



A REVIEW ARTICLE ON DRUG PRICE CONTROL ORDER IMPLEMENTATIONS, IMPACTS AND FLAWS

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ABSTRACT

Patients are becoming increasingly concerned about the rising expense of medical care, and the pricing of many branded drugs sold in India vary widely. The government of India implemented the Drug Price Control Order 2013 with the intention of lowering the price of necessary medications. Drug price control order is helpful for regulating the costs of life-saving medications, which are necessary in the present healthcare and illness landscape. Under Drug price control order, all necessary medications are covered, and a price cap is developed. The Drug price control order order-set cap on drug pricing must be adhered to.

In this article I had discussed about what is Drug Price Control Order, the implementation been made by the Indian government on this order, the flaws been made by the pharmaceutical industry and the impacts of these drug price control order

Keywords: Pharmaceutical industry, price control, drug policy, drug pricing, NPPA, lower drug cost

INTRODUCTION

THE DRUGS (PRICE CONTROL) ORDER (DPCO) – WHAT IS THAT?

under section 3 of the essential commodities act of 1955, the government of India enacted the drug cost control order to control drug prices.

The order includes, among other things, a list of pharmaceuticals with fixed pricing , guidelines for setting drug prices, instructions for carrying out prices set by the government , and saction of breaking rules.

The government has given NPPA authority to carry out the requirements of DPCO [1]

ALL MEDICATIONS SOLD IN THE COUNTRY HAVE PRICE CONTROLS?

No, the National List of Essential Medicines (NLEM) 2011 is utilised to determine essentiality. DPCO 2013 includes 600 scheduled medications from 27 therapeutic areas. Other medications' costs may be regulated if it's in the public interest.

NPPA'S GOAL

In accordance with a September 1994 Cabinet Committee decision to revise Drug Policy, the National Pharmaceutical Pricing Authority (NPPA) was created on August 29, 1997.

The Authority fixes and revises medicine pricing (bulk drugs and formulations) and enforces drug legislation (Prices Control Order and oversight of both controlled and uncontrolled drug pricing).

HISTORY OF DRUG PRICE CONTROL ORDER

- In 1966 the parliament members have felt that the manufacturers are charging a very high rate on the drugs
- In order to control the high rate on the drugs, the drug price control order was passed in 1966 under

section 3 of essential commodities act 1955

- The DPCO 1966 was replaced by DPCO 1970, then in 1974 the Hathi committee was formed and it submitted its report in 1975
- The DPCO 1970 was then replaced by 1987, DPCO 1979 by DPCO 1987
- The DPCO 1987 has been replaced by DPCO 1995 and then finally by DPCO 2013

OBJECTIVES OF DPCO

- To maintain sufficient production
- To supervise the equal distribution
- To maintain and increase supply of bulk drugs
- To make the drugs available at fair price

PHARMACEUTICAL INDUSTRY IN INDIA

- Annual turn over (2016- 17)
- Export of bulk drugs, drug intermediates, formulations, biologicals – RUPEES 289998 crores in 2019-20
- It is the third largest in term of volume and 14th largest in term of value
- USFDA approved plants CDSCO: 153

Access to medicine is a major bother throughout the world, especially in the low

and middle income countries, where the availability of the essential drug is 35% in

the public sector and in the private sector it is of 66% [2].

Table 1: Number Of Drug Under Price Control

Sr No.	Year	No. of drug price control
1	1979	347
2	1987	142
3	1995	76
4	2002	32 app.
5	2013	348
6	2015	376
7	2019	860

THE IMPLEMENTATIONS BEEN DONE BY THE GOVERNMENT ON DRUG PRICE CONTROL ORDER RETAIL PRICES FOR 84 MEDICATION FORMULATIONS ARE SET BY THE DRUG PRICING AGENCY NPPA FOR 2022, including those of treatment of diabetes, headache, high blood pressure.

