

Major Changes to the Regulatory Framework of Medical Devices Effective January 1, 2018

August 2017

Major Changes to the Regulatory Framework of Medical Devices Effective January 1, 2018

August 2017

Nishith Desai Associates
LEGAL AND TAX COUNSELING WORLDWIDE

MUMBAI SILICON VALLEY BANGALORE SINGAPORE MUMBAI BKC NEW DELHI MUNICH NEW YORK

ndaconnect@nishithdesai.com

Contents

1. MEDICAL DEVICE RULES 2017 – AN ANALYSIS	01
I. Definition of Medical Devices	01
II. Introduction of risk based classifications system	01
III. Single window clearance	02
IV. Product standards for medical devices	02
V. Certainty and rationalization of timelines	03
VI. Perpetual licenses	03
VII. Consolidation of registration certificate and import license into a single license	04
VIII. Certainty on consequence of change in licensed particulars	04
IX. Meaning of “change in constitution” finally explained and change in constitution rationalized	05
X. License for sale of medical devices	06
XI. Mandatory recalls on knowledge of risk to safety	07
XII. New thresholds for residual shelf life of imported products	07
XIII. New regulatory framework for clinical investigation of medical device	07
XIV. Debarment on account of supply of misleading information	08
XV. Medical Devices Rules, 2017 to be placed before Parliament	08
XVI. Next steps for existing importers, manufacturers and distributors	09
XVII. An opportunity lost	09
2. REGULATED MEDICAL DEVICES IN INDIA TO LOSE EXEMPTION FROM LABELLING REQUIREMENTS	10
I. Background	10
II. Changes introduced by the amendment with respect to medical devices and its analysis	10
III. Issues	12
IV. Grey areas	12
V. Conclusion	13

1. Medical Device Rules 2017 – An analysis

The Indian Government has finally introduced the Medical Device Rules, 2017 (“**2017 Rules**”). The rules have been drafted with the intention to distinguish medical devices from pharmaceuticals for the purpose of regulation. They will come into effect on January 1, 2018 unless a later date is notified by the government.¹

The key highlights of the 2017 Rules are:

I. Definition of Medical Devices

Under the 2017 Rules, medical devices mean:²

- a. Specific devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals which are notified by the government from the time to time under the Drugs and Cosmetics Act, 1940 (“**D&C Act**”). Some categories of devices have already been notified by the government. A list of classes of currently notified medical devices is annexed as Annexure D.
- b. Specific substances intended to affect the structure or any function of the human body which are notified by the government. At present, the substances notified are mechanical contraceptives (eg. condoms, intra-uterine devices, tubal rings) and disinfectants.
- c. Surgical dressings, surgical bandages, surgical staples, surgical sutures, ligatures, blood and blood component collection bag with or without anticoagulant;
- d. Substances used for in vitro diagnosis (referred to in the 2017 Rules as “In Vitro Diagnostic Medical Device”)
- e. All substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals. This is a catch-all category for substances;

The most important take-away from the definition of medical devices is that only the products that are covered by the definition of medical devices will be regulated by the 2017 Rules.

Unfortunately, since the Act, in which the definition of ‘drug’ includes all the medical devices identified above, remains unamended, the D&C Rules will continue to apply to all medical devices.

However, to avoid confusion, the 2017 Rules do clarify that in case of any contradiction between the provisions of 2017 Rules and the Drugs and Cosmetics Rules, 1945 (“**D&C Rules**”), the provisions of the 2017 Rules will have effect.³

II. Introduction of risk based classifications system

In tune with the global practice, the 2017 Rules will introduce a risk based classification system for regulation of medical devices. The classification would be as follows:

- a. Low (Class A)
- b. Low Moderate (Class B)

1. Rule 1(2) of 2017 Rules.

2. Rule 3(zb) of 2017 Rules.

3. Rule 96 of 2017 Rules.

c. Moderate High (Class C)

d. High (Class D)

The method of classification is described in detail in the first schedule of the 2017 Rules. It is important to note that unlike other countries which give liberty to manufacturers/importers to classify their product for the purpose of registration, the 2017 Rules do not provide this liberty and the manufacturers/importers will have to follow the classification decided by DCGI.⁴ This classification will be made available on the official website of DCGI, i.e., www.cdsco.nic.in.⁵ The classification once done, will unfortunately be non-appealable.

An example of the difference in regulation on the basis of risk-based classification is as follows:

The application for license to import Class A or Class B medical devices from Unregulated Jurisdictions (defined below) can be granted on the strength of a free sale certificate and either of published safety and performance data or clinical investigation in the country of origin. However, an application for import of Class C or Class D medical devices from Unregulated Jurisdictions can be granted only after its safety and effectiveness has been established through clinical investigation in India.

Unregulated Jurisdictions are jurisdictions other than Australia, Canada, Japan, European Union Countries, or the United States of America.

Similarly, for applications for grant of license to manufacture - Class A medical devices do not require prior audit by third party⁶ or official inspection; Class B medical devices require prior audit by third party⁷ but do not require official inspection, and; Class C or Class D medical devices require prior official inspection.⁸

The application for manufacture of Class A or Class B medical device will be assessed by the State licensing authority whereas the application for manufacture of Class C or Class D medical device will be assessed by DCGI.

III. Single window clearance

All applications for import, manufacture, sale or distribution and clinical investigation, whether to be assessed by the DCGI or State licensing authority, will have to be made through a single online portal of the central government. The details of the portal will be notified in the near future.

