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# PROTECTING PATIENTS OR PATENTS? THE CASE FOR RETHINKING DATA EXCLUSIVITY IN INDIA'S DRUG REGULATORY FRAMEWORK

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## ABSTRACT

A constant tension between innovation and access to healthcare characterizes the global pharmaceutical landscape. While patents under the TRIPS Agreement offer innovators a twenty-year monopoly, developing nations such as India have relied heavily on generic competition to make medicines affordable. However, a series of international controversies concerning the quality of Indian generics, from U.S. Food and Drug Administration (FDA) import alerts to recent fatalities linked to substandard syrups exported to Africa, have exposed weaknesses in the domestic regulatory regime.

This paper examines whether the adoption of a Data Exclusivity (DE) framework can provide a middle path between incentivizing high-quality drug development and ensuring affordable access. DE would extend market exclusivity for manufacturers that comply with enhanced regulatory and quality standards, while generics for essential health medicines remain protected to preserve affordability. Drawing from comparative legal perspectives in the United States, Japan, and the European Union, this paper argues for a hybrid structure wherein DE applies to non-essential or advanced therapies, with state-backed insurance mechanisms bridging affordability gaps. Further, the paper interrogates TRIPS flexibilities, particularly compulsory licensing, the Doha Declaration, and Article 3 of TRIPS exceptions, to assess whether such a model could withstand multilateral trade scrutiny. Ultimately, it recommends calibrated reform that strengthens India's regulatory apparatus, leverages DE to attract innovation, and safeguards public health through selective generic protections.

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Keywords: Data Exclusivity, TRIPS Agreement, Generic Medicines, Compulsory Licensing, Pharmaceutical Regulation, India, Access to Medicines

# INTRODUCTION

The relationship between pharmaceutical innovation and public health has always been marked by tension. On the one hand, pharmaceutical companies argue that high costs of research and development (R&D) require strong legal and regulatory protections. On the other hand, governments in developing countries such as India face the challenge of ensuring affordable access to medicines for their populations. This tension has led to long-standing debates over the role of patents, compulsory licensing, and most recently, data exclusivity (DE)[2] in drug regulation.

India is often described as the "pharmacy of the Global South[3]" because of its large-scale production of generic medicines, which supply not only domestic patients but also millions of people in Africa, Asia, and Latin America. The Indian regulatory system, however, has consciously avoided adopting data exclusivity provisions that are common in jurisdictions such as the United States, the European Union, and Japan. Instead, India relies on a framework that prioritizes public health objectives[4], allowing generic manufacturers to rely on existing clinical data once patents expire or when no valid patent exists.

The absence of DE in India has been criticized by some commentators and multinational pharmaceutical companies, who argue that it undermines incentives for innovation and deters investment in high-risk drug research. At the same time, Indian policymakers and health activists counter that introducing DE would effectively create a "backdoor patent", delay the entry of affordable generics, and thereby harm access to essential medicines. This clash of interests has left India in a policy stalemate, with the debate resurfacing during free trade agreement negotiations, particularly with the United States and the European Union.

[2] I Introduction and others, 'DATA EXCLUSIVITIES AND THE LIMITS TO TRIPS HARMONIZATION PETER K. YU'.
[3] 'Pharma's Influence on India's Global Health Engagement | Think Global Health' <https://www.thinkglobalhealth.org/article/pharmas-influence-indias-global-health-engagement> accessed 7 September 2025.
[4] Novartis AG v Union of India (2013) 6 SCC 1

Against this backdrop, the article titled Protecting Patients or Patents? The Case for Rethinking Data Exclusivity in India's Drug Regulatory Framework seeks to revisit the debate by situating India's regulatory choices within broader international practices. It examines whether India's approach adequately balances the twin imperatives of innovation and access, and considers whether a hybrid model, protecting certain categories of innovative medicines through limited DE while safeguarding the dominance of generics in essential drugs, could offer a middle path.

## RESEARCH OBJECTIVES

This paper is guided by four interrelated questions:

1. What is the rationale behind data exclusivity, and how does it operate in major jurisdictions?
2. Why has India resisted adopting DE despite international pressure?
3. Does the absence of DE in India compromise drug quality, investment, or innovation?
4. Can a hybrid regulatory structure, limited DE combined with safeguards for generics, provide a workable compromise consistent with India's international obligations?

