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EVALUATION OF DRUG PRICING REGULATIONS UNDER THE DRUG PRICE CONTROL ORDER (DPCO) AND THEIR IMPLICATIONS FOR INDUSTRY AND PATIENTS.

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Abstract:

The Drug Price Control Order (DPCO) serves as one of India's most significant regulatory mechanisms for ensuring the affordability and accessibility of essential medicines. This study critically evaluates the framework, implementation, and outcomes of drug pricing regulations under the DPCO, with particular focus on their implications for the pharmaceutical industry and patients. The analysis traces the evolution of price control policies from the DPCO 1970 to the current DPCO 2013, examining the transition toward a market-based pricing model linked to the National List of Essential Medicines (NLEM). Using secondary data from the National Pharmaceutical Pricing Authority (NPPA), government reports, and peer-reviewed studies, the research assesses the extent to which the DPCO has achieved its dual objectives of consumer protection and sustainable industry growth.

Findings reveal that while DPCO interventions have effectively reduced prices of essential drugs and improved patient access, challenges persist in balancing affordability with innovation and profitability. Frequent revisions, compliance burdens, and pricing caps have influenced R&D investments and market dynamics, particularly for small and medium-sized enterprises. Conversely, the DPCO's emphasis on transparency and rational pricing has strengthened regulatory oversight and promoted equitable healthcare. The study concludes that a more adaptive, evidence-based pricing framework—integrating pharmacoeconomic evaluations and stakeholder consultation—is essential for achieving long-term equilibrium between public health objectives and industrial competitiveness.

Keywords: *Drug Price Control Order (DPCO), NPPA, pharmaceutical pricing, essential medicines, affordability, regulatory policy, India*

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INTRODUCTION:

Access to affordable medicines is one of the most critical determinants of public health outcomes worldwide. Pharmaceutical pricing regulation forms the cornerstone of government interventions aimed at promoting equity in healthcare systems (World Health Organization [WHO], 2023). Drug prices are influenced by a range of factors, including research and development (R&D) expenditures, production costs, intellectual property regimes, market competition, and national health policies. In both developed and developing economies, excessive drug pricing has emerged as a barrier to equitable access, prompting the adoption of diverse regulatory mechanisms such as reference pricing, reimbursement caps, profit controls, and essential medicines lists (Kaplan et al., 2016).

In India, where approximately 65–70 percent of total healthcare expenditure is borne out-of-pocket by patients (National Health Accounts Report, 2022), price regulation has long been considered an essential policy tool. The pharmaceutical sector in India represents a paradoxical landscape—it is one of the world's largest producers of generic medicines, yet a significant portion of the population struggles with the affordability of essential drugs. This disconnect underscores the importance of evaluating regulatory instruments such as the **Drug Price Control Order (DPCO)**, which directly influences drug affordability, market dynamics, and industrial sustainability.

The DPCO operates under the **Essential Commodities Act (1955)**, empowering the government to fix maximum retail prices (MRPs) of drugs deemed essential for public health. Over the years, the DPCO has undergone several iterations—reflecting shifts in political priorities, economic philosophy, and public-health imperatives. The National Pharmaceutical Pricing Authority (NPPA), established in 1997, functions as the principal body responsible for enforcing these orders and ensuring compliance.

India's pharmaceutical industry contributes significantly to GDP and employment and serves as a global hub for generic drug exports. Therefore, any regulatory intervention in pricing directly affects not only consumer welfare but also industrial innovation and competitiveness. This dual impact creates a policy tension between **affordability** and **sustainability**—a balance that is central to the objectives of the present study.

1.2 Evolution of Drug Price Regulation in India

1.2.1 Early Phase (Pre-1970s)

The roots of drug price regulation in India trace back to the early post-independence period, characterized by limited domestic production capacity and heavy dependence on multinational corporations. In 1956, the Government of India established the **Hathi Committee** to examine the structure of the pharmaceutical sector, which revealed monopolistic tendencies and unjustified price variations. Subsequent reports in the 1960s emphasized the need for systematic control of drug prices to prevent profiteering and ensure accessibility of essential medicines to the population.

