MAKING MEDICINES ACCESSIBLE IN INDIA: A CRITICAL ANALYSIS OF THE LAWS AND POLICIES

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ABSTRACT

The exorbitant costs of drugs and medicines is one of the biggest reasons behind unaffordability and inaccessibility of healthcare and poverty in India. India being a Low and Middle Income Country (LMIC), where majority of the people still live in poverty, people who are sick and are in need of medicines have the choice to either suffer from its debilitating and painful consequences and die or use whatever little means they have to purchase outrageously expensive medicines, which are considered unaffordable even for the well off people in the country, thereby pushing millions into abject poverty. The government has the responsibility, both legal and moral, to make medicines available and accessible to people and to protect them by preventing both the health and economic consequences of diseases. While in India various laws and policies have been put in place to regulate the prices of drugs and medicines, the effects of the cost of medicines are still felt by the people as many studies have revealed. Therefore, in the light of this there is a requirement to critically analyse the laws and policies regulating the prices of medicines in India and to suggest a better way to make medicines available and accessible to everyone in need irrespective of their capacity to pay. This work is an attempt in that direction.

Keywords: *Healthcare, Poverty, Access to Medicines, Right to Health, Affordability and Price Regulation*

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INTRODUCTION

In India more than 94% of the population seek outpatient care and 70% of such expenditure in outpatient care is made towards drugs and diagnostics.[2] Furthermore, as per the study conducted by Public Health Foundation of India, New Delhi, 55 million had been pushed into poverty in 2011-12 due to out of pocket payments, out of which 38 million became poor due to out of pocket payments only towards medicines.[3] This catastrophic financial impact on people leading to poverty needs to be controlled and checked. One of the ways to check this is by regulating and controlling the prices of drugs and medicines. This potentially keeps the medicines within the reach of the people who can't afford costly medicines and also reduces financial impact on people. The recent 12.2 per cent hike in the price of essential medicines as approved by the Central Government[4] due to a rise in the wholesale price index[5] comes as a big disappointment in India's attempts at making drugs and medicines affordable and accessible to poor and vulnerable masses. Such a sharp increase in the price of essential medicines will have severe economic consequences for the poor and vulnerable sections of the society who are already overburdened with exorbitantly high cost of healthcare. Therefore, it is necessary to look into the existing laws and policies in India regulating the price of drugs and medicines. The most important institution responsible for keeping prices of drugs and medicines within check in order to keep them within the reach of the common people is the National Pharmaceutical Pricing Authority (NPPA). We shall therefore start with understanding the role of the NPPA in controlling the prices of medicines.

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[2] 'Change in Medical Expenditure Patterns' (*Press Information Bureau*) <https://pib.gov.in/PressReleasePage.aspx?PRID=1602758> accessed 2 July 2023.

[3] Selvaraj S, Farooqui HH and Karan A, 'Quantifying the Financial Burden of Households' out-of-Pocket Payments on Medicines in India: A Repeated Cross-Sectional Analysis of National Sample Survey Data, 1994–2014' (*BMJ Open*, 1 May 2018) <https://bmjopen.bmj.com/content/8/5/e018020#DC1> accessed 3 July 2023.

[4] 'NPPA Allows Drug Firms to Raise Prices of Essential Medicines from April 1' (*Business Standard*, 3 April 2023) <https://www.business-standard.com/india-news/nppa-allows-drug-firms-to-raise-prices-of-essential-medicines-from-april-1-123040300882_1.html> accessed 3 July 2023.

[5] (*National Pharmaceutical Pricing Authority*) <https://www.nppaindia.nic.in/wp-content/uploads/2023/03/WPI-Om.pdf> accessed 15 July 2023.

ROLE OF NATIONAL PHARMACEUTICAL PRICING AUTHORITY (NPPA) IN ENSURING AFFORDABILITY OF MEDICINES

The National Pharmaceutical Pricing Authority (NPPA) was created in the year 1997, through a government resolution, in order to control prices of medicines to ensure availability, affordability or economic accessibility of medicines.[6] It is now an attached office of the Department of Pharmaceuticals (created on first of July, 2008[7]) in the Ministry of Chemicals and Fertilisers.[8] The purpose for which it was created was to function as an expert body to fix prices and to notify changes in the prices of bulk drugs and formulations in the Scheduled category under the Drugs (Prices Control) Order.[9] It is also authorised to monitor the prices of the decontrolled drugs and formulations.[10] Broadly, it enforces and implements the provisions of the Drug Prices Control Order 1995/2013 as per the powers delegated.[11] The Drug Prices Control Orders are issued by the Central Government under the power conferred by Section 3 of the Essential Commodities Act 1955.[12] Scheduled bulk drug and Scheduled formulation are specified in the First Schedule with Schedule Formulation either individually or in combination of other drugs.[13] [14]