IV. Product standards for medical devices

All medical devices will be expected to conform to the following standards, in the same order of relevance:⁹

- a. A standard notified by central government for the medical device specifically or which has been laid down by the Bureau of Indian Standards (“**BIS**”); or

4. Rule 4(3) of 2017 Rules.

5. Rule 4(4) of 2017 Rules.

6. Rule 20(4)(i).

7. Rule 20(5) r/w Rule 20(6)(iii)

8. Rule 21(1) of 2017 Rules.

9. Rule 7

- b. Where (a) is absent, to a standard laid down by International Organisation for Standardisation (“ISO”) or the International Electro Technical Commission (“IEC”), or by any other pharmacopoeial standards; or
- c. Where both (a) and (b) are absent, to the validated manufacturer’s standards.

The clarity in products by 2017 Rules is a welcome step by the government. For much too long, the medical device manufacturers and importers suffered because of absence of clarity on product standards. The D&C Rules presently states that manufacturers or importers of notified medical devices are required to confirm to BIS standards or in absence of BIS standards, to international standards and such standards as may be specified.¹⁰ There was always a question on which standards would have to be followed when the BIS standards were not available. However, the introduction of 2017 Rules is expected to resolve this issues.

V. Certainty and rationalization of timelines

The government has brought certainty of timelines and has rationalized the time required for obtaining licenses required to market medical devices. Under the 2017 Rules, an applicant can be certain of the time within which its application will be decided and can also plan the time within which it can expect an audit or inspection to happen because timelines have been assigned to each regulatory function. Further, unlike the D&C Rules, the 2017 Rules do not give any scope to the regulators to extend the time-line for coming to a decision for any reason whatsoever. For instance, in case of license to manufacture Class C or Class D medical device, the scrutiny of the application is required to submitted within forty five (45) days of the date of the application,¹¹ the inspection of the manufacturing site is required to be completed before sixty (60) days from the date of the application,¹² the report of the inspection has to be forwarded to the applicant,¹³ and the decision on the application has to be communicated within forty five (45) days from date of receipt of the inspection report.¹⁴

Similarly, a decision on application to import a medical device is required to be communicated within 9 months from the date of the application irrespective of whether the foreign manufacturing site is inspected or not.¹⁵

The 2017 Rules have also introduced the concept of deemed approval in event of non-communication of a decision in application for approval to undertake major change in licensed particulars (the subject of major change in licensed particulars is discussed later in detail). If the appropriate licensing authority i.e. the DCGI or the State licensing authority is unable to communicate its decision on the aforesaid application within the stipulated timeline, i.e., forty five (45) days for manufacture, sixty (60) days for import, then such approvals shall be deemed to have been granted.¹⁶

VI. Perpetual licenses

The licenses granted under the 2017 Rules are perpetual, meaning they will continue to be valid unless they are cancelled. In order to save a license from getting cancelled, the licensee is required to pay a prescribed license retention fee every five years. A delay of ninety (90) days past the five years is acceptable provided the licensee pays a prescribed late fee. However, if the licensee fails to deposit the license retention fee within the aforementioned time-limit, then the license is deemed to have been cancelled.

10. Schedule R-1 of Rules.

11. Rule 21(4)

12. Rule 23(1)

13. Rule 24

14. Rule 25

15. Rule 36(1)

16. Rule 26(iii); Rule 38(vi)

Once a license is cancelled, the licensee will have to apply afresh for the license.

Please note that while the license may be perpetual, if a licensed manufacturer has stopped manufacturing activity or closed the manufacturing site for a period of thirty days or more, it is obligated to inform the appropriate licensing authority.¹⁷

VII. Consolidation of registration certificate and import license into a single license

The 2017 Rules have done away with the requirement of a registration certificate for registration of the foreign manufacturer, its manufacturing site and the products. The only regulatory requirement to be able to import and market products in India is to appoint an authorized agent in India and apply for an import license through it. The immediate outcome of this change is that the hassle of making two separate applications (registration and import license) has vanished and the timeline for obtaining the import license (of nine months) has become certain.

Further, it will not be possible for two different importers to import different products manufactured at the same manufacturing site. Where an importer has been licensed to import certain products from a manufacturing site, all other products manufactured at the same site are mandatorily required to be licensed to the same importer.¹⁸

VIII. Certainty on consequence of change in licensed particulars

The 2017 Rules are clear about the consequences of change in licensed particulars. Any major change requires a prior approval from the appropriate licensing authority (either DCGI or State licensing authority, as the case may be).¹⁹ Any minor change only requires written intimation to the appropriate licensing authority within a period of thirty days.²⁰

What constitutes major change and minor change has also been specified.²¹ For instance, the change in name or address of the manufacturer (whether domestic or foreign) or importer is a major change. A change in design which does not affect quality in respect of its specifications, indication for use, performance and stability of the medical device is a minor change.

This clarificatory inclusion in the 2017 Rules is greatly welcomed. At present, the D&C Rules do not specify what constitutes a major change or a minor change. That is not all. Whether a change in the manufacturing or in processing or in testing or in documentation is major or not is left to the discretion of the licensing authority and triggers the requirement to make a fresh application.²² The challenges of making a fresh application are discussed later with the subject of change in constitution.