1.2.2 DPCO 1970 and 1979

The first formal **Drug Price Control Order (1970)** was introduced under the Essential Commodities Act, marking a major policy shift toward price regulation. The 1970 Order fixed prices for a large number of bulk drugs and formulations, primarily based on cost-plus methodology. However, extensive price control led to administrative challenges and supply constraints. The **DPCO 1979** sought to streamline this system by rationalizing the list of controlled drugs and introducing parameters for cost calculation, including norms for post-manufacturing expenses and mark-ups (Government of India, 1979).

1.2.3 DPCO 1987 and 1995

The **DPCO 1987** further reduced the number of drugs under control and refined the cost-based model. Yet, due to inflation and rising input costs, industry stakeholders argued that strict cost ceilings discouraged investment and innovation. The liberalization period of the 1990s necessitated a more flexible approach. Consequently, **DPCO 1995** was promulgated, reducing the number of scheduled drugs from 142 to 74 and introducing a more selective, market-responsive mechanism. This version also established the **National Pharmaceutical Pricing Authority (NPPA)** in 1997, institutionalizing oversight and enforcement mechanisms (NPPA Annual Report, 1998).

1.2.4 Transition to Market-Based Pricing (DPCO 2013)

The most significant reform occurred with the **DPCO 2013**, which replaced the traditional cost-plus model with a **market-based pricing (MBP)** mechanism. Under this system, ceiling prices are determined by calculating the simple average of prices of all brands of a drug with at least 1 percent market share, as listed in the **National List of Essential Medicines (NLEM)**. This shift represented a move toward greater transparency

and market realism, aligning India's approach more closely with international practices.

The 2013 Order reduced administrative burden and facilitated periodic price revisions while maintaining affordability as a central objective. However, critics argue that MBP may inadvertently allow higher ceiling prices if the market itself is skewed toward premium-priced brands (Chaudhuri, 2019). The policy's reliance on NLEM updates also means that many non-listed but therapeutically important drugs remain outside the ambit of control.

1.3 Regulatory Institutions and Legal Framework

The statutory basis of the DPCO lies in the **Essential Commodities Act (1955)**, which empowers the central government to regulate the production, supply, and distribution of essential commodities, including drugs. The **Department of Pharmaceuticals (DoP)** under the **Ministry of Chemicals and Fertilizers** formulates policy, while the **NPPA** executes it through monitoring, pricing notifications, and enforcement.

The NPPA's responsibilities include:

- Fixing and revising prices of scheduled formulations and bulk drugs.
- Monitoring prices of non-scheduled drugs to prevent profiteering.
- Recovering overcharged amounts from manufacturers.
- Ensuring availability of essential medicines through coordination with state authorities.

Legal mechanisms for redressal include the **review provisions under Paragraph 31 of DPCO 2013**, allowing manufacturers to appeal NPPA decisions before the DoP. Additionally, judicial interventions—such as in *GlaxoSmithKline Pharmaceuticals Ltd. v. Union of India* (2014)—have shaped interpretations of pricing policy, emphasizing procedural fairness and transparency.

1.4 Relevance of Drug Price Control in India's Health-Care Context

India's healthcare system is characterized by pluralistic service delivery and high dependence on private expenditure. Medicines account for nearly 60 percent of out-of-pocket spending, making price regulation indispensable for protecting household financial stability (Pandey & Rao, 2021). The **National Health Policy (2017)** explicitly recognizes affordable access to essential medicines as a core pillar of Universal Health Coverage (UHC).

The DPCO complements other public-health interventions, including the **Jan Aushadhi** generic drug initiative and **Ayushman Bharat – Pradhan Mantri Jan Arogya Yojana (PMJAY)**. Together, these programs aim to minimize the economic burden of illness and promote rational drug use. Nevertheless, balancing price regulation with supply chain viability remains a challenge, especially given the fragmented nature of India's pharmaceutical manufacturing base and distribution networks.

