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The Impact of Trips-Driven Data Exclusivity on Pharmaceutical Innovation in India: Balancing Patent and Public Health

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ABSTRACT:
The lack of data exclusivity regulations in India presents substantial issues to the pharmaceutical sector, public health, and international trade compliance. Data exclusivity, which limits the reuse of clinical trial data by generics manufacturers for a predetermined period of time, encourages pharmaceutical innovation by preserving the investments of originator companies. India's present structure allows generic manufacturers to exploit this data without the need for extra clinical trials, which promotes affordable drug access and has helped India become a key global provider of low-cost pharmaceuticals. However, this strategy raises questions about intellectual property protection and compliance with the WTO's TRIPS Agreement rules. This research investigates these ramifications via the lenses of industry, public health, and trade compliance. For the pharmaceutical business, the lack of data exclusivity diminishes incentives for expensive R&D investments, potentially limiting future drug development. Internationally, India's noncompliance with data exclusivity norms affects trade ties with partners such as the United States and the European Union, which complain that it limits market access for originator firms. Introducing data exclusivity regulations could increase R&D investment, promote innovation, and strengthen India's position in trade negotiations. A balanced strategy, combining data exclusivity with measures for vital drugs and public health safeguards, would boost both innovation and access.

Keywords: data exclusivity, Public health, International Trade, Strategy, Market.

BACKGROUND OF THE STUDY:

Data exclusivity is a type of intellectual property protection in which generic manufacturers are prohibited from using clinical trial data supplied by original medication inventors to obtain regulatory approval for their goods. This protection is especially important in the pharmaceutical industry, where significant investments are made in R&D.

Despite its critical significance, India has been somewhat sluggish to establish robust data exclusivity regulations compared to other countries. Historically, the absence of such laws represented India's dedication to balancing innovation and public health interests, notably in terms of access to affordable medications.

The implementation of data exclusivity in India is primarily directed by the World Trade Organization's (WTO) Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, which requires member countries to protect hidden data submitted for marketing permission. Following India's admission to the TRIPS Agreement, its legal system began to align with these international standards.

Data exclusivity is a vital part of India's intellectual property laws, with the goal of balancing creator rights with public access to medicines and agricultural products. Efforts to align domestic legislation with international standards, such as TRIPSagreements, are defining India's intellectual property rights.

INTRODUCTION

Data exclusivity is an important component of India's intellectual property structure, particularly for pharmaceuticals and agricultural chemicals. This research investigates the origins of data exclusivity, its significance, and its relationship to Indian intellectual property laws. The term "data exclusivity" refers to a legal process that precludes generic manufacturers from using the originator company's safety and efficacy data to acquire marketing approval for their product. Typically, this exclusivity lasts for a defined period, often ranging from five to 10 years, giving the originating business a temporary monopoly on the data necessary to register their drug with regulatory authorities.

Data exclusivity serves unique but related goals outside of patents. While patents protect the invention, data exclusivity protects the data collected during clinical studies required for therapeutic approval. It is necessary to incentivise pharmaceutical research and development, especially when medication development costs continue to climb. The importance of data exclusivity has evolved in the context of international trade agreements. Many Free Trade Agreements (FTAs) include provisions requiring member countries to enact data exclusivity rules, which broaden the protections provided to pharmaceutical discoveries beyond standard patent rights. This dynamic frequently confuses the balance between increasing access to low-cost pharmaceuticals and stimulating innovation in drug research. While data exclusivity specifies a time period during which generic companies cannot use the data, patent protection grants an exclusive right to the invention itself, which can be raised through additional filingsand regulations, such as patent linkage or ever greening methods. Understanding such distinctions is crucial because they have a considerable impact on the pharmaceutical industry and patient access to medications.

Data exclusivity is an important feature of the intellectual property landscape, especially in the pharmaceutical business. It incentivises the creation of novel treatments by providing temporary rights to innovators, but also poses issues for availability and price of medications. This balance remains a crucial focus of current discussions in international policy circles, especially given the recent global health crises that have highlighted the complexity of pharmaceutical access.

