Antitrust Concerns Related To Market Concentration and Competition in the Pharmaceutical Sector

1. Abstract

The pharmaceutical sector, crucial for global health, is increasingly scrutinised for its market concentration and antitrust issues. This paper examines the **implications of market dominance** by a few large pharmaceutical companies and its effect on competition and consumer welfare. By exploring **key antitrust frameworks**, such as the Sherman Act in the U.S. and the Competition Act in India, the study highlights the **challenges in regulating pharmaceutical giants** who often employ **aggressive pricing and market strategies** to maintain dominance. The paper elucidates how monopolistic practices can restrict market access and affordability of essential medicines. It also identifies **significant legal loopholes** that enable these practices, emphasising the need for tighter regulations. The analysis suggests that mitigating monopoly power can enhance market competition, leading to better **consumer access and affordability**. Recommendations include more **robust antitrust enforcement** and policies that balance the need for innovation with the imperative of maintaining competitive markets. This research underscores the critical need for **comprehensive antitrust oversight** to ensure that pharmaceutical markets remain fair and accessible, safeguarding consumer interests in the face of growing market consolidation.

2. Introduction

"Health is not valued till sickness comes." - Thomas Fuller. These words ring especially true when examining the state of the pharmaceutical industry today. Access to life-saving medicines is crucial for preserving public health, yet mounting concerns over **market concentration** and **lack of competition** threaten to undermine this vital sector.

The pharmaceutical industry has long been a bedrock of modern healthcare, developing drugs and therapies that have revolutionised medicine. However, as the 21st century unfolds, the lack of vigorous competition casts a shadow over future innovation. In the words of former FDA Commissioner Scott Gottlieb, **"Competition is at the heart of innovation, and when there isn't vigorous competition, prices rise and innovation is stifled."** The **United States,** historically a **leader in pharmaceutical research and development**, now faces a landscape where a handful of pharmaceutical giants wield immense influence over drug prices and access.

This **concentration of power in the hands of a few corporations** has raised significant antitrust concerns. **The Sherman Act (1890)** in the United States, designed to promote competition and **prevent monopolies**, faces unprecedented challenges in addressing the complex dynamics of the modern pharmaceutical market. As **mergers and acquisitions reshape the industry**, regulatory bodies struggle to balance the benefits of consolidation against the potential harm to competition and consumer welfare. In the U.S., pharmaceutical giants like **Pfizer, Johnson & Johnson, Merck, and AbbVie** dominate the market, wielding significant influence over drug development, pricing, and availability. Similarly in India, while the market is more

fragmented, large corporations such as **Sun Pharma, Lupin, and Dr. Reddy's Laboratories** hold substantial market share. **India's Competition Act (2023)** grapples with similar challenges in maintaining a balance between fostering innovation and ensuring fair competition in this vital sector.

Moreover, the pharmaceutical industry's **formidable barriers to entry**, including the **exorbitant costs of drug development**, **stringent regulatory hurdles**, and the challenges of navigating a **complex intellectual property landscape**, have made it increasingly difficult for new competitors to emerge and disrupt the status quo. This lack of competition has fuelled concerns that the industry's dominant players may be leveraging their market power to protect lucrative franchises, rather than investing in the development of truly groundbreaking therapies that could improve health outcomes.

As the debate over pharmaceutical pricing and access rages on, policymakers and regulators have turned their attention to the **role of antitrust enforcement in promoting competition** and reining in potential anticompetitive behaviour. This paper will examine the antitrust concerns stemming from market concentration in the pharmaceutical industry, analyse the delicate balance between incentivising innovation and ensuring fair competition, and explore potential policy solutions to safeguard patient interests and public health.

3. Literature Review

Statista's report (2024) serves as a foundational source for understanding **global pharmaceutical trends**. While the report outlines dominant industry players and highlights the significance and influence of emerging economies like India, it lacks an in-depth analysis of how market concentration affects competition and pricing on global and regional levels. Within the regional context, the **Indian Brand Equity Foundation (IBEF, 2024)** examines the **role of India** as a major player in the supply of affordable, generic drugs in the international arena. However, it does not sufficiently analyse the regulatory and antitrust issues that arise from this global expansion, particularly concerning dominant Western pharmaceutical companies.