1.5 Economic and Public Health Rationale for Drug Price Regulation

Pharmaceutical pricing occupies a crucial intersection between economics and public health policy. Unlike conventional commodities, medicines possess inelastic demand—patients cannot easily substitute or forgo them, regardless of price (Danzon & Towse, 2019). This asymmetry between producer power and consumer dependency justifies government intervention through price regulation to prevent exploitative practices and ensure social welfare.

In India, the rationale for controlling drug prices is particularly strong due to the high prevalence of out-of-pocket (OOP) expenditure, limited health insurance coverage, and wide disparities in income distribution. Studies show that OOP expenditure on medicines alone accounts for nearly 55–60% of household healthcare spending (National Health Accounts Report, 2022). This has led to catastrophic health expenditures among low-income families, pushing millions into poverty each year (Selvaraj & Karan, 2015).

From an economic standpoint, the **DPCO** aims to correct **market failures** caused by information asymmetry, monopolistic pricing, and profit-driven distribution channels. The essential drug list mechanism ensures that life-saving and commonly used formulations remain accessible and affordable. Public health imperatives—such as controlling communicable diseases, reducing infant and maternal mortality, and managing chronic illnesses—depend heavily on the availability of affordable medicines.

At the same time, India's status as the "pharmacy of the developing world" introduces a unique policy dilemma: the need to balance **domestic access** with **export competitiveness**. Excessive price controls can discourage investment in capacity expansion or innovation, whereas lax

regulation can compromise access. The DPCO thus represents a balancing tool—a means of reconciling the twin objectives of **equity** and **economic growth** in the pharmaceutical sector.

1.6 Impact on Pharmaceutical Industry: Balancing Regulation and Innovation

The Indian pharmaceutical industry is one of the largest globally by volume and among the top ten by value (India Brand Equity Foundation [IBEF], 2023). The country manufactures more than 60,000 generic brands across 60 therapeutic categories and exports to over 200 nations. Despite this success, drug pricing regulations have generated significant debate regarding their implications for profitability, innovation, and market structure.

1.6.1 Effects on Profitability and Market Structure

Empirical studies suggest that DPCO compliance often compresses profit margins, particularly for low-cost generics and small-scale enterprises (Chaudhuri, 2019). By capping ceiling prices based on the simple average of existing brands, the 2013 DPCO inadvertently favors companies with established high-priced brands, thereby skewing the market. Smaller firms, constrained by limited economies of scale and high compliance costs, face difficulty sustaining operations under controlled pricing regimes (Srinivas, 2020).

Furthermore, the frequent revision of price ceilings introduces uncertainty in pricing strategy and financial planning. Manufacturers must continuously monitor NPPA notifications, submit detailed cost and market data, and adhere to strict reporting protocols. The administrative burden is particularly high for formulations under the **National List of Essential Medicines (NLEM)**, where price revision and monitoring are more frequent.

1.6.2 Influence on Research and Development (R&D) and Innovation

Innovation in pharmaceuticals is inherently capital-intensive, requiring long gestation periods and significant risk. A tightly controlled pricing regime can reduce the potential return on investment, discouraging domestic R&D initiatives (Ghosh, 2021). Many multinational companies have scaled down their clinical research operations in India, partly due to regulatory uncertainties and price control mechanisms.

However, proponents of DPCO argue that the focus on **generic manufacturing and process innovation** has been instrumental in positioning India as a global leader in affordable medicines. The challenge lies not in regulation per se, but in the **predictability and stability** of regulatory policies. A transparent, evidence-based framework—one that provides clear differentiation between essential and non-essential categories—can support innovation without compromising affordability.

1.6.3 Impact on Export Competitiveness and Global Perception

India's role as a major supplier of low-cost generics to Africa, Latin America, and Southeast Asia is partly enabled by its domestic regulatory environment. Price control measures, while aimed at domestic affordability, can indirectly enhance export competitiveness by fostering cost efficiency and process optimization. Nevertheless, global buyers and investors often perceive price caps as a sign of policy rigidity, affecting foreign direct investment inflows into the Indian pharmaceutical sector (Kumar & Roy, 2022).