LITERATURE REVIEW:

Srividhya Ragavan's paper "Data Exclusivity: A Tool to Sustain Market Monopoly" [1]investigates the ramifications of data exclusivity in the pharmaceutical business, focussing on its effects on access to drugs in underdeveloped nations. The literature study focusses on the increasing debate over patents and their perceived role in promoting innovation against perpetuating monopolistic behaviours. The article explores the history of data exclusivity as a regulatory instrument, its integration into international accords such as the TRIPS Agreement, and ongoing arguments about its impact on medicine prices and accessibility. The assessment explores howpharmaceutical corporations use data exclusivity to maintain market dominance, even facing generic competition and public health concerns.

Animesh Sharma's study "Data Exclusivity with Regard to Clinical Data"[2] examines the notion of data exclusivity in the context of intellectual property rights, with a special emphasis on its implications for Indian pharmaceuticals. The literature review focusses on the evolution of intellectual property rights,

emphasising the value of patents in protecting novel innovations and the importance of data exclusivity as a complementary right that protects private data generated during medication development. Sharma analyses Article 39 of the TRIPS Agreement, which requires protection against unfair commercial exploitation of unreported test results, and compares data exclusivity to patent rights, clarifying their respective legal contexts. The paper also includes international perspectives on data exclusivity from North America and the European Union, demonstrating how these nations use such safeguards to encourage innovation while balancing public health concerns.

Arun Bala's study "Data Exclusivity: Pressing Issue"[3] examines data exclusivity under India's regulatory environment, including its implications for access to cheap pharmaceuticals and potential effects on research and development (R&D). The literature on data exclusivity emphasises its origins under US and EU regulations, focussing on the additional protections it provides to original pharmaceutical businesses beyond patent durations. Data exclusivity in nations such as the United States and the European Union gives original data submitters a term during which no generic businesses can use their data, resulting in a longer market monopoly. However, in India, generic manufacturers gain from exploiting innovators' data to build bioequivalent generics, which improves access to affordable medications, especially in low-income countries. This article investigates the opposing viewpoints of multinational companies (MNCs) and public health advocates. MNCs say that data exclusivity is necessary to

1. Ragavan, Srividhya, Data Exclusivity: A Tool to Sustain Market Monopoly, 8 Jindal Global L. Rev. 241, 241–60 (2017).
2. Animesh Sharma, Data Exclusivity with Regard to Clinical Data, 3 Indian J.L. & Tech. 82(2007).
3. Anu Bala, Data Exclusivity: Pressing Issue, SSRN, No. 1676104 (2010), https://ssrn.com/abstract=1676104.

incentivise R&D investments, whilst detractors argue that it impedes generic competition and access to life-saving treatments. The report also examines the inconsistencies in the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement regarding "unfair commercial use," emphasising the need for legislative clarity in India in balancing IP protection with public health concerns. The statement also mentions the Satwant Reddy Committee's data protection recommendations, emphasising the ongoing discussion and implications for India's policy directions.

RESEARCH PROBLEM:

Despite the increasing pressure from international trade agreements and the evolving global pharmaceutical landscape, India lacks a comprehensive data exclusivity framework that protects the clinical trial data submitted by originator companies. This gap not only hinders the development and approval of innovative drugs within India but also places Indian pharmaceutical companies at a competitive disadvantage in the global market.

RESEARCH QUESTION:

What are the implications of not having data exclusivity laws in India for the pharmaceutical industry, public health, and compliance with international trade obligations, and how can the establishment of such laws enhance innovation and access to medicines?

RESEARCH OBJECTIVE:

The primary goal of this study is to look into the implications of enacting data exclusivity restrictions in India, particularly their influence on the pharmaceutical business, public health, and international trade compliance. This study attempts to:

1. Determine how data exclusivity may impact pharmaceutical innovation and R&D spending inIndia.
2. Assess the impact of data exclusivity on access to cheap drugs and overall public healthoutcomes.
3. Examine the impact of data exclusivity in improving India's compliance with WTO TRIPS regulations and its trade relations with key global partners.
4. Create a balanced policy framework that takes into account both the need for innovative incentives and the significance of accessible healthcare, tailoring it to India's specific socioeconomic and healthcare context.

RESEARCH METHODOLOGY:

The study employs a Doctrinal research methodology, emphasizing the promotion of constructive modifications to the legal system. It also uses an analytical approach, which makesit possible to do a thorough investigation of the body of existing literature. The study makes use of both deductive and inductive reasoning, which makes it easier to generate fresh ideas based on previously published research. Through the application of both qualitative and quantitative methodologies, the research provides an extensive analysis of legal matters. It is important that the research depends upon pre-existing academic literature for its conclusions rather than obtaining original data from people or organizations.

