Pharma & Healthcare Update

January 24, 2019

PATENTED NEW DRUGS AND ORPHAN DRUGS OUT OF PRICE CONTROL IN INDIA

- The Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) has notified an order amending the Drugs (Prices Control) Order 2013.
- Effective January 3, 2019, manufacturers, importers and marketers of new drugs patented in India are exempt from price control for a period of five years from the date of commencement of their commercial marketing.
- Drugs for treating orphan diseases as determined by the Ministry of Health and Family Welfare will also be exempt from price control.

From January 03, 2019 onwards, the Indian Government has exempted manufacturers, importers and marketers ("**Manufacturers**") of patented new drugs in India from price control for a period of five years (**"New Drug Exemption"**). The five-year window starts from the date when the Manufacturer starts commercial marketing in India. The Government has also exempted such drugs from price control that are used for treatment of a disease that qualifies as Orphan Disease in the opinion of the Ministry of Health and Family Welfare ("**Orphan Drug Exemption**").

The exemptions were introduced by way of an order dated January 03, 2019 (**"Order"**).[1]

As a consequence of the Order, Manufacturers of new drugs patented in India will be free to price the drugs for a period of five years from the date of commencement of commercial marketing of the drugs.

LEGAL BACKGROUND

Nature of Price Control in India

The prices of all drugs and notified categories of medical devices (**"Notified Medical Devices"**) that are sold in India are controlled by the Drugs (Prices Control) Order 2013 (**"DPCO"**). The National Pharmaceutical Pricing Authority (**"NPPA"**) is empowered by DPCO to fix ceiling prices of drugs and Notified Medical Devices that are listed in the schedule appended to the DPCO (**"Scheduled Formulations"**). No manufacturer can price or sell its Scheduled Formulations above the ceiling price fixed by the NPPA. The drugs and Notified Medical Devices that are not part of the schedule to the DPCO (**"Non-Scheduled Formulations"**) are under strict price surveillance. The prices of Non-Scheduled Formulations cannot be increased by more than 10% in any 12 month period.

Definition of a New Drug

A new drug for the purposes of the New Drug Exemption is a drug that has received marketing permission or approval from the Central Drugs Standards Control Organization (**"CDSCO"**). The permission/approval is given to the following kinds of drugs:

i. A drug, including a bulk drug substance, which has not been used in India to a significant extent and whose safety, efficacy and therapeutic value has not been established in India.

ii. A drug which is already approved which is now proposed to be marketed with modified or new claims such as indication, dosage, dosage forms or route of administration.

iii. A Fixed Dose Combination (**"FDC"**) of two drugs individually approved earlier but which are now proposed to be changed for the first time or if the ratio of drugs in an FDC is sought to be changed.

iv. All vaccines and Recombinant DNA (r-DNA) derived drugs, unless certified otherwise.

ANALYSIS OF THE ORDER

Manufacturers of New Drugs patented in India now exempt from price control for five years, but ambiguities in exemption language may result in implementation challenges

Prior to the Order, the scope of price control exemption was limited to only those manufacturers who were producing patented new drugs that were (i) developed through indigenous (i.e. local) research and development and (ii) not produced elsewhere. The New Drug Exemption has removed all localization requirements associated with claiming the price control exemption. Therefore, even importers and marketers of patented new drugs developed and manufactured outside India are now eligible for price control exemption for a period of five years from the start of its commercial marketing. Conversely, domestic manufacturers who manufactured patented new drugs in India and outside India have also become eligible for price control exemption, which was not the case earlier.

However, it is important to note that the drugs covered by the New Drug Exemption are the drugs that are covered only by a product patent and not process patent. If a new drug is covered by a process patent, then the localization requirements still apply. A number of biotechnology based medicines, such as vaccines and biologics, are covered by process patents. The importers and marketers of such medicines still do not have the benefit of price exemption.

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The policy decision to remove the localization requirements as a criteria for price control exemption is expected to make the Indian market attractive to multi-national pharmaceutical companies and to encourage them to introduce new drugs into India. In the past, India's price control regime has forced exit of innovative products out of India[2]. Therefore, the policy decision appears to be a step in the right direction.

However, there are a few ambiguities in the language of the New Drug Exemption that may result in implementation hurdles.

First and foremost, it is not clear how the five year period for the New Drug Exemption will be calculated. The New Drug Exemption can be availed for five years for patented new drugs from the "*date of commencement of its commercial marketing by the manufacturer in the country*"(**"Exemption Date"**). However, there is no legal definition of what amounts to 'commercial marketing' in India. For example, does start of manufacturing at a factory or start of import into India amount to commercial marketing? Or does start of stocking the drug at warehouses amount to commercial marketing? Or does the date of announcement of introduction of the drug in India amount to commercial marketing? Or does making the drug first available at retail stores amounts to commercial marketing? Thus, there is a question mark on the date from which the five year period will be calculated.