17. Rule 26(xii)

18. Rule 34(4)(ii)

19. Rule 26(iii); Rule 38(vi)

20. Rule 26(iv); Rule 38(vii)

21. Sixth Schedule

22. Schedule D(I), Para 3.5 of Rules.

In fact, at present, it is known that the following changes will result in the requirement to obtain a fresh import license:²³

- a. Changes in name and/or address of Indian agent/ Importer or change in constitution after issue of Registration Certificate/ Import License
- b. Change in the Indications and/ or Intended use
- c. Change in constitution

Under the 2017 Rules, the above changes (excepting change in constitution) do not require fresh application. There is one more welcome change. Under the D&C Rules, it is prescribed that the application for registration certificate for import of notified medical devices will be decided within nine months²⁴ and for import license the application is customarily decided within three months after grant of registration certificate. Thus, on an average, a total time of around one year is spent in obtaining the import license. Since it is a considerably long span of time, it is possible that certain changes may occur in the details that were submitted to the licensing authority at the time of making of the application. For instance, it is possible for business reasons that a different manufacturing site is sought to be registered. Ideally, since the application has not been decided, it should be possible for the applicant to revise the application. However, the current practice is that in case of such a change, even if the application has not been decided, a fresh application has to be made.²⁵ Apart from loss of money and resources, this results in loss of valuable time and sometime delays imminent and time-sensitive launch of products. This serious shortcoming appears to have been rectified in the 2017 Rules. Such a change now is required to be informed in writing to the licensing authority.²⁶ Due to this explicit requirement, it should not trigger requirement to make a fresh application.

IX. Meaning of “change in constitution” finally explained and change in constitution rationalized

“Change in constitution” could easily be the most dreaded event under D&C Rules, even more than a “serious adverse event”. This is because no one seems to have any idea about what it means. Having said that, the D&C Rules require that upon its occurrence the license remains valid for three months only. The licensing authority itself has issued several clarifications, FAQs and guidelines over past seventy two (72) years but has not clarified what it means.

But worry no more. The 2017 Rules state that change in constitution of a licensee in relation to:²⁷

- i. *a firm means change from proprietorship to partnership including Limited Liability Partnership or vice versa;*
- ii. *a company means-*
 - a. *its conversion from a private to a public company, or from a public to a private company; or*
 - b. *any change in the ownership of shares of more than fifty per cent. of the voting capital in the body corporate or in case of a body corporate not having a share capital, any change in its membership; and where the managing agent, being a body corporate is a subsidiary of another body corporate, includes a change in the constitution of that other body corporate;*

Therefore, it is now clear that at least after enforcement of 2017 Rules:

1. Change in directors will not result in change in constitution;
2. Change in shareholding by way of sale/investment will not result in change in constitution; and
3. Change of parent shareholder due to restructuring exercise will not result in change in constitution.

23. See Import and Registration of Medical Devices FAQs published by Central Drug Standards Control Organization.

24. Rule 27A(1) Proviso of D&C Rules.

25. FAQ No. 51 under Import and Registration of Medical Devices FAQs published by Central Drug Standards Control Organization.

26. Rule 34(2) Proviso.

27. Rule 3(j)

Whether or not the above events constitutes a change in constitution of the licensee remains an enigma under the Drugs and Cosmetic Rules, 1945.

Let us understand what the practical challenge is if the license only remains valid for a period of three months due to change in constitution. It has already been discussed that it takes around a year to obtain an import license under the D&C Rules. It means that after change in constitution, an importer has only three months at present to import and stock products for domestic market to last for the time when it does not have an import license i.e. at least nine (9) months. This is almost impossible due to production, logistics, storage and commercial considerations. Thus, for many importers today, a change in constitution means halt of business for close to a year.

However, the government seems to have realized this pitfall and has made the process surrounding change in constitution a breeze under the 2017 Rules. Upon a change in constitution as defined before, a manufacturer licensee has forty five (45) days to inform the licensing authority and one hundred eighty (180) days to make a fresh application.²⁸ An importer does not even have to inform the licensing authority but simply make a fresh application in the same time-frame.²⁹ After making such an application, the existing license is deemed to be valid until the fresh application is decided by the licensing authority. Thus, there remains nothing to dread about change in constitution under the 2017 Rules.

X. License for sale of medical devices

The 2017 Rules do not have separate provisions for sale of medical devices. The provisions related to sale of drugs other than homeopathic medicines under the D&C Rules will apply to medical device as if inserted within the 2017 Rules.³⁰ All licenses for sale of drugs other than homeopathic medicines issued prior to commencement of 2017 Rules shall be deemed to be valid for sale of medical devices as well.³¹

The 2017 Rules do, however, address a practical difficulty faced by many distributors in India. Implantable medical devices cannot be self-administered and therefore are seldom bought at retail. They are stocked by hospitals for clinical use as and when required. The hospitals sell the medical device to the patient directly on a unit basis or as part of treatment package. However, considering the medical devices are expensive and its demand is difficult to predict, hospitals are hesitant to purchase medical devices in large quantities. At the same time, some of the medical devices are critical and may be required on short notice, therefore it is in hospital's and patients' interest that the hospital maintains a large stock of medical devices. As a solution to this dilemma, the distributors transfer a sizeable stock of the medical devices to the hospital through a stock transfer. A stock transfer is not a sale, it is merely transfer of stock. As and when the hospital requires a medical devices, it uses it from the stock. The distributor then charges the hospital on the basis of its use. All the unused stock is later re-transferred to the distributor. The proof of stock-transfer of medical devices by distributor to the hospital is a delivery note.