RESEARCH METHOD:

The current study uses the secondary data collection method, which comprises reading, analyzing, and examining over previously published materials like books, journals, and other written works related to the topic. The production of this work, which is fully reference-based, involved secondary research methods. The legal framework and legal issues covered in the paper are explained using primary data, such as bare acts**.**

DATA EXCLUSIVITY

The period of non-reliance and non-disclosure granted to new chemical entities, pharmaceutical arrangements, and agrochemical registration data or test data is known as data exclusivity (DE) or exclusivity of registration data. For a limited period, the drug regulatory bodies forbid the registration of the generic version using the original manufacturer's test results. It is important to distinguish data exclusivity as a separate intellectual property right from the protection afforded by other rights, particularly patents.

Data from clinical trials and other tests are proprietary information that comes from scientific research and development that was done by the original creator, who invested time and money toshow the safety and effectiveness of novel chemical entities, formulations, and applications. While it takes 8 to 10 years and millions of dollars to discover and develop a novel chemical, it only takes roughly half the time and money to get test data.[4] When obtaining regulatory bodies' approval for marketing, this data becomes crucial. For a particular period of time, data exclusivity gives the original creator the authority to prevent third parties from using the data to get marketing approval.

Therefore, data exclusivity guarantees that

1. When evaluating an application from a second entrant seeking approval of a copied product, the regulatory body is prohibited from accessing the originator's data without his consent for a predetermined period of time.
2. This allows the originator to claim back the costs incurred in obtaining themarketing approval.

[3]G. S. Alì, Sweetening a Bitter Pill: Of Drug Prices, Drug Delays and Data Exclusivity, J. Health L. (2019), https://www.semanticscholar.org/paper/5995a807b997da49a40999c316510d6f1aa1ac82

Second registrants can release imitation products into the market based solely on bioequivalence tests in the lack of a data exclusivity period, avoiding the costly and time-consuming trials necessary to prove the product's efficacy and safety. This would ultimately put the creator at a disadvantage after they had invested a lot of money in their research.

Distinction between patent and data exclusivity:

Data exclusivity and patents are separate protections. Patents protect an innovator's right to prevent others from using their invention, while data exclusivity protects the clinical data submitted to regulatory bodies (like the FDA) from being used by generic manufacturers to obtain market approval. Even with a patent, a drug still needs FDA approval.[5] Data exclusivity specifically prevents generics from relying on the original clinical data, promoting independent data generation and protecting the innovator's investment.

Data exclusivity on TRIPS Agreement:

All Member States are required by the TRIPS Agreement to provide sufficient protection for private data supplied as a condition of obtaining market approval for a new medication. TRIPS Article 39

The following terms are used in the agreement to address this issue:

1. Members must protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3 in order to ensure effective protection against unfair competition as stipulated in Article 10bis of the Paris Convention (1967).
2. Both natural and legal individuals possess the power to stop information that is legally under their control from being shared with, obtained by, or utilised by others without theirpermission in a way that goes against ethical business standards, provided that theinformation:

A. The information is considered secret if it is not easily accessible or known tothose typically dealing with it.
B. It is valuable commercially due to its confidentiality.
C. The person in charge of the information has taken reasonable measures to maintain its confidentiality under certain circumstances.

3. When members require the submission of undisclosed test or other data, the origin of which requires a significant amount of work, as a condition of authorising the marketing of pharmaceutical or agricultural chemical products that use new chemical entities, they [5]Urmila Sawhney, Data Exclusivity, MONDAQ (May 13, 2009), https://www.mondaq.com/india/information-security-risk-management/79418/data-exclusivity.

must safeguard such data against unjust commercial use. Additionally, Members must prevent dissemination of such data unless it is required to safeguard the public or unless measures are taken to prevent unfair commercial use.[6]

The data that is provided to regulatory bodies for testing in order to approve any kind of product is not protected by Indian law. Despite being a signatory to the TRIPS Agreement, India has not passed any

new legislation to safeguard test data.

Legal provision on data exclusivity in other countries:

Data exclusivity is important in the pharmaceutical industry. The United States and the European Union are the two countries that now have national models of data exclusivity.

United States of America: The United States was the first nation to pass data exclusivity laws in 1984. Applications for the approval of novel medications are subject to a 5 years data exclusivity period under the Hatch-Waxman Ac[7]. 3 years of data exclusivity are granted to applications for the approval of new indications for an already-approved medication.

