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MEDICAL DEVICE YEARLY WRAP

INTRODUCTION

The medical device industry is, without a doubt, one of India's sunrise industries as it has consistently outshone many other industries in terms of year on year growth. In 2015, the prime minister's flagship 'Make in India' campaign ear-marked it as one of its focus industries. This event implicitly underlined medical device industry's significance and sent clear signals that it has the attention of the government.

Therefore, at the beginning of 2016, there was every reason for the industry to be buoyant and expect that, at least the legacy issues faced by it would be resolved. The events that eventually unfolded, from a legal stand-point, are captured in the paragraphs below. With the benefit of hindsight, we have sought to summarize the major regulatory, legal and tax developments for the medical device industry that took place over the course of 2016. We sincerely hope you enjoy reading it.

DRAFT MEDICAL DEVICE RULES PUBLISHED

In the many ups and downs for the medical device industry this year, the biggest 'up' is undoubtedly the publication of the draft Medical Devices Rules ("**Rules**") by the Central Drugs Standards Control Organization ("**CDSCO**") in October[1].

Before deep-diving into the content of the Rules, one needs to understand why the publication of these rules has, by itself, lifted the spirits of the medical device industry. Since 1989[2], India regulates a few notified medical devices as drugs, by creating a deeming fiction under the Drugs and Cosmetics Act, 1940[3] ("**D&C Act**"). The circumstances in 2005 demanded that more medical devices (including cardiac stents) be brought under some sort of regulatory framework immediately. At that time, everyone thought that this was going to be a temporary and stop-gap arrangement, until the legislators could enact a legislation for medical devices in the following parliamentary session. This, however, did not happen. To be fair to the government, in the last ten years, multiple attempts were made to enact a law for regulating medical devices but they never fructified. The draft Rules represent the latest and most comprehensive attempt to regulate medical devices.

The single most important provision of the draft Rules is that it seeks to bring all medical devices under the fold of regulation, including stand-alone software (with some qualifications). The regulation follows a risk-based classification system and is basically divided into four classes: low risk, low moderate risk, moderate high risk and high risk. The logic behind the regulation is simple – the higher the risk, the higher the level of regulation. For instance, manufacturers and importers who seek to market low risk medical devices would not require a license, unless voluntarily applied for. However, those who seek to market high risk medical devices would require a license and face regular inspection.

Other notable provisions of the Rules include; no cap on the term of license, increase of upper limit of shelf life of medical devices from five years (current requirement) to any term that is supported by safety data, and clarity on what constitutes a 'change in constitution' of a licensee (or more importantly – what does not constitute change in constitution).

The draft Rules, though welcome, are not free from shortcomings. One notable shortcoming is the vagueness surrounding the applicability of the draft Rules to all medical devices on the date of its notification. The reason for vagueness is as follows:

As a legal concept, any rule will always be sub-ordinate to its parent legislation. Therefore, the draft Rules shall always be sub-ordinate to the D&C Act, under which they are proposed to be notified. Section 3(b) (iv) of the Act states that the D&C Act (and consequently any rules notified under it) shall apply to only those medical devices that are notified by the central government. This seemingly defeats the intention behind introducing a wide definition of medical devices and a detailed system of classification. It also begs the following question: Despite the wide definition of medical devices and its detailed system of classification, would the draft Rules effectively apply only to those medical devices that have been notified? Alternatively, what kind of notification would be required from the Central Government for the draft Rules to take their full effect? The medical devices industry will have to wait and watch.

CORONARY STENTS BROUGHT UNDER PRICE CONTROL

On December 21 2016, the government amended the Drug (Prices Control) Order, 2013 ("**DPCO**") and added "coronary stents" under Schedule–I of DPCO[4]. This means that the government would soon fix a price ceiling for

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coronary stents and all manufacturers and importers of coronary stents would not be able to sell them at a price higher than the ceiling price.

As a background, India treats drugs as essential commodities and has enacted a price control order (i.e. DPCO) to ensure access and availability of these drugs. The DPCO mandates that drugs which are part of its schedule (i.e. Schedule-I) shall not be sold at a price higher than the ceiling price fixed by the government. These drugs are called Scheduled Drugs. Drugs that are not covered by Schedule-I of DPCO are called Non-Scheduled Drugs. These Drugs can be sold at any price. However, the prices of Non-Scheduled Drugs cannot be increased by more than ten percent in a span of twelve months. The applicability of DPCO, which essentially deals with drugs, to medical devices may come as surprise to many. This was made possible because, certain notified classes of medical devices are treated as drugs, through a deeming fiction created under D&C Act[5]. Due to this deeming fiction, it is technically possible for the government to bring all notified classes of medical devices under price control. "Cardiac stents" is one of the notified class of medical devices. Therefore, the government was empowered to bring coronary stents (a sub-class of cardiac stents) under price control, and it has done so.

