Pharma & Healthcare Update

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MEDICAL DEVICE WRAP – 2018: LOOKING BACK TO LOOK BEYOND

INTRODUCTION

January 01, 2019 marked the first anniversary of the Medical Device Rules 2017 – India's first step in de-linking medical devices regulations from drugs. 2018 has certainly been an interesting year for medical devices, with a lot of supplementary regulation such as guidance documents and guidelines released in respect of notified medical devices. It also saw the inclusion of an array of additional medical devices into the regulatory framework, which signals the government's intention to revamp regulations in the medical device space.

The Government has also shown a clear inclination to increase India's competitiveness in the global market for medical devices by attracting greater foreign investment and relaxing rules for export. In this yearly wrap, we have attempted to encapsulate the major events in the medical device industry in 2018 and analyze some of these events with the benefit of hindsight. We hope you enjoy reading it.

DEFINITION OF MEDICAL DEVICE IN THE FOREIGN DIRECT INVESTMENT POLICY AMENDED TO ATTRACT FOREIGN INVESTMENT

The Department of Industrial Policy and Promotion ("**DIPP**") - a body under the Ministry of Commerce and Industry entrusted with the role of formulating the Foreign Direct Investment ("**FDI**") Policy - issued a press note on January 23 2018 amending the definition of medical devices under the policy.[1] Under the current FDI policy, the definition of medical devices was subject to amendments to the Drugs and Cosmetics Act, 1940 ("**D&C Act**") – the legislation regulating the manufacture and sale of drugs, cosmetics and medical devices in India. The amendment to the FDI Policy now provides for an independent definition of medical devices, and is no longer subject to amendments to the D&C Act.

The decision to amend the FDI Policy has been taken on a very timely basis in light of the relatively narrow definition under the D&C Act, which defines "Medical Devices" to cover only those notified categories of medical devices (15 currently) that are regulated as drugs under D&C Act. The policy amendment avoids conflicting interpretation of definition of "Medical Devices". The decision restores the status quo whereby a wider range of items may be categorized as medical devices, and a company engaged in its manufacture could attract FDI up to 100% under the automatic route (without prior approval of the government). The items include any instrument, apparatus, appliance, implant, material or other articles, whether used alone or in combination, plus any software tool, intended by its manufacturer to be used specially for human beings or animals for diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder.

ADDITIONAL MEDICAL DEVICES INCLUDED IN THE LIST OF NOTIFIED MEDICAL DEVICES

Four additional medical devices were notified and included within the regulatory framework in 2018. These devices are nebulizer, blood pressure monitoring device, digital thermometer and glucometer (**"New Medical Devices"**).[2] The inclusion of the New Medical Devices will take effect from January 2020.

The Central Drugs Standard Control Organization (**"CDSCO"**) had also proposed to include the following devices in the list of notified medical devices[3]:

1. All implantable medical devices;
2. CT scan equipment
3. MRI equipment
4. Defibrillators
5. Dialysis machine
6. PET equipment
7. X-Ray machine
8. Bone marrow cell separator
9. Surgical gowns and drapes

Save for surgical gowns and drapes, readers may note that the other proposed medical devices were notified in February of this year, and will take effect from April 2020.

Before the inclusion of New Medical Devices in the list of notified medical devices, fifteen medical devices were regulated under the Medical Device Rules 2017. The CDSCO has faced some criticism for regulating relatively low-risk devices such as digital thermometers and surgical gowns while high-risk devices such as pacemakers and defibrillators continue to remain unregulated.[4] Importers, manufacturers and sellers of notified medical devices need to obtain licensing from the CDSCO or the state licensing authority before undertaking those activities. The inclusion of these medical devices would also imply that these devices would fall within the ambit of price control (from the time they take effect). As readers may already know, the prices of drugs (which these devices would be), the prices of which are not fixed (non-scheduled

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formulations under the Drug Prices (Control) Order, 2013), are not permitted to be increased by more than 10% over the preceding 12 months.

