AN ANALYSIS OF DRUGS' PRICING IN INDIA

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ABSTRACT

The Indian Healthcare sector is very vast, and there are numerous laws regarding the manufacturing, availability of drugs and price control, yet the prices of drugs are so high that various sections of people are not able to access them. Drugs include the formulations and all medical devices. The DPCO, 2013, empowers the NPPA to regulate drug prices. All medicines listed in the NLEM (scheduled drugs) are under price control, and non-scheduled drugs (which are not listed in the NLEM) are only monitored by it. The price of drugs is very high due to their trade margin, patent, brand and short list of drugs in the NLEM. Price control of drugs by NLEM covers only around 18% of the total domestic pharma market, which is very low. So, to reduce the cost of medicines, the number of drugs in NLEM should be increased; generic drugs should be promoted; trade margins, patent-based benefits, and branding costs should be controlled; and corruption in this sector must be stopped at all costs. The doctrinal method of research has been adopted to complete the Research Paper. To find out the grey areas, which are a hindrance in reducing the drugs' price, an analysis has been done of the various Indian laws, policies made by the appropriate authority/ government/ s and efforts taken as well.

Keywords: Drugs, Price, Tax, Margin, Corruption.

INTRODUCTION

The Indian Healthcare sector is a very large sphere in terms of revenue and employment, and drugs/medicines are a crucial part of healthcare. If we talk about Allopathic drugs, then India is the world's 3rd largest provider of generic medicines by volume, with 20 per cent of the total global

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demand,[1] and 14th by value. With industry standards compliant, mega production capabilities and a large number of skilled domestic workforces, Indian exports meet the standards and requirements of highly regulated markets of the United States of America, the United Kingdom, etc. Most Indian made pharmaceuticals are low-cost generic drugs, which comprise most of the pharmaceutical export of India, while patented medicines are imported. India has more than 3000 (three thousand) pharmaceutical companies with a highly skilled resource pool and a well-built set-up of over 10,500 manufacturing amenities.[2] Out of these, in excess of 2,000 (two thousand) units are WHO's (World Health Organization's) GMP (Good Manufacturing Practice)[3] approved; more than 250 (two hundred and fifty) are EDQM (European Directorate of Quality Medicines) approved plants; near about 1,100 (one thousand and one hundred) have CEP (Europe's Certificate of Suitability); more than 950 match TGA (Therapeutic Goods Administration) guidelines; and 584 sites are approved by the US FDA (United States Food and Drug Administration). The mass drug clusters are situated in Vadodara, Ahmedabad, Aurangabad, Mumbai, Hyderabad, Pune, Chennai, Bangalore, Mysore and Visakhapatnam.

Despite the above, the price of drugs has been a sensitive subject in our Country, where a large section of people are unable to get proper treatment due to out-of-pocket money power. The affordability of drugs/ medicines is a crucial element in availing medical treatment by all sections of the people, particularly by the indigents of the Country. Therefore, control of the price of drugs has become an urgent necessity in India so that everyone can get proper treatment. According to data by AIOCD- AWACS,[4] around 14 per cent of drugs by value, and 25 per cent by volume, only fall under the price control policy, but it needs to be increased in the interest of the weaker section.

[1] https://www.india-briefing.com/news/indias-pharmaceutical-industry-investment-trends-opportunities-incentives-18300.html/

[2] https://www.investindia.gov.in/sector/pharmaceuticals#:~:text=India%20also%20has%20the%20highest,a%20highly%20skilled%20resource%20pool.

[3] Good manufacturing practice (GMP) is that part of a quality management system to ensure that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization.

[4] AIOCD Pharma soft tech AWACS Pvt. Ltd. is a pharmaceutical market research company formed by All Indian Origin Chemists & Distributors Ltd. (AIOCD Ltd) in a joint venture with Trikaal Mediinfotech Pvt. Ltd. AIOCD AWACS, an organization that has evolved into an IT infrastructure player in Pharma Distribution & Retail. AWACS stands for Advanced Working, Action & Correction System – giving clients early & accurate information to plan strategies & win over competition.

OBJECTIVE OF STUDY

The objectives/aims of this research paper are to analyse the various laws, policies and efforts made/taken by the government(s) regarding Drug pricing and to find out the grey area, by this analysis, which is a hindrance in reducing the price of the drugs.

IMPORTANCE/ SIGNIFICANCE OF THE STUDY

Through this research paper, we will be able to know the process to decide the drug's price, hindrances in reducing the price of the drugs and how they can be removed/ reduced so that suggestions can be given to get medicine at an affordable price to all the needy people.

SCOPE / LIMITATION/ UNIVERSE OF THE STUDY

This research paper will only cover the price of allopathic medicines/ drugs and analysis of the various Indian laws and policies made by & efforts taken by the government of India regarding drug pricing.

METHOD OF STUDY

This paper adopts the Doctrinal Method, and for this purpose, various statutes, books, journals, commentaries, reports, magazines, newspapers, etc. have been referred to. In preparing this paper, evaluative and critical approaches have also been applied.

CONCERNED GOVERNMENT/ S' INSTITUTIONS

There are two key ministries, *i.e.*, the Ministry of Health and Family Welfare (hereinafter referred to as the MoHFW), and the Ministry of Chemicals and Fertilisers (hereinafter referred to as the MoCF), for discharging various roles relating to the pharmaceutical products, health, etc., in the Country. MoHFW is responsible for ensuring quality healthcare by establishing a primary healthcare delivery system linkage with secondary and tertiary delivery systems. It has two departments, *viz*, i) Department of Health and Family Welfare (hereinafter referred to as the DHFW) and ii) Department of Health Research (hereinafter referred to as the DHR). The Directorate General of Health Service (hereinafter referred to as the DGHS) is the attached office of the DHFW and has various offices spread all over the country. The DGHS is involved in the implementation of the health services and renders all the technical advice regarding medical and health matters. Under the DGHS, Central Drugs Standard Control Organization (hereinafter

referred to as the CDSCO) is the national regulatory authority which is responsible for approval of drugs, conducts of clinical trials, laying down the standards of drugs, check and decides the quality of imported drugs, and coordination with State Drug Control Organizations and ensures the rules frame under the Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rule, 1945. On the other hand, DHR is responsible for bringing modern health technologies through research and innovations related to diagnosis, treatment methods, vaccines, etc. Second Ministry, *i.e.,* MoCF, is the administrative body with its three Departments, *viz,* Department of Chemicals and Petrochemicals, Department of Fertilisers, and Department of Pharmaceuticals (hereinafter referred to as the DoP). The DoP was established with the objectives of the pharmaceutical sector and regulates issues related to pricing and availability of drugs, research and development, protection of intellectual property rights, etc. A National Pharmaceutical Pricing Authority (hereinafter referred to as the NPPA), an independent regulator, was constituted as an attached office under the DoP in 1997, for ensuring that drugs are available at an affordable price to the public.

