Pharma & Healthcare Update

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KNEE IMPLANTS GO UNDER SCAPEL OF PRICE CONTROL IN INDIA

- Prices of Knee Implants sold in India have been capped effective immediately
- Trade margins have also been capped
- Price ceiling is applicable to entire stock currently in market as well as in warehouses
- Importers and manufacturers to submit revised price list to government and circulate revised price list immediately to the trade channel to comply with Notification
- Notification suffers from legal shortcomings

After the recent move to fix the price of the coronary stents, the Indian government has imposed a price ceiling on knee replacement systems ("**Knee Implants**") for a period of one year by way of a notification dated August 17, 2017 ("**Notification**"). The price ceiling has been made effective immediately.

The highlights of the Notification are as follows:

- The Notification has categorized Knee Implants into two major categories: Primary Knee Replacement Systems and Revision Knee Replacement Systems.
- In each category, there are four sub-categories: Femoral Component, Tibial Component or Tibial Tray, Articulating Surface or Insert and Patella.
- Under four sub-categories, there are super-sub-categories distinguishable on the basis of feature/material such as titanium alloy, oxidized zirconium, Hi-flex, cobalt chromium, polyethene *etc*.
- The ceiling prices have been prescribed for aforementioned super-sub-categories.
- Ceiling prices are inclusive of all components and consumables, which are used in the knee implant procedure and remain in the body of the patient.
- The details of the price ceiling of various Knee Implants are reproduced at the end of this update. Ceiling prices are inclusive of trade margins.
- Maximum trade margin for distributors and hospitals also been specified and it ranges between 4% - 16% depending on the category of Knee Implants.
- The importers and manufactures who sell Knee Implant directly to the orthopedic healthcare institutions such as hospitals/nursing homes/clinics, without involvement of any distributor, are permitted to offer maximum of 16% margin to such institutions.

Importers and manufacturers may add goods and services tax in the calculation of MRP, if they have actually paid such taxes or if it is payable to the Government on the ceiling price. In the paragraphs below, we have analyzed the impact and legality of the Notification. We have also suggested steps required to be taken immediately by importers and manufacturers of Knee Implants to comply with the Notification.

BACKGROUND

The Indian government regulates prices of essential commodities through a legislation called The Essential Commodities Act, 1955 ("**EC Act**"). Drugs are categorized as essential commodities and all formulations (i.e. medicines) and certain regulated medical devices are regulated as "drugs". The Drugs (Prices Control) Order, 2013 ("**DPCO**") has been issued under the EC Act to regulate prices of all formulations and regulated medical devices. The DPCO contains a schedule that has a list of formulations and certain regulated medical devices which are identified by the Ministry of Health as essential to the nation. These formulations and medical devices are called "Scheduled Formulations". All other formulations and regulated medical devices are called "Non-Scheduled Formulations".

The government is required to fix ceiling prices of Scheduled Formulations. Ceiling price means the price above which any sale of drug to end consumer (usually the patient or his/her representative) would be illegal. The Government does not fix ceiling price of the Non-Scheduled Formulations but instead regulates their prices in a way that no manufacturer or importer can increase its price by more than 10% in a twelve month period.

The government also has a residual power in Paragraph 19 of DPCO to fix prices of any formulation or regulated medical device if there are "extraordinary circumstances" which necessitate doing so in public interest. This provision as such appears to provide wider power to government.

For fixing the price of Knee Implants, the government has used its residual power in Paragraph 19 of DPCO. It has justified presence of extraordinary circumstances by stating the following in the Notification:

- *It is noticed that orthopedic-knee implants are having unjustified, unreasonable and irrational high trade margins*

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leading to their exorbitant prices which affects the out of pocket expenses of patients and lakhs (i.e. hundreds of thousands) *of patients are not able to pay for arthroplasty procedures because of these exorbitant prices and suffering in pain;*

- *The estimates of such patients requiring arthroplasty intervention, both diagnosed and undiagnosed, is about 1.5 to 2 crores* (i.e. 15 million to 20 million) *out of which only about 1 lakh* (i.e. 100,00) *plus well off patients are in a position to pay for it every year;*
- *'osteoarthritis is likely to become fourth leading cause of disability by year 2020' as per the W.H.O Bulletin,2003 ,81,(9);*
- *India is likely to be one of the leading countries of such immobilized citizens in terms of numbers; and*
- *Preventing such a scenario is essential in individual as well as national interest.*

IMPACT

The Notification has taken everyone in industry by surprise, especially because Knee Implants are not Scheduled Formulations. When a formulation or regulated medical device is not a Scheduled Formulation, it implies that the Health Ministry itself does not find it essential for the nation. In fact, the 'National List of Essential Medicines' ("**NLEM**") was comprehensively revised as recent as in November 2015 by the Health Ministry, and Knee Implants did not find a mention in it. Therefore, it is difficult to understand what prompted the government to take such a drastic step of fixing ceiling price of Knee Implants with immediate effect and thereby treating them on par with Scheduled Formulations.