- Paracetamol and caffeine tablets cost Rs 2.88. One rosuvastatin, aspirin, and clopidogrel pill costs Rs 13.91. The NPPA also prolonged the ceiling price of liquid medical oxygen and oxygen inhalation until September 30, 2022, and prices of formulations to decrease cholesterol and triglycerides.
- Voglibose and (SR) Metformin hydrochloride will cost Rs 10.47, excluding GST.
- The NPPA must fix/revise the prices of several restricted bulk drugs and formulations, and enforce price and availability. They keep

decontrolled medicine prices modest.

- The regulator implements the drug order. It must also reclaim amounts overcharged by medication producers [3].

NPPA ALLOWS A 50% PRICE INCREASE FOR IBUPROFEN, RANITIDINE, AND CARBAMAZEPINE THROUGH 2021

- NPPA has raised the ceiling prices of nine scheduled formulations of carbamazepine, ranitidine, and ibuprofen by 50% to ensure their availability. The National Pharmaceutical Pricing Authority (NPPA) said these pharmaceuticals are vital to the nation's public health programme.
- At its June 28 2021 meeting, the NPPA reviewed increased price revisions of several medication formulations under Paragraph 19 of DPCO 2013. Low-priced drugs that were previously subject to price

constraints are being reviewed for price increases.

- Carbamazepine is an anti-epileptic medicine, while ranitidine treats stomach and intestinal ulcers and prevents recurrence. Ibuprofen treats headaches, arthritis, menstrual cramps, toothache, and muscle aches.
- The National Pharmaceutical Pricing Authority (NPPA) said the unavailability of certain formulations should not drive the public to switch to more expensive alternatives.
- NPPA said a one-time price increase of 50% from the current ceiling price is being examined in the public interest as an uncommon move to rectify the problem caused by recurring price control (SCAMHP).
- The regulator was established as an independent regulator for medication pricing to ensure the supply and accessibility of medicines at reasonable prices.
- NPPA sets a ceiling price for all Schedule 1 DPCO 2013 medications and tracks their annual price rises [4].

THE GOVERNMENT OF INDIA EXPECTS TO PRODUCE 122.49

LAKH VIALS OF REMDESIVIR EACH MONTH BY THE YEAR 2021

- Remdesivir's production capacity in India increased from 38.8 lakh vials per month in mid-April to 122.49 lakh vials per month in June 2021. As of this writing, no state or union territory is experiencing a shortage of the antiviral medication, according to information provided to the Rajya Sabha on Tuesday.
- Mansukh Mandaviya, the Union health minister, stated in a written response that shortages of Remdesivir injections were observed on the market in April and May 2021 as a result of an unexpected rise in demand for the medication to treat Covid-19 patients.
- Through numerous advisories, the central drug standard control organisation (CDSCO) has urged the licencing authorities of all states and UTs to direct their enforcement personnel to keep a strict eye out for attempts at the black market or hoarding of controlled substances and to take decisive action against offenders.
- The state government and UTs may closely monitor the manufacture and supply of COVID 19

medications in order to prevent black marketing and hoarding, according to a directive from the National Pharmaceutical Pricing Authority within the Department of Pharmaceuticals

- According to the minister, it may also be ensured that the provisions of the Drug (Price Control) Order, 2013 (DPCO. 2013) regarding compliance with ceiling prices and authorised price increases for scheduled and non-scheduled formulations are not being violated [5].

AS THE PRICE CONTROL LIST GROWS, NEW MEDICINE LAUNCHES DECLINE BY 80% IN 2014

New Delhi: Over the past four and a half years, the number of new drug launches in India has decreased by over 87 percent, and drug producers attribute this to pricing controls and policy uncertainty making India an unappealing location for both domestic and foreign pharmaceutical businesses.

In 2008, 270 new medications were licenced for sale in India; by 2012 and 2013, that number had plummeted to 44 and 35, respectively. According to government statistics, only 56 new drugs were licenced in 2014 up to November.