Hence, regulatory reforms must strike a balance—maintaining public-health safeguards while ensuring that Indian pharmaceutical firms remain competitive globally.

1.7 Implications for Patients: Accessibility, Affordability, and Quality

The ultimate objective of any drug price regulation is to benefit the patient population. In India, where a significant proportion of citizens lack comprehensive health insurance, even minor price fluctuations in essential medicines can have far-reaching consequences.

1.7.1 Improvement in Affordability and Accessibility

Studies conducted post-DPCO 2013 show measurable reductions in the retail prices of several critical drugs such as cardiovascular, anti-diabetic, and anti-infective formulations (NPPA Annual Report, 2021). These price reductions have improved treatment adherence and health outcomes, especially in chronic disease management. For instance, antihypertensive medications under price control became up to 30–40% cheaper within two years of notification (Jain et al., 2018).

However, price regulation alone does not guarantee availability. Certain formulations under strict control have faced temporary shortages due to manufacturers' withdrawal from low-profit segments (Saha & Laxminarayan, 2019). This **affordability–availability paradox** underscores

the importance of complementary policies that address supply chain resilience, procurement efficiency, and quality assurance.

1.7.2 Influence on Quality and Therapeutic Choice

There is limited evidence suggesting that excessive pricing constraints may push some manufacturers toward lower-quality raw materials or reduced packaging standards to maintain profitability (Narula, 2020). Therefore, stringent quality monitoring by regulatory bodies such as the **Central Drugs Standard Control Organization (CDSCO)** becomes vital in parallel with pricing control.

Another concern pertains to **therapeutic substitution**—when manufacturers discontinue controlled formulations and promote alternative molecules not covered under DPCO. This practice, while legally permissible, can undermine the policy's intent if prescribers shift patients to non-controlled, higher-priced alternatives. Thus, the DPCO's effectiveness depends not only on enforcement by NPPA but also on rational prescribing behavior and public awareness.

1.7.3 Socioeconomic Impact and Equity Considerations

The social equity dimension of drug pricing is significant. Price control measures have been shown to disproportionately benefit low- and middle-income groups who rely on retail purchases rather than institutional procurement. DPCO-regulated pricing directly supports **Universal Health Coverage (UHC)** objectives by reducing catastrophic spending. However, disparities persist across urban and rural regions, where distribution inefficiencies and limited healthcare infrastructure limit the reach of affordable drugs (Reddy & Prasad, 2021).

From a gender perspective, women—especially in rural households—are less likely to receive prescribed medicines due to affordability concerns, making price regulation a critical instrument for inclusive healthcare.

1.8 International Comparison of Drug Price Control Mechanisms

Pharmaceutical price regulation is a global phenomenon, though approaches differ significantly across jurisdictions depending on health system design, insurance coverage, and economic conditions. A comparative analysis provides valuable insight into how India's Drug Price Control Order (DPCO) aligns or diverges from international best practices.

1.8.1 The United States: Market-Driven Pricing

The United States operates largely under a **market-driven pricing** model, where government intervention in drug pricing is minimal. Prices are primarily determined through negotiations between manufacturers, insurance companies, and pharmacy benefit managers (PBMs). While this system promotes innovation and R&D investment, it also results in some of the world's highest drug prices (Kesselheim et al., 2016). Policymakers in the U.S. have increasingly debated introducing reference pricing and Medicare price negotiation mechanisms to counterbalance excessive costs (Sachs, 2021).

In contrast, India's DPCO represents a strong state-led intervention model, ensuring price ceilings for essential drugs. While this enhances affordability, it limits profit potential, creating a regulatory landscape opposite to the U.S. approach.

1.8.2 The United Kingdom: Profit Control through PPRS

The United Kingdom employs a **profit control** model through the **Pharmaceutical Price Regulation Scheme (PPRS)**, which allows manufacturers to determine prices but regulates the profits they can earn from sales to the National Health Service (NHS). The scheme incentivizes efficient production while ensuring that public expenditure remains within limits (Danzon & Chao, 2019).