DRUGS

It is important to know the meaning of a drug. A drug is any chemical substance that causes a change in an organism's physiology or psychology when consumed/ externally used. Consumption of drugs can be via inhalation, injection, smoking, ingestion (via a patch on the skin), suppository, or dissolution under the tongue. Drugs are typically distinguished from food and substances that provide nutritional support.

In pharmacology, a drug is a chemical substance, typically of known structure, which, when administered to a living organism, produces a biological effect. A pharmaceutical drug, also called a medication or medicine, is a chemical substance used to treat, cure, prevent, or diagnose a disease or to promote well-being.

'Drug' is defined in the Drugs & Cosmetics Act 1940. This Act also covers the regulation of Ayurveda, Siddha, and Unani medications, as well as rules relating to them. According to this Act 'drug' includes:

i) All medicines intended for internal of external use, all substances that or used for treatment, diagnosis, mitigation or prevention of any disease or disorder of humans or animals and preparations applied on human body for the intention of removing insects like mosquitoes;

ii) Substances, other than food, projected to affect the composition or any function of the human or animal body, or for the destruction of the disease-causing insects in the human or animal body as may be specified by the Central Government's notification in the Official Gazette from time to time;

iii) All devices which are intended for inner or outer use in the treatment, diagnosis, prevention of disease or disorder, or mitigation in human or animals, as may be specified by the Central Government's notification in the Official Gazette from time to time.[5]

iv) Medical equipment, used on humans or animals, is a "drug" under Section 3 (iv)[6] of the Drugs and Cosmetics Act.

v) Further, all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, and manufactured, are included in the definition of drugs under the Ayurvedic, Unani and Siddha medical-path.[7]

Here, it would be appropriate to know the meaning of the 'formulation'. According to Section 2 (i) of DPCO, 2013, "formulation" means a medicine (used as an inner or outer for or in the treatment, diagnosis, mitigation or prevention of disease) processed out of or containing one or more drugs with or without the use of any pharmaceutical aids.

Sections 16, 17, 17A and 17B of the Act define the standards of quality of drugs,[8] Misbranded drugs,[9] Adulterated drugs,[10] and Spurious drugs, respectively.[11] It is not necessary to explain all these here, keeping in view the Paper's topic.

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[5] Section 3 (b).
[6] Ins. by Act 68 of 1982, S.3 (w.e.f. 1-2-1983).
[7] Section 3 (a), Substituted by Act No. 68 of 1982, Sec. 2, for certain words (w.e.f. 1.2.1983).
[8] Standard quality of a drug means, drug complies with the standard set out in the Second Schedule of the Act.
[9] A drug shall be deemed to be misbranded (a) if it is so coloured, coated, powdered or polished that damage is concealed or if it is made to appear of better or greater therapeutic value than it really is; or (b) if it is not labelled in the prescribed manner; or (c) if its label or container or anything accompanying the drug bears any statement, design or device which makes any false claim for the drug or which is false or misleading in any particular.
[10] A drug shall be deemed to be adulterated (a) if it consists in whole or in part, of any filthy, putrid or decomposed substance; or (b) if it has been prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health; or (c) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (d) if it bears or contains, for purposes of colouring only, a colour other than one which is prescribed; or (e) if it contains any harmful or toxic substance which may render it injurious to health; or (f) if any substance has been mixed therewith so as to reduce its quality or strength.
[11] A drug shall be deemed to be spurious (a) if it is manufactured under a name which belongs to another drug; or (b) if it is an imitation of, or is a substitute for, another drug or resembles another drug in a manner likely to deceive or bears upon it or upon its label or container the name of another drug unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug; or (c) if the label or container bears the

RATIONALITY OF PRICE REGULATION/ CONTROL OF DRUGS

Manufacturing, trade & commerce play a vital role in the economy of any country. However, in the mixed economy of India, traders/businessmen, manufacturers, the government and consumers are big stakeholders. The main objective of the manufacturers and traders/suppliers is to earn profit. The price of drugs/goods and services plays a very dominant role in the success of a manufacturer/service provider. If the price of a commodity is very high, the manufacturer/ stockist/trader will be in profit. Among all, the prices of drugs/medicines should be fair, keeping in consideration the quality and quantity of drugs. The role of government is to combine the advantages of manufacturers/traders and the consumer/public at large.

The concept of price control of drugs has its roots in "affordability of medicines to all". The object of various laws/regulations/orders relating to drugs is to provide necessary medicines to needy persons at affordable prices. Keeping in view the constitutional and legal mandate, people cannot be left at the mercy of pharmaceutical companies/traders for the availability of medicines. Moreover, in India, where the majority of people rely upon the government for a medical support system, the necessity of price regulation of necessary drugs increases manyfold. The purchasing power of a major part of the population of India is very low. So, access to the health care facility at an affordable cost is a vital issue in India. The cost of medicine is around 70% to 80% of the total cost pertaining to the outdoor patient and near about 50% for the indoor patient. Thus, the cost of medicine is a governing factor of the health care system.[12]

LEGISLATIONS/ REGULATIONS/ RULES AND ORDERS RELATING TO THE DRUGS

There are various laws relating to drugs in India. The governing statutes, regulations, rules and orders, with the objectives to the development of the pharmaceutical sector and regulate issues related to availability of drugs, research and development, protection of intellectual property right etc. and the controlling & monitoring its prices, are: Drugs and Cosmetics Act, (hereinafter referred to as the D & C Act) 1940; Drugs and Cosmetics Rules, (hereinafter referred to as the D & C Rules) 1945 with its (Amendment) Rules, 2020; Industries (Development and Regulation) Act (hereinafter referred to as the IDRA), 1951; Drugs and Magic Remedies (Objectionable Advertisement) Act of 1954; Essential Commodities Act, (hereinafter referred to as the E C Act) 1955; Prevention of

name of an individual or company purporting to be the manufacturer of the drug, which individual or company is fictitious or does not exist; or (d) if it has been substituted wholly or in part by another drug or substance; or (e) if it purports to be the product of a manufacturer of whom it is not truly a product.