The majority of the major pharmaceutical corporations have removed India from their list of important markets. A senior executive of a top domestic pharmaceutical company stated that the cause is tougher policy measures cutting down on margins, making it less viable as a business proposition for future expansion [6].

52 NEW MEDICATIONS WILL BE PRICED IN 2020

NEW DELHI: The government has purchased 52 new drugs as part of its price control mechanism to keep an eye on the costs of important medications, including several regularly used analgesics and antibiotics as well as those that can be used to treat cancer and skin conditions.

- More than 450 drug formulations are now covered by the **NATIONAL PHARMA-CEUTICAL PRICING AUTHORITY's** price control mechanism as a result of the most recent change, which involves the regulator setting ceiling and retail prices for such medications.
- The drug pricing regulator stated that the NPPA was established by the government to fix or revise the prices of controlled bulk drugs and formulations and to enforce prices and availability of the medicines in the country under the drug price control order. The NPPA has fixed /revised the prices in respect of 52

formulations packs both ceiling and retail price pack under DPCO 2013.

- The biggest pharmaceutical companies likely to be impacted by the most recent price control decision, according to an industry analyst, include Lupin, Cadila, and Merk.
- Common antibiotics and pain relievers, as well as medications used to treat cancer and skin disorders, are among the new drugs that have been placed under price control [7].

2020 MARKS THE EXTENSION OF THE PRICE CAP PERIOD FOR LIQUID MEDICAL OXYGEN AND OXYGEN INHALATION

- The National Pharmaceutical Pricing Authority ("NPPA") has recommended that the price cap on liquid medical oxygen and oxygen inhalation be further extended to another three months past December 31 or until further order, whichever is earlier, after which the issue may be reviewed again. The NPPA is the regulatory body in charge of controlling, monitoring, and ensuring availability and affordability of drug prices.
- Since 2016, the price of oxygen has been regulated. A new lower ceiling

price (a "revised price cap") was announced in the notification dated September 25, 2020 due to the product's increased demand during the COVID-19 pandemic. 10 The NPPA subsequently extended the amended price cap through notices dated March 25, 2021, and September 23, 2021. 12 In the interest of the public, the current Notice further extends the timeline for the new price cap.

- The Government may set drug ceiling prices in light of extraordinary circumstances in the interest of the public for a period of time as it may deem fit, notwithstanding the wholesale price index, under paragraph 19 of the Drugs (Prices Control) Order, 2013 ("DPCO"), India's primary drug price control regulation. Under this clause, the updated price cap has been put into effect [8].

THE FLAWS PRESENT IN THE DRUG PRICE CONTROL ORDER SUPREME COURT INSTRUCTS THE CENTER IN 2015: "RE EXAMINE THE DRUG PRICING POLICY. IT IS UNREASONABLE."

NEW DELHI: On Wednesday 2015, the Supreme Court ordered the federal government to re evaluate its approach to

setting prices for essential medications, describing the current approach as irrational and unreasonable given that some medications have prices that are roughly four thousand times higher than those set by some state governments.

The ministry of chemicals and fertilisers was requested by a court panel led by Justice TS Thakur to examine and explain why the restricted price of vital medications has been set at a high level, preventing the poor from accessing life-saving medication at a fair price [9].

THE SUPREME COURT WILL REVIEW THE DRUG PRICING SYSTEM IN 2013

There are many issues with the current pricing policy, according to Srinivasan. As an illustration, he stated that if a product is 500 mg, it will fall under the price control requirements. If the dosage were increased to 510 mg, however, On Tuesday, the Supreme Court decided to review the newly developed government-created national pharmaceutical price strategy. The policy was created to set the country's costs for vital medications.

Upon receiving a plea from the health professionals contesting the pricing set by the government, a bench presided over by justice G S Singhvi requested the Center to provide its response.