Additionally, antitrust concerns in the Indian context are explored by **Joshi, Shetty and Karande (2019)**. They highlight how **India's competition laws** deriving from the TRIPS (1995) Act have developed in **conflict with the intellectual property regimes of the West**. They do not, however, adequately assess cross-border antitrust issues or the broader global competition between Indian companies and multinational pharmaceutical companies.

OECD's report (2021) and **Pena et al. (2021)** analyse the antitrust concerns of market concentration within the pharma industry in a global context. The reports delve into the **strategies** used by companies **to establish monopoly control** and also examine the **economic implications** of such profit-maximising behaviour. While the OECD's report discusses in depth the market

behaviour and regulatory mechanisms of the West, its limitation to the US and EU understates the competitive role played by emerging economies like India.

Lastly, **Tiwari et al. (2024)** examine **India's competition law with respect to antitrust regulations**. The research discusses prevalent issues of patent abuse and drug pricing and the role of India's legal framework in curbing such issues. The paper, however, does not sufficiently provide recommendations to overcome the loopholes examined within the legal frameworks.

While the existing literature discusses market concentration and antitrust concerns in detail, most of the research is limited to impacts on pricing, accessibility and monopolies. Few studies examine global antitrust concerns in relation to emerging markets like India. Further, while most of the existing research treats market concentration as a broad, overhead phenomenon, this paper analyses **the interplay between regulatory fireworks, institutional failures and enforcement challenges**. It examines in detail the loopholes that exist not just within the global regulatory framework but also in the Indian frameworks. Additionally, this paper explores the role of state intervention in addressing the challenges that exist within the current market system that heavily favours certain dominant pharmaceutical players over others, and proposes targeted reforms to better align India with the global best practices.

4. Understanding Antitrust in Pharmaceuticals

Antitrust legislation encompasses a set of laws and regulations designed to foster fair competition and prevent monopolistic practices in various industries.

What is Antitrust in Pharmaceuticals?

In the context of the pharmaceutical sector, antitrust measures **aim to maintain a competitive landscape throughout the drug lifecycle**, from research and development to manufacturing and distribution. This specialised application of competition law addresses the unique challenges presented by an industry where scientific innovation, intellectual property rights, and public health concerns converge.

The fundamental objective of pharmaceutical antitrust is to strike a **delicate balance between encouraging investment** in drug discovery and **ensuring widespread access to affordable medications**. While patent protections offer necessary incentives for costly research endeavours, they can also be exploited to artificially extend market exclusivity, potentially hindering competition and increasing costs for consumers.

Regulatory bodies pay close attention to the critical juncture when brand-name drugs face generic competition. Of particular concern are **"pay-for-delay" agreements,** wherein established manufacturers compensate generic producers to postpone market entry. Although such

arrangements may benefit the involved parties, they can significantly impede consumer access to less expensive alternatives.

In India, once the CCI's decision is finalised, individuals can seek compensation for losses due to anti-competitive behaviour through the **National Company Law Appellate Tribunal (NCLAT)**. The process is put on hold if the matter is appealed to the Supreme Court and an interim stay is granted.

Antitrust oversight also extends to **corporate consolidations** within the pharmaceutical industry. Authorities evaluate proposed mergers and acquisitions to prevent excessive market concentration, which could lead to reduced competition and inflated drug prices. The goal is to preserve a diverse marketplace that promotes both innovation and healthy price competition.

Pricing strategies form another crucial aspect of antitrust scrutiny in pharmaceuticals. Regulators investigate potential **price-fixing schemes**, **unjustified price hikes** for essential medications, and other anticompetitive pricing tactics that might adversely affect healthcare systems and patients. This vigilance is particularly vital given the critical nature of many pharmaceutical products and the relatively inelastic demand they command.

Furthermore, antitrust law addresses more nuanced forms of potentially anticompetitive behaviour. This includes examining practices like "**product hopping**," where minor drug modifications are made to extend exclusivity periods, as well as assessing **distribution networks** to ensure equitable access for all manufacturers.