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[6] (*National Pharmaceutical Pricing Authority*) <https://www.nppaindia.nic.in/wp-content/uploads/2020/07/Resolution.pdf> accessed 15 July 2023.
[7] 'About the Department department of Pharmaceuticals' (*Department of Pharmaceuticals*) <https://pharmaceuticals.gov.in/about-department> accessed 15 July 2023.
[8] 'About National Pharmaceutical Pricing Authority: Official Website of National Pharmaceutical Pricing Authority, Ministry of Chemicals and Fertilizers, Government of India' (*About National Pharmaceutical Pricing Authority | Official Website of National Pharmaceutical Pricing Authority, Ministry of Chemicals and Fertilizers, Government of India*) <https://www.nppaindia.nic.in/en/about-us/about-national-pharmaceutical-pricing-authority/> accessed 15 July 2023.
[9] Supra Note 5.
[10] ibid.
[11] Supra Note 6.
[12] (*Part II ministry of chemicals and fertilizers department of chemicals …*) <https://nppaindia.nic.in/wp-content/uploads/2020/07/DRUG-PRICE-CONTROL-ORDER-1995.pdf> accessed 15 July 2023.
[13] ibid.
[14] (*The drugs (prices control) order, 2013*) <https://www.nppaindia.nic.in/wp-content/uploads/2018/12/DPCO2013_03082016.pdf> accessed 15 July 2023.

National List of Essential Medicines (NLEM)

The National Pharmaceutical Pricing Authority comes out with the National List of Essential Medicines. The preamble to the NLEM of India 2011 defines essential medicines as the country specific list of medicines based on its peculiar disease burden that "*satisfy the priority healthcare needs of the majority of the population*".[15] The ceiling price of all scheduled formulations that appear in the NLEM is fixed by the NPPA.[16] The DPCO 2013 includes it in the first schedule of the order.[17] Such medicines have to be of assured quality and are to be available at affordable prices at primary, secondary and tertiary level.[18] Its primary targets are cost, safety and efficacy.[19] It also intends to include all medicines included in national health programmes and emerging and reemerging infections.[20] The NLEM is not a direct adoption of the WHO list of Essential Medicines but one specific to the country based on the disease prevalence and cost effectiveness of such medicines in the country. The NLEM 2011 has a total of 348 medicines out of which 181 are for primary, secondary and tertiary level, 106 medicines for secondary and tertiary level and 61 are for only tertiary level.[21] The NLEM 2015 after revision of the 2011 list has a total of 376 drugs.[22] The new NLEM 2022 has a total of 384 medicines.[23] A total of 26 drugs have been deleted from the 2015 list including, among others, three anti-tuberculosis medicines, two used in HIV management, one anti-cancer medicine and one anti-infective medicine.[24] It has also included 34 new drugs including new anti-cancer medicines, new anti-tuberculosis medicines, new anti-

[15] (*National List of Essential Medicines of India - Pharmaceuticals*) <https://pharmaceuticals.gov.in/sites/default/files/NLEM.pdf> accessed 15 July 2023.
[16] Supra Note 13.
[17] ibid.
[18] ibid.
[19] ibid.
[20] ibid.
[21] ibid.
[22](*National Pharmaceutical Pricing Authority*) <https://www.nppaindia.nic.in/wp-content/uploads/2020/08/NLEM-2015.pdf> accessed 15 July 2023.
[23] (*CDSCO*) <https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=OTAxMw> accessed 16 July 2023.
[24] ibid.

diabetic medicines, medicines for COVID-19 management, medicines to treat respiratory diseases have been included.[25] However, the NLEM 2022 has been criticised for not including certain important medicines, especially new cancer treatment medicines, that the patients could have benefitted from inclusion.[26] The patients are still affected by the extremely high cost of treatment. The financial impact of cancer, whether direct or indirect, remains extremely high and debilitating, particularly for the poor, as suggested by many studies and the high cost of care also leads to unaffordability of cancer treatment.[27] [28] A recent study on out of pocket expenditure, catastrophic health expenditure and distress health financing shows that the mean out of pocket expenditure in India is 19,210 Indian Rupees and that cancer treatment has the highest cost reaching 57,232 Indian Rupees.[29] Furthermore, cancer treatment also led to the highest catastrophic health expenditure (at 79 percent) and also highest distress financing (at 43 percent).[30] Another more recent study based on a systematic review with meta-analysis showed that the direct out of pocket expenditure on inpatient and outpatient care for cancer were 83,396.07 Indian Rupees and 2653.12 Indian Rupees respectively.[31] Moreover, it shows that total direct and indirect out of pocket expenditure were 47,138.95 Indian Rupees and 11,908.50 Indian Rupees respectively.[32] The study also showed that 62.7 percent of individuals faced catastrophic health expenditure, which is extremely high and has mostly been financed by borrowing money

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[25] ibid.

[26] 'Cancer Treatment Costs: Little Respite from New List of Essential Drugs' (*Moneycontrol*, 16 September 2022) <https://www.moneycontrol.com/news/trends/health-trends/cancer-treatment-costs-little-respite-from-new-list-of-essential-drugs-9187461.html> accessed 16 July 2023.