[12] According to the personal experience of this Paper's authors.

Black-marketing and Maintenance of Supplies of Essential Commodities Act (hereinafter referred to as the PBMSECA), 1980; Competition Act, (hereinafter referred to as the C A), 2002; Consumer Goods (Mandatory Printing of Cost of Production and Maximum Retail Price) Act, 2006 and various Orders, such as, Drugs (Price) Control Order, (hereinafter referred to as the DPCO) 2013; Medical Devices Rules, 2017 with various amendments in later; Essential Commodities (Control of Unethical Practices in Marketing of Drugs) Order, 2017; Drugs and Clinical Trials Rule, 2019. It would be appropriate to discuss briefly all these here chronologically.

DRUGS AND COSMETICS ACT 1940

This is an Act to regulate the manufacture, distribution, import, and sale of secure, efficient drugs & cosmetics.[13]

Drugs and Cosmetics Rules, 1945: The Central Government made these Rules, as powers conferred by Sections 6 (2), 12, 33 and 33N of the Drugs and Cosmetics Act, 1940, and it contains provisions for categorisation of drugs under given schedules and also contain guidelines for the storage, display, sale, and prescription of each schedule. The D & C Rules were amended in 2021[14] to include added responsibility on a 'marketer'[15] In relation to the quality of drugs and other regulatory compliances, along with a manufacturer.

Industries (Development and Regulation) Act 1951: IDRA Act regulates equitable distribution and the availability at a fair price of articles, manufactured or produced by a scheduled industry. IDRA contains a list of scheduled industries which includes those engaged in manufacturing the articles, *i.e.,* Medical and Surgical Appliances,[16] Drugs and Pharmaceuticals,[17] with others. Section 18G of the Act gives powers to the Government of India (hereinafter referred to as the GoI) to issue orders for controlling prices of articles. Section 15 also gives powers to the GoI to investigate price rise in any articles related to a scheduled industry or industrial undertaking, following which, the

[13] The term 'cosmetics' ins. by Act 21 of 1962, Sec. 2 (w.e.f. 27-7-1964). According to Section 3 (aaa) of the Act, "cosmetic" means any article intended to be poured, rubbed, sprinkled or sprayed on, or introduced into, or otherwise applied to, the human body/ part of body or for promoting attractiveness, cleansing, beautifying, or altering the appearance, and includes any article intended for use as a component of cosmetic.
[14] With effect from March 1, 2021.
[15] A 'Marketer' has been defined as a person who is an agent or in any other capacity adopts any drug manufactured by another manufacturer under an agreement for marketing of such drug by labeling or affixing his name on the label of the drug with a view for its sale and distribution.
[16] Sl. No. 14 of the Act.
[17] Sl. No. 22 of the Act.

GoI can issue directions to control prices of those articles under Section 16. A contravention of GoI's orders under Section 16 or Section 18G is punishable.

Drugs and Magic Remedies (Objectionable Advertisements) Act 1954: This is an Act of the Parliament of India which prohibits advertisements of drugs and remedies that claim to have magical properties, and makes doing so a cognizable offence.

Essential Commodities Act 1955: This Act was made by the Central Government for the control of the production, supply and distribution of, and trade & commerce in certain commodities, in the interest of the general public. Drugs are considered essential for health; therefore, declared essential and put under the Essential Commodities Act. Further, all medical devices, as notified under the Medical Devices Rules, 2017, are under the Essential Commodities Act, 1955.

Prevention of Black-marketing and Maintenance of Supplies of Essential Commodities Act (PBMSECA) 1980: PBMSECA complements the ECA and gives powers to the GoI to issue orders for detaining any person, for a maximum period of 6 months, if s/he acts in a manner prejudicial to the maintenance of supplies of essential commodities. A person is said to act in a prejudicial manner if s/he commits an offence under the ECA or defeats its provisions by dealing in essential commodities with a view to making gains. This Act also applies to drugs, as drugs also come under the ECA Act.

Competition Act 2002: CA also contains sufficient deterrence to price-gouging practices. Section 3 prohibits anti-competitive agreements relating to production, supply, distribution of goods, services, etc., that cause or are likely to cause an appreciable adverse effect on competition in India. Agreements between competitors that trade in identical or similar goods/services, to engage in price gouging, are presumed to cause or be likely to cause appreciable adverse effect on competition, unless they can be shown to increase efficiency in production, supply, etc. For agreements between persons at different levels in the production chain (e.g., distributor and retailer) which involve price gouging, an appreciable adverse effect on competition needs to be proved. Section 4 of the CA restricts exploitative practices by enterprises that enjoy a position of power and can operate independently of competitive market forces or affect competitors or consumers in their favour. These dominant enterprises are prohibited from imposing unfair or discriminatory prices. This Act is also applicable to the Pharma Companies/industries.

Consumer Goods (Mandatory Printing of Cost of Production and Maximum Retail Price) Act 2006: Under this Act, certain guidelines are made so that the buyer is not made to pay more than

the maximum price printed on the products by the manufacturers. A Maximum Retail Price (hereinafter referred to as the MRP) is a value at which any goods/formulation/medicine is sold to a consumer/user, and it is required by the manufacturer to print such MRP on the label of the product. As per Section 2(f) of this Act, Maxim Retail Price is defined as "maximum retail price means such price at which the product shall be sold in retail and such price shall include all taxes levied on the product." It means the Maximum Retail Price is the maximum price the seller can charge from the buyer. MRP includes all taxes/charges. After the implementation of GST, prices of many products have undergone some changes from the previously followed structure. Any retailer asking for GST or other taxes above the MRP of a product can clearly be denied, and the complaint must be lodged against them at the ministry and various anti-profiteering commissions set up in India. Here, it is very important to understand all the factors/ elements of MRP very well.