PRICES OF CORONARY STENTS REVISED

The National Pharmaceutical Pricing Authority ("**NPPA**"), which monitors and fixes prices for pharmaceuticals and certain medical devices issued an order revising the prices for Bare Metal Stents (**"BMS"**) and Drug Eluting Stents (**"DES"**) revised from INR 7,260 and INR 29,600 to INR 7,660 and INR 27,890 respectively.[5] The revised prices will be applicable to coronary stents up till March 31 2019, unless revised further. The NPPA had imposed the first price ceiling on coronary stents in February 2017.[6] Readers may note that with effect from April 1 2019, the prices of coronary stents have been revised to INR 8,261 (for BMS) and INR 30,080 (for DES), accounting for the Wholesale Price Index.

Since 2017, some manufacturers of coronary stents have applied to the NPPA to withdraw their products from the Indian market as they find it unviable to do business in India.[7] The NPPA was initially reluctant to allow manufacturers to withdraw their products. However, since then the NPPA, in principle, has decided not to disallow applications submitted for withdrawal of coronary stents from the market by stent manufacturers or importers.[8]

Under the DPCO, the prior approval of the NPPA is required before a price controlled product can be withdrawn to avoid sudden shortage of such products. Any manufacturer intending to discontinue production or import of any coronary stents is required to furnish information to the NPPA, in respect of discontinuation of production and/or import at least six months prior to the intended date of discontinuation. However, the manufacturer or importer is under an obligation to follow the ceiling price in such manner and till such time prescribed by the Government. This means that despite the six-month notice, the manufacturer/importer is under an obligation to sell coronary stents until the government permits it to cease sale.

After the first order of the NPPA in February 2017 imposing price control on coronary stents, multiple representations were made to sub-classify coronary stents based on incremental innovations and provide differential pricing based on the sub-classifications. However, the NPPA decided against the representations based on inputs received from an expert committee set up to examine the issue.[9] The expert committee cited lack of sufficient clinical evidence to support superiority of one DES over the others, in deciding against the sub-classification. The NPPA has also mandated that the prices for cardiac catheters, balloon catheters and guide wires – all used during angioplasties – should be listed separately, along with its cost. This may be in order for the NPPA to monitor the prices of these components, as was in the case when the NPPA fixed the prices of knee implant systems in 2017.

GUIDELINES FOR PUBLIC PROCUREMENT OF MEDICAL DEVICES RELEASED

In furtherance of the Indian Government's flagship Make in India program, the Department of Pharmaceutical has published the draft Guidelines for Public procurement of Medical Devices under the Public Procurement (Preference to Make in India) Order (PPO), 2017.[10] The policy gives clear preference to medical devices that are manufactured in India and whose raw materials are substantially manufactured in India. The draft was published inviting comments from the public, and final guideline was released in May 2018[11]. It is expected that all government institutions, including public hospitals, shall procure medical devices as per the guidelines only. In order to be eligible for procurement by the public institution, the guidelines mandate that medical disposables and consumables should have 50% local content; medical electronics, hospital equipment, surgical instruments should have 25% local content; implants should have 40% local content and diagnostic reagents/IVDs should have 25% local content. The guidelines also state that the local content requirements would be increased in a phased manner over the course of three years. Local content will be computed on the basis of the cost of domestic components in the device compared to the total cost of the device.

The guidelines also state that preference will be given to local suppliers in terms of procurement. All local suppliers will be required to furnish a self-certification of use of local content prior to bidding for public contracts.

GOVERNMENT RELAXES RULES FOR EXPORT OF PHARMACEUTICALS AND MEDICAL DEVICES

The Central Drugs Standards Control Organization ("**CDSCO**"), has done away with the requirement to obtain a No Objection Certificate ("**NOC**") at the time of export of pharmaceuticals and medical devices.[12]

Under Indian law, a manufacturer and exporter of an unapproved drug requires a NOC from the CDSCO. However, over time, a practice has evolved at various ports to mandate NOC from CDSCO for export of any drug, medical device or cosmetic.

In 2015, the government had relaxed the requirement of obtaining NOC for shipments of drugs, medical devices and cosmetics which were destined for USA, Canada, Japan, Australia or European Union, and had a valid shipping bill in support of the export.[13] This relaxation has now been extended to all countries, provided the export is supported with a valid shipping bill and is undertaken by the manufacturer itself. It is expected that the manufacturer may also be required to furnish a copy of its valid manufacturing license along with the shipping documents for clearance.