While granting the petition, the bench noted that even with the government's

lower drug costs, manufacturers and traffickers still make a profit that ranges from 10% to 1,300% of the cost of producing a drug. Another issue is that drug makers have been granted a stay because they do not agree to sell necessary medications at the revised rates set by the central government.

The estimates provided by the petitioners for samples of 50 medicines, which demonstrated that profit margins of manufacturers and dealers are quite large even with the government Drug Price Control Order, were the basis for the highest court bench's observation.

"We supplied price of 50 drugs and computed the cost based on new pricing policy, which reveals that the makers are still making almost 1,300% more than the manufacturing cost," S Srinivasan, one of the petitioners, stated.

The two-judge panel criticised the Central government for dragging its feet on price fixation for the previous ten years. The bench added that the Centre has done nothing other than form several committees this policy would not apply to the pricing of the identical product.

Additionally, he said that the government had not added enough medications to the list of necessary medications. He suggested that the administration incorporate different pharmacological combinations in the policy.

The government was also condemned by the court for failing to expand the scope of the Drug Price Control Order beyond 1999.

The National Pharmaceutical Pricing Policy was initially drafted in 2011 by the Ministry of Chemicals and Fertilizers, eight years after the PIL was first filed. Health experts criticised it harshly for setting the drug pricing formula in a way that would make medications costly.

The Delhi High Court has issued a stay order on the Centre's Pharma Price Control Order for 151 critical medications after receiving requests from numerous drug manufacturing businesses and their associations. In accordance with the National Pharmaceutical Pricing Authority's (NPPA's) Drug Price Control Order, the companies were required to start selling the listed medications on July 29 at the set pricing. The pharma lobby also intends to file a lawsuit challenging the government's methodology for determining the cost of vital medications [10].

GIVEN THE CONCENTRATION ON EXPANSION, INDIAN PHARMA CANNOT AFFORD TO MISS THE GOVERNANCE BUS BY 2022

The Indian pharmaceutical business has a self-regulatory "Uniform Code of Pharmaceutical Marketing Practices (UCPMP)" to stop unethical marketing practises. Unethical Marketing Under Judicial Examination But brand-related

prescription misconduct has nonetheless happened. In March, the Supreme Court of India sent a notice to the government in response to a petition asking for UCPMP to become mandatory rather than a voluntary code.

The income tax agency searched pharmaceutical makers and distributors in Hyderabad and Delhi-NCR last week for unreported cash sales of medications, according to the finance ministry. At about the same time, the Income Tax (I-T) Department began investigating Bengaluru-based Micro Labs for possible tax evasion. Micro Labs is the manufacturer of the well-known paracetamol brand Dolo, which gained popularity during the Covid-19 outbreak. An I-T raid at Hetero Drugs, a major anti-Covid drug manufacturer, in October of last year allegedly discovered 550 crores in alleged unaccounted income, resulting in the confiscation of 142 crores in suspected cash [11].

SUPREME COURT ORDERS CIPLA TO PAY RS 175.07 CRORE BY 2022 IN THE DRUG OVERCHARGING CASE

The Supreme Court ordered Cipla to pay the Center 175 crore earlier this year in this matter. In a defeat for pharmaceutical corporation Cipla, the Supreme Court on Friday decided in favour of the Center in a case involving the company's overpricing of some medications. The business claimed that the most recent decision came as a

result of an appeal brought up in relation to a previous Allahabad High Court judgement against it and other parties. According to a statement from Cipla, the other cases concerning alleged overcharging that were filed in the Bombay High Court on entirely other grounds are still pending and are still covered by the temporary injunction issued by the Supreme Court.

In these cases, it is alleged that some medications were overcharged in violation of the Drugs (Prices Control) Order (DPCO) 1995. Cipla was unable to provide any additional information regarding the apex court ruling. Several cases on alleged overcharging against Cipla and other domestic and foreign corporations have been filed in various courts across the nation, according to an industry expert.