This model offers a potential learning point for India—balancing flexibility in pricing with monitoring of returns—rather than strict price caps. Unlike the DPCO, which sets product-specific ceilings, the UK system focuses on overall profitability across the company's portfolio, thereby promoting innovation and research while maintaining affordability through public reimbursement mechanisms.

1.8.3 The European Union: External Reference Pricing

Several European nations adopt **external reference pricing (ERP)**, where the price of a drug is determined based on its price in a basket of reference countries. For example, Germany, France, and Italy employ ERP to ensure pricing consistency and affordability (Vogler et al., 2019). However, ERP's effectiveness depends on timely data and comparable economic indicators across countries.

India's market-based pricing under DPCO 2013 partially mirrors ERP logic, as it relies on the existing domestic market average. However, the lack of a dynamic, evidence-based international comparison and pharmacoeconomic evaluation limits the system's ability to adjust prices in line with therapeutic value.

DISCUSSION

The discussion chapter integrates findings from the evaluation of India's **Drug Price Control Order (DPCO)** framework, connecting empirical results with broader theoretical, regulatory, and socio-economic perspectives. The purpose is to critically interpret how DPCO regulations influence the dual objectives of **ensuring affordable access to medicines** and **maintaining industrial sustainability** within the Indian pharmaceutical sector.

The DPCO, first introduced in 1970 under the Essential Commodities Act (1955), has undergone several amendments—culminating in the **DPCO 2013**, which transitioned from cost-based to **market-based pricing (MBP)**. This shift represents a significant policy evolution in India's pharmaceutical governance. The discussion examines how this transition has affected **drug affordability**, **market competitiveness**, **industry innovation**, and **public health equity**.

While the DPCO remains central to India's pharmaceutical pricing policy, its implementation has raised debates regarding the **balance between public interest and economic feasibility**. Studies such as Agarwal and Mohanty (2020) and Prasad and Kotwani (2019) emphasize that although DPCO has enhanced affordability for patients, it has also created **compliance and profitability pressures** for manufacturers. The following sections analyze these intersecting outcomes in detail, focusing on economic, regulatory, and social dimensions.

4.2 The Economic Rationale of Drug Price Regulation

Pharmaceuticals represent a unique market structure characterized by **inelastic demand, information asymmetry, and monopolistic pricing power**. Patients typically have limited ability to compare prices or negotiate costs due to the prescription-based nature of drug consumption. Consequently, government intervention through price control becomes essential to correct market failures and protect consumer welfare (Ghosh, 2018).

In India, where nearly 65–70% of total healthcare expenditure is **out-of-pocket** (MoHFW, 2017), high drug prices directly impact household finances. Price regulation via DPCO has therefore been justified as a **redistributive policy instrument** aimed at achieving social equity. However, unlike other essential commodities, pharmaceuticals have complex cost structures involving research, production, regulatory compliance, and marketing expenses.

The DPCO 2013's market-based pricing mechanism—calculating the ceiling price as the simple average of all brands with ≥1% market share—has been both lauded and criticized. On one hand, it **reflects market realities** and reduces bureaucratic burden; on the other, it **disregards therapeutic value and cost-effectiveness** (Gupta & Saxena, 2020).

In economic terms, MBP may improve pricing transparency but not necessarily ensure **rational pricing**. For example, if all market-leading brands are already priced high, the calculated ceiling price remains elevated, thereby offering **limited patient relief**. Conversely, when competitive generic penetration exists, the average price drops, benefiting patients but potentially compressing industry margins.

Hence, from a welfare economics perspective, DPCO functions as a **second-best policy instrument**—addressing price inflation without distorting supply incentives excessively.

4.3 Implications for the Pharmaceutical Industry

The impact of DPCO on the pharmaceutical industry has been multidimensional—affecting **profitability, R&D investment, production decisions, and market entry strategies**.

4.3.1 Profitability and Margins

Several empirical studies (Gadre & Sharma, 2021; Srinivasan, 2020) have shown that inclusion of drugs under DPCO leads to a **decline in manufacturer profit margins** of up to 20–30% for the affected products. The cost compression particularly affects **small and medium enterprises (SMEs)** that operate on thinner margins compared to multinational corporations (MNCs).

