall of Medical devices: If a manufacturer or authorized agent, as the case may be, considers or has reasons to believe that a medical device which has been imported, manufactured, sold or distributed is not in compliance with the Act, or these rules, he shall immediately initiate procedures to withdraw the medical device in question from the market …	Recall of complete medical device is never required but only of affected batch/es is	Till the time clause is amended understanding needs to be build with regulators

B. Critical Comments on the Medical Device Rules, 2017

S. No.	Section & sub-section	Issue as per rule	Interpretation	Immediate solution for industry
7.	Chapter VI - Labelling of Medical Devices - Labelling of medical devices – 44 (e)	The label shall bear the month of manufacture and date of expiry; alternatively the label shall bear the shelf life of the product.	Manufacturers/importers would have to specify additional details of shelf life/expiry date on the labels.	Manufacturers/importers to initiate the plan for revision of labels to include the details requested by CDSCO
8.	Chapter VI - Labelling of Medical Devices - Labelling of medical devices – 44 (p)	Clause regarding stickering of India specific labels with relevant details where such details not already printed	Ideally the clause needs to mention " where such details not there already before import". Present clause may cause confusion regarding affixing India specific labels on the products imported in India. It is not specified that whether the additional labels can be stickered on the imported devices or not.	Manufacturers/importers can seek approval for their organization as a whole from CDSCO to sticker India specific labels in their respective premises or bonded warehouse.

C. All challenges with degree of criticality

Text Colour	Criticality
Red	High
Royal Blue	Medium
Brown	Low

- There should be a separate definition of Medical Devices under the D&C Act, 1940 and they should not be defined as Drugs.
- Grandfathering clause not included but need to be incorporated when devices are notified as regulated. Already existing devices in India which have proof of usability on or before 31 December 2017 should be.
- The definition of Notified medical devices should include the below text, “Provided that the Medical Device is already being marketed in India, clinical investigations or evaluations should not be a pre-requisite for grant of registration of such medical devices. Till the time orders are not passed to the applicant in terms of rejection or approval the medical device shall be continued for sale and marketing in public interest”.

C. All challenges with degree of criticality

- "Investigational Medical Device" – is not a globally accepted terminology nor definied. This definition is currently mapping the definition of new drugs under Rule 122 (e). In case the definition has to be mapped with the Indian scenario, we recommend the word "New Design" instead of " Major Design Change". The major design change should be part of post approval change management process, provision and requirement therein.

- Clinical Investigations are required for Registration of products not approved in US, UK, Canada, Australia & Japan countries or marketed for less than 2 years and also those without predicate device in India. EU should be included in the list of countries. This requirement will lead to Delay in launch of new devices / technologies.

- There is no clarity in respect to renewal application which will be made under existing Rules after June 1, 2017.

- In case of Devices, approved & marketed in the countries listed, clinical evidence maybe accepted with an undertaking to conduct Post market clinical investigation (PMS) in India.

C. All challenges with degree of criticality

- Requirement of Accelerated and **Real time aging studies** to affect registrations especially when the shelf life will be awarded as per the real time data.
- Sixth Schedule has to be more detailed with specific changes and the action to be taken along with timelines for approvals if required.
- There is no clarity in terms of Forms, reporting criteria, reporting method and analysis process in case of Serious Adverse Event Reporting.
- Probability of manufacturing site inspection during registration. No timelines for inspection of external manufacturing sites fixed in case of site inspection during registration.
- Requirement to comply with BIS standards mandatory wherever applicable.
- Premarket product testing can be mandated.
- Implementation of IFU requirement

C. All challenges with degree of criticality

- Five year shelf life cap – Monitor implementation. It has been noted that even in case of evidence of more than 5 years shelf was available the same has not be approved.
- Require more specific & defined timelines for grant of all types of licenses and their affiliated process.
- In the last column “Brand Name-if registered under Trade Mark Act 1999”, the clause “if registered under Trade Mark Act 1999” should be revisited to possibly delete/remove as in general there is no practice of registering the brand name of the product with Trademark office locally.
- Any violation of the rules shall lead to product recall.


Thank You