There is an ongoing legal dispute about the conversion and packaging expenses, which the DPCO requires to be updated annually. However, the corporation might not face a severe punishment as a result. The National Pharmaceutical Pricing Authority has, however, sent Cipla demand notifications totaling Rs. 1,768 crore in another overcharging-related matter. However, the top court had earlier this year ordered Cipla to pay the government 175 crore in this matter.

If the case was considered by a single judge, the company may have a route open

for appeal; it can approach a Bench, according to a pharma industry analyst. The lawsuit was settled in 2003, but the expert said it still has implications for other businesses facing comparable problems with prices. On Friday, the BSE saw a more than 2% decline in Cipla's share price, dropping to \$582 [12].

PHARMA LOBBYISTS PETITION THE DELHI HIGH COURT FOR A DRUG PRICE CONTROL ORDER; 2022

Two drug companies contested the Delhi High Court's decision to regulate 50 non-essential drugs. According to the Indian Pharmaceutical Alliance and Organization of Pharmaceutical Producers of India, the NPPA lacks the jurisdiction to determine medicinal need. The petition claimed the NPPA listed non-essential items without consulting the department of pharmaceuticals. On July 10, NPPA capped 50 cancer and diabetes medications. 50 medicines have 108 US brands. NPPA cuts prices 10–35%.

Last week, India limited 50 diabetic and cardiac drugs. Forbes Mumbai: India's price cap increase boosted sales. Last week, India limited 50 diabetic and cardiac drugs. Sanofi India's MRP. AIOCD AWACS reports a 139-crore reduction in sales. Sarabjit Kour Nangra of Angel Broking says multinationals need volume. Prices vary.

Market generic. India challenged Novartis and Pfizer's medicinal patents. Noncritical therapy are limited. National Pharmaceutical Pricing Authority may manage cancer, HIV, TB, malaria, asthma, and immunisation pricing. Nomura Holdings Inc. said the 50 chemicals represent 6% of India's medical market. Saion Mukherjee and Lalit Kumar fear more regulations, even if they won't impact profitability. Affected companies include Sanofi India Ltd., Abbott Laboratories, and AstraZeneca. "We'll tell the industry," Sanofi India emailed. India won't change quality, access, or delivery. This week, Sanofi India plummeted 9% and on July 14, 10.2%. The FDA warned on July 10 that brand-generic price swings signal a market failure. Each molecule cost 25% more than all others. India capped prices on 348 essential medications in July 2013. Industry organisations may fight a new limiting rule, Motilal Oswal Securities said July 14. Angel Broking's Nangra said overseas affiliates must lengthen product launches, give more therapies, and enhance sales rep efficiency if the judgement stands. Nomura claimed Sanofi and generic businesses' enoxaparin injections are affected. China and India want better drug access, lowering prices. Attraction Roche won't defend Herceptin's Indian patent, allowing generic entrance [13].

THE ABC LABORATORIES' SPECIAL LEAVE PETITION WAS DENIED BY THE SUPREME COURT IN 2022

ABC Laboratories Pvt. Ltd.'s claim to deduct doctors' gifts was denied on Feb. 22. Justices Uday Umesh Lalit and S. Ravindra Bhat maintained the Madras High Court's ruling that pharmaceutical companies can't provide doctors gifts and deduct the expenditures under Section 37(1) of the Income Tax Act, 1961 (the Act). Each party's and the Supreme Court's key points are summarised here.

Section 142(1) of the Act asked the appellant why they should not deduct INR 4,72,91,159/- spent on complimentary gifts to doctors to promote "Zincovit." Hospitality, conference fees, gold coins, LCD TVs, fridges, and computers were gifts.