It is interesting to note that there is a concept of date of marketing permission/approval in case of new drugs. A marketing permission/approval is granted by the CDSCO to the importer or manufacturer of a new drug once the safety, efficacy and therapeutic value of that drug has been established in India through clinical trials. The date of marketing authorization is the date the manufacturer of the drug receives permission/approval from the CDSCO to market the drug in India. However, this date is different from the date of its commercial launch in India, which the CDSCO has itself acknowledged in its communications.[3] Therefore, it may not be appropriate to equate date of receipt of marketing authorization to date of commercial marketing of the drug in India. Interestingly, in the past, price control exemptions have been granted from the date of receipt of marketing approval to manufacturers even though the law stipulated that the exemption would start from the date of commercial production.[4]

The second major ambiguity is with respect to extent of benefit that would be available to different Manufacturers of the same drug. It may be noted that the New Drug Exemption exempts 'Manufacturers' of patented new drugs from price control as opposed to exempting the drug itself. Therefore, multiple Manufacturers (i.e. manufacturers, importers, marketers) of the same drug can avail the New Drug Exemption. The challenge will arise when the date of commercial marketing of different Manufacturers will vary. Since the New Drug Exemption is Manufacturer specific and not drug specific, it may lead to a situation where one Manufacturer has exhausted its time-limit for enjoying the New Drug Exemption while another Manufacturer has just started out. This could possibly result in creation of IP licensing structures where a new drug enjoys price exemption for the tenure of its patent life by simply changing hands. We understand that the policy assumes that a patented drug would not change hands, but that may not be a right assumption to make.

The third major ambiguity is with respect to limitations with 'new' status of new drugs. A new drug continues to remain a new drug for four years from the date of first approval.[5] Therefore, at the end of the fourth year from the date of its marketing authorization, the new drug will cease to be a new drug. Assuming that such a drug has a product patent right from the date of its marketing authorization and begins its commercial marketing from same date, even then at the expiry of four year period, the drug will not remain a new drug. The New Drug Exemption, however, can be availed until expiry of five years from the date of its commercial marketing. So, in the fifth year, would the exemption still be available given that the drug is no longer a new drug? The time-line of four years during which a drug remains a new drug is, in practice, further reduced because it takes a minimum of four months to obtain NPPA's clearance to avail the exemption after it is approved for marketing in India.[6] In the past, while issuing price control exemptions, this technical aspect of 'newness' has been overlooked. However, in case multiple Manufacturers seek to claim price control exemption for the same drug, this technicality may pose a problem. We hope that the Government will issue a clarification soon to resolve this ambiguity because it has the potential to complicate the eligibility criterion for availing the exemption.

The Health Ministry gets power to Exempt Drugs Used for Treating Orphan Diseases from Price Control

Drugs for treating rare (orphan) diseases (**"Orphan Drugs"**) would now onwards be exempt from price control under the DPCO if the Health Ministry decides to do so. The term 'Orphan Drugs' or 'orphan disease' has not been defined in any legislation currently in force in India. However, the draft rules released by the Health Ministry to put in place a comprehensive regulatory framework for clinical trials in India define Orphan Drugs as a *'drug intended to treat a condition which affects fewer than two lac person in India.'* India also has a National Policy on Treatment of Rare Diseases (**"NPTRD"**) which seeks to assist patients who are undergoing treatment for rare diseases. The NPTRD identifies some common rare diseases such as Haemophilia, Thalassemia, Sickle-cell Anaemia and Primary Immunodeficiency in children, auto-immune diseases, Lysosomal storage disorders such as Pompe disease, Hirschsprung disease, Gaucher's disease, Cystic Fibrosis, Hemangiomas and certain forms of muscular dystrophies.[7]

The Orphan Drug Exemption is expected to give impetus to research and development of such drugs. It has been reported that due high costs of drug development, pharmaceutical companies are not incentivized to invest resources in finding cures for rare diseases as the revenue from the sale of the Orphan Drug may not be sufficient recover the costs of research and development of such Orphan Drug. Price control on Orphan Drugs can make it doubly harder for pharmaceutical companies to recoup their investment and can stump innovation.[8]

India is becoming an increasingly lucrative market for pharmaceutical companies to invest in due to a rapidly growing population and an increasing middle class with the resources to afford more expensive drugs.[9] The Government of India has also launched new schemes with the aim of increasing health insurance penetration in India.[10] The Orphan Drug Exemption is expected to encourage domestic companies to develop drugs for orphan diseases and to foreign pharmaceutical companies to market their drugs in India. However, in order to give effect to the Orphan Drug Exemption, the Health Ministry must now clarify the criteria that it will apply to determine when a drug can be called as an Orphan Drug. We understand that this may take a fair amount of time due to absence of disease prevalence data, as noted in the NPTRD.

April 01, 2025

Vaibhav Parikh, Partner, Nishith Desai Associate on Tech, M&A, and Ease of Doing Business

March 19, 2025

SIAC 2025 Rules: Key changes & Implications

February 18, 2025

Government can now source Drug Price Data from any pharmaceutical market data specialization company

Apart from introducing the New Drug Exemption, the Order has also amended the DPCO in a manner that gives the Government the flexibility to obtain Drug Price Data, required under the DPCO for purpose of price fixation, from any pharmaceutical market data specializing company as decided by the Government. Earlier, Drug Price Data was required to be sourced exclusively from IMS Health. However, in practice, the NPPA was frequently relying on AIOCD-Pharmatrac data to fix prices. The NPPA has also developed its own in-house database of drug prices, called IPDMS, and this amendment should give it the ability to rely on data from AIOCD-Pharmatrac or IPDMS or such other sources as it deems fit.