The D&C Rules requires that any sale or distribution should be recorded by the distributor. A stock transfer is not a sale or distribution, therefore it is not recorded by the distributor. However, the presence of stock at the hospital may be interpreted as an act of distribution. This can lead to unnecessary investigation against the distributors by the licensing authority. In order to resolve this complication, the 2017 Rules have permitted supply of implantable medical devices against a delivery note (challan).³²

28. Rule 27.

29. Rule 39.

30. Rule 87(1).

31. Rule 87(2).

32. Rule 88(1).

XI. Mandatory recalls on knowledge of risk to safety

The 2017 Rules make it mandatory³³ for manufacturers and importers to immediately initiate recall in case it has reasons to believe that a medical device is likely to pose risk to the health of a user or patient during its use and therefore may be unsafe. The recall should aim to withdraw the medical device in question from both the market as well as patients, indicating reasons for its withdrawal. The manufacturer and importer initiating recall is required to inform the licensing authority about the details of the recall.

In contrast, the D&C Rules do not obligate the manufacturer or importer to recall medical devices upon knowledge of risk to user or patients.³⁴ There is also no explicit requirement to report the facts leading to a recall, unless the medical device is “new” and is required to submit periodic safety update reports and have a system of pharmacovigilance in place.³⁵

XII. New thresholds for residual shelf life of imported products

The D&C Rules prescribe that all imported products should have a minimum residual shelf life of sixty (60) percent on the date of import unless specific permission is obtained to the contrary.³⁶ This becomes an issue for importers of medical devices which have a short claimed shelf life.

The 2017 Rules have addressed the issue by relaxing the residual shelf life requirement for medical devices with short shelf life.³⁷ Any medical device, whose total shelf life claim is

- a. less than ninety (90) days, will be allowed to be imported if it has more than forty (40) per cent residual shelf-life on the date of import
- b. between ninety (90) days and one (1) year, will be allowed to be imported if it has more than fifty (50) per cent residual shelf-life on the date of import
- c. is more than one (1) year, will be allowed to be imported by the licensing authority if it has more than sixty (60) per cent residual shelf-life on the date of import.

XIII. New regulatory framework for clinical investigation of medical device

The 2017 Rules will introduce a new regulatory framework for clinical investigation of medical devices. Some of the interesting provisions of this framework are:

- a. A fixed timeline of ninety (90) days has been prescribed for the licensing authority to arrive at a decision on application for permission to conduct clinical trial;
- b. After obtaining permission to conduct clinical trial, the first subject is required to be enrolled within one year;

33. Rule 89(i).

34. Rule 26(v); Rule 74(j); Rule 78(i) of D&C Rules

35. Schedule Y, Para 3(4)

36. Rule 31 Proviso of D&C Rules.

37. Rule 47

- c. New concepts of Pilot Study (i.e. exploratory study) and Pivotal Study (i.e. confirmatory study) have been introduced with respect to approval of investigation medical device;
- d. New concept of “substantial equivalence” to predicate devices has been introduced with respect to approval of medical devices other than investigational medical devices;
- e. The clinical performance evaluation of In Vitro Diagnostic Devices is now part of the regulatory framework;
- f. Any institute, organization, hospital run or funded by the Central Government or the State Government is exempted from payment of fees for conduct of clinical investigation; and
- g. Academic clinical trials do not require prior approval of the licensing authority for its initiation if the data generated during the study will not be used for obtaining manufacturing or import license.

XIV. Debarment on account of supply of misleading information

The 2017 Rules frown upon submission of misleading information along with an application for grant of any license. It prescribes that any applicant found guilty of submitting misleading, or fake, or fabricated documents, may be debarred by the appropriate licensing authority for such period as it may deem fit.³⁸ In other words, if any misleading or false information is found to have been submitted to the licensing authority, then it can debar the applicant from doing business in India.

The provision appears to be based on the jurisprudence of strict liability. It does not matter whether the applicant knew or intended to submit misleading or false information. This should act as a wake-up call to importers, manufacturers, distributors and researchers to ensure that all information that is finally submitted by it (or on its behalf) is verified prior to submission.

XV. Medical Devices Rules, 2017 to be placed before Parliament

The Medical Device Rules, 2017 will be issued under the Act. The Act requires that every rule made under it is laid down before each House of Parliament, for a total period of thirty days. If both Houses agree to make any modification in the rules or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be.

Thus, the 2017 Rules will soon be placed before the Indian Parliament. It will be interesting to see whether the Indian Parliament effects any modification to the 2017 Rules or rejects it completely. However, given the political and economic scenario, either event seems unlikely.

³⁸. Rule 93(1).

XVI. Next steps for existing importers, manufacturers and distributors

After the commencement of 2017 Rules, all licenses and registrations for medical devices issued under the D&C Rules that are valid on the date of commencement, shall be valid at least until July 31, 2018 or until the expiry date of the license or registration, whichever is later (“**Grace Period**”). Upon expiry of the Grace Period, all existing licensees will require a license issued under the 2017 Rules. Therefore, there is no need to rush to adopt to the 2017 Rules. However, it is important to start preparing for the new regulatory regime under 2017 Rules.

It is not clear whether existing licensees could voluntarily surrender their license before expiry of the Grace Period in order to obtain a license under the 2017 Rules. However, such a step is not advisable. This is because the license fees paid to obtain the license under Rules is far cheaper than the license fees prescribed in 2017 Rules. By opting to surrender the license, the licensee would effectively end up forfeiting the license fees already paid and incur expense of higher license fees. In case the decision to surrender is being contemplated for taking benefit of the beneficial provisions of 2017 Rules (eg. change in constitution), then such rationale needs to be re-evaluated because the 2017 Rules clarify that the existing license under the Grace Period shall be deemed to be valid under the corresponding provision of 2017 Rules. Therefore, all existing licensees should be able to derive the benefit of 2017 Rules during the Grace Period despite transacting on a license issued under the Rules.

