Competition and Regulation in India 2023

Regulatory Deficit in Access to Equitable Healthcare

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CHAPTER 12

Pricing and Availability of Medical Devices

Introduction

The Indian Government has been steadily progressing towards instituting an accessible and affordable healthcare system across the country. The price control of drugs and medical devices has been recognised as a key tool to achieve this objective.

In pursuance of this approach, the recent policy documents including the National Medical Device Policy[1] which was approved by the Cabinet Ministry in April 2023[2] and the Parliamentary Standing Committee Report on the Medical Devices: Regulation & Control[3] identify price regulation of medical devices as an important area of focus and encourages the Government and the medical device industry to collaborate and progress towards a price-conducive ecosystem to cater to the needs of the public.

The price regulation of medical devices in India is dispersed across various laws including sectoral, consumer and general price regulation laws. Therefore, the legal understanding of price regulation of medical devices is derived through various pieces of parallel enactments.

Regulation of Medical Devices

The Drugs and Cosmetics Act, 1940 (D&C Act) is the primary statute that regulates medical devices in India. The Medical Device Rules, 2017 (MDR) issued under the D&C Act provides for the standards, clinical investigation, registration, and licencing of medical devices in India. The Central Drugs Control Standards Organisation (CDSCO) and state licensing authorities overlook the enforcement of the MDR. Under this framework, medical devices which are specifically notified by the Government are governed as 'drugs.'[4]

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Therefore, to regulate devices which are manufactured and imported in India, the Government notified individual devices as 'drugs' from time to time.

Subsequently, given the expanding market for medical devices, the Government recognised the need to regulate all medical devices in India. As a result, on February 11, 2020, the Government notified an expansive definition for 'medical devices' which covers all devices including software, accessories, and components where the intended function is diagnosis, prevention, monitoring, treatment or alleviation of any disease, disorder, injury, or disability.[5]

Effectively all medical devices have been brought under the ambit of the MDR since April 01, 2020. The CDSCO has also assigned risk classification for all devices by way of classification notices issued for various categories of medical devices including respiratory, pain management, ENT, oncology, urology, paediatrics, software as a medical device, nephrology, cardiology etc. Devices which fall within the definition but are not risk-classified by the CDSCO are non-notified devices at present. Typically, manufacturers and importers of such devices obtain a no-objection certificate from the CDSCO.

However, the primary medical device framework – the D&C Act and the MDR – itself does not contain any provisions for price regulation of medical devices. Nonetheless, this framework is integral to understanding the applicability of price regulation to medical devices as only notified and regulated medical devices are subject to the price regulation regime as detailed further below.

Evolution of Medical Device Price Regulation

The price control regime for medical devices runs parallel to the licensing regime. The legal basis for price control of medical devices is derived from the general price control regulation which flows from the Essential Commodities Act, 1955 (EC Act). The EC Act regulates the production, supply and distribution of certain commodities which are declared to be 'essential' to make them available to consumers at fair prices. In pursuance, a list of commodities has been included in the Schedule to the EC Act which are considered essential. One such item is 'drugs' as defined under the D&C Act.[6]

Hence, in the application, all notified medical devices by falling within the ambit of 'drugs' will be considered an 'essential commodity' in India.

The Drugs Price Control Order, 2013 (DPCO) has been issued under the EC Act, to enable the Government to regulate the price of all drugs and notify medical devices. The DPCO is administered by the National Pharmaceutical Pricing Authority (NPPA).

Traditionally, medical devices were excluded from the ambit of price control given that the DPCO was interpreted to apply only to pharmaceutical products by definition of 'drug' being restricted to medicines and pharmaceutical preparations. Subsequently from 1982 onwards when medical devices were first brought within the definition of 'drugs' under the D&C Act, devices which were periodically notified by the Government were subject to DPCO compliances.

Consequently, Disposable Hypodermic Syringes; Disposable Hypodermic Needles; Disposable Perfusion Sets; In Vitro Diagnostic Devices for HIV, HBsAg and HCV; Cardiac Stents; Drug Eluding Stents; Catheters; Intra Ocular Lenses; I.V. Cannulac; Bone Cements; Heart Valves; Scalp Vein Set; Orthopaedic Implants; Internal Prosthetic Replacements etc. came to be price regulated in India. However, on February 11, 2020, when the Government decided to regulate all medical devices and medical equipment by notifying them as 'drugs', it automatically subjected them to the provisions of DPCO.[7]

Hence, the NPPA regulates the price of medical devices through three mechanisms: price caps, price monitoring and trade margin rationalisation. These are discussed in detail below.