Maximum Retail Price includes (After the implementation of the Central Goods and Services Tax Act, 2017) - Manufacturing Cost (actual cost of Product) + Packaging/presentation Cost + Marketing/advertisement expenses + Profit Margin of the manufacturer + Carrying & Forwarding Agent margin + Stockist/ Whole-saler/ Trader/ Dealer Margin[18] + Transportation + Retailer Margin + GST. We can understand this well by taking an example of MRP. For this purpose, the things required are i) MRP, ii) retailer margin, iii) GST value (5%/ 12%/ 18%), and iv) stockist, Whole-seller/ Trader/ Dealer margin.

Suppose price determined by Manufacturer of a product (including Manufacturing Cost (actual cast of Product) + Packaging/presentation Cost + Marketing/advertisement expenses + Profit Margin of the manufacturer + Carrying & Forwarding Agent margin) is Rs. 100/- (Basic Price for Stockist), GST value is 12%, Stockist margin is 10% and retailer margin is 20%, then the MRP will be determined in the following manner.

Sale Price for Manufacturer:

Basic Price for stockist = Rs. 100

+ GST (12%) = Rs. 12

Total = Rs. 112

This manufacturer's sale price, i.e., Rs. 112, will be the purchase price for Stockists.

[18] First point of seller.

Sale Price for Stockist:

Basic Price for stockist = Rs. 100

+ Margin of Stockist (10%) on Basic Price = Rs. 10

+ GST on both Basic Price and Margin of Stockist = Rs. 11

Total = Rs. 121

This Sale Price for the stockist, i.e., Rs. 121, will be the purchase price for the retailer.

Sale Price for Retailer:

Basic Price for Retailer {Basic Price for stockists (Rs. 100) + Margin of Stockist (Rs. 10)} = Rs. 110 + Margin of Retailer's (20%) on basic price on Retailer = 20% of Rs. 110 = Rs. 22

+ GST (12%) on both Basic Price for Retailer + Margin of Retailer's = Rs. 15.84

Total = Rs. 147.84

This Sale Price for the retailer, i.e., Rs. 147.84, will be the MRP.

Drugs (Price) Control Order 2013:[19] The Department of Pharmaceuticals, Ministry of Chemicals and Fertilisers, notified the DPCO in May 2013 with the purpose of providing basic health care and medicines at an affordable price across the country, and this Order empowers the NPPA to regulate prices of drugs. Before 2013, the DPCO, 1995, included only 74 (after 2013, 394) bulk medicines within its ambit, and the pricing of the drugs was fixed based on manufacturing costs declared by the drug manufacturers. As per this Order, all strengths and dosages specified in the National List of Essential Medicines (hereinafter referred to as the NLEM and it is Schedule I of the DPCO, 2013) are under price control. And the price of non-specified drugs in NLEM is only monitored by NPPA. Price 'control' and price 'monitored' by NPPA will be explained later.

Medical Devices Rules 2017:[20] These Rules attempt to establish a uniform regime for Indian medical device manufacturing and marketing. The applicability of these Rules is to substances as identified in the Rules and also such devices which are notified as drugs from time to time under

[19] Issued to regulate the prices of certain drugs. and supersession of the Drug (Prices Control) Order, 1995.
[20] This Rules issued by the Central Govt. under powers conferred by Secs. 12 & 33 of the D & C Act, 1940 (23 of 1940), after consultation with the Drugs Technical Advisory Board,

the D & C Act, 1940. In furtherance of this, the Central Government issued a Gazette Notification on 11th Feb., 2020,[21] *inter alia*, declaring all medical devices essentially as drugs. By doing so, the prices of medical devices are now regulated and monitored in accordance with the provisions of the DPCO, 2013.

Drugs and Clinical Trials Rule 2019:[22] These rules are notified, primarily with the intention to regulate clinical trials in the country and the Classification of medical devices. The provisions of these rules were invoked by the Drugs Controller General of India. The Rules apply to all or any new drugs, investigational new drugs, orphan drugs, phytopharmaceutical drugs, clinical trials, and biomedical and health research. The Rules override Part XA and Schedule Y of the Drugs/Medicines and Cosmetics Rules, 1945. Earlier regulations and Schedule Y will still be applicable for veterinary use drugs.

DRUGS PRICING/POLICY OF DRUGS PRICING

The Government does not control the prices of all drugs, and various drugs are left to market forces. There are two categories of drugs in terms of the controlling/monitoring of their prices. The first category is called Scheduled/ controlled drugs (which are specified in the NLEM), and the second is Non-scheduled/Uncontrolled drugs (which are not on the NLEM).

The policy about drug pricing began with the DPCO of 1962 and was followed by Orders in 1970, 1979, 1987, 1995 and in 2013. DPCO, 2013, empowers the NPPA to control the prices of the drugs.[23] The NPPA, an independent body of experts in the Ministry of Chemicals and Fertilisers, implemented a National Pharmaceuticals Price Policy (hereinafter referred to as the NPPP) in 2012 to regulate the prices of scheduled and non-scheduled drugs. The NPPA enforces these prices and the availability of the medicines. NPPA fixes two types of prices, *viz*. Ceiling prices for scheduled medicines and non-ceiling prices for non-scheduled medicines. Ceiling price[24] is calculated by the

[21] This Notification has been in effect since April 1, 2020.
[22] This Rules issued by the Ministry of Health and Family Welfare (Department of Health and Family Welfare), under powers conferred by Secs. 12 & 33 of the D & and C Act, 1940 after consultation with the Drugs Technical Advisory Board.
[23] The NPPA, the State Drug Controllers and District Drugs Inspectors are the enforcing agencies at national/ state/ district level respectively.
[24] A ceiling price is a government-imposed price control, or limit, on how high a price is charged for a product. Governments use price ceilings to protect consumers from conditions that could make commodities prohibitively expensive. In the case of each bulk drug, which is under price control a single maximum selling price is fixed that is applicable throughout the country. To achieve uniformity in prices of widely used formulations, the Modifications in Drug Policy envisage that there should be ceiling prices for commonly marketed standard pack sizes of price-controlled formulations which would be obligatory for all, including small scale units, to follow. Powers under

NPPA according to the formula given in DPCO, 2013, by following a market-based methodology and a non-ceiling price[25]. It is only monitored by it.