Relevant Laws

- **Regulatory Framework in India**

With the establishment of the World Trade Organization (WTO) in 1995, an act called the **Trade-Related Aspects of Intellectual Property Rights (1995)** introduced substantial changes to patent laws, transitioning from process patents to product patents and implementing **stricter patentability criteria** and **exclusive marketing rights (EMRs)**. Driven by the '**Big Pharma**' - a group of companies that dominate the pharmaceutical sector - this act severely restricted the accessibility and affordability of generic drugs for developing countries. India, too, had to comply with these measures when it became an official WTO member. These changes had far-reaching effects on India's pharmaceutical industry, which had so far been a key global supplier of affordable generic medicines.

The impact of the TRIPS Agreement (1995) on Indian pharmaceutical patenting sparked extensive debates, with advocates claiming that it fostered innovation and enhanced intellectual property protection, while critics argued over the issues of medicine affordability and accessibility, and

public health. However, there existed a certain **loophole** in the TRIPS agreement i.e., **it did not sufficiently define 'invention' nor did it establish the criteria for patentability**.

Taking advantage of this loophole, the Indian government allowed the manufacture of previously patented medicines with minor modifications. The new medicines could not be patented as an effort to prevent evergreening and allow the growth of local manufacturers. Thus, the impact on India as a global supplier of generic drugs was not a heavy one, and the country continues to retain its position today. Despite this, certain issues still exist within the Indian pharmaceutical industry, as is discussed in the later sections.

Today, India's pharmaceutical industry is governed by stringent laws and regulatory bodies to ensure the safety, quality, and affordability of medicines. The **Drugs and Cosmetics Act, of 1940** regulates drug manufacturing, distribution, and sales, ensuring compliance with safety standards. The **Drug (Price Control) Order, 2013** controls prices of essential medicines through mechanisms like setting ceiling prices. The **National Pharmaceutical Pricing Authority (NPPA)** enforces these regulations, fixing prices and monitoring pharmaceutical market dynamics. Together, these regulations promote public health by ensuring access to safe and affordable medicines while supporting industry growth through fair competition.

- **Regulatory Framework in the United States**

In the United States, the **FDA** oversees pharmaceutical and medical device regulation. It approves drugs based on safety and efficacy evaluations, monitors post-market safety, and sets manufacturing standards. The FDA's enforcement powers include **product recalls** and **legal actions** against non-compliance. Contrastingly, in India, the **Competition Commission of India (CCI)** regulates market competition in the pharmaceutical sector under the **Competition Act of 2023**. It investigates anti-competitive practices and reviews mergers to maintain fair market conditions. The FDA and CCI agencies play pivotal roles in their respective countries, influencing global pharmaceutical markets through their regulatory actions.

5. Market Dynamics

Ranking	Name	Symbol	Market Cap Oct 16 2023	Country
1	Eli Lilly	LLY	$578.3B	U.S.
2	Novo Nordisk	NVO	$452.8B	Denmark
3	Johnson & Johnson	JNJ	$377.7B	U.S.
4	Merck	MRK	$263.9B	U.S.
5	AbbVie	ABBV	$261.2B	U.S.
6	Roche	ROG.SW	$222.4B	Switzerland
7	AstraZeneca	AZN	$212.2B	UK
8	Novartis	NVS	$201.1B	Switzerland
9	Pfizer	PFE	$181.3B	U.S.
10	Amgen	AMGN	$152.0B	U.S.

Image 1: Key Players in Pharmaceutical Industry (2024)

Source: The World's 50 Largest Pharmaceutical Companies

The global pharmaceutical market is poised for substantial growth from 2023 to 2030, with a projected **Compound Annual Growth Rate (CAGR) of 5.27%**. Starting at USD 1,494,397.5 million in 2022, the market is anticipated to reach USD 2,033,543.8 million by the end of the forecast period. This growth will span key regions including North America, Europe, Asia-Pacific, South America, the Middle East, Africa, and other global markets. The market dynamics are shaped by a **diverse product landscape** encompassing both **prescription (Rx)** and **over-the-counter (OTC) categories**, with significant applications in treating cardiovascular diseases, pain management, diabetes, cancer, respiratory illnesses, and more.

Leading players such as **Takeda, Merck & Co., Johnson & Johnson, and Pfizer** drive competition and innovation in the industry. Market expansion is driven by factors such as **increasing healthcare demand**, **technological advancements**, and **rising incomes** in emerging markets. Strategic mergers, acquisitions, and ongoing research and development efforts also contribute significantly to shaping the market's trajectory.

