Exploring Indian Data Exclusivity: Issues and Prospects

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Abstract

This paper examines the complex world of data exclusivity in India, highlighting the ramifications for public health, the economy, and the law. International trade agreements and other regulatory procedures have an influence on India’s pharmaceutical industry, even if there are no explicit requirements for data exclusivity. This study provides an in-depth understanding of the intricate details related to data exclusivity in the Indian context by means of a thorough examination of pertinent laws, regulations, and case studies. It looks at the possible advantages and difficulties of data exclusivity for competition, innovation, and the availability of reasonably priced medications. It also assesses how data exclusivity affects India’s generic medication market and attempts to strike a balance between public health needs and pharmaceutical innovation. This study adds to the existing discussion on data exclusivity in India by combining legal, economic, and public health viewpoints. It also offers insights into possible policy options to handle this complex problem.

Keywords: Intellectual property, Patents, Generic medicines, Data exclusivity, Compulsory Licensing, TRIPS flexibilities, Trade agreements.

1. Introduction

In the global pharmaceutical business, data exclusivity is a crucial problem that presents both obstacles and possibilities for nations such as India. India, dubbed the “ pharmacy of the world,” has a thriving generic medication market that provides poor nations with reasonably priced pharmaceuticals. But the advent of trade agreements and data exclusivity policies has left India at a crossroads. The Indian pharmaceutical industry may change as a result of data exclusivity, a kind of intellectual property protection that gives the creator of a pharmaceutical product exclusive marketing rights based on results from clinical trials. Although India’s intellectual property rules do not specifically include data exclusivity, the country’s

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changing regulatory landscape raises questions about how it may affect pharmaceutical innovation, generic competition, and patient access to medications.²

1.1. Objective of the study

- The study evaluates the financial effects of data exclusivity on innovation, affordability, competition, and pricing in the pharmaceutical industry.
- The study also examines data exclusivity from the standpoint of public health, with a particular emphasis on how it affects health outcomes, the availability of reasonably priced medications, and the role of India’s generic drug sector.
- The study intends to add to a thorough knowledge of data exclusivity in India and provide insightful information to academics, policymakers, and pharmaceutical industry stakeholders.

2. Legal Framework of Data Exclusivity in India

Data exclusivity, a critical component of intellectual property rights in the pharmaceutical sector, overlaps with India’s legislative framework for patents, regulatory clearances, and international trade agreements. This section offers a comprehensive analysis of the legal framework pertaining to data exclusivity in India.³

It includes a review of intellectual property rights, a study of pertinent legislation and regulations, and a look at the effects of trade agreements with other countries.

2.1. Overview of Intellectual Property Rights in India

For the Indian pharmaceutical industry in particular, there are a number of rules and regulations that regulate intellectual property with the goal of encouraging innovation while protecting the public interest. The main piece of law pertaining to patents is the Patents Act, 1970, which was significantly modified in 2005 to conform to global norms established by the World Trade Organization’s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).⁴ Pharmaceutical items and techniques that satisfy the requirements of innovation, inventive step, and industrial application are eligible for patent protection under the Patents Act of 1970. Nonetheless, several types of innovations are expressly prohibited from becoming patentable, such as those related to horticulture or agriculture, plants, and animals. To address public health concerns and facilitate access to pharmaceuticals, the Act also provides mechanisms for forced licensing and patent revocation.⁵

Although India has a strong patent system, there is no particular statute concerning data exclusivity in India. In contrast to some countries like the US and the EU, where data exclusivity clauses are part of their legal frameworks, India’s approach to data exclusivity is still growing and subtle.

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2.2. Analysis of Relevant Laws and Regulations

Due to a lack of data exclusivity requirements, the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945 are the primary statutes governing pharmaceuticals in India. The approval, production, importation, and marketing of pharmaceutical products including generic medications are governed by these rules.6

Instead of spending money and time on clinical trials, generic medicine makers in India may apply for marketing clearance under the present regulatory framework by submitting bioequivalency or bioavailability studies. This strategy makes it possible for generic copies of proprietary medications to enter the market more quickly, increasing competition and bringing down costs.

