AN OVERVIEW ON THE NATIONAL PHARMACEUTICAL PRICING POLICY, 2012

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ABSTRACT

This paper aims to analyse the impacts and aftermath of the National Pharmaceutical Pricing Policy, 2012 which incorporates the principles for pricing of Essential Drugs as laid down in the "National List of Essential Medicines- 2011".

It highlights the background of control over price of drugs, the various objectives and principles that the policy aims at achieving along with certain exemptions from the same. It also includes the analysis of the 2012 policy along with a landmark ruling under the subject matter delivered by the Honourable Supreme Court of India.

BACKGROUND OF CONTROL OVER PRICE OF DRUGS

The control of price of drugs in India was as a result of Chinese Aggression and Declaration of Emergency in the country in 1962. This resulted in the promulgation of Drugs (Display of Prices) Order, 1962 and the Drugs (Control of Prices) Order, 1963. The Orders were promulgated under the Defence of India Act, 1963. These Presidential Orders so promulgated had a chilling effect on the prices of medicines w.e.f. 1st April 1963. A regime of controlling price of drugs had commenced. Several ordered were passed in the country from time to time to regulate and control the price of drugs. The Essential Commodities Act was enacted in the year 1955 which declared certain drugs under the category of Essential Commodities. The various orders brought into effect were based on different principles where the span of control of prices and the nature of control of prices was different in every order. All the policies enacted aimed at one larger goal of balancing the growth of the industry and the availability of drugs by controlling the prices of these drugs in the interest of the larger benefit of the society.

The immediate previous policy in place for regulation and control of price of drugs was the Drug Policy of 1994, which was implemented through the Drug (Price Control) Order, 1955. This was introduced as a result of changes in the economy which took place due to liberalisation and the allowance of foreign direct investment in the country, including the pharmaceutical industry. The policy aimed at controlling the price of drugs based on the economic criteria as represented in the particular market share of different companies in the context of total market sales turnover of various drugs.[1] In 1970, the Drug Price Control Order (DPCO) was introduced along with an amendment to Patents Act, 1970 that derecognized the concept of product patenting in India.

With further liberalisation of the economy, there was Foreign Direct Investment in the Pharmaceutical Industry. This was allowed through the Automatic Route without prior approval of the Government of India with a limit raised up to a 100%. Thereafter, to advance this span of control over pricing, a new pharmaceutical policy was enacted in 2002. Under this policy, the parameters of market share were relaxed and all the drugs where the per unit price did not exceed Rupees 2.0 were excluded from the ambit of the control. This Drug Policy of 2002 was later challenged in the High Court of Karnataka, where the Court by way of an order dated 12.11.2002 directed a stay on the implementation of this policy.[2] This order was appealed to by the Government whereby the Supreme Court vacated the stay vide an order dated 10.03.2003 and observed that the petitioner shall consider and formulate appropriate criteria for ensuring that essential and life saving drugs do not fall outside the ambit of price control. A further direction was issued to review the nature of drugs and to classify them as essential and lifesaving till 2nd May 2003.

[1]Gazette Notification No. 31011/16/2012 PI-II dated 7th December 2012. Available at http://pharmaceuticals.gov.in/sites/default/files/National%20Pharmaceutical%20Pricing%20Policy%202012_1.pdf accessed on 25th October 2018 at 13:00 hours; National Pharmaceutical Pricing Policy, 2012 (NPPP-2012). Available at https://www.jetro.go.jp/ext_images/world/asia/in/ip/pdf/nppp_2012_en.pdf accessed on 25th October 2018 at 13:00 hours.

[2] Drug Price Control Orders (DPCO). Available at http://www.arthapedia.in/index.php?title=Drug_Price_Control_Orders_(DPCO) accessed on 26th October 2018 at 12:30 hours.

Therefore, to effectively implement the aforementioned decision, the Policy of 2002 was never made effective and the Drug Policy of 1994 continued to be in effect till 2012.