The pharmaceutical sector faces challenges from recent global events like the **COVID-19 pandemic** and geopolitical tensions such as the **Russia-Ukraine conflict**. These events have influenced market dynamics, prompting adaptations in consumer behaviour and business strategies. Shifts towards **digital platforms**, increased **demand for online healthcare solutions**, and adjustments in supply chains are notable responses to these unprecedented challenges.

Geographically, robust growth is observed across regions including the United States, Europe, China, Japan, India, Southeast Asia, Latin America, and the Middle East & Africa. Each region offers unique opportunities and challenges, influencing market strategies and investment decisions. Strategic insights from this comprehensive report provide stakeholders with essential information to navigate evolving market landscapes, capitalise on growth opportunities, and effectively manage risks.

Within the Indian context, over the past few decades, India's **export of formulations** has grown exponentially, from **less than $0.5 billion in the early 1990s** to **$16 billion in 2019**. Today, the country holds a **20% global supply share** in generic medicines. With a **10-12% growth rate**, India's pharmaceutical sector is expected to reach **$100 billion by 2025**, driven by its robust domestic manufacturing base.

This growth is largely due to **merger and acquisition activities** by Indian pharma hubs, which have partnered with foreign companies to enhance their global competitiveness. However, these mergers have led to India losing its price competitiveness, particularly with emerging economies like China. India's pharmaceutical industry has gained international recognition as the "**Pharmacy of the World**," particularly for its role in supplying vaccines, essential medicines, and medical supplies during the COVID-19 pandemic.

Factors Influencing the Prevalence of Antitrust in the Pharmaceutical Industry

The pharmaceutical sector presents unique challenges in competition and regulation. Unlike other markets, this industry is not based on individual choice or perceptions of well-being. Instead, drugs are considered **'credence goods'**, for which consumers rely on medical advice. This reliance makes **medical care a key driver of demand**. However, many healthcare providers are unaware of the potential outcomes of some drugs and the **medical representatives** of pharma companies who are employed to bridge this information gap, are more often than not, **imperfectly knowledgeable** and **biased** due to the incentive to promote the sales of the product without adequate regard for its efficacy or safety.

Pharmaceutical companies face **low-price sensitivity** amongst consumers because of the difference their products make between life and death. This **willingness to prioritise well-being** even at the cost of other needs makes matters like immunisation against communicable diseases a **priority of public policies**. Further, some pharmaceutical drugs are termed **'merit goods'** i.e., their availability to all people is considered a matter of **basic human rights**.

Patents serve as a **cornerstone of innovation** within the pharmaceutical industry by granting investors exclusive rights over the development and manufacture of medicines and related products. While this protection incentivises research and development, it also creates a monopoly

market. The **economic costs** of this patent are **underscored by the steep investments** required for drug development which often costs billions of dollars and takes up, on an average, 15 years of development.

However, the **exclusivity period** of a patent incentivises companies to **maximise profits in the limited timeframe** which leads to issues of antitrust and market concerns. There are broadly 2 main strategies for ensuring monopoly over the market - **patent-based strategies** and **market-based strategies**. The former engages with what is called **'evergreening'** i.e., companies secure secondary patents to ensure exclusivity which delays competition from alternative generic drugs, the latter ensures patent protection from **product-based coordination**. Both of these strategies make up the anticompetitive behaviour within this industry.

Globally, these dynamics are further compounded by **mergers**, **aggressive marketing budgets** and the significant **influence of healthcare providers** on consumer choices. In India, the situation is especially serious due to a greater lack of awareness, information, and education amongst consumers, limited coverage of health insurance, the absence of large, well-informed and cost-conscious institutional purchasers, and weaknesses in the regulatory framework. On the supply side, the pharmaceutical industry worldwide is dominated by a handful of firms, reinforced by patent protection, mega-mergers, and large advertising and marketing budgets directed at healthcare providers who influence consumer 'choice'.

6. Consumer Welfare and Antitrust Cases

<u>The Aspen Case</u>

Aspen is a South African pharmaceutical company that operates in the European Union (EU) and has subsidiaries in the **European Economic Arena (EEA)**. Starting in **2017**, the Times reported on Aspen's secret plan to **destroy essential cancer medicines** unless price increases were agreed upon by national purchasing authorities. Within this context, the **EU's Antitrust Regulation** prohibits the abuse of dominant market positions and is enforced by national competition authorities. When the Commission found indications of significant price increases for off-patent medicines, they opened an investigation into Aspen.