The Notification is likely to adversely affect all importers of Knee Implants because the government has significantly reduced the trade margins for the importers as well as the distributors and hospitals. For instance, as per the calculations published by The National Pharmaceutical Pricing Authority ("**NPPA**"), the price of the most expensive femoral component available in Indian market prior to Notification was INR 169, 123. After the Notification, all femoral component will have to be priced in the range of INR 28,090 – INR 38,740 depending upon their categorization. Similarly, prior to the date of the Notification, the price of the most expensive tibial component in the market was INR 122,336. After the Notification, all tibial component will have to be priced in the range of INR 16,990 – INR 24,280 depending upon their categorization.

ANALYSIS

As described earlier, the Notification has been issued using the residual power given to the NPPA to fix ceiling prices of any formulation or regulated medical device. Power under Para 19 is supposed to be exercised in extra-ordinary circumstances and when doing so is necessary and in public interest.

Whether extraordinary circumstances and public interest tests have been satisfied

The claim of NPPA that *"patients requiring arthroplasty intervention, both diagnosed and undiagnosed, is about 1.5 to 2 crores* (i.e. 15 million to 20 million) *out of which only about 1 lakh* (i.e. 100,00) *plus well off patients are in a position to pay for it every year"* does not appear to be supported by any study. From a review of the record of discussions of the authority on ceiling price fixation of knee implants dated August 14, 2017 published by NPPA ("**Record**"), it appears that the assertion of NPPA regarding number of Indians who require arthroplasty intervention (15 million to 20 million) is unsupported. The only study mentioned in the Record that could be thought of giving support to this assertion is a WHO publication which states that 9.61% men and 18% of women above the age of 60 globally may be suffering from Osteoarthritis. However, it is difficult to understand how the result of the aforesaid publication could be extrapolated to reach the estimate provided by NPPA generally i.e. for all age groups of Indian population. Further, and more importantly, there is no co-relation between the number of people who have chosen not to undertake knee implants surgeries despite suffering from osteoarthritis and the role of their position to pay in making of this choice. It is a known fact that knee implant surgery is not the only treatment available for osteoarthritis and a lot of Indians resort to drug-based treatment or alternative system of medicine (ayurveda, homeopathy, yoga *etc.*) for treatment. Hence, it is difficult to accept that "extra-ordinary circumstances" existed that required intervention of NPPA and that its decision to fix ceiling prices of Knee Implants was actually in "public interest".

Moreover, a close reading of Paragraph 19 also indicates that the NPPA is bound to fix ceiling for a specified period only. In the case of knee implants, the price ceiling has been fixed for a period of one year. The statutory requirement of fixing ceiling price for a specified period and not permanently implies that the power of Paragraph 19 has to be exercised in circumstances that are time-bound. In other words, the extra-ordinary circumstances should be interpreted to cover only those circumstance that require intervention for a limited period of time. Generally speaking, the disease prevalence of osteoarthritis or the cost of the Knee Implants does not appear to have undergone a dramatic change from 2013 (when the DPCO was introduced) to reach a conclusion that "extra-ordinary" circumstances have arisen in which time-bound intervention would change the circumstances back to "ordinary". Not much is expected to change in a period of one year when the Notification would cease to apply, unless its application is further extended by the government. Therefore, it begs the question whether "extra-ordinary circumstance" as envisaged by Paragraph 19 of DPCO had arisen in the first place that warranted action by NPPA.

The NPPA seems to have derived the necessary confidence from the division bench judgment of Bombay High Court in *Indian Pharmaceutical Alliance and Anr. v. Union of India and Ors.* (WP 2700/2014) delivered last year because it has cited the case in the Notification. In this case, the Hon'ble High Court had upheld the decision of NPPA to cap prices of certain life-saving drugs with a permissible 25% inter-brand variation *i.e.* the price of the costliest brand and cheapest brand of the same medicine could not vary by more than 25% of its retail price. However, the facts and circumstances of that case do not apply to Knee Implants. First of all, the case pertained mostly to life-saving drugs. Knee Implants are not life-saving medical devices. And more importantly, in that case, the NPPA had stuck to the procedure prescribed in the DPCO and fixed ceiling price as per the procedure laid down in DPCO. The NPPA had not fixed trade margins for the medicines in question like in the case Knee Implant. In fact, in the judgment, the Hon'ble High Court itself has stated "*It is not as if in individual cases these powers cannot be questioned.*"

Whether the method for determination of ceiling price is in line with the applicable policy and provisions

The DPCO was published in furtherance of The National Pharmaceutical Pricing Policy of 2012 ("**NPPP**"). The NPPP

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lays down the policy framework for price fixation of drugs. It states that "*The regulation of prices of drugs in the National Pharmaceuticals Pricing Policy 2012 would be on the basis of regulating the prices of formulations through Market Based Pricing (MBP). This is different from the earlier principle of regulating the prices through Cost Based Pricing (CBP) under the Drug Policy 1994.*" Under the cost based pricing system, the NPPA used to determine the cost of manufacturing or landed price of the imported drugs and fixed profit margins for each level of distribution starting from the manufacturer. In light of NPPP, the DPCO now employs a formula based on market price rather than the cost based pricing system.