XVII. An opportunity lost

Though the 2017 Rules have introduced a number of business friendly provisions, one cannot help but regret that it was an opportunity lost to bring more change. The fact of the matter is that even after commencement of the 2017 Rules, medical devices will continue to be deemed to be drugs, since the definition of medical devices is tied to the definition of drugs under Act. This has repercussions under other laws, most important of which is the price control legislation – the Drugs (Price Control) Order, 2013 issued under the Essential Commodities Act, 1955. The Essential Commodity Act, 1955 has notified drugs as defined under Act as essential commodity. Due to the reference to this definition, medical devices which are deemed to be drugs, are also currently subject to limited price control. Had the government separated the definition of medical devices from the definition of drug, the tragedy that inadvertent and unintended price control of medical devices is today would have been avoided.

Having said that, there is no doubt that the fact of notification of the 2017 Rules and the very real possibility of it coming into effect in 2018 should be celebrated!

2. Regulated medical devices in India to lose exemption from labelling requirements

On June 23 2017, the Government of India notified an amendment to a law that regulates contents of labels of all pre-packaged goods sold in India. The amendment takes effect from January 1, 2018. The most significant aspect of the amendment is that the application of this law has been extended to all regulated medical devices, which presently enjoy exemption. The label of all regulated medical devices sold in India will have to bear certain additional declarations and particulars, failing which, criminal prosecution may be initiated.

In this update, we have discussed the background and analysis of the amendment in the paragraphs below.

I. Background

The Legal Metrology Act, 2009 (“**LM Act**”), as its name suggests, lays down the standards of measurements in India (metrology means the science of measurement). It prescribes the units of weights and measures (eg. Liter, meter, kilogram, second etc.) that are to be followed for any measurement. The LM Act also mandates that all pre-packaged commodities (“**pre-packaged goods**”) should carry declarations and particulars that may be prescribed by the government from time to time. These declarations and particulars are prescribed in the Legal Metrology (Packaged Commodities) Rules, 2011 (“**LM Rules**”). Any person who sells or distributes a pre-packaged good that does not carry the required declarations and particulars is punished with a fine of INR 25,000 (approx. USD 390) and INR 50,000 (approx. USD 780) respectively for the first two offences and fine of INR 1,00,000 (approx. USD 1550) or simple imprisonment of a term up to one year or both for subsequent offences.

Regulated medical devices at present are exempted from compliance with the LM Rules. This is because ‘drugs’ that are covered by Drug Price Control Order, 2013 (“**DPCO**”) are exempted from the application of LM Rules. All regulated medical devices are, in fact, notified and regulated as ‘drugs’ under Indian law.

The LM Rules were amended by the Government of India on June 23, 2017. We have described and analyzed the major changes introduced by the amendment in the paragraphs below:

II. Changes introduced by the amendment with respect to medical devices and its analysis

1. *Regulated medical devices to comply with LM Rules:* LM Rules will apply to regulated medical devices from January 1, 2018. At present only 15 categories of medical devices are regulated. As many of our readers are aware, the Medical Device Rules, 2017 will take effect from January 1, 2018. The Medical Device Rules, 2017 intend to bring all medical devices within its fold. In other words, the government intends to regulate all medical devices as “drugs” from January 1, 2018 or soon thereafter.

If the LM Rules had not been amended, the impact could have been that no medical device would have been regulated by LM Rules from January 1, 2018 owing to the exemption for drugs. By notifying the amendment, the government has made it clear that it wants to ensure that all medical devices (both regulated and unregulated) remain within the scope of the LM Rules after January 1, 2018.

2. But what does that mean? It means that :
 - a. The label of the regulated medical devices will have to carry the following additional declarations and particulars:
 - i. Maximum retail price (“**MRP**”);
 - ii. Common or generic name of the commodity;
 - iii. month and year in which the commodity is manufactured or packed or imported;
 - iv. name, address, telephone number, e-mail address of the person who can be or the office which can be contacted, in case of consumer complaints;
 - v. Actual corporate name and complete address of domestic manufacturer or importer or packer;
 - vi. Other particulars and declarations that are discussed in paragraphs below.
 - b. The label of wholesale package ³⁹ of regulated medical devices will have to carry the following declarations:
 - i. The name and address of the manufacturer or importer or where the manufacturer or importer is not the packer, of the packer
 - ii. the identity of the commodity contained in the package
 - iii. the total number of retail package contained in such wholesale package or the net quantity in terms of standard units of weights, measures or number of the commodity contained in wholesale package
 - c. The domestic manufacturer, packer or importer of regulated medical devices will have to register themselves under appropriate authority identified by the LM Rules
 - d. Any alteration of any declaration or particular on the label may require permission from the appropriate authority identified by the LM Rules
 - e. Any revision in price due to change in a central tax ought to be intimated to the public, distributors and the appropriate authority identified by the LM Rules.
3. *New declaration of country of origin to be made:* All medical device importers will have to declare the name of country of origin or manufacture or assembly on the package.

Please note that most of these declarations are not required under the Rules issued under the Drugs & Cosmetics Act, 1940 (“**D&C Rules**”) or the DPCO. The only overlap is the name and address of the manufacturer or importer, net quantity and expiry date.

4. Declaration to be made on the outer package only: Where a pre-packaged good has two or more levels of packaging, it has been clarified that no such declarations on the inner package is required, if the outer package contains all declarations required under the LM Rules. This may be relevant to manufacturers and importers of medical devices, who sometimes put an additional quality packaging on the medical device. In such cases, it should be sufficient compliance of the LM Rules if the mandatory declarations and particular appear on the quality packaging only.

