Pharma & Healthcare Update

June 06, 2023

NEW JOLT FOR THE INDUSTRY: PRICES OF DRUGS AND DEVICES LOSING PATENT PROTECTION TO BE REDUCED BY 50%

The Drugs Price Control Order, 2013 ("**DPCO**")- the primary drugs and medical devices price regulation has been amended on May 11, 2023[1] ("**DPCO Amendment**") to include a new formula for the calculation of price of drugs and devices going off-patent. The ceiling price of patented drugs and devices will have to be reduced by 50% on expiry of the patent.

Over the last few years, the NPPA had informally adopted the 50% reduction approach while deliberating the pricing of off-patent Fixed Dose Combinations ("**FDC(s)**"). The DPCO Amendment streamlines the process of calculating the price of all patented drugs on expiry of patent protection, as opposed to the current practice where the NPPA has adopted the method on a case to case basis.

The DPCO Amendment reiterates the Government's intention to regulate pricing of patented drugs. The current National List of Essential Medicines ("**NLEM**") 2022, includes several patented drugs and are therefore, required to comply with the ceiling price caps which are fixed by the National Pharmaceutical Pricing Authority ("**NPPA**").

The DPCO Amendment comes as jolt to multinational pharma companies charging high prices for patented and innovative formulas even after the expiry of the patent. Therefore, despite the loss of monopoly of the manufacturer/importer, the affordability and accessibility of such drugs did not improve.

This update discusses the applicability, provisions and implication of the DPCO Amendment.

Applicability of the DPCO Amendment

The DPCO Amendment applies to patented drugs and devices which are included in Schedule I of the DPCO. For background Schedule I to the DPCO is based on the NLEM and the drugs and devices listed in the Schedule are subject to price control and therefore "Scheduled Formulations/Devices."

What does the DPCO Amendment do?

The DPCO Amendment inserts new provisions for determination of price of Scheduled Formulations/Devices which will go out of patent protection :

1. *New Formula for Determining the Price of Off-Patent Drug*

On expiry of the patent[2], the retail price of the "new drug"[3] which is a Scheduled Formulation/Device shall be revised to 50% of the current ceiling price.

The current ceiling price is calculated and notified by the NPPA as per Paragraph 4(1) of DPCO- the simple average of price to retailer (PTR) in respect of all branded-generic and generic versions of that particular Scheduled Formulation Device having a market share of 1% and above, and then adding a retailer margin of 16 %. The ceiling prices are notified by the NPPA annually.

2. *Revision of Price of the Off-Patent Drug After One Year*

After one year, the ceiling price of scheduled formulation will be revised again based on market data. The timeline for one year is calculated basis the (i) date on which the retail price was fixed as per item or (ii) the date on which "price to retailer" of at least one company fixed per item and captured in the pharmaceutical market database whichever is later.

Why was the DPCO Amendment introduced?

The current mechanism for fixing the price of new drugs available in the market (in the absence of a specific formula for off-patent drugs) is basis the six-months' prior market data. Consequently, there is no substantial reduction in the price of the drug even after the expiry of the patent. In noting that the benefit of price reduction would not be passed on to the consumer, the NPPA has been contemplating new methods of price fixation of Schedule Drugs/Devices going off-patent.

The 33rd meeting of the Multidisciplinary Committee of Experts[4] held in 2021 was one of the first times the Committee

Research Papers

Evolution of Generative AI
July 11, 2024

From Capital to Impact: Role of Blended Finance
June 15, 2024

Opportunities in GIFT City
June 14, 2024

Research Articles

Private Client Insights - Sustainable Success: How Family Constitutions can Shape Corporate Governance, Business Succession and Familial Legacy
January 25, 2024

Private Equity and M&A in India: What to Expect in 2024?
January 23, 2024

Emerging Legal Issues with use of Generative AI
October 27, 2023

Audio

Pursuing Remedies against Non-signatories in Investment Agreements
July 03, 2024

Why is the ad industry unhappy with MIB's self-declaration mandate?
June 18, 2024

Incorporation of arbitral clause by reference: Position in India and other Asian Jurisdictions
June 12, 2024

NDA Connect

Connect with us at events, conferences and seminars.

NDA Hotline

Click here to view Hotline archives.