- The announcement responded to the CBDT Circular¹ of August 1, 2021, which said pharmaceutical companies, healthcare-related businesses, and other entities cannot deduct illegal expenses under Section 37(1) of the Act. The Indian Medical Council Regulations, 2002 (IMCR) were changed on December 14, 2009 to prevent doctors from accepting gifts, travel accommodations, hospitality, cash, or other monetary advantages. After

- the modification, expenses weren't repaid.
- Unhappy with the ruling, he appealed.
 - Appellant stated IMCR didn't bind pharmaceutical companies or Apex. Pharmaceutical corporations could give gifts to doctors.
 - The applicant cited High Court rulings² to argue that IMCR only applies to medical practitioners, not donors.
 - The appellant cited earlier rulings³ and said the IRS couldn't deny a tax break based on expenses.
 - The Court knew that Parliament's aim in inserting Explanation 1 to Section 37(1) of the Act was to include criminal actions, which must be interpreted strictly rather than broadly.
 - The appellant also claimed the CBDT circular violated IMCR by restricting pharmaceutical companies. According to many rulings, the CBDT circular could only take effect prospectively, not retroactively.
 - Even if providing gifts to doctors isn't a "crime," IMCR prohibits it, according to income. Apex shouldn't deduct taxes on its gifts, even though it can't be penalised.

- The revenue claimed the Indian Penal Code, 1860, the Prevention of Corruption Act, 1988, and IMCR showed Parliament sought to ban free gifts.
- Allowing Apex to get the tax benefit would prevent Revenue from collecting tax on that amount.
- Supreme Court denied appeal after hearing both parties [14].

FOLLOWING ACCUSATIONS REGARDING BLACK MARKETING, NPPA REQUESTS OPENNESS FROM REMDESIVIR MEDICINE MANUFACTURERS FOR 2020

Delhi, Mumbai: India's medication pricing agency has asked details on remdesivir price movement and manufacturing following complaints about black marketing. It has also demanded increased transparency from the antiviral's makers. The National Pharmaceutical Pricing Authority (NPPA) has also recommended a remdesivir helpline and asked dealers and hospitals to publicise the drug's pricing. DCGI had asked states to monitor the distribution of Covid-19 medicine.

We advise making drug pricing public to protect individuals from being deceived. According to NPPA chairwoman Shubhra Singh, we've also requested a helpline. Because it's not a listed substance, the NPPA has limited price control." In this scenario, DPCO gaps matter. Since it's not

a schedule I substance, the NPPA has little to argue. A source said the NPPA can only implement price controls during the annual price increase.

Paragraph 19 of the DPCO 2013 grants the drug price regulator the ability to decide or alter the ceiling price or retail price of any drug in the public's interest. Participant: "We must balance cost and availability, thus paragraph 19 can be decided at any time. The DCGI has asked state pharma agencies and the NPPA to enforce the maximum retail price of Covid-19 to prevent black marketing.

Gilead Sciences, the medicine's importer, received an import licence on June 1 but hasn't shipped the drug. Hetero, Cipla, and Mylan are other drug suppliers. Somani prohibits overpricing and black marketing of remdesivir injection. Somani advocated keeping a watchful eye on the situation. Families of Covid-19 patients claimed in the Local Circles community forum that wholesalers and pharmacist shops were charging between Rs 15,000 and 60,000 for remdesivir [15].

IMPACT ON THE DRUG PRICE CONTROL

IMPACT OF THE 2017 DRUG PRICE CONTROL ORDER ON PHARMACEUTICAL COMPANY ECONOMICS

- Paracetamol, atorvastatin, aspirin, and metformin are popular generics.

5 NEML 2011 and DPCO identify these clinically utilised drugs. CIMS INDIA provides branded formulation data. 6 DPCO 2013 branded pharmaceutical MRPs vary, according to analysis. Kumar et al. found that 60% of anti-hypertensive drugs matched DPCO prices.