Further, in accordance with the guidelines and order issued by the Supreme Court in the aforementioned case, the Ministry of Health and Family Welfare revised the List of Medicines to be considered as essential medicines under the National List of Essential Medicines (NLEM) in 2003. National List of Essential Medicines is defined under the DPCO as the National List of Essential Medicines, 2011 as notified and revised by the Ministry of Health and Family Welfare (MOHFW) from time to time.[3] The Government of India, MOHFW is supposed to ensure quality healthcare system by assuring availability of safe and efficacious medicines. The medicines under NLEM have been categorised based on their therapeutic use. This is the sole reason why a medicine containing more than one remedies appear in several categories.[4] These medicines shall be made available to the larger population of the country at affordable costs with assured quality. The primary purpose of NLEM, 2011 is to promote rationale use of medicines keeping in mind the three important aspects which are: cost, safety and efficacy. The need to update the previous lists released in 1996 and 2003 respectively was felt with a rise in introduction of newer medicines, issues of changing diseases, identification of acceptable risk-benefit as well as the therapeutic profile of some medicines.

The Policy on price control of patented drugs has evolved from the Pranab Sen Committee Report of 2005, leading to a National Pharmaceutical Policy in 2006 and the subsequent report of BK Singh Committee in 2013.[5]

Therefore, in 2012 it was recognized by the Government of India that medicines constitute a major portion of the expenditure from the pocket of a patient and therefore, there existed a need

[3] Id.
[4] National List of Essential Medicines, 2011.
[5] Government Price Control on Patented Medicines in India- May, 2015. Available at https://www.indiaoppi.com/sites/default/files/PDF%20files/Position%20on%20%20Price%20Control%20on%20Patented%20Medicine%20-%20May%2C%202015.pdf accessed on 25th October 2018 at 16:00 hours.

to put an end to such soaring prices of medicines.[6] The Government notified the National Pharmaceutical Pricing Policy (NPPP), 2012 with its main objective being the establishment of a regulatory framework for pricing of drugs in order to ensure the availability of 'essential medicines' at reasonable and affordable prices. This was done keeping in mind the provision of providing a sufficient opportunity to the pharmaceutical industry for innovation and competition to foster overall growth of the Pharma industry. Thereafter, in light of the NPPP, DPCO was issued in 2013 replacing the earlier DPCO. The earlier Order regulated prices of only 74 bulk drugs[7] whereas the current DPCO regulates the prices of as many as 348 medicines. This Order now allows the NPPP to regulate the prices of 348 essential drugs which fall under the scope of NLEM, 2011. The former regulated the prices of drugs based on the manufacturing costs stated by the respective manufacturers whereas in the latter ceiling prices would be calculated by taking an average of all drug brands having a market share of more than 1% in the market.[8]

OBJECTIVES OF 2012 POLICY

The National Pharmaceutical Pricing Policy has replaced the Drug Policy, 1994. The 1994 policy needed revision to face and avert the challenges posed by the competitive international pharmaceutical industry in a globalised economy along with a need to meet the requirement of safe and quality medicines at reasonable prices.

The present policy has limited its scope to the principles for pricing of essential and generic drugs as enunciated under the National List of Essential Medicines, 2011. The most essential duty of a democratic state is to ensure the welfare of its people by providing adequate means for people to do so. One of the most important aspects of this is healthcare. Due to changing times,

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[6] Gazette Notification No. 31011/3/2017-Policy dated 31st March 2017. Available at http://pharmaceuticals.gov.in/sites/default/files/Policy.pdf accessed on 30th October 2018 at 15:00 hours.

[7] Paragraph 2(a) DPCO, 1995. Any pharmaceutical, chemical, biological or plant product including its salts, esters, stereo-isomers and derivatives, conforming to pharmacopoeial or other standards specified in the Second Schedule to the Drugs and Cosmetics Act, 1940, and which is used as such or as an ingredient in any formulation.

[8] Madhulika Vishwanathan, *Drug price control order (DPCO) 2013: What's in store?* Available at https://spicyip.com/2013/05/drug-price-control-order-dpco-2013.html accessed on 26th October 2018 at 23:00 hours.

numerous kinds of diseases have taken birth which pose a threat to mankind. In such scenarios, it is the duty of the state to make sure that the general public, especially the lower strata of the society is facilitated with affordable medicines to lead a healthy and dignifies life. However, the overall growth of the economy matters too due to which the Pharma industry has to be given some incentives in the form of patented drugs and innovations to foster and promote creativity and competition along with industrial application.