The industry has, however, raised concerns how the inclusion of coronary stents may disincentivize newer technologies being brought to India[6], as well adversely affect the current 'Make in India' push in the medical devices sector[7]. Representations have also been made stating that a large proportion of cost to the patients in relation to stents are from the medical procedure itself and not the stent[8], thereby defeating the purpose of the exercise. There have also been requests for differential pricing, as newer generation stents are superior to the more widely used stents.[9]

The National Pharmaceutical Pricing Authority ("**NPPA**"), the agency in-charge of administration of DPCO, has reportedly swung into action and has sought information on Price to Retailer / Price to Stockists / Price to Hospital, the Moving Annual Turnover and Maximum Retail Price from manufacturers, importers and marketers in the wake of the impending responsibility to fix the prices of coronary stents.[10] The Delhi High Court, in response to a Public Interest Litigation, has reportedly directed the Central Government to notify the ceiling price of coronary stents by March 1, 2017[11] and the NPPA has also announced stakeholder consultations, slated for January, 2017[12].

As this is a policy decision, the intention of the government ought to be respected. However, the process and method seems to be susceptible to challenge. There is some scope to argue that instrumentality of DPCO is not suitable for the purpose of introducing price ceiling over medical devices. For example, the DPCO uses 'price to retailer' (**PTR**) method to arrive at a price ceiling. PTR is easily available for drugs but is difficult, or even non-existent sometimes, in case of medical devices. This problem is further evidenced by the fact that the NPPA had to extend the deadline for submission of PTR and other pricing details, since concerned parties were unable to submit such data in time. There is also some scope to doubt whether the government could extend DPCO to medical devices as the power to fix price ceiling emanates from Essential Commodities Act, 1955 (which does not identify medical devices as essential commodity) and not D&C Act (which creates the deeming fiction to treat notified classes of medical devices as drugs).

It remains to be seen how the government intends to ensure that all players in the market are satisfied with its course of action. However, it is now clear that price control for medical devices is a reality.

SEPARATE QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES PROPOSED

The government published a draft of Schedule M-III ("**Schedule**") to the Drugs & Cosmetics Rules, 1945 in June. The draft Schedule contains the requirements for quality management systems ("**QMS**") for notified medical devices and in-vitro diagnostics. Since QMS is a technical subject, it may not suit the taste of all readers. Therefore, the specific contents of Schedule M-III will not be discussed in this piece. However, the relevance of this development is of general importance and the same is discussed below.

At present, the manufacturers of notified medical devices have to comply with QMS which was drafted for drug manufacturers. Since medical devices and drugs are fundamentally different, needless to say that compliance with a QMS crafted for drug manufacturers inconveniences (and sometimes harasses) the medical device manufacturers. For instance, it is critical for drug manufacturers to test the raw materials before processing it to produce the finished formulations because the raw material would change its composition in course of the manufacturing process. However, it is not so critical to test raw material for medical device manufactures because the raw material, many a times, is a finished medical device which is only to be packaged in a retail box. The raw material (i.e. the finished medical device) continues to be the same medical device until packaging. Similarly, there may be requirement to have a quarantine area for storing drug and drug components, because exposure to certain chemicals may be hazardous to the human body. But many medical devices, especially those that are used within the body, are inert and are made of inert materials, such as titanium. It may not serve any purpose to have a quarantine area to store inert materials and medical devices. However, given the requirement to observe QMS applicable to drugs, medical device manufacturers have to necessarily oblige. The draft Schedule is reported to introduce rational QMS for medical device manufacturers based on international standards as ISO 13485[13] and is therefore expected to ease the process of manufacturing medical devices.

It would be unfair on the government to comment that it is not aware of these issues faced by medical device industry. In fact, multiple versions of the draft Schedule have been published in the past few years. Unfortunately, none of the versions, including the current one, has been notified as law yet and there is no clear indication from the government on when the draft Schedule would be notified. It seems the medical device industry will have to wait.

VALIDITY OF FREE SALE CERTIFICATES FOR MEDICAL DEVICES EXTENDED, IMPORT DUTIES HIKED

Since April, state-level licensing authorities have the power to issue free sale certificate ("**FSC**") for notified medical devices for a term that is co-terminus with the validity of the manufacturing license of the manufacturer[14]. Prior to April, the state-level licensing authorities used to issue FSC for a term of two years.