39. “wholesale package” means a package containing-

- (i) a number of retail packages, where such first mentioned package is intended for sale, distribution or delivery to an intermediary and is not intended for sale direct to a single consumer; or
- (ii) a commodity sold to an intermediary in bulk to enable such intermediary to sell, distribute or deliver such commodity to the consumer in smaller quantities;
- (iii) ten or more than ten retail packages provided that the retail packages are labeled as required under the LM rules.

Similarly, retail packs of medical devices may be packed in packs of three or packs of five etc. In such cases as well, putting mandatory declarations and particulars on the outer packaging should be sufficient compliance of the LM Rules. Please note the aforesaid clarification applies to retail packages only and not to wholesale packages. In case of wholesale packages, each retail package is required to be labeled separately.

III. Issues

Multiple regulators for same subject: At present, the labelling requirements of regulated medical devices are prescribed by the D&C rules and DPCO. After the amendment, LM Rules will be added to this list. One major inconvenience of being subjected to multiple laws is that alteration of any particular or declaration on the label may require approval (or no objection) of multiple authorities which may result in loss of precious time. In order to avoid approaching different regulators for approval, it is suggested that separate labels are affixed on the medical device to meet the requirements of different laws.

Another inconvenience of being subject to multiple law is that any non-compliance of labelling requirements that are common to these laws (i.e. name and address of the manufacturer or importer, net quantity and expiry date) may lead to parallel prosecution under these laws.

Multiplicity of proceedings for non-compliance of LM Rules: The enforcement of LM Rules is done at a state-level. This means that every state in India has its own enforcement wing to examine violations that take place with respect to pre-packaged goods sold in that state. This could be a matter of concern for medical device companies that have a pan-India presence because in case of any enforcement action due to alleged non-compliance in one state, there is a risk that same enforcement action may be initiated in the remaining 28 or so states of India.

Draconian law: The LM Act is a draconian piece of legislation because it does not prescribe a process for showing cause behind any alleged non-compliance. In other words, the law itself does not prescribe any process that supports issuance of show-cause notice prior to proceeding for prosecution. In fact, it is common for companies in India to have directly received a notice that orders the company to admit the alleged offence or resolve the matter before court after a criminal case has been lodged against the company and its officers responsible for the operation of the company (usually its directors). There is little or no scope for submitting an explanation to the officer who issues the notice.

IV. Grey areas

The amendment to LM Rules are not without grey areas. In our view, the biggest grey area is the use of expression “not for commercial or trade purpose” in the definition of “institutional consumer”. In case the sale of pre-packaged goods is to institutional consumer, then LM Rules are not required to be complied with. In case of such sales, the LM Rules require manufacturer, importer or packer to label the pre-packaged goods with the declaration - “not for retail sale”. The exemption is significant because it reduces the administrative cost of labelling as well as the probability of occurrence of non-compliance, given that there is little to be declared on the label.

For the benefit of the reader, the amended definition of institutional consumer is as follows:

■ *“Institutional consumer” means the institution which buys packaged commodities bearing a declaration ‘not for retail sale’, directly from the manufacturer or from an importer or from wholesale dealer for use by that institution and not for commercial or trade purposes* ■

In the old definition of institutional consumer, the expression “and not for commercial or trade purpose” was absent. The scope of the aforementioned expression is not clear because the expression has not been defined in the amendment. Specifically, it is not clear whether exhausting a pre-packaged commodity while providing a service would amount to using the pre-packaged commodity for “commercial or trade purpose”. For instance, if medical devices such as catheters are used while rendering service to a patient as part of a treatment package and such catheter is not invoiced separately to the patient, can the hospital that offers such a treatment be said to be an ‘institutional consumer’? It is unclear, how the suppliers of medical devices to the hospitals are supposed to understand whether or not the medical device will be used by the hospital for commercial or trade purposes.

Some of the other grey areas that have come to our notice are:

1. How should a specialized and unique medical device, which does not have a comparator, declare its “common or generic name” on its label? and
2. Would declaration of date in day-month-year format, which is the international standard, suffice for the purpose of declaration of date of import or manufacture given that the LM Rules require such declaration in month and year format?

V. Conclusion

The requirements to put new declarations and particulars on the label as per the LM Rules and be regulated by LM Rules may understandably lead to some anxiety amongst manufacturers and importers of medical devices. However, given that manufactures and importers of almost all pre-packaged commodities (including unregulated medical devices) sold in India are complying with these labelling requirements at present and are also regulated by LM Rules, the amendment should not be difficult to adopt to. In fact, there is sufficient time left to adopt to the compliance requirements of the LM Rules since the amendment comes into effect on January 1, 2018.

Also, in the available time, it will be helpful if the medical device industry could seek clarity on various grey areas that exist within the amendment, especially the scope of expression “commercial or trade purpose” in the context of hospitals and their use of medical devices in treatment of patients. A clarification that allows hospital to be treated as institutional consumer in aforementioned context may make a significant difference in the impact of the amendment on manufacturers and importers of medical devices.

About NDA

Nishith Desai Associates (NDA) is a research based international law firm with offices in Mumbai, Bangalore, Palo Alto (Silicon Valley), Singapore, New Delhi, Munich and New York. We provide strategic legal, regulatory, and tax advice coupled with industry expertise in an integrated manner.

As a firm of specialists, we work with select clients in select verticals on very complex and innovative transactions and disputes.

Our forte includes innovation and strategic advice in futuristic areas of law such as those relating to Bitcoins (block chain), Internet of Things (IOT), Autonomous Vehicles, Artificial Intelligence, Privatization of Outer Space, Drones, Robotics, Virtual Reality, Med-Tech, Ed-Tech and Medical Devices and Nanotechnology.