Concerns are raised, nevertheless, about the possible effects on innovation and market exclusivity for pharmaceutical firms that are the originators when data exclusivity clauses are absent. When data exclusivity is lacking, generic producers may depend on the information provided by original manufacturers to get marketing authorization for their goods, raising concerns about equity and incentivizing creativity.7

2.3. Impact of International Trade Agreements

India’s involvement in international trade accords, especially the TRIPS Agreement, has an impact on the country’s IP environment. India must abide by the TRIPS Agreement’s basic criteria for intellectual property protection, which include clauses pertaining to trade secrets, patents, trademarks, and copyrights. India is required to do so as a WTO member.8

The TRIPS Agreement requires member governments to ensure adequate protection and enforcement of intellectual property rights, including patents, even if it does not specifically demand data exclusivity.9 Consequently, in order to adhere to the TRIPS Agreement and preserve its ability to address public health issues and advance medication accessibility, India has modified some of its domestic laws, such as the Patents Act, 1970.

Moreover, India’s intellectual property policy is impacted by its involvement in regional and bilateral trade agreements, including the Free Trade Agreements (FTAs) with other nations and the Comprehensive Economic Partnership Agreement (CEPA) with Japan. These contracts often include clauses pertaining to intellectual property rights, such as data exclusivity, which might have an impact on the laws and policies of India.

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7 Dhar Bishwajit, Gopakumar K M, Data exclusivity in pharmaceuticals: Little basis, false claims, Economic and Political Weekly, 2006, 5075.
In short, while though India’s legal system offers strong protection for intellectual property rights, such as patents, the lack of explicit data exclusivity laws raises concerns about how this would affect competition, innovation in the pharmaceutical industry, and patient access to treatment. The regulatory environment is made more complex by the effects of international trade agreements, which emphasises the need of carefully balancing the goals of public health with the protection of intellectual property in India’s pharmaceutical industry.\textsuperscript{10}

3. Economic Implications of Data Exclusivity

Impacting innovation incentives, competitive dynamics, drug price, and accessibility, data exclusivity has far-reaching economic consequences for the pharmaceutical sector. This section explores the economic implications of data exclusivity in India, including how it affects competition, innovation in the pharmaceutical industry, and the availability of medications on the market.\textsuperscript{11}

3.1. Incentives for Pharmaceutical Innovation

By granting the original firms exclusive rights over the clinical trial data that is submitted to regulatory bodies, data exclusivity is sometimes presented as a way to encourage pharmaceutical innovation. The exclusivity period, which varies between five to ten years under different legal systems, gives the original creators a brief monopoly to recover their R&D expenses and make money from their novel goods.\textsuperscript{12}

Concerns about the influence on incentives for pharmaceutical innovation are raised by the lack of particular data exclusivity laws in India. When it comes to safeguarding the investment made in creating clinical trial data, data exclusivity is different from patents, which provide exclusive rights over the product or method itself. In the event that data exclusivity is compromised, generic manufacturers may depend on this information to get marketing permission for their goods, hence reducing the motivation of original manufacturers to engage in expensive and hazardous research and development projects.\textsuperscript{13}

Opponents counter that by creating obstacles to entry for generic producers, data exclusivity may hinder competition and innovation and restrict access to reasonably priced medications. Furthermore, issues have been brought up about the abuse of data exclusivity by original manufacturers to prolong market exclusivity beyond the duration of the patent, postponing the arrival of generic rivals and maintaining exorbitant medication costs.

\textsuperscript{10} Grabowski H, Data exclusivity for new biologicals, Duke University, Department of Economics Working Paper, June 2007, 3.
3.2. Effects on Competition and Market Dynamics

When data is not made publicly available, it may have a major effect on the dynamics of pharmaceutical market competitiveness, including whether or not generic versions of proprietary pharmaceuticals become available and how much they cost. Data exclusivity prevents generic copies of copyrighted medications from entering the market by giving originator businesses exclusive rights over the clinical trial data. This allows originators to retain monopolistic pricing power for a certain amount of time.

The lack of data exclusivity rules has aided in the quick introduction of generic alternatives in India, where generic competition is essential for lowering prescription costs and improving access to medications once patents expire. Patients and healthcare systems alike have benefited from the accessibility of affordable generic medications made possible by this competitive environment.\(^\text{14}\)

Advocates of data exclusivity contend, however, that it fosters innovation by giving original enterprises a window of market exclusivity to recover their R&D expenditures. They argue that by offering a guaranteed return on investment, data exclusivity promotes funding for high-risk research and development initiatives, especially for illnesses with unmet medical needs.

