Terror of 10 MB, a cross-sectional study investigates the regulation to the prospective of medical device

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INTRODUCTION

In India, at present, only notified medical devices are regulated as drugs under the Drugs and Cosmetics Act 1940 and Rules made thereunder in 1945. In the first schedule of Rule 2 of MDR 2017 specified that the Class of medical devices shall be published on the Central Drugs Standard Control Organization (CDSCO) website and Central Licensing authority may notify addition, deletion in such list of medical devices from time to time. CDSCO has already displayed the list of medical devices with classification, which is dynamic in nature. As per Medical Device Rules (MDRs)[1] and Regulations, medical devices other than in vitro diagnostic medical devices shall be classified on the basis of parameters specified in Part I of the first Schedule (i) low risk (Class A); (ii) low moderate

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Table 1: Various stakeholders involve in medical device decision-making

| Stakeholders   | Role                                                                 |
|----------------|----------------------------------------------------------------------|
| CDSCO          | Central licensing authority in whole of India                        |
| SLA            | State Licensing Authority in the designated state                    |
| MOHFW          | Ministry of health and family welfare’s in matters related to approval of new drugs including biopharmaceutical products and clinical trials |

CDSCO: Central Drugs Standard Control Organization, SLA: State Licensing Authority, MOHFW: Ministry of Health and Family Welfare

risk (Class B); (iii) moderate high risk (Class C); and (iv) high risk (Class D). The manufacturers of medical devices as specified in the rules will be required to meet risk proportionate regulatory requirements based on the best international practices. The National Accreditation Board for Certification Bodies will assess their competence in terms of required human resources and other requirements as shown in Table 1.

Medical devices are to be granted which belongs to Class A, without audit of site. In these cases, self-certification of manufacturer needs to be submitted for issuing the license. However, conformance with quality management system checked by notified bodies and state licensing authority will issue the license to manufacture of medical devices (Class A and B). Central Licensing Authority is issuing license after inspection and compliance as per quality. Quality Management system along with ISO 13485 for manufacturing of Class C and Class D medical devices. Import and export of all medical devices is regulated by CDSCO.[2]

Approval of clinical investigation of medical devices (i.e., new devices) at par with international practices is governed by CDSCO under the separate provisions of MDR rule 2017.[2] The renewal of license is not required because as per the government notification, perpetual license is being given by CDSCO. These rules are found as a milestone for all stakeholders, i.e., innovators, manufacturers, providers, consumers, buyers, and regulators.[3] The simplicity and transparency create a trustworthy environment between the investors and regulators which will ensure best quality, safety, and efficacy of medical devices.[3]

MATERIALS AND METHODS

It was a cross-sectional questionnaire-based study carried out among various stakeholder including regulators and industry people. Three hundred stakeholders(300) participated in this study. The questionnaire was designed and tested among small groups for doing a pilot study. The modified questionnaire was given to all participants. The questionnaire having 25 important questions/comments was given to participants after explaining the purpose of the study. Any doubts regarding questionnaire were clarified by the investigators. Thirty minutes was given for filling the questionnaire. The response in terms of responders versus nonresponders, agree versus disagree, yes versus no was recorded and analyzed by descriptive statistics using Sigma Plot 14.0 (Systat Software, Inc., San Jose, USA).

Format of questionnaire as given below

As shown in Table 2, questionnaire related to medical device has been put the stakeholders for their responses on this important issue.

RESULTS AND DISCUSSION

The United State Food Drugs Administration was the first regulatory body to publish guidelines on specific regulatory pathway for the approval of Medical Device in the year 1976. These rules were titled as “Medical Devices Rules 2017” and with time have they been updated and improvised according to the requirements. Whereas in India, rules for MDRs 2017 has been published in 2017. The present study demonstrate current understanding of rules, emerging issues, and challenges as well as potential recommendations further enhance the awareness, usage, and diversification of medical devices.

Most of the stakeholders working in the field of medical devices have understanding of its rules and regulations. Approximately 80% of these stakeholders understand MDR 2017 very well. They have proper undertaking about accessibility of these regulations. Interestingly, about 96% stakeholders mentioned that these rules are easily available and can be access using website of CDSCO www.cdsco.gov.nic.in. To further understand their depth in such rules, we have asked them about grouping of medical devices. It was found that 34% of stakeholders were not aware about such grouping of medical devices [Figure 1]. The stakeholders welcomed the initiative of the government to make management representative is responsible for legal representative as per MDR 2017 and indispensable legal action against management representative if the products are found not of standard quality. Surprisingly, only 50% people were aware of this important enforcement [Figure 1]. World is witnessing many updated labeling systems and same is to be implanted in Medical Devices. About 15% people consider that there is a need for inclusion of barcode, identification mark, etc., for medical devices (Class C and Class D). In Medical Devices Rules 2017 classification on the risk based, i.e. Class A, Class B, Class C, and Class D [Figure 2].