We specialize in Globalization, International Tax, Fund Formation, Corporate & M&A, Private Equity & Venture Capital, Intellectual Property, International Litigation and Dispute Resolution; Employment and HR, Intellectual Property, International Commercial Law and Private Client. Our industry expertise spans Automobile, Funds, Financial Services, IT and Telecom, Pharma and Healthcare, Media and Entertainment, Real Estate, Infrastructure and Education. Our key clientele comprise marquee Fortune 500 corporations.

According to the recent report by India Brand Equity Foundation (IBEF), India's Civil Aviation Industry is on a high-growth trajectory expected to grow from being the 9th largest aviation market in the world with a size of around US\$ 16 billion to being the 3rd biggest by 2020 and the largest by 2030.

The Government of India (GOI) also envisions airport infrastructure investment of US\$ 11.4 billion under the Twelfth Five Year Plan (2012-17). It has opened up the airport sector to private participation. The Airports Authority of India (AAI) also aims to bring around 250 airports under operation across the country by 2020. We at NDA accordingly prepare ahead, envisaging the coming 10 to 15 years, in order to provide clients appropriate insights based on our understanding of current as well as future legal and regulatory issues.

Our ability to innovate is endorsed through the numerous accolades gained over the years and we are also commended by industry peers for our inventive excellence that inspires others.

Most recently, NDA was ranked the 'Most Innovative Asia Pacific Law Firm in 2016' by the *Financial Times - RSG Consulting Group* in its prestigious **FT Innovative Lawyers Asia-Pacific 2016** Awards. While this recognition marks NDA's ingress as an innovator among the globe's best law firms, NDA has previously won the award for the 'Most Innovative Indian Law Firm' for two consecutive years in 2014 and 2015.

As a research-centric firm, we strongly believe in constant knowledge expansion enabled through our dynamic Knowledge Management ('KM') and Continuing Education ('CE') programs. Our constant output through Webinars, Nishith.TV and 'Hotlines' also serves as effective platforms for cross pollination of ideas and latest trends.

Our trust-based, non-hierarchical, democratically managed organization that leverages research and knowledge to deliver premium services, high value, and a unique employer proposition has been developed into a global case study and published by John Wiley & Sons, USA in a feature titled 'Management by Trust in a Democratic Enterprise: A Law Firm Shapes Organizational Behavior to Create Competitive Advantage' in the September 2009 issue of *Global Business and Organizational Excellence (GBOE)*.

A brief below chronicles our firm's global acclaim for its achievements and prowess through the years.

- **IDEX Legal Awards:** In 2015, NDA won the “M&A Deal of the year”, “Best Dispute Management lawyer”, “Best Use of Innovation and Technology in a law firm” and “Best Dispute Management Firm”. Nishith Desai was also recognized as the ‘Managing Partner of the Year’ in 2014.
- **Merger Market:** has recognized NDA as the fastest growing M&A law firm in India for the year 2015.
- **Legal 500** has ranked us in tier 1 for Investment Funds, Tax and Technology-Media-Telecom (TMT) practices (2011, 2012, 2013, 2014)
- **International Financial Law Review (a Euromoney publication)** in its **IFLR1000** has placed Nishith Desai Associates in Tier 1 for Private Equity (2014). For three consecutive years, IFLR recognized us as the Indian “Firm of the Year” (2010-2013) for our Technology - Media - Telecom (TMT) practice.
- **Chambers and Partners** has ranked us # 1 for Tax and Technology-Media-Telecom (2015 & 2014); #1 in Employment Law (2015); # 1 in Tax, TMT and Private Equity (2013); and # 1 for Tax, TMT and Real Estate – FDI (2011).
- **India Business Law Journal (IBLJ)** has awarded Nishith Desai Associates for Private Equity, Structured Finance & Securitization, TMT, and Taxation in 2015 & 2014; for Employment Law in 2015
- **Legal Era** recognized Nishith Desai Associates as the Best Tax Law Firm of the Year (2013).

Please see the last page of this paper for the most recent research papers by our experts.










Disclaimer

This report is a copyright of Nishith Desai Associates. No reader should act on the basis of any statement contained herein without seeking professional advice. The authors and the firm expressly disclaim all and any liability to any person who has read this report, or otherwise, in respect of anything, and of consequences of anything done, or omitted to be done by any such person in reliance upon the contents of this report.

Contact

For any help or assistance please email us on ndaconnect@nishithdesai.com or visit us at www.nishithdesai.com

The following research papers and much more are available on our Knowledge Site: www.nishithdesai.com

 <p>Fund Structuring and Operations</p> <p>Fund Structuring & Operations Global, Regulatory and Tax developments impacting India focused funds</p> <p>June 2017</p>	 <p>Social Impact Investing in India</p> <p>Social Impact Investing in India A Supplement to Corporate Social Responsibility & Social Business Models in India - A Legal & Tax Perspective</p> <p>May 2017</p>	 <p>The Curious Case of the Indian Gaming Laws</p> <p>The Curious Case of the Indian Gaming Laws Legal Issues Demystified</p> <p>June 2017</p>
 <p>Corporate Social Responsibility & Social Business Models in India</p> <p>Corporate Social Responsibility & Social Business Models in India A Legal & Tax Perspective</p> <p>May 2017</p>	 <p>Incorporation of Company/LLP in India</p> <p>Incorporation of Company / LLP in India FDI</p> <p>April 2017</p>	 <p>Outbound Acquisitions by India-Inc</p> <p>Outbound Acquisitions by India Inc. A Review on Outbound Acquisitions by Indian Companies with a Focus on United States, United Kingdom and Australia</p> <p>September 2014</p>
 <p>Internet of Things</p> <p>Internet of Things Legal & Tax Issues</p> <p>January 2017</p>	 <p>Doing Business in India</p> <p>Doing Business in India With Special Reference to Tax Treaties between India and</p> <p>June 2016</p>	 <p>Private Equity and Private Debt Investments in India</p> <p>Private Equity and Private Debt Investments in India</p> <p>June 2015</p>

