Pharma & Healthcare Update

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REGULATED MEDICAL DEVICES IN INDIA TO LOSE EXEMPTION FROM LABELLING REQUIREMENTS

Highlights:

- Regulated medical devices will have to bear additional information on label from January 1, 2018
- Declaration of country of origin or manufacture or assembly made mandatory on label of imported medical devices (both regulated and unregulated) from January 1, 2018

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.

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:

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. [Our analysis of the Medical Devices Rules, 2017 is available here]

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[1] of regulated medical devices will have to carry the following declarations:

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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. 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.

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.

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 manufacture, 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 a 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.

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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?

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.

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You can direct your queries or comments to the authors

[1] “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.

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