The Commission's inquiry revealed several things:

- Aspen had implemented **price increases of 70-90%** for **6 off-patent cancer drugs** which lacked viable alternatives in the market
- The company's **profit margins** were significantly **higher than industry norms**
- Aspen had indulged in **stock allocation systems** and other retaliatory tactics to compel compliance from the national authorities

The inquiry lasted 4 years and in 2021, a settlement was reached wherein Aspen agreed to **reduce** the **net prices** for the medicines **by an average of 73% across all EU nations**. These retroactive price adjustments were implemented in October 2019 and the company had to agree to continue the **supply of these drugs for an average of 10 years** provided the company met certain conditions set by regulators.

The agreement to provide the drugs for a set number of years in future not only **mitigated any supply chain disruptions** for consumers but also ensured the **affordability of medicines**. The payments to the victims of overpricing strategies were calculated based on excess revenues generated by Aspen. Lastly, the reduction of process benefitted the **national health systems** within the EU as well as **public health insurance systems**.

This case set broader implications for the future of antitrust laws in the EU because it was the **first EU investigation into excessive pricing** within the pharmaceutical sector, one that regulatory bodies avoided making a formal decision on. While a settlement was reached, the case highlighted the challenges of proving excessive pricing due to practical hurdles in assessing fair price levels in the pharmaceutical domain. The case also set a precedent in terms of demonstrating the importance of the Competition Act protecting consumer welfare.

The Novartis Case

Novartis is a Swiss company and a global leader in the pharmaceutical industry. One of its key drugs, **Glivek** is prescribed to treat **Chronic Myeloid Leukaemia (CML)** and **Gastrointestinal Stromal Tumours (GST)**. Glivec was **patented** in **over 35 countries** but in 1998, when it filed for a patent in India, it faced a major challenge. As explained earlier, India's Patent Law of 1970 allowed the manufacture of generic drugs that had undergone minor modifications which meant that patents did not apply to such drugs.

In **2006**, therefore, the **Indian Patent Office rejected Novartis' application**, arguing Glivec was merely a modified version of an already existing drug called **'imatinib mesylate'**. Novartis proceeded to challenge this decision in multiple courts, including the Indian Supreme Court (SC), which, in **2013**, ruled in favour of the Indian Patent Office. The SC upheld that under **section 3(d) of the Indian Patents Act of 1970, the increased bioavailability of Glivec did not equate to enhanced therapeutic efficacy.**

This judgement not only exemplified India's stance on the evergreening of patents but also underscored the Indian government's prioritisation of public health. As a result of the SC's decision, Glivec became available to the public at the cost of **₹8000 against the initial ₹1,20,000** being charged by Novartis.

Thus, both the Aspen and the Novartis cases underline the importance of regulation and Competition Acts in the case of antitrust policies of pharmaceutical companies that interfere with market competition and consumer welfare.

7. Challenges Within the Pharmaceutical Industry

Despite a comprehensive understanding of the rules and regulations intended to guide the pharmaceutical sector towards ethical practices, unfair practices and illegalities persist. These issues arise because businesses in the sector have identified and exploited certain loopholes in the law. For the benefit of society as a whole, these loopholes must be identified and addressed with strict actions to ensure ethical conduct and protect public welfare. Some of these loopholes are mentioned below:

Generic Challenges

One of the challenges that has arisen is that **branded manufacturers** - or Big Pharma - have often **restricted generic manufacturers from accessing samples** of their goods to prevent entry of competing goods. This has especially been seen in countries like **Canada** where manufacturers have also utilised **exclusive arrangements to control prices and supply chain**s of branded drugs. This is largely due to the loopholes in the existing Competition Act, that the government is now attempting to amend.

The **weak enforcement of pricing regulations** is another challenge that has arisen. **Patent laws** continue to create **monopolies**, making essential drugs **unaffordable** for many. The balance between innovation and affordability remains unresolved, especially in developing countries. **Insufficient use** of mechanisms like **patent pools and compulsory licensing** exacerbates the accessibility issue, as the pharmaceutical industry prioritises protecting intellectual property over increasing drug availability.