While large firms often offset losses through non-scheduled formulations and exports, smaller firms experience **financial strain and reduced**

manufacturing flexibility. This creates a consolidation tendency, where small players exit price-controlled segments, inadvertently leading to **market concentration**—contrary to DPCO's pro-competition intent.

4.3.2 Impact on Research and Development

Price control policies, when extended indiscriminately, can reduce incentives for R&D investment. According to Balasubramaniam (2019), innovation thrives under conditions where companies can anticipate reasonable returns. In India, where generic manufacturing dominates, the shift toward **incremental innovation and formulation improvement** requires predictable pricing environments.

DPCO's rigid price ceilings for certain formulations disincentivize investment in **product differentiation**, as marginal improvements do not yield proportional market rewards. Consequently, some firms prefer focusing on export markets where pricing is more flexible.

4.3.3 Compliance and Administrative Challenges

Compliance with NPPA's reporting and price revision requirements adds an administrative burden, especially for companies with large product portfolios. The need to submit regular Form V and VI filings, maintain margin justifications, and adjust labeling with ceiling price notifications increases operational overhead. The 2022 introduction of **IPDMS 2.0** has streamlined data submission but still requires technical adaptation by smaller firms.

In summary, while DPCO serves the public interest by preventing exploitative pricing, it also **alters industrial behavior**, steering firms toward non-controlled therapeutic segments and exports, thus influencing domestic drug availability.

4.4 Patient-Centric Implications of the DPCO

The ultimate objective of the DPCO framework is to ensure that **essential medicines remain affordable and accessible** to patients. The impact on patients can be assessed in three dimensions: affordability, availability, and accessibility.

4.4.1 Affordability Gains

Data from NPPA (2023) indicates that after DPCO 2013 implementation, average retail prices of scheduled formulations declined by **15–25%** across key therapeutic areas such as cardiovascular, anti-diabetic, and anti-infective segments. This price moderation translated into tangible **household savings**, especially for chronic disease patients dependent on long-term medication.

4.4.2 Availability Concerns

However, affordability gains sometimes come at the cost of **reduced availability**. Some manufacturers discontinue low-margin products, creating temporary shortages or regional supply gaps (Mukherjee & Kaur, 2021). This phenomenon is particularly evident in antibiotics and injectables, where production costs are high relative to controlled prices.

To counter this, NPPA periodically issues directives under **Paragraph 21 of DPCO 2013** to ensure continuous supply. Nevertheless, logistical enforcement remains challenging in India's fragmented distribution system.

4.4.3 Accessibility and Health Equity

From a public health perspective, the DPCO has played a significant role in reducing **catastrophic health expenditure**. Prasad and Kotwani (2019) observed that DPCO-covered drugs have a **higher consumption rate** among low-income populations. The scheme thus indirectly supports **Universal Health Coverage (UHC)** and aligns with **Sustainable Development Goal 3 (Good Health and Well-being)**.

However, accessibility disparities persist. Urban and private-sector pharmacies often have better availability of DPCO-listed medicines than rural outlets or public hospitals. This indicates the need for **integration with national procurement and insurance programs**, such as Jan Aushadhi and Ayushman Bharat.

4.5 The Regulatory Performance of NPPA

The **National Pharmaceutical Pricing Authority (NPPA)**, established in 1997, is the cornerstone of India's price regulation system. It exercises quasi-judicial powers to fix, monitor, and enforce ceiling prices. Evaluating its performance involves examining efficiency, transparency, and stakeholder engagement.

4.5.1 Efficiency and Enforcement

Over the past decade, NPPA has enhanced its enforcement capacity through digital tools like **Pharma Sahi Daam App** and **IPDMS**. These platforms allow consumers to check notified ceiling prices and enable real-time monitoring of price compliance. Between 2013 and 2023, NPPA issued over **2,000 price notifications** and recovered approximately **₹6,000 crore** in overcharged amounts (NPPA, 2023).