It is also worth noting that in the past, data from pharmaceutical market data specializing companies has been found to be erroneous.[11] Therefore, the Order, in effect, allows the Government to corroborate data from multiple sources. As a result the Government can be sure that it is relying on statistically sound data when arriving at conclusions with respect to drug pricing.

Government is now empowered to consider Drug Price Data for any month for fixing prices

The Order also gives new power to the Government to use Drug Price Data of any month for the purposes of fixing prices as it deems fit, as long as it is necessary to do so.

The reason behind the change is that the existing language of the DPCO ties the Government to use Drug Price Data of last six months only, but such data is not always immediately available.[12]

While the discretion with the government to is not unguided, it is still fairly broad and could be used in a manner that is extremely prejudicial to the industry. For example, if Drug Price Data has not been available for a couple of years, then the Order essentially allows the government to go back as far as 2012 for Drug Price Data and use it to fix prices of drugs. Historic Drug Price Data may not reflect the realities of the day, such as change in cost of raw materials or increase in minimum wages *etc.* Therefore, it would have been to better if the Order had also defined a look back period of, say, two years for the Government to obtain Drug Price Data, when necessary.

CONCLUSION

The Order appears to be a step in the right direction. By carving out exemptions for Orphan Drugs and relaxing the price control regime applicable to Manufacturers of patented new drugs, the Government has made a strong case for pharmaceutical companies to market their innovative drugs in India. The Order also has a significant public interest element because many innovative lifesaving drugs that are available to foreign patients are not available to Indian patients today. For instance, from 2010 to 2014 only seven oncology drugs were introduced in India even though 50 breakthrough cancer therapies were rolled out globally in the same period.[13]

However, as pointed out in the analysis section above, there are some ambiguities in the Order that may create hurdles for both domestic and multi-national companies to avail the exemptions. Having said that, given the focus of the Indian government on ease of doing business in India, we are confident that the Government will take note of these ambiguities and clarify them very soon.

Pharma & Life Sciences Team

[1] Order S.O 39(E) dated 03 January 2019, Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals).

[2] Article on Abbott withdrawing coronary stents from the Indian Market available at: https://www.thehindubusinessline.com/companies/abbott-withdraws-one-more-stent-from-indian-market/article23681106.ece (last checked January 24, 2019); https://www.thehindubusinessline.com/companies/medtronic-to-withdraw-latest-stents-from-india-after-price-cap/article9660174.ece (last checked January 24, 2019).

[3] DCGI Circular F. No. 12-01/12- DC Pt- 127 dated January 10, 2013, available at http://cdsco.nic.in/writereaddata/cancellation_of_permission.pdf (last checked January 24, 2019).

[4] Order by National Pharmaceutical Pricing Authority available at: http://www.nppaindia.nic.in/ceiling/press29oct15/so3131e-20-11-15.html (last checked January 24, 2019).

[5] S.122-E Drugs & Cosmetics Rules 1945 (last checked January 24, 2019).

[6] As per NPPA's official process for granting clearance for exemption, available here: http://www.nppaindia.nic.in/order/letter-24-9-14.pdf (last checked January 24, 2019).

[7] National Policy on Treatment of Rare Diseases available at: https://mohfw.gov.in/sites/default/files/Rare%20Diseases%20Policy%20FINAL.pdf (last checked January 24, 2019).

[8] Fiona M. Scott Morton, '*The Problems of Price Control*', Cato Review of Business and Government, available at: https://www.cato.org/publications/commentary/problems-price-controls (last checked January 24, 2019).

[9] Global Pharma Looks to India: Prospects for Growth available at: https://www.pwc.com/gx/en/pharma-life-sciences/pdf/global-pharma-looks-to-india-final.pdf (last checked January 23, 2018).

[10] Pradhan Mantri Jan Arogya Yojana available at: https://www.pmjay.gov.in/about-pmjay (last checked January 24, 2018).

[11] Order by Department of Pharmaceuticals in M/s Win Medicare Pvt. Ltd. against price fixation of "Povidone Iodine Solution 10% available at" http://pharmaceuticals.gov.in/sites/default/files/Speaking%20Order%20Win%20Medicare%20443-34.pdf (Last checked January 24, 2019).

[12] Order by National Pharmaceutical Pricing Authority available at: http://www.nppaindia.nic.in/ceiling/press02November18/FormulationPrices(02)-Withdrawal.pdf (last checked January 24, 2019).

[13] India got only 7 out of 50 global cancer drugs in 5 years available at: https://timesofindia.indiatimes.com/india/india-got-only-7-of-50-global-cancer-drugs-in-5-years/articleshow/58087833.cms (last checked January 24, 2019).