PRINCIPLES OF 2012 POLICY

The major principles on which the regulation of prices in the NPPP is based are mainly:

1. Essentiality of Drugs
2. Control of Formulations Prices only
3. Market Based Pricing

The principle of "Essentiality" for the regulation of prices is fulfilled by conforming to the mist of essential medicines as notified under the NLEM as updated from time to time, the most recent being in 2011. The Director General of Health Services (DGHS) constitutes an Expert Core Committee which prepares the NLEM as a result of a combination of the World Health Organisation Model List of Essential Medicines, Essential Drugs List in various States, the various medicines used in several National Health Programmes and Emergency Care Drugs. This list contains all such medicines that satisfy the priority health needs of the population of the country. Such medicines are required to be made available at all times in sufficient quantities in the appropriate dosage forms.

The principle of controlling the prices of formulations only has been adopted due to the following reasons:

1. That the Bulk drug including the Active Pharmaceutical Ingredient may not necessarily be meeting the criteria of essentiality. Due to this, various formulations may or may not be considered as essential in the interest of larger healthcare needs of the public.

2. Due to an emphasis on price control from the initial bulk drug stage has resulted in a shift of manufacture of drugs away from the ones notified as bulk drugs under price control. Therefore, a cascading effect has been created on the formulations manufactured which has adversely affected the availability of such formulations.

3. The consumer who is concerned only about the price of the end product avails no benefits by the task of pricing both the bulk drug and the formulations so made.

4. A barrier in the emergence of new companies exists in the price-controlled segment as the manufacturer is required to sell at a fixed price, therefore, giving preference to an existing buyer rather than to a potential new entrant. This has a result of not fostering competition i.e. being anti-competitive in the market as new entrants are blocked from entering into the market.

The principle of Market Based Pricing (MBP) has been adopted in the policy as contrast to the Cost Based Pricing (CBP) system under the previous 1994 Drug Policy for the following reasons:

1. CBP requires manufacturers to provide a detailed variety of data to show the calculation of prices of drugs on a yearly basis, which is highly resisted by manufacturers resulting in a possible manipulation of data. However, under MBP the information available in the public domain is the basis of pricing, making it more transparent and fairer.

2. CBP provided for controlling of prices on the basis of 'lowest common denominator' which made it difficult for a new entrant to enter the market. This hampered competition by not making the process fair for all, adversely affecting the consumers as well as the growth of the industry.

3. The pricing of manufactured drugs is determined by the various market forces depending on changing market conditions. It would lead to severe distortions if pricing is done based on the cost of inputs used in manufacturing whereby the particular inputs themselves are not being subjected to any form of price control. Under the new policy, fixation of Ceiling prices[9] would provide for ample space for manufacturers to position themselves under the appropriate price band, thereby fostering competition in the market.

An authority namely the National Pharmaceutical Pricing Authority (NPPA) has been established to keep a check on the fixation of ceiling prices by various manufacturers. An annual increase in price will be allowed for the medicines mentioned under NLEM, 2011 as per the Wholesale Index Price as notified by the Department of Industrial Policy and Promotion.[10] The NPPA will also separately notify the revised Ceiling Prices as applicable on the 1st April every year. In situations where companies do not fix their prices in conformity with the revised notification, NPPA shall take appropriate action to have the prices revised in accordance with the same.

The present policy involves price control of essential medicines alone. This will imply that non-essential drugs should not be under the price-controlled regime and their prices shall be determined based on market forces. However, a check has to be placed on overall drugs and therefore, where the prices of such non-essential drugs is increased at a rate above 10% per annum, the government is empowered to reduce the prices below the limit for the subsequent 12 months. Further, imported drugs have been brought within the ambit and control of the current policy.

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[9] Ceiling prices of 464 formulations (amounting to nearly 7000 different stock keeping units) have been fixed by the government after the announcement of National List of Essential Medicines (NLEM), 2015 and Revised Schedule-I. This has resulted in effective savings to the consumers of the country Rs. 2288 Crore by way of reduced prices. *Press Release, Ministry of Chemicals and Fertilizers, Government of India dated 27th September 2016*. Available at http://pib.nic.in/newsite/PrintRelease.aspx?relid=151146 accessed on 2nd November 2018 at 10:00 hours.