[27] (*Financial toxicity in cancer care in India: A systematic review*) <https://www.thelancet.com/pdfs/journals/lanonc/PIIS1470-2045(21)00468-X.pdf> accessed 15 July 2023.

[28] Dinesh TA and others, 'Economics of Cancer Care: A Community-Based Cross-Sectional Study in Kerala, India' (*South Asian journal of cancer*, 2020). <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6956579/#:~:text=%5B15%5D%20The%20cost%20of%20treatment,36%2C812.> accessed 16 July 2023.

[29] Kastor A and Mohanty SK, 'Disease-Specific out-of-Pocket and Catastrophic Health Expenditure on Hospitalization in India: Do Indian Households Face Distress Health Financing?' (2018) 13 PLOS ONE.

[30] ibid.

[31] YA; DAR, 'Out-of-Pocket, Catastrophic Health Expenditure and Distress Financing on Non-Communicable Diseases in India: A Systematic Review with Meta-Analysis' (*Asian Pacific journal of cancer prevention : APJCP*) <https://pubmed.ncbi.nlm.nih.gov/33773528/> accessed 16 July 2023.

[32] ibid.

or selling assets.[33] It is in light of this that the criticism of non-inclusion of many new and effective anti-cancer medicines in the list of essential medicines leading to these useful and life saving medicines being beyond the reach of the majority of people becomes relevant.[34] The magnitude of this problem becomes clearer when we see that the projected number of cancer patients in India to be at 29.8 million by the year 2025.[35] Therefore, although inclusion of four new anticancer medicines is appreciated, it is clear that much more could have been done by including newer and useful medicines in the list given that the anticancer medicines included in NLEM 2022 is less comprehensive than WHO Essential Medicines List 2021.[36] Besides this, there are many important life saving drugs required in the treatment of many non-communicable diseases like cancer, diabetes, HIV etc. the non-inclusion of which in the list has led to their prices being high and therefore out of reach of the people.

MAJOR OBJECTIONS AGAINST PRICE CONTROL OF MEDICINES

It is clear that regulating the price of essential medicines is an important step in ensuring accessibility and affordability of care. Otherwise, many important drugs will be beyond the reach of the general masses.[37] [38] Fixing ceiling price or maximum retail price

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[33] ibid.

[34] Chandna H, 'Health Matters: Govt's Revised List of Essential Medicines Is a Mixed Bag with More Misses, Fewer Hits' (*News18*, 19 September 2022) <https://www.news18.com/news/india/health-matters-govts-revised-list-of-essential-medicines-is-a-mixed-bag-with-more-misses-fewer-hits-5986417.html> accessed 16 July 2023.

[35] Kulothungan V;Sathishkumar K;Leburu S;Ramamoorthy T;Stephen S;Basavarajappa D;Tomy N;Mohan R;Menon GR;Mathur P;, 'Burden of Cancers in India - Estimates of Cancer Crude Incidence, Ylls, Ylds and Dalys for 2021 and 2025 Based on National Cancer Registry Program' (*BMC cancer*) <https://pubmed.ncbi.nlm.nih.gov/35546232/> accessed 17 July 2023.

[36](*Home*) <https://cdsco.gov.in/opencms/opencms/en/Home> accessed 2 September 2023.

[37] 'Cancer Drug Price Goes up from Rs 8,000 to Rs 1.08 Lakh' (*DNA India*) <https://www.dnaindia.com/india/report-cancer-drug-price-goes-up-fromrs-8000-to-rs-108-lakh-2022667> accessed 17 July 2023.

[38] 'NPPA's U-Turn on Capping Prices of 108 Drugs for Cardiac, Diabetes' (*Moneylife NEWS & VIEWS*) <https://www.moneylife.in/article/nppas-u-turn-on-capping-prices-of-108-drugs-for-cardiac-diabetes/38932/68482.html> accessed 17 July 2023.

of medicines has had the effect of great amounts of savings for the people.[39] Similarly, the Ministry of Chemicals and Fertilisers has also claimed that price rationalisation by the NPPA initiated in February, 2019 had the effect of a great reduction in the price of anticancer medicines.[40] However, there are various criticisms of such regulation of price as well. Prices of medicines are controlled by putting them in the list of essential medicines, regulating the price by imposing a ceiling price and sometimes even restricting intellectual property rights. It is argued that such price control measures make voters happy but adversely affect the healthcare system and innovation in healthcare.[41] That due to absence of strict quality control the reduction of price has led to a fall in the quality of medicines.[42] Furthermore, reduced profit margin due to controlled price of medicines has also led to less expenditure in research and development and also reduced investment in this sector.[43] Besides this, manufacturers of drugs have also moved from producing and promoting price controlled drugs in the national list of essential medicines to those that are not on the list or have adopted other strategies like promoting Fixed Dose Combinations,[44] something peculiar to India, of medicines not on the list and also non-standard doses.[45]

MECHANISM FOR REGULATION OF DRUG PRICES

For a clearer understanding of how the prices of drugs are regulated let's look at the mechanism provided in the DPCO 2013 for the said purpose.