Video

Self Declaration Certificate For Ads: Decoding The Complexities Of Ad Regulations

suggested an alternative approach to the calculation of the price for off-patent Scheduled Drugs/Devices. In determining the price of FDC containing a patented component, the Committee noted that if the price is calculated based on the six month prior market data, the price of the patented period would be taken into consideration and hence the benefits of price rationalization due to expiry of patent will not be realized. Therefore, the Committee recommended that a reduction of 50% be allowed on the patented component to arrive at the final price. Subsequently in the 89th NPPA meeting[5] the recommendation was accepted and the ceiling price list was issued.

There has been no specific rationale to the application of the 50% reduction method, however, in the 40th meeting of the Multidisciplinary Committee of Experts[6] the Committee deliberated on the issue of calculation of price of a FDC with a patented component. It was noted that if the calculation of retail price of the drug based on six- month prior data is lower than the claimed price and the calculated price, the same should be allowed.

With the passage of the DPCO Amendment now, it appears that the 50% reduction rule will be applicable universally.

Implication of the DPCO Amendment

Prior to 2022, there were no patented drug formulations and devices included in Schedule I of the DPCO. Primarily, only manufacturers[7] of FDC which were patented and contained a Scheduled Drug component would approach the NPPA to determine the price of the drug at the time of losing patent protection in India.

However, in a first, the NLEM 2022 includes specific patented drugs including anti-TB and anti-HIV drugs. Hence, the Government has clarified the methodology for the calculation of the price at the time of expiry of the patent for the said Scheduled Formulations. Further, the DPCO Amendment creates an universal approach to the price regulation of such drugs as opposed to the current practice where the NPPA determines the price on a case to case basis.

Seperately, it may also be noted that the DPCO provides a five-year exemption for patented drugs and devices.[8] On the expiry of five years, if the product is a Scheduled Formulation/Device, it is subject to the ceiling price limits notified by the NPPA. However, subsequent to the expiry of the patent, the calculation as per the DPCO Amendment will take effect for the calculation of the ceiling price for the first year.

Further, it may also be noted that the NPPA is vested with discretionary powers to fix the price of drugs in public interest.[9] This provision allows the NPPA to determine the ceiling price or profit margins for specific drugs and medical devices at any given point in time, irrespective of whether ceiling prices were previously notified. This provision may be invoked over and above the price reductions as per the new price calculation method for off-patent drugs if the NPPA identifies the necessity to increase the affordability and accessibility of a specific drug/device.

– Varsha Rajesh, Eshika Phadke, Darren Punnen & Dr. Milind Antani

You can direct your queries or comments to the authors

[1]DPCO Amendment dated May 11, 2023, accessible here: https://eg azette.nic .in/Write ReadData/ 2023/ 245 818.pdf

[2]Patent protection is granted for 20 years under the Indian Patent Act, 1970.

[3]The DPCO defines a 'new drug' as " formulation launched by an existing manufacturer of a drug of specified dosages and strengths as listed in the National List of Essential Medicines by combining the drug with another drug either listed or not listed in the National List of Essential Medicines or a formulation launched by changing the strength or dosages or both of the same drug of specified dosages and strengths as listed in the National List of Essential Medicines."

[4]Accessible here: https://www.npp aindia.nic.in /wp-content/ uploads/20 21/06/33rd- MDC-Meeting- Minutes.pdf (last accessed on June 1, 2023).

[5]Accessible here: https://www.nppain dia.nic.in/wp-co ntent/uploads/ 2021/07/89th -Meeti ng_M inutes_u pload.pdf (last accessed on June 1, 2023).

[6]Accessible here: https://www.nppaindia .nic.in/wp-cont ent/uploads/2 022/03/40th -MDC-Minu tes.pdf (last accessed on June 1, 2023).

[7]"Manufacturers" for the purpose of DPCO includes manufacturer, importer and marketer.

[8]In order to avail this exemption the drug/device should be patented under the Indian Patent Act, 1970.

[9]Paragraph 19, DPCO.

July 08, 2024

Future of India-Mauritius tax treaty – Impact of new Protocol on M&A deals and Private Equity structures

April 23, 2024

Q&A 2024 Protocol to the Mauritius India Tax Treaty

April 22, 2024