Price Regulation Under DPCO

The regulation of prices of devices under the DPCO is two-fold – price control and price monitoring:

Price Control Regime

A schedule to the DPCO contains a list of a few notified medical devices which the government believes are "essential" for the Indian population. The list contained in the Schedule is based upon the NLEMs which is issued by the Government periodically. Currently, the National List of Essential Medicines, 2022 forms Schedule-I to the DPCO. Coronary stents are one such example. Accordingly, the NPPA is empowered to fix the prices of devices listed in Schedule-I to the DPCO (Scheduled Devices).

Hence, ceiling prices are prescribed for Scheduled Devices which manufacturers, importers and distributors are required to comply with in setting the retail prices and determining the profit margins for the supply of the devices to consumers. At present, Intrauterine Devices, Bare Metal Stents, Drug Eluting Stents, and Condoms are regulated as Scheduled Devices.

Price Monitoring Regime

Whereas devices which are not included in Schedule-I to the DPCO are governed as Non-scheduled Devices. Unlike Scheduled Devices, the price is not fixed for Non-scheduled Devices. Nevertheless, such devices continue to be price-regulated and the manufacturers/importers/marketers of these devices are restricted from increasing the price of the device by more than 10 percent over any given preceding 12-month period.[8]

Exemptions for Patented Devices

A five-year exemption (calculated from the date of commencement of commercial marketing in India) from the applicability of DPCO is provided for medical devices which are proposed to be introduced in the Indian market are (i) are either patented under the Indian Patent Act, 1970 (**Patents Act**) or (ii) producing by a new process developed through indigenous research and development (process patent) patented under the Patents Act.[9]

Trade Margin Rationalisation Approach

Distinct from the price control and monitoring regime, the NPPA is also vested with certain discretionary powers to fix the price of drugs in the public interest under DPCO.[10] In such instances, the prescribed methods for price fixation for Scheduled and Non-Scheduled Formulations under the DPCO do not apply. Instead, the NPPA issued special orders about the pricing of the specific medical device which are applicable to its manufacturers and importers.

Typically, the orders issued by the NPPA under this provision prescribe certain ceiling price caps and profit margins i.e., caps on the profit margins of manufacturers/importers and distributors. The application of this provision is also known as the Trade Margin Rationalisation Approach (TMR) since it strikes a balance between the affordability for the patient with profitability for the manufacturers.

In India, as early as 2018, the NITI Aayog had contemplated adopting the TMR approach for devices considering the practice of excessive profiteering in the healthcare industry.[11] In putting forward this proposition, the NITI Aayog proposed a stringent approach whereby the trade margin was to be calculated as the difference between the price to patients (i.e., the maximum retail price) and the price at which the manufacturers sell the drugs/devices to distributors.

At a global level, the World Health Organisation (WHO) introduced the Guidelines on Country Pharmaceutical Pricing Policies, in 2020[12] to provide for a set of recommendations on how countries can approach price control. Broadly, inclining towards the TMR approach, the WHO has made pricing recommendations including regulation of mark-ups in the pharmaceutical

supply and distribution chain; use of internal reference pricing between similar drugs available within the territory of the country; application of cost-plus pricing formulae for pharmaceutical price-setting; use of external reference pricing; and promotion of use of generic medicines.

In addition to the DPCO price control and price monitoring regulations, the TMR approach has subsisted parallelly over the years with the NPPA imposing margin caps on several medical devices including knee implants[13]; pulse oximeters; blood pressure monitoring machines; nebulisers; digital thermometers; and glucometer.[14]

Impact of Price Regulation on Medical Devices

Price regulation of medical devices has a direct impact on the supply and availability of the devices in the market and the compliances required to be undertaken by the importers, manufacturers, marketers, and distributors of devices. Some of these have been discussed below in brief.

Price Fixation and Variations

In fixing prices of devices, the importers, manufacturers and marketers should adequately recognise if the medical device is scheduled, non-scheduled, or regulated by way of TMR. Accordingly, prices of medical devices for which ceiling prices have been prescribed by the NPPA (specifically Scheduled Devices and devices which are notified by TMR notifications) should be made available in the market in compliance with the prices fixed.