The NLEM was first released in 1996 as Schedule I of the DPCO. It was later revised in 2003, 2011, 2015 and 2022. Only those drugs that satisfy the priority healthcare needs of the majority of the population are brought within price control by including them in the NLEM.[26] NLEM is a dynamic list and is revised from time to time by the MoHFW. The list then forms part of the DPCO, 2013, as Schedule I. Every few years, the Health Ministry, in consultation with experts, draws up an NLEM. The Standing National Committee on Medicines (hereinafter referred to as the SNCM) was constituted by the Health Ministry in 2019 to revise the NLEM, 2015. The DoP has decided that the ceiling price for formulations specified under Schedule I of the DPCO, 2013 (NLEM), will be mandatorily fixed every five years. This order has been brought into effect with an amendment in paragraph 18 of the DPCO, 2013.[27] The Centre, on September 13, released the National List of Essential Medicines (NLEM), 2022, comprising 384 drugs and approximately 955 formulations across 27 therapeutic categories, Which Came into Force On 13th November, 2022. NPPA under DoP fixes the ceiling price of scheduled medicines as per provisions of the Drugs (Prices Control) Order, 2013. All the manufacturers are mandated by law to follow the ceiling prices fixed and notified by the NPPA from time to time, or else they risk facing recovery of the overcharged amount along with interest, and in some cases, a penalty.

Regarding the prices of the non-scheduled/uncontrolled category of drugs, there is no price cap, but the price can be increased in the MRP only up to 10% per year. Here, the manufacturer is free to decide the prices and margins at all levels, *i.e.,* for the manufacturer itself, for stockists and retailers. The manufacturer of non-scheduled drugs (drugs not under direct price control) is not required to take price approvals from NPPA for such drugs. If the price is bigger beyond 10% yearly, the NPPA penalises the company for overcharging. This present policy may, in fact, encourage retailers and wholesalers to sell medicines of higher MRP. This may favour the larger pharmaceutical

DPCO, are exercised for fixation/ revision of ceiling prices. The fixed/ revised ceiling price by NPPA are notified in the Official Gazette/ Gazette of India (Extraordinary).

[25] Non - ceiling prices fixed by NPPA under DPCO, are specific to a particular pack size of scheduled formulation of a particular company. Hence, they are formulation specific and company specific. The prices fixed for non-ceiling packs are communicated to the respective firms by issuing office orders. In such order, usually excise duty element is shown separately. However, local taxes are not included in the non-ceiling price.

[26] The National list of essential medicines is one of the key instruments in balanced healthcare delivery system of a country which inter alia includes accessible, affordable quality medicine at all the primary, secondary, tertiary levels of healthcare. Realizing this GOI, MOHFW decided to have its own essential medicines list. The first National List of Essential Medicines of India was prepared and released in 1996. This list was subsequently revised in 2003 and 2015.

[27] Notification S.O. 3249(E) issued on August 12, 2021.

companies, who may be able to tweak their MRPs to maintain profits. The central government is reviewing a proposal from the pharmaceutical industry regarding trade margin rationalisation on non-scheduled drugs in the form of capping trade margin.[28] A report by the Committee on High Trade Margins in the Sale of Drugs, constituted by the Government in 2019, said that representations received by the Committee, along with drug names, alleged that the trade margin allowed to retailers goes up to even 1800% or more.[29] ADEH (Association of Doctors for Ethical Healthcare) has said that trade margin should be capped at a maximum of 30 per cent from the factory price to the consumer, or an alternative formula which takes into account landed or ex-factory cost plus 30 percent trade margin should be opted for to calculate the retail price of a drug which should be inclusive of retail and wholesale margin, logistics and inventory cost. All medicines must bear the cost price and MRP to make the profit margin transparent, ADEH has said. The association added that all branded medicines should be sold with the chemical or pharmacological name only, and the name of the company should be mentioned on the cover separately, while there should be no trade names.[30]

The NPPA convened a meeting with the representatives of drug associations that have long been proposing a "one molecule-one MRP" formula on non-scheduled drugs instead of capping trade margins. It needs to adopt a One nation, One molecule, One MRP strategy together with a price control policy on Active Pharmaceutical Ingredients (APIs).[31] NPPA, under extraordinary circumstances, can control the price of any drug for a certain period of time, under the provisions of DPCO, 2013. In addition, under Para 19 of the DPCO, 2013, the government has special powers to bring any item of medical necessity under price controls. Under the trade margin rationalisation approach, the NPPA has also fixed trade margins of non-scheduled formulations of 42 select anti-cancer medicines. Putting a cap on the trade margin of 42 select non-scheduled anti-cancer medicines by the National Pharmaceutical Pricing Authority (NPPA)

[28] Trade margin refers to the price difference between what the manufacturer sells to a wholesaler, who, in turn, sells to stockists and retailers, and the maximum retail price a consumer pays.
[29] http://www.nppaindia.nic.in/wp-content/uploads/2019/03/Notification-25.02.2019-Final.pdf,
[30] https://www.moneycontrol.com/news/trends/doctors-body-pitches-for-capping-for-30-percent-trade-margin-for-all-drugs-in-india-9341591.html,
[31] All drugs are made up of two core components: i) The API is the central ingredient and ii) The excipient includes substances other than the drug that help deliver the medication to your system.
Excipients are chemically inactive substances, such as lactose or mineral oil in the pill. These materials are used to help the medication remain stable and to control absorption when you take the drug.

resulted in a reduction of up to 90 per cent in the maximum retail price of 526 brands of these drugs.[32]

As mentioned earlier, price control now extends to medical devices as well if they are included in the NLEM List. Presently, very few medical devices are included under NLEM. For the remaining medical devices, which have not been included in the NLEM, their prices are treated as non-scheduled drugs.