- Price variances may be attributed to the parent company's economic objectives, expected return on investment, total cost of production, distribution, and drug advertising, and the pharmaceutical sector's nature.
- Wide DPCO MRP deviations signal noncompliance and higher patient, societal, and healthcare expenditures. DPCO's cost-analysis indicated 100% to 500% brand-name price differences.
- Essential Commodities Act sections 7, 9, and 10 can be used. Disobeying the DPCO order can result in three to seven years in prison and the recovery of overcharges and interest as land tax arrears. 4
- Most Indians lack health insurance and pay for care themselves. Doctors can affect pharmaco-economics by promoting DPCO-equivalent brands. Generics cheaper

brand-name drugs. Medical schools should teach rational prescribing, p-drug selection, and generic prescribing to reduce drug therapy costs.

- If pricing limitations are too strict, low-profit drugmakers may halt production. Lower profits could hinder medication development. Fixed dose combos and paracetamol 650 mg are non-price-controlled (the price-capped amount is 500 mg). Balance profit, pharmaceutical availability, and DPCO compliance [16].

ACCORDING TO A PHARMACEUTICAL BUSINESS, THE PRICE IMPLEMENTATION UNDER DPCO 2013 WILL HAVE AN IMPACT ON PROFITS

- XXX Ltd., a pharmaceutical business, said today in NEW DELHI that the government's new medicine pricing policy hurt its revenue and profitability.
- The Indian government notified the Drugs (Prices Control) Order, 2013 on May 15, 2013, bringing a new drug price policy to 348 formulations on the National List of Essential Medicines (NLEM).
- "Businesses must adopt the new price 46 days after notification.

Profitability and income will decrease." Addition

- They say the government has published the maximum price for 270 formulas and will soon release the rest.
- The company included this in its financial statements for the three months ending June 30, 2013.
- First-quarter net profit fell 43% to Rs 22.18 crore from Rs 38.92 crore a year earlier [17].

THE COMPANY'S QUARTERLY REVENUE DECLINED TO RS 167.08 CRORE IN JUNE 2013 FROM RS 168.40 CRORE IN JUNE 2012. IMPACT OF THE 2017 DRUG PRICE RESTRICTION ORDER ON THE SMALL-SCALE PHARMACEUTICAL SECTOR

- Objective This study aimed to determine how medicine price control legislation (Drug Price Control Order, 2013) affected atorvastatin's retail market share in India.
- India from 2012 to 2015
- Pharmaceutical sales audit data set for 48 months from January 2012 to December 2015 from IMS Health (formerly IQVIA).
- Evaluation In India, atorvastatin has a percentage of the statins market.

- After receiving the price control notification, atorvastatin's monthly market share increased by 0.12% (p 0.001; 95% CI 0.06 to 0.18). (Drug Price Control Orders, 2013). After 31 months of price ceiling notifications, atorvastatin's market share was 3.4% higher than expected. In sensitivity analysis with a control, the average monthly market share of atorvastatin (5 mg and 10 mg) increased 0.16 percent (p0.001; 95 percent confidence interval [CI] 0.08 to 0.24).

PRICE LIMITATION AS A FORM OF PUBLIC INVOLVEMENT INCREASED ATORVASTATIN SALES IN INDIA.IMPACT OF THE 2017 DRUG PRICE RESTRICTION ORDER ON THE SMALL-SCALE PHARMACEUTICAL SECTOR

DPCO helped domestic small-scale pharmacies. Small firms offer affordable drugs, unlike big pharma. NPPA has price-regulated 348 medicines and 652 formulations (National Pharmaceutical Pricing Authority, 2018). These are life-saving drugs. Small domestic pharmaceutical companies that offer low prescription pricing have benefited since they develop generic pharmaceuticals that are less expensive than brand-name rivals (Bio spectrum, 2017). New drug legislation

hurt the profitability of pharmaceutical market leaders. The Drug Pricing Act encourages foreign drug companies to compete by delivering cheaper pricing. Small-scale drug prices climbed, making them profitable.