As per MDR 2017, *In vitro* diagnostic shall be classified as:

1. Part I and Part II of the First Schedule on identified factors.
   1. Low risk (Class A); (ii) low moderate risk (Class B); (iii) moderate high risk (Class C); (iv) high risk (Class D).
### Table 2: Questions related to new medical device rule - 2017 (Central Drugs Standard Control Organization)

| Questions                                                                 | Option 1 | Option 2 |
|---------------------------------------------------------------------------|----------|----------|
| Are you aware about MDR 2017?                                            | Yes      | No       |
| MDR 2017 standard is easily available                                     | Agree    | Disagree |
| Do you have idea about MD grouping?                                       | Yes      | No       |
| A person or organization who is not aware for ISO 13,485 can understand  | Agree    | Disagree |
| MDR 2017                                                                   |          |          |
| Management representative is required for MDR                            | True     | False    |
| QMS system is integral part of MDR 2017                                  | True     | False    |
| Current MDR labeling is sufficient                                        | Agree    | Disagree |
| Clinical investigation is clearly defined in MDR                         | Yes      | No       |
| MD classification is done on the basis of risk                            | True     | False    |
| Are you satisfied with MDR rule?                                         | Yes      | No       |
| Is MDR is based on schedule M?                                           | Yes      | No       |
| All the MD concern persons are not aware about complete MDR standards   | True     | False    |
| Does MDs have some serious adverse effects?                              | Yes      | No       |
| Price regulations on MDs by NPPA are industry favorable or not?          | Yes      | No       |
| Whether current regulation of MDR supports the industry                 | Yes      | No       |
| Is document submission, process of MDR is handy                          | Yes      | No       |
| 10 mb data space on www.cdscomdonline.gov.in portal is sufficient        | True     | False    |
| Online payment system is little complex for all class MDs. Helpline      | True     | False    |
| support is very poor                                                      |          |          |
| There is no provision to make online payment for Class A and B devices  | True     | False    |
| Provision for online application of FSC, market standing certificate and | True     | False    |
| NOC is not available                                                      |          |          |
| Gamma sterilization facilities are very limited in India on technical    | Agree    | Disagree |
| background considering product and process performance qualification     |          |          |
| Personnel are involved in MDs are well trained and qualified             | Yes      | No       |
| India is good in export of MD                                             | Agree    | Degree   |
| Bridge courses to empower to manpower involved in MDs are utmost         | Yes      | No       |
| necessary                                                                |          |          |
| Government of India included MDs in its popular scheme in Ayushman Bharat| Yes      | No       |

MDs: Medical devices, MDR: MD rule, CDSCO: Central Drugs Standard Control Organization, NOC: No objection certificate, QMS: Quality management system

### Figure 1: Responses of various stake holders on important questions related to Medical Devices and its regulations

Fifty-six percent of the stakeholders are not satisfied with the current MDR 2017 as amended by the Ministry of Health and Family Welfare because industry feels that there is requirement of separate medical devices bill with
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Figure 2: Responses of various stake holders on important questions related to Medical Devices and its regulations

Although government of India has been taking several initiatives to facilitate the single window system for the industry; however, 97% stakeholder feels that the procedures are not very handy [Figure 2]. The limitations of documents size 10MB is critical concern and it is become a Terror of 10MB for the industry [Figure 2]. There is urgent need for making a suitable platform for system to accept the application in its original size without any limitation of space. If such initiatives are being taking care properly the medical devices industry will flourish. Such initiatives and incentives help industry to develop quality products and to export in the various countries and also make in INDIA campaign success as initiatives by Prime Minister of India.

As shown in Table 3, India has also introduced regulations as per majority of countries including the USA, UK, Japan, Singapore, and Canada in 2012. The majority of stakeholders agree with the opinion that entry of medical device is a welcome step from government and same can be considered as a boon for the patients undergoing life-threatening diseases.

There is no doubt that medical device enhance the life span of patients. However, major stakeholders disagree that it can be better option from innovator product.

The study surface the limitation about the qualified personnel involves in medical device. As major people believe that there is lack of expertise in this field. The same can be achieved through government initiatives for bridge courses which is also strongly felt by the major stakeholders participated in the study. Another important concern raised by participated was the affordability and pricing. There is
no proper regulation for the pricing and market access. In addition, medical device is compared with approved product rather than innovator products which affect the quality. However, industry has further limitation of timeline of the product access to the market. Considering the data generation as per need of regulators is uphill task for industry. Industry is also raise the concern for single window approval system of medical device. As government giving export incentives in varied products, industry is advocating similar incentive to support the medical device production and export.[10]

CONCLUSIONS AND RECOMMENDATIONS

Medical devices show immense hope in the field of medicine because of their potential use and low cost than their original biologics. Although there are many countries that have not approved the use of Medical devices also, there are few countries that have issued regulatory guidelines for medical devices hesitate to accept in using them. Their nonacceptance is due to very low knowledge of the medical devices. This issue can be resolved by initiating new schemes that could educate patients and distributors about the efficacy and safety of the medical devices. Different countries have issued different set of guidelines with no common regulation worldwide. Countries should work toward setting a new common set of guidelines for the easy flow of trade. This would allow a uniform harmonization of a medical devices and their easy acceptance in different countries which would further help in fast treatment of a disease and easy availability and accessibility of the medicine to the patients. Government of India should come with a medical device bill for the betterment of the industry and people.

Following needed to be taken consideration for improving perceptions, enhance the perspective usage of medical devices through promulgation and implementation of rules and regulation for all the stakeholders: educate patients, professionals’ about medical devices; make better marketing and pricing policies to ensure benefits to the manufactures and patients; assess patients’ indifferent geographical locations through patent studies.

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Conflicts of interest
There are no conflicts of interest.

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