## METHODOLOGY AND SCOPE

The study relies on a doctrinal research method, analyzing statutory frameworks, case law, policy documents, and scholarly commentary. Comparative perspectives from the U.S., EU, and Japan are integrated to highlight the global dimensions of the issue. The scope is limited to the regulatory and intellectual property (IP) aspects of drug approvals; it does not examine broader issues of pharmaceutical marketing or pricing beyond the DE debate.

## PATENT PROTECTION VS DATA EXCLUSIVITY

Pharmaceutical regulation involves two distinct but often conflated mechanisms of protection: patent rights and data exclusivity (DE). While both delay generic entry, their legal basis, scope, and

policy rationale differ significantly. Understanding this distinction is essential before evaluating India's regulatory stance[5].

## PATENT PROTECTION

Patents are a form of intellectual property right granted to an inventor who discloses a novel invention that meets the criteria of novelty, inventive step, and industrial applicability[6]. In pharmaceuticals, patents usually cover new molecules, formulations, or processes. A standard patent term lasts twenty years from the date of filing[7], during which no other party may manufacture, use, or sell the invention without authorization.

The justification for patents rests on the incentive theory of IP law. By ensuring temporary monopoly profits, innovators are encouraged to invest in costly and uncertain research. Once the patent expires, generic producers are free to manufacture the same drug, thereby reducing prices and increasing access.

## DATA EXCLUSIVITY

Data exclusivity, by contrast, does not flow from intellectual property law but from regulatory law. When a pharmaceutical company seeks marketing approval for a new drug, it must submit clinical trial and toxicological data to demonstrate safety and efficacy.[8] Under a DE regime, regulators are barred from allowing generic companies to rely on this data for a defined period.

Thus, even if a patent expires, or if no patent was granted, a generic manufacturer cannot obtain marketing approval without conducting its own costly and ethically complex clinical trials[9]. In practice, this creates a second layer of market exclusivity.

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[6] Jae Sundaram, *Pharmaceutical Patent Protection and World Trade Law: The Unresolved Problem of Access to Medicines* (Routledge 2018).

[7] Section 53 of the Patent Act, 1970

[8] Khushbu Kumari, 'Reassessing The Data Exclusivity Regime For The Indian Pharmaceutical Industry' (thesis, Open Access Te Herenga Waka-Victoria University of Wellington 2024) <https://openaccess.wgtn.ac.nz/articles/thesis/Reassessing_The_Data_Exclusivity_Regime_For_The_Indian_Pharmaceutical_Industry/25857238/1> accessed 6 September 2025.

[9] *Roche v Cipla* (2009) 160 DLT 328 (Del)

## THE OVERLAP AND EXTENSION OF MARKET EXCLUSIVITY

Although patents and DE are independent, they often overlap. For example, in the United States, a new chemical entity (NCE) may enjoy five years of DE in addition to the twenty-year patent term. In the European Union, the "8+2+1" model offers eight years of DE, two years of marketing exclusivity, and a possible one-year extension for new indications[10]. Japan provides eight years of DE for new drugs.

This sequencing can effectively extend monopoly control beyond the patent period, leading critics to call DE a form of "evergreening"[11]. Proponents argue, however, that it is necessary to prevent free-riding on the originator's costly clinical trials.

## THE INDIAN POSITION

India has consciously resisted adopting a DE regime. The Drugs and Cosmetics Act, 1940 and the New Drugs and Clinical Trials Rules, 2019 mandate the submission of safety and efficacy data but do not recognize any exclusivity over such information[12]. Regulators may rely on submitted data to approve generic versions once the drug is off-patent or if compulsory licensing is invoked.

This approach reflects India's broader policy of prioritizing public health and access to affordable medicines. International trade negotiations, particularly with the United States and European Union, have repeatedly pressured India to adopt DE, but successive

[10] Brook K Baker, 'Ending Drug Registration Apartheid: Taming Data Exclusivity and Patent/Registration Linkage' (2008) 34 American Journal of Law & Medicine 303 <https://www.cambridge.org/core/journals/american-journal-of-law-and-medicine/article/abs/ending-drug-registration-apartheid-taming-data-exclusivity-and-patentregistration-linkage/C142ABF663B292D71B2B460D9E3A54F8> accessed 6 September 2025.

[11] *Novartis AG v Union of India* (2013) 6 SCC 1.

[12] Prashant Reddy T., 'Data Exclusivity Debate in India: Time for a Rethink' (2014) 10 Indian Journal of Law andTechnology8 <https://heinonline.org/HOL/Page?handle=hein.journals/indiajoula10&id=8&div=&collection=>.