However, resource limitations—both technical and manpower—restrict its ability to monitor all retail outlets nationwide. Establishing **state-level Price Monitoring Cells (PMCs)** under DPCO has partially addressed this gap but coordination challenges remain.

4.5.2 Transparency and Data Quality

Transparency in price fixation remains a concern. Although the market-based methodology is formula-driven, **lack of public access to raw data** on brand prices and market shares limits external scrutiny. This opacity sometimes fuels disputes between NPPA and industry associations over the validity of price caps.

Moving forward, publishing anonymized datasets or third-party audits could improve accountability and trust.

4.5.3 Stakeholder Consultation

Unlike developed markets that involve multiple stakeholder consultations during pricing decisions, NPPA's process is relatively **top-down**. The inclusion of patient groups, pharmacists, and consumer organizations in consultative mechanisms could help align pricing with real-world health needs.

Interpretation of Findings: Evolution and Rationale of DPCO

The Drug Price Control Order (DPCO) has evolved as a cornerstone of India's pharmaceutical pricing framework, representing the government's effort to ensure equitable access to essential medicines while sustaining a viable pharmaceutical industry. The findings of this study reaffirm that drug price regulation in India has undergone a complex evolution — from **cost-based pricing models** of the early DPCO iterations (1970–1995) to the **market-based pricing** (MBP) framework introduced through the DPCO 2013 (Srinivasan, 2020). This shift was motivated by the need to simplify administrative oversight, align domestic pricing with global trends, and balance affordability with industrial competitiveness (Prasad & Kotwani, 2019).

Under the cost-based model, ceiling prices were determined by assessing manufacturing costs, margins, and distribution expenses, which often led to disputes over cost declarations and inconsistent enforcement (Ghosh, 2018). The transition to MBP under the National Pharmaceutical Pricing Policy (NPPP) 2012 was intended to bring transparency and predictability. The DPCO 2013 thus established a **formula-based approach**, where the ceiling price of scheduled formulations was determined as the **simple average of prices of all brands with at least 1% market share** (NPPA, 2019).

The findings suggest that this policy transition achieved mixed results. On one hand, the simplification of pricing reduced administrative disputes and enabled broader compliance among manufacturers. On the other hand, the MBP model, being dependent on prevailing market prices, indirectly allowed **price escalation in essential drugs** when the reference brands were already priced high (Mukherjee & Kaur, 2021). Consequently, the intended affordability objective was only partially realized.

The rationale behind DPCO's continued enforcement remains rooted in **Article 47 of the Indian Constitution**, which obliges the state to improve public health and nutrition. The inclusion of essential medicines under price control through the **National List of Essential Medicines (NLEM)** forms the normative basis of the DPCO mechanism. Findings indicate that successive NLEM revisions (2003, 2011, 2015, 2022) progressively aligned with the WHO Model List of Essential Medicines, extending coverage to life-saving antibiotics, antidiabetics, and oncology drugs (WHO, 2021; DoP, 2022).

Empirical studies show that price reductions following DPCO 2013 ranged between **10–35%** across categories such as cardiovascular and antidiabetic drugs, though variations existed based on competition intensity and distribution margins (Sahu & Dey, 2020). However, the regulatory rigidity also discouraged certain multinational corporations (MNCs) from launching innovative products promptly, leading to a **drug-lag effect** in the Indian market (Agarwal & Mohanty, 2020).

Therefore, the findings highlight the inherent tension between **affordability and innovation** — a recurring theme in pharmaceutical policy. The government's focus on affordability has largely succeeded in controlling retail-level inflation of

essential drugs, but industry stakeholders argue that profitability erosion and compliance burden could restrict future R&D investments (Gadre & Sharma, 2021). Hence, the rationale of DPCO as a **public health safeguard** is justified, but its economic design requires dynamic recalibration to avoid stifling innovation.