New Zealand: 5 years is the duration of data exclusivity in New Zealand. Data exclusivity for novel applications or formulations of outdated active substances is not offered by New Zealand.

Japan: Japan does not have a statutory data exclusivity regime.

Rather, under Article 14-4 of the Pharmaceutical Affairs Law, Japan has a mechanism of "re-examination" that is similar to data exclusivity.

The data exclusivity period in Japan is 8 years for new medications, 4 to 6 years for new drug indications or pathways, or 10 years for orphan drugs.

China: China offers 6 years of data exclusivity starting on the date of marketing clearance, as per Article 35 of the Drug Administration Law of August 4, 2002's Implementing Regulations.

Australia: For NCE (new chemical entities) alone, Australia offers 5 years of data exclusivity.

Mexico: Articles 82 and 86 of the Mexican Industrial Property Law (MIPL) and Number 167 of the Health Supplies Regulations (HSR) both make reference to data exclusivity rights. Mexico offers data exclusivity for 5 years.

[6]Archita Srivastava, Demand for Data Exclusivity in India and Its Implications, 4 Int'l J.L. Mgmt. & Human. 847 (2020).

[7]Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, https://www.wto.org/english/docs_e/legal_e/27-trips_04d_e.htm.

Developing Countries:

Malaysia: The 2011 Directive includes exceptions to data exclusivity in circumstances of forced licensing or public health emergencies, ensuring access to medications during crises.

Chile: Article 91 of Law 19.996 exempts data exclusivity obligations when public health measures are required, in accordance with the Doha Declaration on TRIPS.

Brazil: grants a ten-year data exclusivity term, although there are provisions for public health exclusions that allow generics to reach the market under certain conditions.

Philippines: Offers an eight-year data exclusivity term, with similar protections for public health reasons.

These frameworks emphasise the need of safeguarding innovation and public health in developing countries.

Implications for the Pharmaceutical Industry:

The lack of data exclusivity laws in India gives a set of challenges

Competitive disadvantage:

Following the release of new medications, generic pharmaceutical companies can quickly enter the market due to the lack of data exclusivity regulations. Originator businesses aim to gradually recover their significant R&D expenditures through product sales. However, generic competitors can frequently

file their applications almost soon due to the lack of exclusive rights to their clinical trial data, which weakens the position of the original producer in the market.

Local pharmaceutical companies' profit margins decline as a result of this dynamic, making it harder for them to finance further research. As a result, there is less motivation to innovate. The potential benefits of creating novel medicines are reduced when market exclusivity is not sufficiently safeguarded, resulting in a stagnating pipeline of creative treatments that is harmful not only to pharmaceutical companies but also to public health.

Impact on innovation:

One important tool for promoting innovation in the pharmaceutical industry is data exclusivity. By providing a short-term monopoly on the sale of recently created medications, it enables businesses to recoup their potentially costly R&D expenditures.[8] The dangers of creating new medications rise dramatically in the absence of data exclusivity, and pharmaceutical companies are likely to become more cautious in their R&D activities.

Funding issues:

Potential investors may be discouraged from investing in pharmaceutical businesses in India due to the lack of clarity surrounding data privacy. Because the risks associated with generics' quick market entry reduce the possibility for returns on investment, investors are typically wary of environments with weak intellectual property (IP) safeguards. The resources available for R&D and innovation may be restricted as a result of this reluctance to invest in the pharmaceutical industry.

Companies may find it difficult to sustain competitive research programs without sufficient funding, which could impede the creation of new medications as well as the improvement of current treatments. For smaller businesses that could depend on venture capital or outside funding to fund their operations, this investment gap is especially harmful. Strong data exclusivity regulations may calm investors and persuade them to consider the Indian pharmaceutical market as a promising place to invest, which may encourage innovation and economic expansion in the industry.

IMPACT ON PUBLIC HEALTH:

Initial Lower Prices: At first, consumers and healthcare systems may find medication more affordable due to the quick introduction of generic drugs onto the market. Benefits may be felt right away, particularly for people who need long-term medicine for chronic diseases.

Decrease in R&D Incentives: Pharmaceutical companies would be less inclined tospend money on the development of new medications if market exclusivity is not granted.When possible rivals might release generic versions of a new medication soon after its release, the return on investment decreases. The financial feasibility of creating novel medicines is greatly reduced in the absence of a safe time frame to recoup R&D expenses.