FORMULA TO DECIDE THE CEILING PRICE

The DPCO, 2013, follows a market-based pricing mechanism. The ceiling price is worked out on the basis of the simple average price of all brands having at least 1 per cent market share of the total market turnover of that drug, plus the retailer's margin. The ceiling prices of scheduled medicines will be allowed an annual increase as per the Wholesale Price Index, as notified by the Department of Industrial Policy and Promotion.

Methodology for fixation of the ceiling price of a scheduled formulation:[33] The ceiling price of a scheduled formulation of specified strengths and dosages as specified under the first schedule, calculated as under:

First the Average Price to Retailer of the scheduled formulation is calculated as: Average Price to Retailer = (Sum of prices to retailer of all the brands and generic versions of the medicine having market share more than or equal to one percent of the total market turnover based on moving annual turnover of that medicine) / (Total number of such brands and generic versions of the medicine having market share more than or equal to one percent of total market turnover based on moving annual turnover for that medicine).

Thereafter, the ceiling price of the scheduled formulation is calculated as- Ceiling price of the scheduled formulation = Average Price to Retailer x (1+M/100), where Average Price to Retailer = Average Price to Retailer for the same strength and dosage of the medicine as calculated in step 1 above; M = % Margin to retailer and its value, at present time is 16%

The ceiling price is then notified in the official Gazette.

[32] https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/cap-on-trade-margin-of-42-non-scheduled-cancer-drugs-by-nppa-led-to-up-to-90-pc-reduction-in-mrp-mansukh-mandaviya/articleshow/85208815.cms

[33] Detailed Methodology is given under Para 6, DPCO, 2013.

The MRP of scheduled drugs/formulations shall be fixed by the manufacturers on the basis of the ceiling price notified by the Government. It means, MRP = Ceiling price + GST + retailer's margin. Currently, the wholesale and retail trade margins on scheduled drugs are 8% and 16%, respectively, whereas for non-scheduled drugs, the wholesale and retail trade margins are 10% and 20%, respectively. Based on these trade margins, the National Pharmaceutical Pricing Authority (NPPA) fixes the drug price. Retailer margin can't exceed 16% for scheduled drugs in NLEM.[34]

In exercise of the powers conferred under para 18 (i) of the Drugs (Prices Control) Order, 2013; The revision of ceiling prices based on moving annual turnover value shall be carried out, as and when the National List of Essential Medicines is revised by the Ministry of Health and Family Welfare or five years from the date of fixing the ceiling price under this Order whichever is earlier.

ELEMENTS OF DRUG'S PRICE

The factors based on which the price of the drugs is decided, we can broadly divide them into two categories: A) Manufacturing cost, and B) Other costs.

Manufacturing Cost: Manufacturing Cost means the total of all costs incurred by a company/ manufacturer related to the manufacture of a batch or lot of Bulk Drug Substance. It includes **the cost of direct** material and labour, quality assurance/quality control, depreciation, as well as applicable Allocable Overhead and Third-Party costs relating to manufacturing (e.g., royalty), shipping and handling, duty, and insurance, etc.

Trade Margin: One of the biggest contributors to the prices of pharmaceutical products in the country is trade margin, or the margins that pharmaceutical companies allow in their distribution chain, including but not limited to wholesalers/distributors/retailers. However, a trade margin is a powerful tool for a manufacturer to incentivise the trader/retailer to dispense a particular manufacturer's products. Thus, there is a tendency to offer higher trade margins, which in turn affects the pricing of drugs.

Tax: Goods and Services Tax (GST) was introduced in 2017 and has impacted various goods/ services/ industries, including the pharmaceutical sector. GST's primary objective was to bring the sale of products and services under a unified taxation system across India, and has ensured a

[34] Para 4 of DPCO, 2013. All India Organisation of Chemists and Druggists (**AIOCD**), a representative body of 9.4 lakh chemists across the country, has urged the National Pharmaceutical Pricing Authority (NPPA) to allow 10 per cent trade margin for wholesalers on price to retailer (PTR) and 20 per cent for retailers on maximum retail price (MRP) of drugs.

seamless tax collection system, and to remove the cascading effect of the taxes. The cascading effect of taxes means the levy of tax on tax. GST would be levied only towards the net value added portion and not towards the entire portion of value, as the taxpayer would enjoy input tax credit. Under GST, the tax slabs are divided into five taxation rates, i.e., Nil, 5%, 12%, 18% and 28%. GST levy on pharmaceutical products is- Nil, 5%, 12% and 18%. One of the notable features of pharmaceutical products is that they do not fall within the 28% GST slab rate. Here it will be pertinent to analyse the prices of drugs before the enforcement of the Central Goods and Services Tax Act, 2017, which came enforce on 1st July, 2017, and after. The GST rate on a commodity has been fixed such that the incidence due to the new rate is approximately equal to the earlier tax incidence due to VAT, excise duty and local tax. VAT was 5% and excise duty – where applicable – was 6% of 65% of the MRP. After GST, drugs (which are not under price control) are allowed a 10% price increase every April as per the DPCO 2013. Previously, the pharmaceutical industry attracted eight different types of taxes. But GST has merged all these taxes into one, thereby removing the cascading impact of many taxes. GST will also rationalise the supply chain, thereby improving operational efficiency. One thing to note here is that price control of drugs by NLEM covers only around 18% of the total domestic pharma market, which is very low.[35]

Patent: A patent[36] is granted to the company that developed the drug, and gives an exclusive right to sell the drug as long as the patent is in effect to that company. Like this, patents protect the investments made for research and development and create an incentive for innovation. Therefore, companies keep the price of drugs high to recoup their costs until the duration of the patent. Drugs, whose patent term has expired, come within the public domain, and then these drugs can be made by other companies and can be sold in the market as generic or branded medicine, and then their prices go down. In January, 2019, as a result of an amendment to the DPCO, 2013, the Central Government has exempted new drugs, patented under the Indian Patent Act, 1970, from price control for five years from the date of their marketing. Thus, patented drugs fall out of the scope of price control, albeit for a period of five years. Further, drugs used for treating orphan/rare diseases

[35] https://theleaflet.in/increase-in-drug-prices-will-hit-people-hard-need-for-re-orienting-drug-pricing-and-production-policy/#:~:text=This%20order%20affects%20nearly%20872,total%20pharma%20market%20in%20India. 'Increase in Drug Prices Will Hit People Hard – Need for Re-orienting Drug Pricing and Production Policy', the Leaflet constitution First, retrieved on 03.11.2022.