Within the **European context**, **'pay for delay' cases** have emerged in bulk in the past decade where the European Commission (EC) had to penalise companies that were exchanging **commercially sensitive information**, **fixing minimum sales prices**, and **allocating quotas**, besides engaging in **abusive patenting strategies** within the pharmaceutical market. A major case within this context was the **'Servier' case** where a company called **Teva** was under surveillance for striking **under-the-table deals** with another company called **Cephalon** for a drug to treat sleeping disorders. Post this case, and several others, the EC has attempted to increase antitrust scrutiny of the pharmaceutical industry and widen its surveillance beyond cartel investigations.

There is also the issue of the **spread of misinformation** where certain companies spread misleading information regarding **competitor products** to **encourage the use of alternatives**.

This abuse of a dominant position within the market often promotes the monopolisation of pharmaceuticals which is further linked to price control and supply chains.

Then there is the issue of **DTC advertising** which remains controversial, often manipulating consumer behaviour and overstating benefits while understating risks. The **ethical integrity** of DTC advertising is still questioned, **compromising consumer decision-making**. Efforts to achieve balanced advertising that thoroughly covers both the pros and cons of drugs remain insufficient, **perpetuating misinformation** and influencing patient choices.

Lastly, **transparency in trials** remains a broadly controversial topic - not just in the general context but within the Indian context too. Relationships between pharmaceutical companies and healthcare professionals still face scrutiny for potential conflicts of interest affecting patient care. The **lack of transparent disclosures** continues to raise concerns about **biased medical advice** influenced by financial ties to pharmaceutical companies. Efforts to rebuild trust through transparency are ongoing but have not fully addressed the issue, leaving patients uncertain about the impartiality of their healthcare providers.

The pharmaceutical industry continues to face significant ethical challenges that harm society. Persistent issues in pricing practices, clinical trials, DTC advertising, patent protection, and conflicts of interest demand immediate and sustained action. A **multi-stakeholder approach** involving regulatory bodies, healthcare professionals, and patient advocacy groups is crucial for fostering an ethical and transparent industry that prioritises patient well-being.

Challenges Within the Indian Context

A. Patent Evergreening

Patent evergreening refers to the practice of **obtaining additional patents for minor modifications to existing patented drugs**, allowing patent holders to extend their monopoly beyond the original term. This **delays the availability of generic drugs** and prolongs patent terms, leading to higher drug prices and reduced access to affordable medicines.

As explained before, patenting medicines that are manufactured with minor modifications to the original formula is not allowed under the provisions of the **Indian Patents Act of 1970**. Sections **3(d), 3(e) and 3(i)** are specifically designed to **prevent patent evergreening**. However, there exist several challenges in the actual implementation.

The **Indian Patent Office** often grants patents **without a written approval or spoken order** owing to **lack of detailed scrutiny**. This results in **high error rates** where patents often end up being revoked in later stages either through judicial processes or post-grant opposition. Previous research has estimated the **IPO's error rate to be 72%** in the case of secondary patents.

B. Loopholes in the Competition (Amendment) Bill, 2023

This bill aims to strengthen the Competition Commission of India (CCI) by preventing and punishing anti-competitive practices. The bill **expands the definition of anti-competitive agreements**, **increasing penalties** for anti-competitive behaviour and providing false information. Moreover, the bill has increased the maximum penalty for anti-competitive agreements and abuse of dominant position **from 10% to 30% of overall corporate turnover.** However, there are certain loopholes and challenges within the bill:

- The bill **lacks a proper definition of "significant adverse effect on competition"** (SAEC), which while giving **wide-ranging powers to the government**, also allows for manipulation of loopholes by the big pharma. Thus, there is a need for better clarity on what SAEC looks like to prevent the persistence of antitrust in the Indian pharmaceutical sector.
- The Bill also allows parties to **settle anti-competitive behaviour cases** by
  a) admitting guilt,
  b) voluntarily undertaking certain commitments, or
  c) settling with a lower penalty.

In cases involving **abuse of dominance vis-a-vis anti-competitive agreements**, parties can offer a commitment after the CCI passes its preliminary order. However, all such **early redressal mechanisms are not available** as a matter of right to the liable parties and neither are any of the CCI's decisions appealable. Ultimately, the settlement **exposes the liable parties to potential compensation claims without the admission of guilt** in the commitment process.