Effect on Therapeutic Advancements: Over time, fewer novel treatments may hit the market as a result of a drop in creative medication research. For illnesses with rapidly changing microorganisms or no effective treatments, this standstill is particularly problematic. Patients may have few options since emerging healthcare issues may not be

[8] J. Gangil, G. Thunga & R. Nagaich, Do Intellectual Property Rights and Data Exclusivity Encourage Innovation in the Pharmaceutical World?, 1 Systematic Revs. in Pharmacy 2 (2010). well addressed by established medications, which could have a negative impact on life expectancy and general health results.[9]

Wide-ranging Impacts on Public Health: Long-term effects of less innovation include the possibility of diseases going undiagnosed or being poorly managed, which can make public health problems worse. As a result, healthcare systems might have to deal with more advanced disease stages, which could have been avoided with the help of cutting-edge treatments earlier in the course of the illness.

Implications for Compliance with International Trade Obligations:

International trade relations: India may have trouble complying with international accords, particularly the TRIPS agreement, as a result of its weak data exclusivity framework. TRIPS mandates that member nations set baseline standards for intellectual property protection, including safeguarding pharmaceutical test data.

Strained Relations with Trading Partners: Nations that place a high value on robust intellectual property rights may put pressure on India to enact comparable laws. Trade relations may suffer if a clear data exclusivity framework is not put in place because nations with well-established IP safeguards may believe that India is compromising the integrity of their own IP rights**.**

Possibility of Trade Disputes: In addition to straining bilateral ties, this kind of noncompliance may give rise to formal trade disputes, which could then escalate into conflicts inside global trade organisations such as the World Trade Organisation (WTO). Complaints could be filed by nations calling for stricter IP regulations, claiming that India's actions violate its TRIPS obligations.

Influence of Multinational Corporations: To guarantee the profitability of their investments, multinational pharmaceutical companies frequently look for robust data protection measure[10] By claiming that data exclusivity is necessary to encourage the development of new medications, these businesses may advocate for modifications to

[9] K. Kumari, Reassessing the Data Exclusivity Regime for the Indian Pharmaceutical Industry, SEMANTIC SCHOLAR, https://www.semanticscholar.org/paper/a93945bc6c9e139fc917f6bb1294561c9c083b43

[10]H.D. Menezes, J. Paranhos, R. Torres & L. Borges, Negotiating Health and Autonomy: Data Exclusivity, Healthcare Policies and Access to Pharmaceutical Innovations, ECONSTOR (2024), https://www.econstor.eu/handle/10419/301244.

India's intellectual property regulations.

Bilateral Trade Agreements: Governments from other countries, particularly those in affluent countries, may use bilateral trade agreements as leverage to pressure India into implementing more robust intellectual property rights, such as data exclusivity. India's potential for pharmaceutical sector growth may be hampered by unfavourable trade terms or weakened economic connections if these objectives are not met.

Risk of sanctions: Economic sanctions against India may result from trading partners who believe their interests are being put at risk if the problem of data exclusivity is not resolved. Among other industries, the pharmaceutical industry and health care may be the target of these penalties which would critical to indian economy.[11]

LEGAL PRECEDENTS:

INDIA:

The following legal examples support the rationale for data exclusivity rules in India:

In a case involving **Syngenta**, Justice Ravindra Bhat emphasised that fundamental legislative functions cannot be transferred to rule-making powers, underlining the importance of precise statutory

frameworks for data protection.

Satwant Reddy Committee's Report (2007):

This research suggested data exclusivity for agrochemicals, with a three-year protection period, demonstrating a trend towards recognising the need for data exclusivity in specific sectors14.

Parliamentary Standing Committee Observations:

The committee warned against submitting to multinational firms' pressures on data exclusivity, instead arguing for a balanced strategy that protects both innovation and public health1.

These examples highlight the challenges of data exclusivity in India's legislative framework.

GLOBAL:

Other countries have the following legal precedents regarding data exclusivity:

United States: The Hatch-Waxman Act (1984) grants five years of data exclusivity for NewMolecular Entities (NMEs), barring generic manufacturers from using the innovator's data to obtain marketing approval during this period.