3.3. Pricing and Affordability of Medicines

Concerns over pharmaceutical prices and accessibility to cheap healthcare are at the heart of the data exclusivity argument, especially in developing nations like India. Because it delays the arrival of generic competition, data exclusivity may have an influence on medication pricing by enabling originator businesses to keep higher prices for their proprietary treatments throughout the exclusive period.\(^\text{15}\) Affordable medications are vital to guaranteeing access to necessary treatments in India, since a sizable section of the population pays for healthcare out of pocket. The rapid emergence of generic alternatives has been made possible by the lack of data exclusivity rules, which has resulted in competitive pricing and improved patient affordability.

The absence of data exclusivity, however, can also discourage original pharmaceutical firms from releasing cutting-edge medications on the Indian market, especially if they believe there would be little chance for them to recover their R&D costs.\(^\text{16}\) This may restrict patients access to novel medications and ground-breaking treatments, especially for conditions with limited patient populations or expensive R&D.

So there are conflicting objectives between fostering pharmaceutical innovation and guaranteeing access to reasonably priced medications, making the economic effects of data exclusivity in India complicated and multidimensional. By giving originator businesses the exclusive right to use clinical trial data, data exclusivity may encourage innovation, but it may also impede competition and affordability by delaying the arrival of generic alternatives. In India’s pharmaceutical industry, data exclusivity presents economic issues


\(^{16}\) Regulatory Data Protection – A Building Block for pharmaceutical R&D, OPPI position paper, 9.
that must be addressed by striking the correct balance between protecting intellectual property rights and promoting public health goals.\textsuperscript{17}

4. Public Health Perspective

The public health viewpoint on data exclusivity in India is critical because it directly affects access to low-cost medications, the role of India’s generic drug sector, and, ultimately, health outcomes and patient welfare. This section looks at these issues through the perspective of public health, emphasising how data exclusivity affects the people and healthcare system in India.\textsuperscript{18}

4.1. Access to Affordable Medicines

For a nation like India, where a large percentage of the people pays for their own medical treatment out of pocket, the availability of low-cost medications is an urgent matter of public health. In order to manage chronic illnesses, provide access to necessary therapies, and meet public health goals, affordable generic medicine availability is crucial.

By delaying the arrival of generic rivals on the market, data exclusivity might affect access to reasonably priced medications by extending the monopolistic pricing for proprietary treatments. When drugs are delayed, the cost of care may increase, leaving many patients particularly those from underprivileged origins or marginalised communities, unable to pay necessary treatments.\textsuperscript{19} The lack of data exclusivity rules has made it easier for generic alternatives to enter India quickly when patents expire, a country where the generic drug business is essential to the provision of inexpensive medications to both domestic and developing nations.\textsuperscript{20} Millions of people now have better access to medications because to the competitive ecosystem that has made low-cost generic medications more readily available. Proponents of data exclusivity contend, however, that it encourages pharmaceutical innovation by giving original businesses a window of market exclusivity to recover their R&D expenditures. They argue that by providing incentives for investment in high-risk research and development projects, this exclusivity period will eventually lead to the creation of novel medicines and cures that will meet unmet medical needs.\textsuperscript{21}

4.2. Role of India’s Generic Drug Industry

India’s generic medication sector is well-known across the globe for producing affordable, high-quality generic pharmaceuticals. This has earned the country the nickname “pharmacy of the world.” The generic drug sector is essential to the delivery of reasonably priced medications to emerging nations with comparable healthcare issues as well as the local market.

Data exclusivity affects market access and competitive dynamics, which in turn affects the role of the generic medication business in India. Without data exclusivity clauses, Indian generic producers may quickly enter the market when patents expire by using the clinical trial data provided by original manufacturers to get marketing clearance for their generic copies of protected medications.

Because of the intense competition, India’s generic drug market has flourished, bringing down drug costs and improving patient access to reasonably priced medications both nationally and internationally. But the lack of data exclusivity can also discourage original pharmaceutical firms from bringing cutting-edge medications to the Indian market, especially if they believe there won’t be many possibilities for them to recover their R&D costs.