[10] Id.

EXEMPTIONS IN 2012 POLICY

Certain drugs have been exempted from the price-controlled regime in order to promote Research & Development and innovation.

1. Where a new drug patented under the Indian Patents Act, 1970 is developed by indigenous R&D, which has not been produced elsewhere, the manufacturer would be eligible for an exemption from price control in respect of that drug for a period of 5 years.

2. Where a drug has been developed using a new process through indigenous R&D having being patented under the Indian Patents Act, 1970, the manufacturer shall be eligible for an exemption from price control in respect of that drug for a period of 5 years.

3. Where a new formulation has been developed involving a new delivery system, it will be eligible for an exemption from price control for a period of 5 years from the date of its market approval in India. In such a case, a Certification of innovation may be provided by the office of Drug Controller General of India (DCGI).

A LANDMARK JUDGMENT

In *Modi-Mundipharma Pvt. Ltd. v Union of India*[11], the petitioner being a pharmaceutical company filed a petition challenging a Standing Order[12] passed by the Assistant Director, NPPA to extend that it included the formulation -TRD Contin 100mg, tablet CR 10, within the scope of ceiling price fixed for 'Tradamol Tablet'. It was stated in a communication dated 5.7.2016, issued by the Director, NPPA that the ceiling price of Tradamol 100mg tablet was fixed as per Section 2.2.3 of

[11] 2018 SCC Online Del 9904.
[12] Standing Order No. 1687 (E) dated 9.5.2016.

the NLEM, 2015[13]. The petitioner was directed to comply with pricing the formulations below the ceiling price of Rupees 18.25 per tablet and submit a compliance report to the NPPA.

Meanwhile, by virtue of Section 3 of the Essential Commodities Act, 1955, the respondent notified DPCO, 2013. Thereafter, the respondent issued another notification resulting in an amendment to Schedule-I of the DPCO, 2013 by substituting NLEM, 2015 in place of NLEM, 2011. So, now the formulations of Tradamol tablet and injection were included in Schedule-I under NLEM, 2015 having the potency- 50mg, 100mg and 50mg/ml respectively. The petitioner claimed that this formulation was not included within the ambit of NLEM, 2013 and hence, not a 'scheduled formulation' within the meaning of DPCO, 2013. Thus, not being subject to price control. This was substantiated by the petitioner stating that a Continuous Controlled Release Dual Mechanism Drug Delivery System, known as 'CR Technology', has been used to develop the drug. This is an innovative drug delivery system and therefore, the formulation cannot be read within the DPCO, 2013.

However, the respondents contended that the mere fact that NLEM, 2015 does not include such strength or dosage does not imply that the same cannot be read within DPCO, 2013. This simply means that the same can be considered separately for the purpose of fixing prices.

The court, post consideration of the arguments from both sides held that, merely because a formulation is excluded from NLEM, 2015 does not mean that it escapes the purview of DPCO, 2013. In the present case, a plain reading of Section 2(v) of DPCO, 2013[14] would indicate that a formulation is considered as 'non-scheduled' when the formulation of a dosage and strength is not specified in Schedule-I. however, the scope of this exclusion is restricted by virtue of

[13] Gazette Notification No. 31015/4/2016-PI.I. Government of India has notified the National List of Medicines (NLEM), 2015 on 23.12.2015 and Department of Pharmaceuticals vide S.O. No. 701(E) dated 10.03.2016 has amended Scheduled-I of DPCO, 2013 for substituting NLEM, 2015. Available at http://pharmaceuticals.gov.in/sites/default/files/reviewapplication-JB-Chemical.pdf accessed on 3rd November 2018 at 15:00 hours.

[14]Definition of "non-scheduled formulation". A formulation, the dosage and strengths of which are not specified in the First Schedule, DPCO, 2013.

Explanation 1 to Schedule I.[15] Therefore, this implies that Explanation 1 attempts to widen the scope of Schedule I by including formulations other than the ones mentioned under the Schedule.

Further, in light of Explanation 2 to Schedule I[16], it was observed that since the present case does not dispute the fact whether CR Technology is a novel drug delivery system, the said formulation in question cannot be said to be included under DPCO, 2013 for the reason of it not being specifically mentioned. Hence, the notification fixing ceiling price of Tradamol tablet at Rupees 18.25 per tablet cannot be extended to the formulation – TRD Contin 100mg. tablet CR 10 manufactured by the petitioner.