This change in position is expected to benefit the domestic industry tremendously because of its focus on contract manufacturing for foreign customers.

GROUPING GUIDELINES FOR MEDICAL DEVICES

The Ministry of Health and Family Welfare (**"MoHFW"**) has released Grouping Guidelines for Medical Device Applications (**"Grouping Guidelines"**) that allow license applicants to apply for a single license in respect of a group medical devices having the same or similar intended uses.[14]

A single application may be made in respect of a group of medical devices if they fall into one of the six applicable categories for grouping i.e. (i) single (ii) family (iii) in-vitro diagnostics test kit (iv) system (v) in-vitro diagnostics cluster and (vi) group. As an outcome of the Grouping Guidelines, manufacturers of first aid kit containing multiple medical devices such as bandages, gauze, drapes and thermometers can apply for a single license in for manufacturing the first aid kid as opposed to a separate license to manufacture each of the components of the first aid kit. The same also applies to medical devices like glucometer (which will soon be regulated as a notified medical device), test strips, control solutions and linearity solutions that can be licensed as a System as opposed to individual devices.

Manufacturers who wish to sell medical devices licensed as part of a group individually, will need to obtain a separate licenses in respect of that medical device.

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CONCLUSION

With more devices being included in the list of medical devices and new clarifications and guidelines being issued by the regulator on a frequent basis, the industry has a lot to look forward to in 2019. One of the biggest concerns for the medical device industry is the uncertainty around price control. This uncertainty may be resolved over the year, given that the government is looking into revising the pricing framework. Despite some challenges, the medical device industry is poised to offer unprecedented opportunities to both existing and future investors.

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

[1] Press Note by Department of Industrial Policy and Promotion on 'Review of Foreign Direct Investment policy on various sectors, available at: https://dipp.gov.in/sites/default/files/pn1_2018.pdf.

[2] Notification S.O 5980(E) by the Ministry of Health and Family Welfare available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MzE0Mw==.

[3] Public Notice by Central Drugs Standard Control Organization available at: http://www.cdsco.nic.in/writereaddata/2018_06_22_Public%20notice%20for%20commen.pdf (last checked January 28, 2018); Public Notice by Central Drugs Standard Control Organization available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MjE2OA==.

[4] News Article on notified medical devices available at: http://www.pharmabiz.com/NewsDetails.aspx?aid=112754&sid=1.

[5] Order of National Pharmaceutical Pricing Authority available at: http://www.nppaindia.nic.in/order/revised_prices(coronary-stents).pdf.

[6] Order of the National Pharmaceutical Pricing Authority available at: http://nppaindia.nic.in/ceiling/press13Feb2017/so412e-13-02-17.pdf.

[7] Abbott withdraws one more stent from India available at: https://www.thehindubusinessline.com/companies/abbott-withdraws-one-more-stent-from-indian-market/article23681106.ece

[8] Office Memorandum by National Pharmaceutical Pricing Authority available at: http://www.nppaindia.nic.in/order/coronarystent_discontinuation(21022018).pdf.

[9] Minutes of 173rd and 41st meeting of National Pharmaceutical Pricing Authority on February 13, 2017 available at: http://www.nppaindia.nic.in/minutes/minutes-2016-17/minutes-172mt-20-02-17.pdf.

[10] Department of Pharmaceuticals' Notice available at: http://pharmaceuticals.gov.in/sites/default/files/Guidelines%20for%20implementation%20of%20Public%20procurement.pdf (last checked January 28, 2019).

[11] Notification of final guidelines for implementing provisions of PPO in Medical Devices; available at: http://pharmaceuticals.gov.in/sites/default/files/Final%20Guidelines.pdf

[12] Central Drugs Standards Control Organization's Notice available at: http://cdsco.nic.in/writereaddata/order21_3_2018.pdf.

[13] Central Drugs Standards Control Organization's Notice available at: http://www.cdsco.nic.in/writereaddata/notice11-12-2015.pdf.

[14] Grouping Guidelines for Medical Device Applications available at: http://www.cdsco.nic.in/writereaddata/Guidelines%20on%20Grouping%20of%20Medical%20Device%20and%20IVD_1.pdf.