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[39] (*Fixation of ceiling prices/MRP of medicines resulted in total savings of Rs. 11,463 crores to public: Shri Mansukh L. Mandaviya*) <https://pib.gov.in/newsite/PrintRelease.aspx?relid=180915> accessed 17 July 2023.
[40] (*NPPA plays crucial role in making cancer drugs affordable*) <https://pib.gov.in/Pressreleaseshare.aspx?PRID=1670707>accessed 17 July 2023.
[41] Khan AU, 'India's Drug Price Fix Is Hurting Healthcare' (*mint*, 29 October 2019) <https://www.livemint.com/politics/policy/india-s-drug-price-fix-is-hurting-healthcare-11572334594083.html> accessed 17 July 2023.
[42] Pradhan S, 'India's Price Control Policy Has Destroyed Drug Manufacturers. This Is How They Can Be Saved' (*ThePrint*, 20 December 2019) <https://theprint.in/opinion/indias-price-control-policy-has-destroyed-drug-manufacturers-this-is-how-they-can-be-saved/338095/> accessed 17 July 2023.
[43] ibid.
[44] Gautam CS and Saha L, 'Fixed Dose Drug Combinations (Fdcs): Rational or Irrational: A View Point' (2008) 65 British Journal of Clinical Pharmacology 795.
[45] ibid.

How ceiling price of scheduled formulation is calculated

This applies to scheduled formulations under the first schedule of the order with strengths as provided therein. It is a market based approach to pricing of medicines. This is done by first calculating the average price to the retailer of the scheduled formulation. The average price to retailer P(s) is calculated by summing up the prices to retailers of all brands and generic versions of the medicine with a market share of one percent or more of the total market turnover which is then divided by the total number of such brands or generic versions as specified above.[46] Thereafter the ceiling price of the scheduled formulation P(c) is calculated by the formula,

$$P(c)=P(s).(1+M/100),$$

Where, M is the "*% of margin to the retailer and its value = 16*".[47]

The said ceiling applies to imported formulations too.[48] Furthermore, the margin to the retailer as provided in para 7 is sixteen percent of the price to the retailer.[49] The maximum retail price of such scheduled formulation is determined by adding the ceiling price with local taxes wherever it is applicable.[50]

As can be seen this approach is a market based approach that sets the ceiling price based on the average price to the retailer. This means that when such price caps are set some small producers of drugs may be at a disadvantage due to small returns compared to large producers who have the advantage of volume of sales. Furthermore, under this approach the essential medicines are still left for the patients to buy for themselves. In the absence of appropriate information relating to drugs and medicines and the overall information asymmetry working against patients, the patients still end up spending a huge amount on purchasing medicines among other healthcare expenditures.

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[46] (*The drugs (prices control) order, 2013*) <https://www.nppaindia.nic.in/wp-content/uploads/2018/12/DPCO2013_03082016.pdf> accessed 19 July 2023.
[47] ibid.
[48] ibid.
[49] ibid. at Para 7.
[50] ibid. at Para 8.

Trade Margin Rationalisation and Non-scheduled Medicines

A big contributor to the increased price of medicines is the trade margin allowed on such medicines. Trade margin is the difference between actual price at which the retailer sells the goods and the price at which the retailer has purchased from the manufacturer. Trade margin in medicine is then the percentage of the price that is allowed to the distribution chain including wholesalers and retailers by the pharmaceutical companies. For formulations in the first schedule of the DPCO 2013, whose ceiling price is limited by the NPPA, the margin to the retailer is capped at sixteen percent. However, for drugs in the non-scheduled category there is no mechanism under the existing law that allows the control of price of such drugs by regulating the trade margins. This is why pharmaceutical companies allow huge trade margins to retailers to promote the sale of the drugs manufactured by them leading to customers paying exorbitant higher prices for such drugs. There is therefore a necessity to regulate the price of drugs in the non-scheduled category by regulating the trade margin. The existing control over the pricing of non-scheduled formulations that the government has is under para 20 of the DPCO 2013 that empowers the government to monitor the price of all drugs including non-scheduled drugs.[51] The only power under this provision is to ensure that the maximum retail price of a drug is not increased by more than ten percent of the price of the drug in the preceding twelve months.[52] The capping of the trade margin is however necessary to ensure affordability and accessibility of drugs. Para 19 of the DPCO 2013, however, allows the government in extraordinary circumstances to fix the ceiling price or retail price of certain drugs for a certain period if the government considers it necessary in the public interest.[53] In exercise of the power conferred under this para the government has, after being satisfied of the extraordinary circumstances, recently put a cap of thirty percent on trade margins and directed the manufacturers to fix the retail price based on the price to the stockist of non-scheduled formulations that contain forty two anticancer drugs in the public interest.[54] This was