4.3. Impact on Health Outcomes and Patient Welfare

When it comes to health outcomes and patient welfare, the effect of data exclusivity is multidimensional, with implications for the pricing of treatment, the availability of therapy, and the innovation factor. In order to manage chronic illnesses, meet public health goals, and enhance population health outcomes generally, access to reasonably priced medications is essential.22

Data exclusivity may affect the availability and cost of medications, which can have an effect on health outcomes, especially for conditions with few or expensive treatment alternatives. Data exclusivity clauses may cause delays in the introduction of generic rivals, which can raise prescription costs and prevent many patients, especially those from underprivileged origins or marginalised communities from accessing necessary medicines.

Furthermore, by restricting access to cutting-edge medicines and treatments offered by originator businesses, the lack of data exclusivity may also have an impact on patient welfare. Patients suffering from uncommon illnesses or ailments with unfulfilled medical demands could have difficulties obtaining innovative therapies if original manufacturers believe there are insufficient chances for them to recover their research and development expenditures without data exclusivity.23 To sum up, the public health viewpoint on data exclusivity in India is essential for assessing how it affects patient welfare and health outcomes in the long run, as well as access to reasonably priced medications and the role of the generic drug sector.24 To guarantee fair access to necessary medicines and advance population health and well-being generally, it is crucial to strike a balance between intellectual property protection and public health goals.25

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23 Ibid.
24 Ibid.
4.4. Analysis of Data Exclusivity Cases in India

Multiple high-profile instances have cast doubt on the effects of data exclusivity on India’s pharmaceutical sector and patients ability to get the medications they need, even though the country does not have any explicit laws governing the practice. The disagreement over the patenting of the cancer medication Glivec (imatinib mesylate) between Novartis and the Indian government is one instance of this.

The Indian Patent Office denied Novartis 2006 patent application for imatinib mesylate in its beta-crystalline form due to a lack of inventive step and originality. Novartis appealed this ruling in Indian courts, claiming that the country’s patent laws did not adhere to global norms established by the World Trade Organization’s (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The Indian Supreme Court rendered a historic ruling in 2013 in the case, upholding the Indian Patent Office’s interpretation of the law and the exclusion of incremental advances from patentability. Novartis patent application was rejected. The decision reinforced India’s commitment to striking a balance between public health interests and intellectual property protection, highlighting the significance of medical accessibility and cost.

The dispute around the inclusion of data exclusivity clauses in India’s 2016 draft National Intellectual Property Rights Policy is another noteworthy instance. Public health activists and civil society organisations opposed the proposed rules, claiming that data exclusivity would hurt India’s generic pharma sector and restrict access to reasonably priced medications.

The case studies draw attention to the intricate legal, economic, and public health issues that surround data exclusivity in India, highlighting the need of careful study and well-considered policy choices to handle the potential and problems it brings.

5. Challenges and Controversies

Data exclusivity presents a range of challenges and controversies in the context of India’s pharmaceutical landscape, encompassing opposition from civil society and public health advocates, potential risks to access to medicines, and legal and ethical considerations. This section examines these challenges and controversies in detail.

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5.1. Opposition from Civil Society and Public Health Advocates

A number of civil society organisations and public health activists have voiced their objection to the concept of data exclusivity. These individuals claim that it has the potential to harm India’s generic drug sector and restrict access to medications that are inexpensive. Data exclusivity clauses, according to critics, perpetuate monopolistic pricing for patented medications, rendering many patients, especially those from underprivileged or marginalised communities unable to pay necessary therapies.30

Furthermore, advocates for public health and civil society groups express worries about how data exclusivity affects competitive dynamics and pharmaceutical innovation. They contend that data exclusivity would discourage generic producers from joining the market, lowering competition and impeding the development of reasonably priced substitutes for proprietary medications.