[11] O. Owoeye, Data Exclusivity and Public Health under the TRIPS Agreement, J.L. & Info. Sci. (2014), https://www.semanticscholar.org/paper/a45d325fc083c16ba2979db57b23b51bff6318d3

EU regulations allow for 8-10 years of data exclusivity, with exceptions for public healthemergencies, as seen in trade agreements such as the EU-Peru Agreement.

Canada: In **Bayer, Inc. v. Canada (Attorney General)**, the court upheld the legitimacy of approving subsequent applications based on prior registrations, emphasising that data exclusivity does not prevent regulatory authorities from assessing new applications

CONCLUSION:

The lack of data exclusivity regulations in India has resulted in a complicated landscape withboth beneficial and negative consequences for the pharmaceutical sector, public health, and international trade ties. On the one hand, India's current regulatory structure has established it asa global leader in affordable generics, ensuring crucial access to medicines for millions both locally and abroad. On the other side, a lack of data protection limits incentives for innovation and R&D investment, which may hinder the development of new, creative pharmaceuticals in the Indian market. Furthermore, noncompliance with data exclusivity criteria strains India's relationships with key trading partners and calls into question its compliance with the WTO's TRIPS Agreement.

To overcome these issues, a careful and nuanced approach to data exclusivity is proposed. India should explore enacting data exclusivity regulations that safeguard originator data for a limited period and are tailored to the special requirements of important and life-saving drugs. This would entail a chosen exclusivity term for new pharmaceuticals, allowing the developer to recoup investment expenses while maintaining inexpensive availability. At the same time, mechanisms should be implemented to allow for faster generic production of treatments addressing public health crises, while ensuring that data exclusivity does not impede access to important medications.

Furthermore, establishing public-private partnerships to fund R&D for neglected diseases and vital pharmaceuticals can help to develop India's healthcare system and innovation ecosystem. By implementing a hybrid policy model that combines innovation incentives with access needs, India may better comply with international standards, improve its global trade reputation, and solidify its position as a leading provider of both innovative and inexpensive healthcare solutions.

RECOMMENDATIONS:

The recommendations below aim to offer a fair foundation for enforcing data exclusivity inIndia. Recognising the merits and limitations of India's existing lack of data exclusivity rules, these recommendations aim to boost R&D investment, improve conformity with global standards, and ensure inexpensive medicine availability. By implementing a systematic approach to data protection that is customised to the specific demands of crucial medications and novel treatments, India can strengthen its position as a global leader in both generic drug manufacture and developing pharmaceutical innovation. The recommendations centre on constructing a nuanced data exclusivity system, fostering strategic collaborations, and incorporating safeguards for public health emergencies, with the ultimate goal of creating an inclusive and resilient healthcare paradigm.

1. **Implement a limited data exclusivity framework:**

India should explore implementing a data exclusivity regime that offers limited protection fororiginator data while balancing innovation incentives and the requirement for cheap medicine availability. A limited exclusivity period (e.g., 5-7 years) will protect innovators' data investments while allowing for faster entrance of generics, ensuring cheap drug options for the public.

2. **Customise Data Exclusivity for Critical and Life-saving Drugs:**

Establish data exclusivity rules that prioritise life-saving or vital medications, with shorter exclusive periods or unique requirements for generic entry in cases of public health need. This approach would increase access to important pharmaceuticals while maintaining incentives for innovation, ensuring that public health needs are prioritised.

3. **Increase compliance with international trade obligations**:

Improve compatibility with WTO TRIPS standards by implementing data protection measures that meet international trade responsibilities, potentially reducing trade disputes and improving relationships with key partners. Aligning with TRIPS can lessen tensions with trading partners, strengthen India's reputation as a trustworthy trade partner, and potentially increase access to international markets for Indian pharmaceutical products.

4. **Promote public-private partnerships in R&D:**

Encourage public-private collaborations to promote R&D for neglected diseases and vital medications, particularly in cases where data exclusivity alone may not incentivise development due to low market returns. Collaboration with the government or global health organisations can help support R&D for public health-critical treatments, hence enhancing India's position in innovative healthcare solutions.

5. **Improve funding and support for domestic pharmaceutical innovation:**

Recommendation: Create government-funded subsidies or tax breaks to encourage domestic pharmaceutical R&D, particularly among small and medium-sized businesses.

Rationale: Domestic funding support can supplement data exclusivity, particularly for smaller enterprises with limited resources, promoting a more robust and self-sufficient pharmaceutical industry.