ANALYSIS

It is imperative to take into account the value of innovative pharmaceuticals, including the huge amount of investment required to develop pharmaceuticals, when determining pricing for patent drugs. To focus only on the price of medicines while ignoring its value to the patient is a short-sighted approach. The share of expenditure on medicines is oftentimes a small component of the total cost of healthcare for an individual patient, particularly with the availability of lower cost generics (same salt medicines). This can and should be covered through adequate health insurance.

A pricing scheme, based on therapeutic equivalents and comparison with generic products, will not be an effective price determination methodology. Government pricing policies should be developed in the context of India's health system's objectives and shall recognize the value of

[15] Explanation 1 under Schedule-I, DPCO, 2013. When a dosage form is not mentioned under the Schedule, it would still be read within the Schedule, if it does not have any significant difference in terms of pharmacokinetics or pharmacodynamics or an efficacy-safety profile as mentioned in the List.

[16] Explanation 2 under Schedule-I, DPCO, 2013. Formulations developed by way of incremental innovation or a novel drug delivery system like sustain release/ control release can be said to be included only if such have been specified in the list against a medicine.

innovation as critical to expanding access and availability of innovative medicines for Indian patients.[17]

In February 2014, the Ministry of Chemicals & Fertilizers formed an Inter-Ministerial Committee under the Chairmanship of the Joint Secretary, Department of Pharmaceuticals, to look into the issue of price negotiations of patented drugs. It was suggested that while framing a policy for price negotiations of patented drugs, the Committee should factor in the growth of the industry and changes in the disease profile of the country. Also, the healthcare systems of Sri Lanka, Thailand, Malaysia and countries with similar problems to India could be studied. However, certain sections of the Committee have strong views that patented drugs, with the exception of those that qualify for exemption from price control under Para 32 of DPCO 2013, should be compulsorily brought under the price control mechanism prior to grant of marketing approval.[18]

CONCLUSION

On the note of a concluding remark it can be said that, excessive control over price of drugs will not have a good impact on the pharmaceutical industry. The purpose with which the Government undertakes control over price of drugs is to make such drugs affordable, available and accessible. However, excessive price control reduces the attractiveness of the pharmaceutical industry in turn hampering the growth of drug manufacturing companies as they face cost constraints. Domestic manufacturers make generic drugs at a much cheaper price hence, attracting customers to purchase these alternative substitutes.

In price-controlled segments, as a manufacturer is required to sell at the prices fixed, barriers to entry into the market are created by focussing on existing buyers thereby not providing a fair opportunity to a new entrant. This can be considered to be anti-competitive as new entrants

[17] Id.
[18] Id.

resist from entering into the market. Such a control in price may adversely impact locally-manufactured generic alternatives as it reduces the price of the MNC labelled options, thereby decreasing the price gap and perhaps making the MNC label more attractive for consumers.[19]

Some lessons that can be learnt from the study of this Policy are that licenses should be issued to some local manufacturers so that few drugs which are out of reach of some people are easily accessible. One most important effort that Government should focus upon is strengthening our R&D sector in the country and making it more lucrative for foreign firms to invest in Pharmaceutical sector, thereby amounting to an increase in efficiency in production, supply, distribution, storage, acquisition or control of goods/ services[20]. This would result in fostering healthy competition in the relevant market if at all Joint Ventures are promoted as a method of entry into a foreign market.

[19] Dr. Navita Mahajan —Case Study On *Government 's Drug Pricing Control And Strategies By Pharma Companies for Retailing*, International Journal of Business and Management Invention (IJBMI), Vol. 07 No. 02, 2018, pp. 16–22. Available at https://www.ijbmi.org/papers/Vol(7)2/Version-1/B0702011622.pdf accessed on 3rd November 2018 at 18:00 hours.

[20] Proviso to Section 3(3) Competition Act, 2002. Provided that nothing contained in this sub-section shall apply to any agreement entered into by way of joint ventures if such agreement increases efficiency in production, supply, distribution, storage, acquisition or control of goods or provision of services.