Scheduled Devices: The manufacturers, importers and marketers of Scheduled Devices should comply with the ceiling price caps notified by the NPPA from time to time.

Non-Scheduled Devices: There are no specific price caps, however, there is a restriction on increasing the price of Non-Scheduled Medical Devices by more than 10% over any given preceding 12-month period.

Devices Subject To TMR: If the NPPA deems a medical device to be necessary for public health or essential, the NPPA may notify ceiling pricing or profit margins for such devices therefore, requiring the manufacturers, importers, and marketers to ensure that the device is available at the notified price in the market. To implement the TMR approach and set price caps, the NPPA may seek pricing information from the manufacturers, importers, and marketers of all medical devices from time to time.

Further, in terms of undertaking price variations, all importers, manufacturers and marketers of medical devices will have to be cognisant of variations of the MRP declared on the label of their medical devices. The MRP of the product

should not be varied by more than 10 percent in any 12-months period, the variation of more than 10 percent will be recovered as 'overcharging' from the business concerned.

Ongoing Compliances

The DPCO requires that regulated medical devices and medical equipment must be labelled with their maximum retail price that is to be set by the importer/manufacturer/marketer. The said price must be prefixed by the words "Maximum Retail Price" and suffixed by the words "inclusive of all taxes." Further, all importers, manufacturers and marketers of medical devices and medical equipment will have to submit prices to distributors/stock lists, prices to retailers/hospitals and retail sale prices in the format prescribed in DPCO and undertake periodic filings with the NPPA.

Penalties

Any violation of DPCO is serious because its parent legislation, the EC Act stipulates that any breach of DPCO may result in imprisonment and fine for the company and person(s) in charge of the company for the conduct of its business. However, undoubtedly, the most draconian provision of DPCO is the liability to deposit any amount 'overcharged' by the importer or manufacturer in breach of DPCO in addition to the interest and penalty.

Conclusion and the Way Forward

While parallel developments under the D&C Act and MDR are coherent in terms of how medical device regulations are shaping in India, price regulation of devices continues to be a regulatory conundrum. While the efforts taken by the NPPA with respect to the adoption of TMR and inclusion of certain medical devices in the DPCO Schedule signify the clear intent to price monitor, there are pitfalls from an implementation and compliance perspective. Nevertheless, price regulation of medical devices in India is at a budding phase and it remains to be seen how the Government and the industry arrive at a robust mechanism.

Based on the recently approved Medical Device Policy, 2023, the focus of the Government is to promote innovation in the medical device industry through the establishment of academic and research institutions, innovation hubs and the creation of skilled domestic human resources. The Policy also envisages the creation of a coherent pricing regulation for medical devices to make available quality and effective medical devices to all citizens at affordable prices and at the same time balance the needs of the industry.

As can be seen from the previous sections, price regulation of medical devices in India is at a nascent stage and the jurisprudence currently evolving. While there is no specific guidance on law regarding the pricing of medical devices,

the DPCO continues to apply to all regulated medical devices in the same manner as it does to pharmaceutical products. While it is appreciated that all devices are price-regulated and that the NPPA has also made special efforts to adopt the TMR approach under extraordinary circumstances, there are certain nuances for the medical device industry which need to be considered. Some of the key considerations here are as follows:

Regulation of Non-Notified Devices

As discussed above, although a broad definition has been notified to cover all medical devices, devices which are yet to be assigned a risk classification by the CDSCO are non-notified at present. Consequently, while the MDR-related compliances (licensing requirements) should not be applicable, there is no clarity on whether the DPCO would be applicable given that such devices will still fall within the ambit of 'drugs' for the D&C Act read with the EC Act. Given that the consequence of non-compliance with the DPCO is high, further clarity is anticipated on these aspects.

Risk in Price-Capping for Scheduled Devices

Medical device life cycles are fundamentally different from that of pharmaceutical products. Typically, medical devices involve several components each of which could be regulated as a distinct medical device. For instance, standalone software embedded in a medical device could be an independent device as well form a component of another medical device.

Therefore, in such instances if the final product is regulated as a Scheduled Device and the component device continues to be non-scheduled, issues with respect to pricing and profitability may arise since the cost of the component medical device itself may be significantly higher than the ceiling price of the Scheduled Medical Device. In such instances, manufacturers, importers, and distributors of Scheduled Medical Devices would be awry of entering the Indian market due to low profitability.