Moreover, many who oppose data exclusivity argue that it can result in needless clinical trial duplication, raising healthcare costs and postponing patient access to cutting-edge therapies. They stress the significance of alternate systems, such as compulsory licencing, patent pools, and public financing for R&D, that support pharmaceutical innovation while guaranteeing access to reasonably priced medications.31

5.2 Potential Risks to Access to Medicines

Data exclusivity has the power to affect people’s ability to get the medications they need, which is a major worry, especially in developing nations like India where healthcare costs are already high. Data exclusivity clauses have the potential to postpone generic rivals arrival on the market, extending the monopolistic price of proprietary medications and preventing patients from finding more reasonably priced options.32

Furthermore, data exclusivity could discourage generic medicine producers from releasing their own copies of copyrighted medications, especially if the expense of carrying out clinical studies is too high. Patients may have fewer alternatives as a consequence, especially those who depend on government-funded healthcare programmes or have low incomes.33

Moreover, data exclusivity clauses may cause original manufacturers to hoard clinical trial data, preventing access to crucial information needed for the regulatory approval of generic medications. This may postpone the release of generic substitutes, worsening patient access obstacles.

31 UN Conference on Trade and Development, TRIPS Agreement and Developing Countries (UNCTAS/ITE/1) 48 (1996).
33 Ibid.
5.3 Legal and Ethical Considerations

The exclusivity of data creates a variety of legal and ethical concerns, notably with relation to the rights to intellectual property, the availability of medications, and the goals of public health. Legally speaking, there are concerns over whether data exclusivity clauses are compatible with current intellectual property rules in India and international trade agreements.\(^{34}\)

Furthermore, data exclusivity presents moral dilemmas on how to strike a balance between promoting pharmaceutical innovation and guaranteeing that the general public has access to reasonably priced medications. Data exclusivity is criticised for favouring private interests above those of public health, which might jeopardise patient welfare and exacerbate health disparities.\(^{35}\)

Additionally, clauses pertaining to data exclusivity may give rise to questions concerning accountability and transparency in the pharmaceutical sector, especially with respect to the release of clinical trial data and its implications for public health and patient safety. The fair allocation of healthcare resources and the prioritisation of public health needs above private interests are also aspects of ethics. To sum up, data exclusivity raises a number of issues and debates in the Indian pharmaceutical industry, such as resistance from public health and civil society groups, possible hazards to medication accessibility, and ethical and legal issues. In order to overcome these obstacles, a careful balance between encouraging pharmaceutical innovation and guaranteeing that the general public has access to reasonably priced medications must be struck.\(^{36}\)

6. Prospects and Policy Recommendations

Data exclusivity poses complex challenges in the Indian pharmaceutical landscape, requiring a nuanced approach to balance innovation incentives with public health priorities. This section presents prospects and policy recommendations aimed at addressing the multifaceted issues surrounding data exclusivity in India.

6.1. Balancing Innovation and Public Health Priorities

The goal of policy initiatives should be to find a middle ground between encouraging innovation in the pharmaceutical industry and ensuring that the general public has access to medications that are within their price range. Although data exclusivity could encourage original firms to spend money on research and development (R&D), legislators need to make sure that these incentives don’t prevent patients from receiving necessary medications.\(^{37}\)


\(^{37}\) See generally Uttam Gupta, Data-Exclusivity vs patent: The myths and the realities, HIN. BUS. LINE., (May. 16, 2006).
Putting in place measures to combat data exclusivity abuses and to encourage competition in the pharmaceutical industry is one way to strike this balance. This might include taking steps like limiting the length of time that data exclusivity periods can last, putting in place requirements for compulsory licencing in order to encourage generic competition, and encouraging openness in the regulatory and pricing procedures.\(^\text{38}\)

In addition, governments have to investigate other avenues for fostering pharmaceutical innovation and guaranteeing the availability of reasonably priced medications, including government financing for research and development, patent pools, and technology transfer arrangements. These systems may encourage innovation and make generic alternatives more accessible to patients.\(^\text{39}\)

### 6.2. Strengthening Regulatory Frameworks

By enhancing regulatory frameworks to promote transparency, accountability, and public health goals, governments should explore strengthening regulatory frameworks in order to overcome the issues that are created by data exclusivity.\(^\text{40}\) Among other things, this entails improving regulatory control of clinical trial data and guaranteeing prompt access to crucial data for regulatory clearance of generic medications.

Aside from that, authorities have to look at ways to align India’s IP rules with global norms while allowing room for manoeuvre to take up public health issues. This may include a review of current rules and regulations to guarantee compliance with global trade accords while preserving India’s capacity to advance the availability of reasonably priced medications.