C. Hurdles in the Drug Approval Process

In **2023, the Organisation of Pharmaceutical Producers of India (OPPI)** - which represents Indian pharma giants - revealed that **launching new drugs** in India takes at least a **4-year delay** while **vaccines** face delays of up to **7-9 months** compared to countries like the US owing to complex regulatory mechanisms and requirements. The **Subject Expert Committee** - one of the regulatory bodies - is responsible for months of delays, even after approval has been recommended, for the issuance of the official approval. These lengthy approval timelines also **prevent India** from **participating in global clinical trials.**

D. MSMEs

India has around **10,000 pharma manufacturing units**, **80 per cent** of which are micro-small and medium-scale facilities. MSME units often **lack fully-equipped quality control labs** and

also have **data integrity issues**. Another issue is the **payment delays** faced by MSMEs which significantly impacts their cash flow, making it difficult for MSMEs to cover **operational and logistical costs** or **engage in growth projects** such as investment in new technologies. Moreover, in 2023, the government identified **over 65%** of MSME pharmaceutical companies **producing substandard drugs**, following a risk-based inspection, following a nationwide crackdown on substandard and spurious medicines by the Central Drugs Standard Control Organisation (CDSCO).

E. Lack of Transparency in Clinical Trials

To enhance transparency of clinical trials, the government tabled the **2023 Drugs, Medical Devices and Cosmetics Bill** which aimed to replace the Drugs and Cosmetics Act of 1940. However, the bill faced a lot of **opposition** from pharmaceutical and related companies. The **Medical Technology Association of India**, for instance, along with the other industry leaders urged stakeholders to be consulted before finalising the bill and emphasised the importance of maintaining quality and incorporating existing regulations.

Pharma MSMEs too criticised the Bill, claiming it aims to **favour large pharmaceutical companies** by centralizing regulatory powers, which they argue is unconstitutional. They point to previous **unsuccessful centralization attempts** and express concerns about **increased regulatory control** and **potential corruption**. MSMEs also highlight the **economic and employment impact** of potentially shutting down small units due to stringent regulations.

This debate underscores the need for careful legislative scrutiny to balance quality standards with the interests of all stakeholders, including ensuring affordable drug prices and preventing undue centralization of regulatory power.

8. Recommendations

<u>Generic Recommendations</u>

A. Clarification of Jurisdiction in M&A

- Governments - particularly those of the EU - should establish **transparent** and **adaptable anti-trust frameworks** concerning M&A transactions. Additionally, they should **prioritise fair competition** by establishing **clear guidelines** on merger controls in innovative markets like pharmaceuticals.

B. Enable Access for Private Plaintiffs

- In the Canadian context, the government should encourage the use of the **newly introduced legal avenue** which grants **private plaintiffs the right to seek redress**

against abuse of dominant provisions.

- Additionally, there is a need for regulatory bodies to lay down **clear procedures** for generic manufacturers and private companies to fight against monopoly practices to foster a competitive marketplace.

C. Strengthening Merger Controls

- There is a need to **update the threshold criteria for merger control.** For instance, the government of **Germany** made recent amendments to their competition law which captures **high-value transactions with low turnover** - which helps to address acquisitions with significant economic impact, despite limited financial turnovers, efficiently. This allows governments to regulate and prevent anti-competitive consolidations and monopoly practices within the pharmaceutical industry.

D. Patent Settlements

- There is a need for governments to **increase scrutiny of pharmaceutical patents that can stifle competition**. Implementation of stringent regulations will ensure fair competition between generic and branded drugs which will increase accessibility of medicines and benefit public health in the long run.

<u>Recommendations for the Indian Government</u>

A. Overcoming Patent Evergreening

- **Updating Guidelines for Examining Pharmaceuticals:** The International Patent Office (IPO) should **enhance the Guidelines for Examination of Pharmaceutical Applications by including the Novartis Standard,** best practices of the IPO, and clear instructions on patentability and exclusion. They should also be regularly updated to reflect the latest judicial precedents.
- **Anti-Evergreening Checklist for Examiners**: The IPO's First Examination Report (FER) lacks a checklist for **detecting secondary patents**. To address this gap, a detailed scrutiny of applications suspected of secondary patenting is recommended. The checklist should address **potential misinterpretations of section 3(d)** of the Indian Patents Act, and ensure rigorous scrutiny of secondary patents.
- **Amendment of the Indian Patents law**: The current anti-evergreening provisions are often misused by applicants due to conditional exceptions on patentability. Therefore a **complete bar on secondary patents** and **amending conditional exceptions** to include all types of secondary patents is recommended. Further, **disclosure requirements** for secondary patents should be strengthened.