Paragraph 19 read with definitions of ceiling price[1] and retail price[2] would reveal that government is bound to follow other provisions of DPCO for fixing ceiling price under Paragraph 19. For instance, ceiling price itself is defined as the price that is fixed "in accordance with the provisions of" DPCO. As mentioned above, the provisions of DPCO prescribe a market based pricing formula to fix ceiling prices that basically averages the price to retailer (i.e. price at which a company or its distributors sell a drug to retailer) by the number of manufacturers and importers in the market whose sale exceed a certain minimum threshold. Since the DPCO does not employ a cost-based pricing system, the provisions of DPCO do not envisage fixation of trade margins of the manufacturer, importer and the trade channel.

However, in contrast, through the Notification for Knee Implants, the NPPA has done exactly what it did not have the power to do - It has fixed margins for the trade channel and (indirectly) fixed trade margin for the manufacturers and importers. In fact the Record states at one point that:

"Based on the data analysis there was no doubt that the market based pricing system has failed to address the disproportionately high trade margins and profiteering at the cost of the patients and knee implants…"

And while justifying the decision to move away from the methodology of price fixations specified under DPCO, the Record states that:

"It was an accepted principle of price fixation of imported drugs under DPCO 1995, where a maximum 50% over import price was stipulated as a fair ceiling price"

Therefore, it is arguable that the Notification suffers from "over-reach" of powers and is bad in law, and therefore liable to be struck down as void. The support for this argument can be taken from the decision of the Supreme Court in *Secretary, Ministry of Chemicals & Fertilizers Government of India* v *Cipla. Ltd and others* (AIR 2003 SC 3078), where it was observed that:

"Where the Central Government as the delegate of legislative power announces a rational policy in keeping with the purposes of enabling legislation and even lays down specific criteria to promote the policy, the criteria so evolved become the guide-posts of its legislative action. While classifying the drugs for the purpose of price control, it is not open to the Government to flout or debilitate the set norms which it professed to follow in the interest of transparency and objectivity. Otherwise, there will be an element of arbitrariness and the delegated legislation will not withstand the test of Article 14."

Other shortcomings

The Notification has other shortcomings as well. It does not appear that NPPA has applied its mind appropriately. For instance, while evaluating the landed price of imported Knee Implants, NPPA has stated that "*Landed price or import price includes … overheads of the Indian office and its margin as well*". Such a statement is factually incorrect. The concept of landed price is fundamental to the final ceiling price, because in order to arrive at the ceiling price, NPPA has only averaged the landed price and added margins to it which would be sufficient for the industry in the purely subjective assessment of NPPA. If NPPA has got the concept of landed price wrong, then it is doubtful whether the ceiling price arrived at on the basis of landed cost is appropriate or not. It is established in law that when an act of the government suffers from non-application of mind, it does not meet the non-arbitrariness threshold required of all government action under the Indian Constitution and such action is liable to struck down as illegal by virtue of Article 14 of the Constitution

NEXT STEPS

Since the Notification is effective immediately, all importers and manufacturers must ensure that their Knee Implants are not sold above the ceiling price after August 16, 2017. Should that happen, the government may recover the difference in the sale price and ceiling price from the manufacturer or importer on the grounds of "overcharging".

In order to ensure that the Notification is complied with, the importers and manufacturers of Knee Implants should immediately issue price list in Form – V as prescribed in Schedule II of the DPCO to the NPPA both online through Integrated Pharmaceutical Database Management System (IPDMS) and physically. A copy of the price list issued in Form -- V should also be sent immediately to all State-level Drug Licensing Authorities as well as to its distributors/dealers/orthopedic healthcare institutions so that existing stock is not sold at a price higher than the ceiling price. It is not mandatory to re-label or re-sticker existing stocks with the ceiling price. All new stock should be released to market with the revised price on its label.

CONCLUSION

The sudden imposition of price fixation on Knee Implants has not only taken the Knee Implant industry by surprise but has shaken the entire medical device industry. The Notification has been issued without any prior intimation. One wonders what will happen next, especially since the Medical Device Rules, 2017 will make all medical devices to fall within the ambit of DPCO from January 1, 2018 and become subject to the government's residuary power to fix ceiling prices. The language of the provision that gives residual power to the government is broad enough to allow the government to fix ceiling price of any medical device.