Furthermore, measures to strengthen regulatory competence and enforcement mechanisms, particularly in relation to intellectual property rights and pharmaceutical regulation should be given top priority by policymakers via capacity-building initiatives. Regulatory frameworks that are stronger may help patients have easier access to safe, efficient, and reasonably priced medications while also fostering public trust in the pharmaceutical industry.\(^\text{41}\)

### 6.3. Promoting Access to Medicines through Alternative Mechanisms

It is important for policymakers to investigate alternate strategies in addition to resolving the issue of data exclusivity in order to increase access to medications for the general public. This involves taking steps to improve the cost and accessibility of necessary therapies, such as enacting price caps, buying in bulk, and encouraging generic replacement.\(^\text{42}\) Moreover, enhancing healthcare delivery systems and increasing access to healthcare services should be top priorities for policymakers when it comes to infrastructure expenditures...
in the healthcare sector. By lowering the burden of illness and improving patient outcomes, improved healthcare infrastructure may lessen the need for pharmacological treatments.

In addition, authorities have to support programmes that stimulate basic science and the creation of critical medications for untreated illnesses and ailments.\textsuperscript{43} To fill up the gaps in research and development, this may include rewarding creativity via grants, tax breaks, and public-private partnerships.

In short, tackling the issues raised by data exclusivity requires a thorough and multidimensional strategy that strikes a balance between the goals of public health and innovation incentives. Policymakers may create a pharmaceutical landscape that puts patient welfare first while encouraging innovation and competition in the Indian pharmaceutical industry by putting into practice proposals for policies that seek to promote openness, accountability, and access to medications.\textsuperscript{44}

7. Conclusion

With ramifications for innovation incentives, competitive dynamics, and access to inexpensive medications, data exclusivity poses a complicated and multi-faceted challenge in the Indian pharmaceutical industry. The results are summarised in this conclusion, along with future research and policy approaches to address the potential and problems associated with data exclusivity in India.

7.1 Summary of Findings

Among the most important results from the investigation on data exclusivity in India are:

- The absence of clear regulations pertaining to data exclusivity in India’s legal framework has resulted in a complex regulatory landscape that is shaped by intellectual property laws, regulatory frameworks, and international trade agreements.
- By giving originator businesses the only right to use clinical trial data, data exclusivity might have an adverse effect on pharmaceutical innovation by perhaps discouraging generic competition and restricting access to reasonably priced medications.
- Without data exclusivity clauses, generic alternatives have entered India more quickly than they otherwise would have, bringing down drug costs and improving patient access to medications both locally and internationally.
- Data exclusivity is fraught with difficulties and conflicts, including resistance from public health and civil society activists, possible threats to medication availability, and ethical and legal issues.

\textsuperscript{43} Mrs. Reddy et. al., Report on steps to be taken by Government of India in the context of Data Protection Provisions of Article 39.3 of TRIPs Agreement, GOVT. OF INDIA (2007).

Research and policy initiatives in the future should concentrate on the following areas to tackle the problems and possibilities caused by data exclusivity in India:

- To evaluate the effect of data exclusivity on competitive dynamics, pharmaceutical innovation, and drug access in India, further investigation is required. Research investigations that explore the correlation between data exclusivity clauses and health outcomes might provide significant knowledge on the efficacy of current regulatory structures.

- The implementation of safeguards to avoid abuses of data exclusivity and the promotion of competition in the pharmaceutical industry should be the top goals for policymakers in their attempts to strike a balance between innovation incentives and public health concerns.

- In order to ensure that patients have timely access to reasonably priced medications, it is possible to advance openness, accountability, and public health goals by fortifying regulatory frameworks and improving regulatory monitoring of clinical trial data. Encouraging the public to have access to medications by various means, such as price regulations, bulk purchases, and investments in healthcare infrastructure, may improve the accessibility and cost of necessary therapies.

- To create evidence-based policies that prioritise patient welfare while encouraging innovation and competition in the Indian pharmaceutical market, stakeholders including government agencies, pharmaceutical companies, civil society organisations, and foreign partners must collaborate.

In last, tackling the intricacies of data exclusivity in India requires an all-encompassing and cooperative strategy that strikes a balance between public health concerns and innovation incentives. Policymakers can create a pharmaceutical environment that puts patient welfare and innovation first while promoting equal access to cheap medications via the implementation of evidence-based policies and stakeholder discussion.