[51] ibid. at Para 20.
[52] ibid.
[53] ibid. at Para 19.
[54] Para 15, (*Order - National Pharmaceutical Pricing Authority*) <http://nppaindia.nic.in/wp-content/uploads/2019/03/Notification-25.02.2019-Final.pdf> accessed 19 July 2023.

done, among others, for reasons that include poverty caused by extraordinary out of pocket expenditure on medicines and therefore the need to ensure affordability, lack of substantial control over pricing of non-scheduled drugs especially due to high trade margin, the fact that out of pocket expenditure from hospitalisation due to cancer is 2.5 times the overall average of hospitalisation expenditure and catastrophic expenditure in cancer being the highest among all noncommunicable diseases, the requirement of universal access to healthcare at affordable prices and more specifically the need to make cancer drug affordable to ensure treatment at the earliest for greater curability.[55]

The NPPA has also by an order issued on 3rd June, 2021 exercising its power under Para 19 of the DPCO 2013 put a cap of seventy percent on the trade margin of Oxygen Concentrator on the price to the distributor for, among others, the reason that medical oxygen is an essential life saving drug in COVID care which had the effect of rising demand for oxygen concentrators leading to higher price.[56]

Very recently, there has also been reports of rationalisation on trade margins on drugs that are priced at rupees hundred or above that include drugs for the treatment of chronic kidney diseases, antibiotics, antivirals and some anticancer drugs.[57]

Price Control of Patented Drugs

While the prices of the scheduled formulations as are in the NLEM are regulated as discussed above and trade margins have been rationalised for some of the non-scheduled drugs by the NPPA by exercising powers conferred by the DPCO 2013, there are many other patented drugs, that are extremely important life saving drugs, required for treatment of people in need. Controlling the prices of such drugs raises many

[55] Paras 4, 5, 6, 7, 8, 9, 10, 11, 12 and 13 (*Order - National Pharmaceutical Pricing Authority*) <http://nppaindia.nic.in/wp-content/uploads/2019/03/Notification-25.02.2019-Final.pdf> accessed 19 July 2023.
[56] (*II - National Pharmaceutical Pricing Authority*) <https://nppaindia.nic.in/wp-content/uploads/2021/06/227375.pdf> accessed 19 July 2023.
[57] Standard B, 'Streamlining Trade Margins on Drugs Priced RS 100 and above Likely' (*Business Standard*, 30 August 2022) <https://www.business-standard.com/article/economy-policy/trade-margin-rationalisation-likely-on-drugs-priced-rs-100-and-above-122083000993_1.html> accessed 19 July 2023.

concerns including that it may negatively affect and dis-incentivise innovation and affect availability and accessibility of lifesaving drugs. Before doing a deeper analysis of price control of drugs under patent and its effects, let's look at how DPCO 2013 deals with patented drugs. Para 32 of the DPCO 2013 talks about cases in which provisions of this order are not applicable. Subpara (i) of para 32 says that these provisions shall not be applicable for a period of five years from the day that commercial production has been started within the country to a manufacturer who is producing a new patented drug that have been patented under the Indian Patent Act of 1970 as a product patent, which is not produced anywhere else and if such medicine has been developed through indigenous research.[58] This provision has however been amended and the non-applicability is now for a period of five years from the date that the manufacturer or importer has started commercial marketing in the country.[59] This means that the protection will also be available to drugs that are not developed in India. Subpara (iii) of Para 32 extends this protection to a new drug that involves a new delivery system that has been developed through indigenous research and is for a period of five years from the date of receiving market approval in the country.[60] The Amendment of 2019 provides the protection for an unlimited duration also to drugs that are used for treatment of orphan diseases as decided by the Ministry of Health and Family Welfare of the Government of India.[61] This protection is available even when the drug is not under patent or is not a new drug. The reason why this protection is provided is because the number of individuals who are suffering from such rare diseases is small, which means that the market for manufacturers of medicines to treat such diseases is also small.[62] Without such protection these manufacturers will not have much incentive to innovate and invest in the production of medicines for treatment of such rare diseases.

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[58] Para 32 (*The drugs (prices control) order, 2013*) <https://www.nppaindia.nic.in/wp-content/uploads/2018/12/DPCO2013_03082016.pdf> accessed 19 July 2023.
[59] Drug (Price Control) Amendment Order, 2019. <https://www.nppaindia.nic.in/wp-content/uploads/2021/01/6th-DPCO-2013-Amentment-dt-03.01.2019.pdf> accessed 19 July 2023.
[60] Supra note 57.
[61] Drug (Price Control) Amendment Order, 2019. <https://www.nppaindia.nic.in/wp-content/uploads/2021/01/6th-DPCO-2013-Amentment-dt-03.01.2019.pdf> accessed 19 July 2023.
[62] National Policy for Treatment of Rare Diseases, Ministry of Health and Family Welfare, Government of India.
<https://main.mohfw.gov.in/sites/default/files/Rare%20Diseases%20Policy%20FINAL.pdf> accessed 19 July 2023.