Specific Considerations for the Trade Margin Rationalisation Approach

While TMR is generally favoured, there are divergent views on its adoption. Some medical device companies believe that the point of first sale for importers should be the point where the medical device is sold to the first hand i.e., the distributor. Whereas, a contrary approach is to cap the profits basis the difference in price to the consumer and the price of manufacturing/import of the device.

Further, there are several procedural and conceptual ambiguities in the application of the TMR approach currently given that there is no transparency and intelligibility on what datasets the NPPA used to compute margins, how

this information is verified and other considerations have been considered for determining 'public interest' to reach the trade margins.

Separately, it may be noted that the Competition Commission India in its Market Study on the Pharmaceutical Sector in India[15] noted the challenges of applying the TMR approach to all products. Notably, one such challenge which was recorded was that since TMR is applied on a case-to-case basis, healthcare professionals may be inclined towards prescribing products which are not price-regulated through the TMR approach. Therefore, in the adoption of TMR availability of alternate therapies will need to be examined as well.

Endnotes

1 Approach Paper on Draft National Medical Device Policy, 2022, accessible at: https://pharmaceuticals.gov.in/sites/default/files/Public%20Notice%20and%20Approch%20paper%20on%20draft%20NMDP%202022.pdf (last accessed on December 22, 2022).

2 Ministry of Chemicals and Fertilizers Press Release dated April 26, 2023, accessible at: https://pib.gov.in/PressReleaseIframePage.aspx?PRID=1919984

3 Hundred Thirty Eighth Report On "Medical Devices: Regulation & Control" Pertaining to Department of Health & Family Welfare presented by the Department-Related Parliamentary Standing Committee on Health And Family Welfare One, accessible at: https://rajyasabha.nic.in/rsnew/Committee_site/Committee_File/ReportFile/14/160/138_2022_9_17.pdf (last accessed on December 22, 2022).

4 Section 3(b) of the Drugs and Cosmetics Act, 1940 defines 'drug' to include "devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette."

5 Ministry of Health and Family Welfare Notification S.O. 648(E) dated February 11, 2022, accessible at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTU0OA== (last accessed on December 2, 2022) defines 'medical device' as "all devices including an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may assist in its intended function by such means for one or more of the specific purposes of –
   (i) diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;
   (ii) diagnosis, monitoring, treatment, alleviation, or assistance for, any injury or disability;
   (iii) investigation, replacement or modification or support of the anatomy or of a physiological process;
   (iv) supporting or sustaining life;

(v) disinfection of medical devices; and
(vi) control of conception."

[6] Drugs have been classified as 'essential commodities' under Entry 1, Schedule, EC Act.

[7] National Pharmaceutical Pricing Authority, Ministry of Chemicals and Fertilizers, Order dated March 31, 2020, accessible at: https://www.nppaindia.nic.in/wp-content/uploads/2020/04/Order-dt.01.04.2020-for-govt-Mediacl-Devices-under-DPCO-2013.pdf

[8] Paragraph 20, DPCO.

[9] Paragraph 32, DPCO.

[10] Paragraph 19, DPCO.

[11] NITI Aayog, Rationalization of Trade Margins in Medical Devices - A Consultation Paper, (June 08, 2018).

[12] World Health Organisation Guidelines on Country Pharmaceutical Pricing Policies, 2020, https://www.who.int/publications/i/item/9789240011878 (last accessed on December 22, 2022).

[13] Notification dated August 17, 2017, National Pharmaceuticals Pricing Authority, http://www.nppaindia.nic.in/wp-content/uploads/2018/08/NPPA-has-fixed-Ceiling-prices-of-orthopedic-implants-knee-replacements-under-para-19-of-Drugs-prices-control-order-DPCO-2013-1.pdf (last accessed on December 22, 2022).

[14] Notification dated July 13, 2021, National Pharmaceuticals Pricing Authority, https://www.nppaindia.nic.in/wp-content/uploads/2021/07/Notification-TMR-5-Medical-Devices.pdf (last accessed on December 22, 2022).

[15] Competition Commission India Market Study on the Pharmaceutical Sector in India, available at: https://www.cci.gov.in/images/marketstudie/en/market-study-on-the-pharmaceutical-sector-in-india1652267460.pdf (last accessed on December 22, 2022).