A FSC acts as proof of safety of a medical device since it certifies that the medical device is actually sold in the country of manufacture. Numerous countries require importers of medical devices to furnish a FSC from the country of manufacture prior to allowing sale of the imported medical devices in their territory.

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The directive is expected to save manufacturers of notified medical devices from the inconvenience of approaching the state-level drug regulator every two years for a FSC. They will now have to approach the regulator every five years (which is the standard term of a manufacturing license).

With a view to promote the domestic manufacturing of medical devices in India, the Central Government in January imposed higher import duties on certain medical devices, while simultaneously reducing import duties on raw materials, parts and accessories used for manufacture of medical devices.[1516]

The announcement was apparently made without prior public consultation and drew criticism from some quarters of the industry. The Confederation of Indian Industry ("**CII**") pointed out that an increase in the customs duty would result in an effective increase of 18-28% which is likely to be passed on to the patients[17]. The Federation of Indian Chambers of Commerce and Industry ("**FICCI**") expressed that while intention to increase domestic production was laudable, the duty hike at this point would raise costs. FICCI stated that the hike should have been introduced in a phased manner and that it ought to be rolled back.[18] Another concern, raised by the Medical Technology Association of India was that of smuggling, since India's neighbors would have much lower customs duty[19].

As per law, the removal of specific concession does not disable an assessee to avail benefit of general concessions. Some medical device importers were able to avail general concessions and could prevent the end consumer from taking the full burden of the increase in import duty.

In course of 2016, there was no study undertaken and published by the government that could objectively evaluate the policy benefits and of the government's sudden decision. Therefore, it is difficult to comment on the outcome of the decision of the government. What could be said with some certainty, however, is that the medical device importers would have faced inconvenience.

GOVERNMENT RELAXES REQUIREMENTS TO ENABLE DOMESTIC MANUFACTURERS TO PARTICIPATE IN PUBLIC TENDERS

Sometime around August, the Ministry of Health and Family Welfare reportedly issued an advisory to desist from insisting on US FDA approved medical devices in public tenders and accept locally manufactured medical devices[20].

This move is expected to level the playing field for domestic manufacturers and appears to be aimed at lowering the cost of healthcare for the common man. It is certainly a step in the right direction.

However, it undeniable that there are concerns surrounding quality of certain domestically manufactured medical devices for the simple reason that not all medical devices are regulated by the Indian government. Barring a few notified classes, medical devices do not mandatorily have to comply with any strict quality management system. Even the notified classes of medical devices are struggling with quality management system, since the system was originally designed for guaranteeing the quality of drugs. However, having said that, the quality of notified classes of medical devices from safety point cannot, and should not, be doubted.

MEDICAL DEVICES PARKS TO COME UP IN INDIA

In line with the 'Make in India' campaign and the push to get medical device manufacturers to produce locally, the government, particularly the Ministry of Chemicals and Fertilizers, intends to set up medical devices parks in various parts of the country. One such park has already been instituted in Andhra Pradesh at a cost of Rs. 1200 crore[21], with multiple other states such as Maharashtra and Gujarat proposing to follow suit. Originally mooted in 2015, the primary aim of the project is to improve domestic production of medical devices.

Mr. Ananth Kumar, the Minister for Chemicals & Fertilizers, estimates that medical devices parks would bring down indigenous manufacturing costs by close to 30%.[22] In an import-driven industry with high product costs, this could amount to a significant cost reduction for patients.

CONCLUSION

There is no doubt that the medical device industry has the potential to be one of India's biggest success stories. The government focus on the industry was evident in 2016. Amongst other things, the government attempted to delink medical device industry from the 'shackles' of the pharmaceutical industry, incentivized local production by withdrawing import duty concessions and sought to encourage domestic manufacturing by promoting medical device manufacturing parks.

However, from an industry point of view, one cannot help but feel that the government in 2016 sometimes acted in an incoherent manner, by taking two steps ahead and one step back. One hand, some of the crucial and long-awaited legislative changes were codified and finally published. On the other hand, a medical device was brought under price control and certain import duty exemptions were withdrawn hastily without public consultation.

As the industry welcomes 2017 with the hope of notification of the draft Rules and Schedule, publication of new code for promotion and a separate treatment for price control, it is only fair to say that the new-year promises to be both exciting and challenging for the industry!

– Darren Punnen, Anay Shukla & Dr. Milind Antani
You can direct your queries or comments to the authors

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