However, it has the effect of making the cost of treatment of such diseases very high, since the drug manufacturers have to recover the costs involved in research and development.[63] At the same time due to the extremely high cost of such medicines the government is incapable of providing such medicines for free.[64] Moreover, there are also macro allocative concerns about optimal use of limited resources to help a larger number of people with smaller amounts of resources.[65] The government's policy seems therefore to be to incentivise the market to invest more into treatment of rare diseases, by providing these exclusive marketing rights, so that these treatments are available in the market, albeit at a high cost. However, the costs of such medicine remain so high that they are beyond the reach of most patients in a country like India. Therefore, the government needs to put in place strategies to keep the prices in check to ensure accessibility and affordability of such medicines.

Based on the above legal analysis it can be seen that the overall position is that patented drugs of the kind as discussed above are not subjected to price control under the DPCO 2013 for a period of five years. However, patented drugs can otherwise be subjected to price control under the DPCO 2013.

PRICE CONTROL OF DRUGS AND ITS EFFECTS

One very important question that now remains to be addressed is whether price control of drugs is the right way to ensure availability and affordability of drugs or it should be left to the market forces. The usual criticism of price control of any sort is that it has a negative effect on innovation since the profit margin of the drug manufacturers go down leading to less money used in research and development. This then means that fewer new medicines are available for treatment of diseases affecting availability and accessibility of drugs. Furthermore, it is said that price control may also make manufacturing of low cost medicines unviable for small and new entrants in the business and thus negatively affecting availability and accessibility of medicines.

[63] ibid.
[64] ibid.
[65] ibid.

However, on the other hand, we have seen that lack of any price control, at least on the essential medicines, has the effect that many lifesaving drugs are beyond the reach of many and remain unaffordable for many. I shall not here be doing any in depth analysis of the impact of price control measures on innovation as that is beyond the scope of this work and much work on this has already been done. I shall analyse the question based on the existing studies and suggest possible options for India to adopt in order to ensure healthcare for all and fulfil its goal of achieving Universal Health Coverage.

One of the often heard arguments against price control of drugs is that regulations involving control of drug prices can have serious impacts in the pharmaceutical industry. This argument suggests that if the government were to try, by such price control measures, to make drugs more affordable then it will also negatively affect innovation in the pharmaceutical industry ultimately affecting availability of drugs. Since pharmaceutical innovation is in particular a highly complex, risky and time-consuming process, a decrease in innovation can be directly attributed to strict price control measures. Furthermore, it is said that having more such regulations will also mean that pharmaceutical companies have to dedicate more resources into complying with such regulations and that will have the effect that less resources will be available for research and development activities. When it comes to the international market, it is said that such measures could also have the effect of delaying such products' entry in countries that are not willing to pay higher prices. Besides the above, it is also generally understood that if the money available to a pharmaceutical company is reduced due to control of prices of drugs, then they will have less resources available to spend on research and development.

Among others, two important studies can be referred to in regard to the arguments above. One titled “An Economic Assessment of the Relationship between Price Regulation and Incentives to Innovate in the Pharmaceutical Industry”[66], is a study sponsored by Novartis, a Swiss Pharmaceutical Company, that explores how pricing and reimbursement regulations may possibly impact innovation in

[66] (*ESMT White Paper - E.ca*) <https://www.e-ca.com/wp-content/uploads/2009_wp-109-03.107655.pdf> accessed 19 July 2023.

pharmaceuticals.[67] More specifically, the study involves a qualitative investigation into the "*likely strategic response of pharmaceutical companies*" due to such regulation with respect to their research and development activities.[68] Secondly, the study involves "*quantitative evaluation of such effects in the context of a calibrated decision-theoretic model of drug development*" wherein pharmaceutical firms look to the future in considering how they'll price their drugs in the future in making their current decisions about development.[69] Essentially their study is to identify the adverse effects of pricing and reimbursement regulations on innovations by pharmaceutical companies.[70] Moreover, they also look into how such adverse effects of these regulations of the present happen in the future in terms of the number and characteristics of drugs that will be launched in the future, since the drug discovery and development is a long term process. They conclude that designing an optimal pricing and reimbursement regulation requires trading the benefits of more affordable and cost-effective drugs against the cost of less pharmaceutical innovation, with fewer projects developed and more so in low-margin therapeutic areas that are not considered innovative when launched.[71] Broadly, it means that if the drugs are made more affordable and cost-effective through price regulations there will be fewer innovations. Moreover the adverse effects of pricing and reimbursement regulations introduced in the present is seen in the number and characteristics of drugs to be launched in the future market.[72] The policy makers then have to make a balanced choice between innovation and future availability of new drugs and affordability of drugs now.