NDA Insights

TITLE	TYPE	DATE
Blackstone's Boldest Bet in India	M&A Lab	January 2017
Foreign Investment Into Indian Special Situation Assets	M&A Lab	November 2016
Recent Learnings from Deal Making in India	M&A Lab	June 2016
ING Vysya - Kotak Bank : Rising M&As in Banking Sector	M&A Lab	January 2016
Cairn - Vedanta : 'Fair' or Socializing Vedanta's Debt?	M&A Lab	January 2016
Reliance - Pipavav : Anil Ambani scoops Pipavav Defence	M&A Lab	January 2016
Sun Pharma - Ranbaxy: A Panacea for Ranbaxy's ills?	M&A Lab	January 2015
Reliance - Network18: Reliance tunes into Network18!	M&A Lab	January 2015
Thomas Cook - Sterling Holiday: Let's Holiday Together!	M&A Lab	January 2015
Jet Etihad Jet Gets a Co-Pilot	M&A Lab	May 2014
Apollo's Bumpy Ride in Pursuit of Cooper	M&A Lab	May 2014
Diageo-USL- 'King of Good Times; Hands over Crown Jewel to Diageo	M&A Lab	May 2014
Copyright Amendment Bill 2012 receives Indian Parliament's assent	IP Lab	September 2013
Public M&A's in India: Takeover Code Dissected	M&A Lab	August 2013
File Foreign Application Prosecution History With Indian Patent Office	IP Lab	April 2013
Warburg - Future Capital - Deal Dissected	M&A Lab	January 2013
Real Financing - Onshore and Offshore Debt Funding Realty in India	Realty Check	May 2012
Pharma Patent Case Study	IP Lab	March 2012
Patni plays to iGate's tunes	M&A Lab	January 2012

Research @ NDA

Research is the DNA of NDA. In early 1980s, our firm emerged from an extensive, and then pioneering, research by Nishith M. Desai on the taxation of cross-border transactions. The research book written by him provided the foundation for our international tax practice. Since then, we have relied upon research to be the cornerstone of our practice development. Today, research is fully ingrained in the firm's culture.

Research has offered us the way to create thought leadership in various areas of law and public policy. Through research, we discover new thinking, approaches, skills, reflections on jurisprudence, and ultimately deliver superior value to our clients.

Over the years, we have produced some outstanding research papers, reports and articles. Almost on a daily basis, we analyze and offer our perspective on latest legal developments through our "Hotlines". These *Hotlines* provide immediate awareness and quick reference, and have been eagerly received. We also provide expanded commentary on issues through detailed articles for publication in newspapers and periodicals for dissemination to wider audience. Our *NDA Insights* dissect and analyze a published, distinctive legal transaction using multiple lenses and offer various perspectives, including some even overlooked by the executors of the transaction.

We regularly write extensive research papers and disseminate them through our website. Although we invest heavily in terms of associates' time and expenses in our research activities, we are happy to provide unlimited access to our research to our clients and the community for greater good.

Our research has also contributed to public policy discourse, helped state and central governments in drafting statutes, and provided regulators with a much needed comparative base for rule making. Our *ThinkTank* discourses on Taxation of eCommerce, Arbitration, and Direct Tax Code have been widely acknowledged.

As we continue to grow through our research-based approach, we are now in the second phase of establishing a four-acre, state-of-the-art research center, just a 45-minute ferry ride from Mumbai but in the middle of verdant hills of reclusive Alibaug-Raigadh district. The center will become the hub for research activities involving our own associates as well as legal and tax researchers from world over. It will also provide the platform to internationally renowned professionals to share their expertise and experience with our associates and select clients.

We would love to hear from you about any suggestions you may have on our research reports.

Please feel free to contact us at
research@nishithdesai.com

Nishith Desai Associates

LEGAL AND TAX COUNSELING WORLDWIDE

MUMBAI

93 B, Mittal Court, Nariman Point
Mumbai 400 021, India
tel +91 22 6669 5000
fax +91 22 6669 5001

SILICON VALLEY

220 S California Ave., Suite 201
Palo Alto, California 94306, USA
tel +1 650 325 7100
fax +1 650 325 7300

BANGALORE

Prestige Loka, G01, 7/1 Brunton Rd
Bangalore 560 025, India
tel +91 80 6693 5000
fax +91 80 6693 5001

SINGAPORE

Level 30, Six Battery Road
Singapore 049 909
tel +65 6550 9856

MUMBAI BKC

3, North Avenue, Maker Maxity
Bandra-Kurla Complex
Mumbai 400 051, India
tel +91 22 6159 5000
fax +91 22 6159 5001

NEW DELHI

C-5, Defence Colony
New Delhi 110 024, India
tel +91 11 4906 5000
fax +91 11 4906 5001

MUNICH

Maximilianstraße 13
80539 Munich, Germany
tel +49 89 203 006 268
fax +49 89 203 006 450

NEW YORK

375 Park Ave Suite 2607
New York, NY 10152
tel +1 212 763 0080