[36] A patent is a form of intellectual property that protects an invention. It gives the inventor exclusive rights to produce, use and sell their invention for a set period.

(those affecting not more than five lakh persons in India) will also be exempted from the provisions of DPCO, 2013.

Brand[37] **vs Generic:**[38] Generic drugs are considered worldwide. However, in India, generic drugs are made available under multiple brands by different companies. Generic drugs are approximately the same dosage, intended use, effects, side effects, route of administration, risks, safety, and strength as the branded drugs. In other words, their pharmacological effects are the same as those of their brand-name counterparts. Actually, generic drugs are only cheaper because the manufacturers have not had the expenses of their marketing/promotion. When a company brings a new drug into the market, the company has already spent substantial money on research, development, marketing and promotion of the drug, and that's why it costs more. There are a few differences, however. Generic and branded medications don't look the same. Generics may have slightly different inactive ingredients (fillers, binders, flavours, etc.). These don't affect how the medicine works.[39] A brand drug is given the name by the producing company, and a generic drug is referred to by the name of the active ingredient.[40] Brand names are usually capitalised, while generic names are not. Generally, doctors prescribe branded medicine for patients.

Bribes in the Name of Gifts to Doctors: Pharmaceutical companies present very expensive gifts to doctors for prescribing their medicines. Actually, giving such an expensive gift is not a gift; rather, it is a bribe. Recently, one such case was found about the anti-fever drug Paracetamol tablet 'Dolo-650'. A PIL (Public Interest Litigation) filed by an NGO (Federation of Medical and Sales Representatives Association of India) before the Supreme Court of India stating that the Central Board of Direct Taxes (CBDT) has accused the Bengaluru-based drug firm 'Micro Lab Ltd', Dolo-650 maker Pharmaceutical Company, had invested 1,000 (one thousand) crores in freebies to doctors for prescribing to patients its anti-fever drug/Dolo 650 m.g. tablets. Micro Labs/Drug maker has termed the allegations that such freebies to doctors to promote its anti-inflammatory drug Dolo 650 as baseless. The Court posted the case for further hearing on Sept. 29, 2022. To what extent this allegation is a lie and to what extent it is true, it will be known later, but pharmaceutical companies indeed present gifts to medical practitioners. It is a tradition in our society to give gifts on some occasions, but it is not a healthy tradition to present gifts to doctors by pharmaceutical

[37] Section 2 (c) defines as: "brand" means a name, term, design, symbol, trademark or any other feature that identifies one seller's drug as distinct from those of other sellers.
[38] Section 2 (j) defines as: "generic version of a medicine" means a formulation sold in pharmacopeial name or the name of the active pharmaceutical ingredient contained in the formulation, without any brand name.
[39] https://www.medicinenet.com/generic_drugs_are_they_as_good_as_brand-names/views.htm
[40] https://www.rosemedicalgroups.org/blog/difference-between-brand-name-and-generic-drugs#:~:text=While%20brand%20name%20drug%20refers,as%20the%20brand%2Dname%20drug

companies because the cost of all these gifts will be added to the price of the drugs by the manufacturing company, and the price of the drugs will be increased. At present, one thing is being discussed further in the Country, that is, gift and freebies should be differentiated by making a law.

Other: There is also a lot of corruption in the medical field. People's illiteracy and helplessness are taken into account a lot in this field. For example, i) the manufacturer increases the strength and doses of drugs (which are mentioned in the NLEM) a little more and launches them in the market to avoid the ceiling price. There are many other factors/corruptions, which do not directly affect the price of drugs but increase the cost of health care, like theft of drugs by the employees of the hospitals, bribes to provide immediate medical care, Unnecessary drugs and tests prescribed by doctors, adulterated drugs proliferate, etc. Lack of professional ethics and deficient laws regulating corruption in the medical healthcare field, and the hard process of prosecution, are also important causes for the emergence and spread of corruption.

ONLINE PHARMACIES

Online pharmacies are internet-based vendors that sell medicines and include both legitimate and illegitimate pharmacies. Online pharmacies offer better pricing than offline stores, with increased access, lower transaction and product costs, convenience and greater anonymity for consumers. They offer accessibility to people with limited mobility and people in remote areas. These provide MedAlerts/ Medi-Alerts (personalised & unlimited medicine reminder service), discounts, doorstep delivery within a short time, and validation of prescription through licensed pharmacists. Information about substitutes and adverse effects is also available on these sites.[41] The Country has seen a growth spurt in online pharmacies, which, on the one hand, is viewed as increasing healthy but uncontrolled competition in the market.

Laws for E-commerce are ill-defined and subject to varied interpretations. Various laws, such as the Information Technology Act, 2000; the Drug and Cosmetics Act, 1940; the Drugs and Cosmetics Rules, 1945; the Pharmacy Act, 1948; and the Indian Medical Act, 1956, govern the online pharmacies in India. Many of these, including the Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954, with its Rules 1955, under which drug advertisements are regulated, were written when the use of computers and the internet was not as prevalent as it is now. Laws do exist for online pharmacy stores in India. As per the Indian laws, medicines can be sold only by a registered pharmacy that has a retail license and a registered pharmacist on its payroll.

[41] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5155458/

A prescription for medicines ordered is mandatory, except for the sale of over-the-counter products.[42] The Government, on 18 August, 2018, published a draft of a proposed amendment to the D & C Act, to include a Chapter on the sale of drugs by an e-pharmacy, the same having been embroiled in a legal tussle, with established trade organisations stanchly opposing the amendments.