A second study in the Indian context titled "Who Benefits from Pharmaceutical Price Controls? Evidence from India[73]" is a study of price control in the Indian market and its effect on access to medicines in rural and urban areas.[74] It is essentially a study

[67] ibid.
[68] ibid.
[69] ibid.
[70] ibid. at page 9
[71] ibid. at page 19
[72] ibid.
[73] Dean EB, 'Who Benefits from Pharmaceutical Price Controls? Evidence from India - Working Paper 509' (*Center For Global Development | Ideas to Action*) <https://www.cgdev.org/publication/who-benefits-pharmaceutical-price-controls-evidence-india> accessed 19 July 2023.
[74] ibid.

of the effects of price control measures in India, which is a market based price ceiling imposed both on patent and generic medicines.[75] The study also looks into the impact of such measures on medicine quality. It is in light of the price ceiling on medicines in the NLEM the price of which is regulated by the NPPA under the DPCO 2013.[76] The results of this study show an 11.6 percent drop in the price of controlled products when compared with non-controlled products.[77] The price decrease has been noticed in all firms including multinational firms, exporter firms and local firms with multinational firms showing the highest decrease.[78] The study further shows a 4.3 percent decrease in sales at the SKU level with more drop for local and exporting firms at 5.3 and 4.7 percent respectively and at the same time there was not any significant drop for multinational firms.[79] The study also showed that multinational firms gained significant market share and local firms lost market share.[80] The results further show more local firms exiting the market after the price control and no significant impact on firm exit for exporter and multinational firms.[81] Therefore the study suggests that since the local producers produce low cost medicines, their exit would affect price sensitive customers i.e. those who are poor or live in rural areas.[82] It also shows that local firms are only exiting from price controlled formulations but not the non-price controlled ones.[83] Based on the results, the study concludes that while such price control has been beneficial to consumers due declining price and higher quality drugs, they have also adversely affected some consumers due to the exit of low cost and low quality producers and thus negatively affecting the price sensitive consumers and beneficially the quality sensitive consumers.[84]

[75] ibid. at page 1 & 2.
[76] ibid. at page 7.
[77] ibid. at page 22 and 23.
[78] ibid.
[79] ibid. at 23.
[80] ibid. at 27.
[81] ibid.
[82] ibid.
[83] ibid. at 28.
[84] ibid. at 29.

THE ROLE OF PUBLIC EXPENDITURE IN HEALTHCARE RESEARCH TO MAKE MEDICINES ACCESSIBLE

A great amount of credit is generally given to pharmaceutical companies for their efforts in healthcare research and development. However, the public sector also contributes greatly to fundamental research in healthcare. A research titled, "Contribution of NIH funding to new drug approvals 2010-16" shows that funding by the National Institute of Health (NIH) of the United States of America had contributed to published research with every one of the 210 new drugs that were approved by the Food and Drug Administration during the period of 2010-16.[85] It also shows that more than ninety percent of the funding is for basic research involving biological targets of drugs and not drugs themselves.[86] The study thus shows the significance of public expenditure in basic research is important and greatly helpful for applied research by the pharmaceutical industry to be possible. The public sector has a great role in the discovery and development of new drugs and it is the NIH funding of basic research that greatly contributes to bringing new products to market.[87] Therefore, the public and the private sector have to work together in both basic and applied research for innovations in healthcare and great deal of benefits derived by the private sector in further development of medicines can be credited to the fundamental research and the initial development of drugs funded by the state. Furthermore, these fundamental researches also happen in the universities and other places which are possible due to governmental funding. Therefore, it seems reasonable to expect that private companies also make the drugs and medicines available to the public at reasonably affordable prices thereby justifying many of these price control measures. However, since price control also affects innovation the policy makers have to find a sweet spot between the requirement of innovation and making drugs affordable and accessible to all by bringing down the price of medicines. This apart affordability of medicine and innovation in healthcare will also be improved by increased government expenditure on basic and fundamental research in healthcare.

[85] Galkina Cleary E and others, 'Contribution of NIH Funding to New Drug Approvals 2010–2016' (2018) 115 Proceedings of the National Academy of Sciences 2329.
[86] ibid.
[87] ibid.

CONCLUSION AND SUGGESTIONS

Based on the above discussion on different issues relating to regulation of price of drugs and medicines, certain observations can be made here. Despite disagreements it can be agreed that limiting drug prices is a tricky and complicated issue. However, this isn't the reason for not having any regulation of prices. Affordability and availability of drugs and medicines are urgent issues that can make a difference between life and death in many cases. Keeping that in mind the government has to ensure availability and affordability in medicines using policies that not only ensure availability and affordability but also facilitate and encourage research and development in medicine so that more effective, path breaking and innovative treatments are available in the future ensuring availability in medicines. It is with this idea in mind certain important suggestions can be made.