IMPACT OF THE 2017 DRUG PRICE RESTRICTION ORDER ON THE LARGE-SCALE PHARMACEUTICAL SECTOR

IPA ordered Lupin, Novartis, and SUN Pharma to cut medicine prices by 50 to 80%. (Bio spectrum, 2017). Due of low profits, big pharmaceutical corporations won't supply necessary drugs. Over 84% of India's pharmaceuticals, 70% made by medium- and large-scale pharmaceutical businesses, have price limitations. Many corporations ceased selling popular, largely generic, drugs. Larger companies had issues with employment, export expansion, R&D, new formulas, and investors (Bio spectrum, 2017).

Pharmaceutical firms are hampered by excessive pricing restrictions. Roche, Bayer, Novartis, and Glenmark lost money owing to generic drug competition from Aurobindo and Lupin. Drugmakers closed R&D because of price limitations. Sanofi India shifted its R&D centre to China in 2015 (2017).

STATISTICAL SIGNIFICANCE OF THE IMPACT OF DPCO 2013

India's Jubilant Life Sciences has increased product sales. Since DCPO was established in 2013, branded and generic pharmaceutical sales have soared. USFDA regulations have limited generic sales. 2014

sales of generic and brand-name drugs grew 20% and 10%. Radiopharmaceuticals, CMO of sterile injectables, and allergy therapy products have grown local and worldwide sales millions of Indian Rupees.

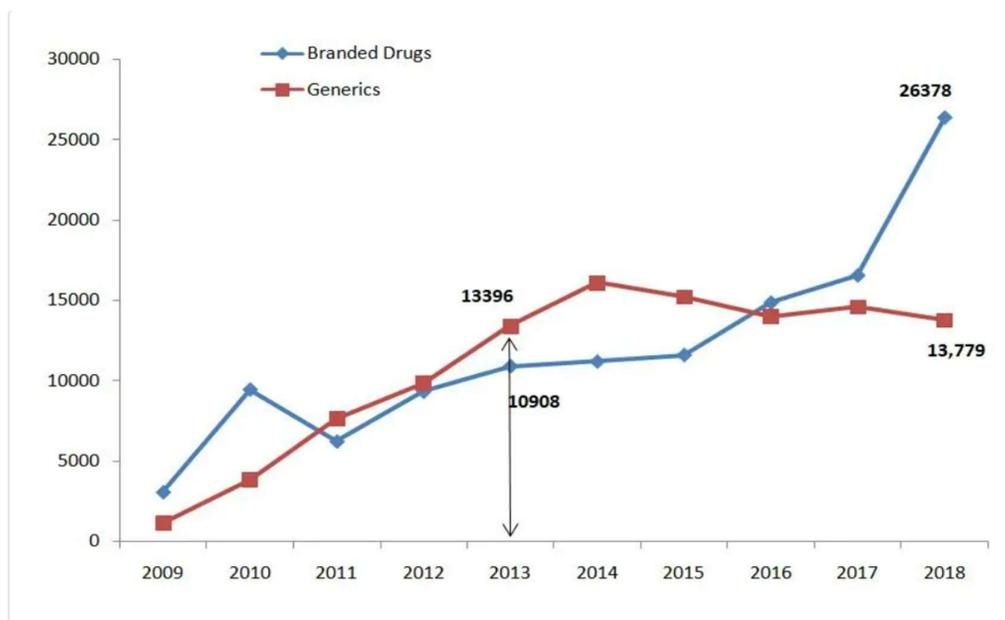


Figure 1: Trend line of sales of generic and branded drugs by Jubilant Lifesciences [18]

CONCLUSION

If implemented out with specified provisions, DPCO may not be a pain to pharma. It must also make improvements and increase advantages for profitable enterprises, especially those participating in innovation-driven activity.

DPCO should increase access to vital medicines and encourage pharma businesses to invest in innovation, quality, and expansion.

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