It is interesting that simultaneous with the issuance of the Notification, the news reports suggest that there is a new Pharmaceutical Policy in the making which would seek to regulate trade margins specifically, something the current one (i.e. NPPP) does not envisage at all.[3] Other news also hint at curbing of the NPPA's powers or scrapping of the NPPA as whole.[4] All of this points towards a possible shift in the regulatory framework surrounding pharmaceuticals and medical devices in the country. It is the need of the hour that the medical device industry takes collective action to engage with the government and jointly arrive at a policy that is certain, fair and transparent for all the

stakeholders.

TABLE

Sl. No.	Orthopedic knee Implant system	Component	Feature/Material of the knee implant	Units (In No.)	Ceiling Price (In Rs.)	Ceiling price (Approx. Dollars)	Trade margins for Stockist/ distributors	Trade margins for Hospitals/ clinics/ nursing homes
	PRIMARY							
1.	Primary knee replacement system	Femoral component by whatsoever name/specification	Titanium alloy (all variants) coated	1	38,740	603.80	12	4
2.	Primary knee replacement system	Femoral component by whatsoever name/specification	Oxidized zirconium (OxZr) alloy (all variants)	1	38,740	603.80	12	4
3	Primary knee replacement system	Femoral component by whatsoever name/specification	Hi-flex	1	25,100%	403.05	12	4
4	Primary Knee replacement system	Femoral component by whatsoever name/specification	Cobalt chromium (CoCr) alloy (all variants)& other than at serial no 1,2 and 3	1	24,090	375.47	16	8
5	Primary knee replacement system	Tibial component or Tibial tray by whatsoever name/specification	Titanium alloy (& it's all variants) coated	1	24,280	378.43	12	4
6	Primary knee replacement system	Tibial component or Tibial tray by whatsoever name/specification	Oxidized zirconium (OxZr) alloy	1	24,280	378.43	12	4
7	Primary knee replacement system	Tibial component or Tibial tray by whatsoever name/specification	Cobalt chromium (CoCr) alloy & other than at Serial no 5 and 6	1	16,990	264.81	16	8
8	Primary knee replacement system	Articulating surface or Insert by whatsoever name/specification	Any Material	1	9,550	148.85	16	8
9	Primary knee replacement system	Patella by whatsoever name/specification	Any Material	1	4,090	63.75	16	8
10	Primary knee replacement system	Component having Tibial tray and Insert combined as single unit by whatsoever name/specification	Polyethylene or crosslinked polyethylene or highly crosslinked polyethylene or any other material	1	12,960	202.00	16	8
11	Primary knee replacement system	Components having Tibial Tray and Insert combined as single unit by whatsoever name called	Tibial: Metallic Insert: Polyethylene or Cross- linked polyethylene or highly cross-linked Polyethylene or any other material	1	26,546	413.75	16	8
	REVISION							
12	Revision Knee Replacement system	Femoral Component by whatsoever name/specification	Any material	1	62,770	978.34	12	4
13	Revision Knee Replacement system	Tibial component or Tibial Tray by whatsoever name/specification	Any material	1	31,220	486.60	12	4
14	Revision Knee Replacement system	Articulating surface or Insert by whatsoever	Any material	1	15,870	247.35	12	4

		name/specification						
15	Revision Knee Replacement system	Patella by whatsoever name/specification	Any material	1	4,090	63.75	12	4

NOTE:

1. Special orthopedic implants for cancer/tumor will follow the rates of Revision Knee replacement, however if the import prices are higher than the ceiling price of such implants, importers may add a total margin of maximum 30% over the import price of the first batch of such implant launched in India as the ceiling price for 45 days from the issue of the Notification and apply to NPPA for a retail price notification at the earliest. The maximum trade margin permissible for distributor/stockist and hospitals/nursing homes/clinics is 16 percent and 8 percent of computed ceiling price respectively.

– Anay Shukla, Dr. Milind Antani, Gowree Gokhale & Niranjan Sudhir
You can direct your queries or comments to the authors

[1] Para. 2.(d): *Ceiling Price means a price fixed by the Government for Scheduled formulations in accordance with the provisions of this Order.*

[2] Para. 2.(z): *Retail price means the price fixed by the Government for a new drug under paragraph 5.*

[3] http://timesofindia.indiatimes.com/business/india-business/draft-pharma-policy-calls-for-trade-margins-cap/articleshow/60119520.cms (last accessed August 22, 2017).

[4] http://timesofindia.indiatimes.com/india/did-government-mislead-delhi-high-court-on-move-to-scrap-drug-body/articleshow/56978091.cms as last seen on August 22, 2017 (last accessed August 22, 2017).