While it is important that prices of medicines are controlled to ensure availability and affordability of drugs and medicines, innovation is also important for the treatment of critical diseases and for more effective and path breaking treatments in the future. Therefore, while controlling the price such factors have to be kept in mind. However, it is also worth mentioning that a large amount of expenditure incurred by the healthcare industry is spent on marketing that barely contributes anything to innovation in medicine.[88] This means that before healthcare industry clamours about how price control affects innovation, they also need to be more transparent, or be required legally to be transparent, about how the money is actually spent on research and development. If the figures about how much is actually spent on research and development and how much on marketing is clear then there could be a more rational approach to regulating the price of medicines. This can be done while policy makers also take seriously and are conscious of the fact that drug development is a complex, lengthy and an uncertain process that involves taking lots of risks in terms of investment of money and resources

[88] It has been found that the healthcare industry in the United States spends 30 billion dollars on marketing which may also have the effect of overdiagnosis and overtreatment apart from the fact that the money is not spent on research and development.
Rapaport L, 'U.S. Health Care Industry Spends $30 Billion a Year on Marketing' (*Reuters*, 8 January 2019) <https://www.reuters.com/article/us-health-medical-marketing-idUSKCN1P22GG> accessed 2 September 2023.

without any outcome and therefore such costs are included in decisions relating to limiting prices.

However, since the government has the responsibility to realise healthcare for all and also of realising Universal Healthcare Coverage, the more effective approach would be one where all such drugs and medicines are procured by the state to be provided to the people. This would mean that individuals do not suffer, overspend or get poor quality medicines, when the state plays a major role in ensuring appropriate medicines of the adequate quality are available and prescribed when necessary. State playing such a major role would ensure that medicines of appropriate quality are available in adequate quantity as per the need of the people. Since the state is the major procurer of medicines, this would also ensure that its position is used to negotiate prices and ensure drugs and medicines of adequate quality are procured from competing manufacturers. Since information asymmetry, as discussed earlier, is one of the major factors behind higher expenditure by individuals on medicine, state providing medicines will have the effect of preventing such avoidable expenditures. Moreover, at the same time the state can also promote local manufacturers of quality medicines. This would also mean that the state will have the power to promote healthy and beneficial competition among manufacturers to produce cost-effective and quality medicines at affordable prices which are necessary for the population.

The state must provide all individuals essential medicines as are in the National List of Essential Medicines for free of cost. This would also be in fulfilment of the Universal Healthcare Coverage[89] and the Right to Health under International Law[90] [91]

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[89] 'SDG Target 3.8 | Achieve Universal Health Coverage, Including Financial Risk Protection, Access to Quality Essential Health-Care Services and Access to Safe, Effective, Quality and Affordable Essential Medicines and Vaccines for All' (*World Health Organization*). <https://www.who.int/data/gho/data/themes/topics/indicator-groups/indicator-group-details/GHO/sdg-target-3.8-achieve-universal-health-coverage-(uhc)-including-financial-risk-protection> accessed 1 August 2023.

[90] 'Access to Medicines - a Fundamental Element of the Right to Health' (*OHCHR*) <https://www.ohchr.org/en/development/access-medicines-fundamental-element-right-health#:~:text=From%20a%20human%20rights%20perspective,strengthen%20their%20national%20health%20systems.> accessed 1 August 2023.

[91] 'Access to Medicines and the Right to Health' (*OHCHR*) <https://www.ohchr.org/en/special-procedures/sr-health/access-medicines-and-right-health> accessed 1 August 2023 .

that requires the state to provide everyone with such essential medicines.[92] Instead of the market approach to controlling prices of essential medicines and leaving it up to individuals to buy them, the state should procure such medicines at competitive prices and provide them free of cost to all who need them. This way the government can ensure innovation in healthcare even when essential medicines are made available to all of adequate quality and quantity. Furthermore, the state providing essential medicines for free would also mean that other strategies by drug companies like promoting fixed dose combinations and non-standard doses would also be averted.

Besides the above, all other medicines could be provided by the state at reasonable prices to the population. For life saving drugs in the non-scheduled category apart from Trade Margin Rationalisation (TMR), the government should also make efforts at procuring them and distributing them at affordable prices to patients in need. Moreover, the governmental role in procuring and providing medicines would also mean that medicines of adequate quality at affordable prices are also procured from generic manufacturers. In all cases of such medicine procurement the government can also adhere to strict standards to maintain quality of medicines.

All the above are still being referred to in the context of outpatient care and all inpatient care and the requisite medicines and drugs are to be provided by the state in fulfilment of the Universal Health Coverage and the Right to Health under the International Law. All of this will however be possible only if government expenditure and investment in healthcare is substantially increased. Such expenditure has to be increased in order to improve the healthcare infrastructure, goods, services and facilities and also increase governmental funding of research and development in healthcare and allied sciences apart from encouraging such research in private sectors. This approach to ensuring affordability in healthcare of medicines and drugs fits perfectly into a model of healthcare that maximises the benefits to be derived from the limited resources available to the government and therefore requires the government to provide, among others, all essential drugs free of cost to patients besides inpatient drugs. Furthermore, it also fulfils the requirement of providing patients and care seekers appropriate and

[92] 'Essential Medicines' (*World Health Organization*) <https://www.who.int/southeastasia/health-topics/essential-medicines> accessed 1 August 2023.

correct information relating to health and healthcare services and the requirement of maintaining transparency at every stage with a patient centric approach. This will ultimately have the effect of improving efficiency, quality and cost-effectiveness in providing healthcare services to all as is the legal and moral responsibility of the states.