The study further interprets DPCO as an instrument of **pharmaceutical governance** rather than mere price control. The institutionalization of the **National Pharmaceutical Pricing Authority (NPPA)** as an autonomous regulator has strengthened regulatory credibility. Yet, the findings underscore that **data-driven monitoring** and **real-time market surveillance** remain areas requiring major enhancement. The implementation of **Integrated Pharmaceutical Database Management System (IPDMS 2.0)** (NPPA, 2022) is a significant step toward digital compliance, ensuring transparency in price submissions and stock reporting.

In summary, the evolution and rationale of DPCO reflect India's ongoing struggle to balance **equitable access**, **economic sustainability**, and **industrial competitiveness**. The findings reaffirm that while the DPCO has succeeded in curbing extreme price disparities and safeguarding patient interests, its future effectiveness depends on integrating **value-based pricing**, **health technology assessment (HTA)**, and **adaptive regulation** mechanisms aligned with global best practices (Brahmachari & Prakash, 2022).

5.3 Impact of DPCO on the Pharmaceutical Industry

The pharmaceutical industry's response to DPCO has been heterogeneous, reflecting the diversity of market participants — from large domestic generics manufacturers to multinational innovators. Findings from policy analyses and industry surveys indicate that **DPCO implementation has led to measurable effects on profitability, investment behavior, and competitive dynamics** (Bhattacharjee & Sharma, 2021).

5.3.1 Profitability and Market Structure

One of the most immediate impacts of DPCO is on profit margins of manufacturers producing scheduled formulations. The ceiling prices enforced under DPCO 2013 reduced average retail prices by 20–35% for key therapeutic categories (NPPA, 2019). For major Indian generic firms, this led to an estimated **5–10% erosion in EBITDA margins** between 2013 and 2017 (Gadre & Sharma, 2021). However, the findings also reveal compensatory trends — firms have increasingly shifted focus toward **non-scheduled formulations** and **export markets** to offset domestic revenue pressures (IBEF, 2023).

The market-based pricing approach has unintentionally encouraged **product diversification** rather than innovation. Companies often reformulate or repackage existing molecules into new dosage forms to escape DPCO coverage, reflecting the unintended **regulatory arbitrage** behavior (Gupta & Saxena, 2020). This phenomenon underscores the need for a broader essential medicine definition and improved surveillance of substitute products.

CONCLUSION:

The Drug Price Control Order (DPCO) remains a cornerstone of India's pharmaceutical regulatory framework, reflecting the government's commitment to ensuring equitable access to essential medicines at affordable prices. Through successive reforms—from the cost-based model of earlier decades to the market-based pricing system introduced under DPCO 2013—the policy has sought to strike a delicate balance between public health imperatives and the commercial viability of the pharmaceutical industry.

This evaluation highlights that while the DPCO has been instrumental in containing drug prices and safeguarding consumer interests, its implementation has also presented complex challenges for manufacturers. Price ceilings imposed on essential drugs have effectively curbed excessive pricing and enhanced patient affordability, especially for low-income populations. However, they have simultaneously constrained profit margins, influenced product portfolio decisions, and, in some instances, disincentivized innovation and research investments. Small and medium-sized pharmaceutical enterprises, in particular, face greater compliance and financial pressures due to frequent revisions and administrative requirements under NPPA oversight.

Despite these concerns, the DPCO has played a vital role in improving price transparency, rationalizing profit structures, and aligning pharmaceutical pricing with ethical healthcare objectives. Its alignment with the National List of Essential Medicines (NLEM) ensures that critical drugs remain accessible to the public, reinforcing India's position as a global leader in affordable medicine production. Yet, the persistence of issues such as supply shortages, quality variations, and uneven enforcement indicates the need for a more adaptive and evidence-based approach.

Going forward, the effectiveness of drug price regulation in India will depend on integrating pharmacoeconomic assessment, real-world data, and stakeholder engagement into policy

formulation. A dynamic pricing framework—complemented by measures to support innovation, strengthen compliance monitoring, and incentivize quality manufacturing—can help achieve a sustainable balance between affordability and industrial growth. Ultimately, the DPCO's future success lies in evolving from a purely regulatory instrument into a comprehensive healthcare policy tool that harmonizes economic efficiency with social welfare.

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