COURTS' ROLE

Indian constitutional courts have time and again used their inherent powers to pass orders on grounds of equity and justice. Article 142 of the Constitution of India empowers the Supreme Court of India to pass orders for doing complete justice in matters before it. The High Courts have also exercised inherent powers pursuant to Section 151 of the Code of Civil Procedure, 1908, which preserves courts' power to pass necessary orders to meet ends of justice. Recently, the Supreme Court recognised the key role of private players in containing COVID-19 and passed an order directing the government to ensure that all COVID-19 testing is done free of cost (in government and private laboratories). The Delhi High Court, while deciding a dispute between an importer and distributor, also directed those prices of imported COVID-19 testing kits, to be supplied to private and public agencies, be capped at INR 400 per piece.

EXECUTIVE'S EFFORTS

The Government has brought all medicines under the purview of GST. Apart from this, the GoI funds and operates several healthcare schemes and policies to minimise the price and to provide free/affordable and quality treatment to Indian citizens, some of which may be noteworthy:

i) Pradhan Mantri Jan Arogya Yojana (PM-JAY),[43]

ii) Pharmaceutical Policies,

iii) Telemedicine Practice Guidelines, 2020,[44]

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[42] *Ibid*.

[43] PMJAY is also known as Ayushman Bharat Pradhan Mantri Jan Arogya Yojana Scheme, Prime Minister Shri Narendra Modi announced the launch of (PMJAY) Ayushman Bharat Yojana in his Independence Day speech of the year 2018. Pradhan Mantri Jan Arogya Yojana (PMJAY) is a flagship National Health Protection Scheme funded by the Government of India. Ayushman Bharat Yojana subsumes the Senior Citizen Health Insurance Scheme (SCHIS) and Rashtriya Swasthya Bima Yojna (RSBY) and is also known as the AB-PMJAY scheme. Ayushman Bharat Yojana scheme caters not only the poor but rural families too, which is why it is economically beneficial to the poor and destitute households in rural and urban areas.

[44] On March 25, 2020, the Ministry of Health and Family Welfare, India, had released the "Telemedicine Practice Guidelines" for allopathic registered medical practitioners (RMPs). This guideline is prepared by the Board of Governors, Medical Council of India, in partnership with the National Institution for Transforming India (Aayog).

iv) Scheme for Promotion of Bulk Drug Parks,

v) Production Linked Incentive Scheme for Promoting Domestic Manufacturing of Medical Devices,

vi) Scheme for Promotion of Medical Device Parks,

vii) P M Atmnirbhar Swasth Bharat Yojana,

viii) National Health Policy, 2017,

ix) National Health Mission,

x) The Uniform Code of Pharmaceutical Marketing Practices,

xi) Central Government Health Scheme, xii) Mission Indradhanush,

xiii) Pradhan Mantri Bharatiya Janausadhy Pariyojana,

xiv) SUGAM [45] etc.

CONCLUSION

The DPCO, 2013, empowers the NPPA (National Pharmaceutical Pricing Authority) to regulate drug prices. According to the DPCO, 2013, all strengths and dosages, given in the NLEM (scheduled drugs), are under price control, and non-scheduled drugs (which are not enumerated in NLEM) are only monitored by it. Above the limitations of the strengths and dosages of the drugs, which are mentioned in NLEM, are also treated as non-scheduled drugs. For example, anti-fever drug Paracetamol tablet 'Dolo-650' (650 mg dose) is not under price control because its limited dose, i.e., up to 500 mg tablet, falls under the ceiling price. In this way, the manufacturer increases the strength and dose of drugs (which are mentioned in the NLEM) a little more and launches them in the market to avoid the selling price. For scheduled drugs, the government sets a ceiling price,

This would be included in the Appendix V of 2002 Regulations on "Professional Conduct and Ethics" under the Indian Medical Council Act, 1956. This amendment is valid according to the National Medical Commission Act, 2019, Section 61 (Subsection-2). The guidelines enable the RMPs to deliver healthcare using technology. The guidelines include all the channels of communications (text, audio, video, etc.).

[45] SUGAM is an e-Governance system to discharge various functions performed by CDSCO under the Drugs and Cosmetics Act, 1940. The software system developed is an online web portal where applicants can apply for NOCs, licenses, registration certificates, permissions & approvals. It provides an online interface for applicants to track their applications, respond to queries and download the permissions issued by CDSCO. It also enables CDSCO officials to process the applications online, generate the permissions online and generate MIS reports.

and it can be sold at this ceiling price with GST and the retailer's margin, which is called MRP. The wholesaler's and retailer's margins for these drugs can't exceed 8% and 16%, respectively. Thus, the MRP of these drugs can't exceed a certain limit. But no such limit can be fixed by the Authority in respect of non-scheduled drugs because here the authority/government only monitor that price and can be increased in the MRP only up to 10% per year by the manufacturer. Here, the manufacturer is free to decide the prices and a margin at all levels and also is not required to take price approvals from NPPA for such drugs. If the price is increased beyond 10 per cent annually, the NPPA intervenes and penalises the company for overcharging.

Around 14 per cent of drugs by value, and 25 per cent by volume, only fall under the price control policy. Price control of drugs by NLEM covers only around 18% of the total domestic pharma market, which is very low. Due to limitations on the strengths and dosages of the drugs, which are imposed in NLEM, high strengths and dosages of the drugs are removed from the List.

Despite the various laws and efforts taken by the government and judiciary, the price of drugs is very high due to their trade margin, patent, brand, and imposition of limits relating to strengths and dosages of the drugs,' & don't put a lot of drugs in the NLEM. It needs to be increased in the interest of the weaker section.

SUGGESTIONS

- The number of drugs in NLEM should be increased, keeping in view the interest of the public as well as pharmaceutical companies.
- Limitations of the strengths and dosages of the drugs, which are imposed in NLEM, should not be imposed.
- Generic drugs should be promoted in place of branded drugs.
- Corruption, in this sector, must be stopped at all costs.
- Appropriate provisions should be made to control/ regulate Online Pharmacies by the competent authority.