B. The Competition (Amendment) Bill, 2023

- In most cases of Competition Bills around the world, **cartels or horizontal agreements** have not been excluded from the provision of settlement and commitment mechanisms. There is a need for India to adopt this provision given the widespread presence of cartels within the Indian pharmaceutical market. This is necessary because the **exclusion of these entities** would **aggravate the backlog of cases** within the Supreme Court and other appellate authorities.
- The current Bill assigns a very **stringent timeline** for those opting for the settlement and commitment mechanism which may actually **impair better offers on the table** because of the limited timeframe which restricts detailed discussions. Further, taking an example from the provision of penalty timeframes in the rest of the world, India too can ensure **maximum liability** while maintaining a dynamic market without imposing stringent time bars.

C. Streamlining the Drug Approval Process

- The administrative delay in the drug approval process can be combated with a **single-window clearance system** where a **unified regulatory authority** is given the responsibility for drug approvals, thereby **reducing time-to-market**. This would also free up resources to work on fostering innovation in the long run.
- Further, implementing a **fast-track approval system for critical drugs** like the COVID-19 vaccine would help boost research and development efforts.

D. MSME's in India

- There is a need for the government to establish a **pharmaceutical-specific venture fund** to channel public resources into drug discovery, design, and development, while also assisting the MSME sector in **PPP (public-private partnership) mode**.
- Moreover, a panel of experts and consultants can be formed to assist MSMEs in **transferring available technologies** from different sectors to facilitate technological advancement and guidance.

E. Strengthening the Generic Drug Framework

- **Comprehensive Restructuring**: There is a need to overhaul the CSDCO to function as an autonomous body funded with the **latest technological infrastructure** and **surveillance mechanisms**. Additionally, there is a need to **hire skilled personnel**, which is an extremely urgent challenge faced by CDSCO. In 2023, for instance, it was reported that **over 60 per cent of drug inspector posts lay vacant** in the CDSCO and that junior officers were being assigned additional charge of inspectors. The CDSCO thus needs to enhance transparency and engage with the consumer base to rebuild trust. T
- **Improving Coordination:** There is a need to **strengthen state-centre coordination** in terms of regulatory bodies to **enforce uniform quality standards** and overcome inter-state disparities. To implement this, the Centre can introduce a **unified drug**

regulatory portal for **real-time data sharing** between regulators. Further, **coordination cells** can be set up to act as an **intermediary for review meetings** concerning standardised testing in states.

- **Proactive Monitoring and Accountability Measures**: The current framework should include **regular audits on quality control by CDSCO, harsher penalties**, and **mandate** the **immediate recall of substandard drugs**. This will help prevent incidents like the export of contaminated cough syrups to West Africa. The implementation of **pharmacovigilance units** will also help **monitor adverse drug reactions** for a faster government response.

9. Conclusion

In conclusion, the pharmaceutical industry stands at a crossroads where the imperative of fostering competition clashes with the realities of market consolidation. As highlighted throughout this research, the dominance of a few major corporations has led to significant antitrust concerns, impacting **drug pricing, innovation, and patient access** worldwide. In the United States, regulatory frameworks like the Sherman Act are grappling with these challenges, while in India, the Competition Act strives to balance innovation incentives with fair market practices amidst a fragmented landscape.

The barriers to entry in pharmaceuticals, including **high development costs, complex regulatory requirements, and intellectual property protections**, exacerbate the concentration of market power among established players. This concentration stifles competition, limiting the availability of affordable medications and **hindering the introduction of novel therapies** that could enhance public health outcomes.

To address these issues effectively, this paper proposes a comprehensive strategy centred on enhancing the utilization of generic drugs. By implementing **stringent regulatory standards, streamlining approval processes**, and **expanding initiatives like the "Jan Aushadhi" program**, India can foster a more competitive market environment. Moreover, investing in education and awareness campaigns will empower healthcare professionals and consumers alike, promoting trust in generic medications and reducing dependency on costly branded drugs.

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