# INTERNATIONAL PRACTICES OF DATA EXCLUSIVITY

Data exclusivity is not a uniform concept; its scope and duration vary significantly across jurisdictions. Examining the practices of the United States, the European Union, and Japan highlights both the rationale for DE and its practical impact on drug markets.

## THE UNITED STATES

The United States Food and Drug Administration (FDA) provides a structured DE regime under the Hatch-Waxman Act of 1984. Key features include:

1. New Chemical Entities (NCEs): Five years of data exclusivity for NCEs, during which generics cannot rely on the originator's data for approval.
2. New Clinical Investigations: Three years of DE may be granted for new clinical investigations (such as new indications or dosage forms).
3. Biologics: Under the Biologics Price Competition and Innovation Act (BPCIA), 2009, biologic products receive twelve years of exclusivity.

The U.S. regime reflects a deliberate balance: encouraging innovation through strong exclusivity while enabling generic challenges through the Abbreviated New Drug Application (ANDA) system once DE expires. However, studies suggest that DE has contributed to higher drug prices and delayed generic competition, especially in the biologics sector.

## THE EUROPEAN UNION

The European Union employs what is commonly referred to as the "8+2+1" model[13]:

1. Data Exclusivity (8 years): During the first eight years after authorization, generic manufacturers cannot rely on the innovator's data.
2. Marketing Exclusivity (2 years): For two additional years, generics may receive approval but cannot launch their products.

[13] Eur. Medicines Agency, *Scientific Guidelines on Data Exclusivity* (2021).

3. Additional 1 Year: A further one-year extension is possible if a new therapeutic indication providing significant clinical benefit is approved within the first eight years[14].

This regime offers up to eleven years of effective exclusivity. The European Commission justifies the framework as ensuring both innovation incentives and eventual generic access. Critics argue that the extended exclusivity contributes to delays in affordable medicine availability across member states, although the centralized approval system reduces duplication of trials and regulatory processes.

## JAPAN

Japan's data exclusivity system is linked to its re-examination period under the Pharmaceuticals and Medical Devices Agency (PMDA). New drugs typically receive eight years of exclusivity, during which the regulator reviews accumulated safety and efficacy data and prohibits generic reliance on the innovator's submission.

This period may be extended to up to ten years for drugs addressing rare diseases or public health priorities. Japan's model is therefore both a regulatory safeguard and an incentive mechanism, ensuring post-market surveillance while limiting generic entry[15].

## COMPARATIVE INSIGHTS

A comparison of these models shows three important trends:

- Duration Matters: The length of exclusivity—ranging from five years in the U.S. to potentially eleven years in the EU—directly affects the timing of generic entry and medicine prices.
- Biologics Receive Special Treatment: Both the U.S. and Japan provide longer exclusivity for biologics, reflecting the high costs and risks associated with their development.[16]

[14] Aaron S. Kesselheim et al., *Clinical Evidence and Data Exclusivity: What's at Stake?*, 360 New Eng. J. Med. 1851 (2009).

[15] Ryuji Naito, *Regulatory Data Protection in Japan: Balancing Innovation and Public Health*, 23 J. Intell. Prop. L. & Prac. 481 (2018).

[16] Sundaram (n 3).

- Policy Priorities Differ: While Western nations emphasize innovation and investment incentives, developing countries prioritize affordability and access[17].

### LESSONS FOR INDIA

For India, these international models underscore the potential costs of adopting DE. Extended exclusivity could delay the country's thriving generic industry, undermine its role as a supplier of affordable medicines, and raise out-of-pocket expenditures for patients. At the same time, refusing DE may limit incentives for high-risk innovation and could discourage multinational pharmaceutical investment. India must therefore weigh whether aspects of these models can be adapted in a hybrid framework that suits its unique socio-economic conditions.

## INDIA'S REGULATORY STANCE AND CRITICISMS OF DATA EXCLUSIVITY

### LEGAL FRAMEWORK IN INDIA

India does not currently recognize a formal system of data exclusivity. The primary legislation governing pharmaceuticals is the Drugs and Cosmetics Act, 1940, and the Drugs and Cosmetics Rules, 1945, which require submission of clinical trial data for new drugs. However, the Act does not confer any exclusivity over such data.[18]

### JUDICIAL APPROACH

Indian courts have generally viewed data exclusivity claims with skepticism, emphasizing public health. In Novartis AG v. Union of India[19], the Supreme Court declined to expand intellectual property protection through "evergreening" patents and underscored the importance of balancing innovation with access.[20]Although the case focused on patents under S 3(d) of the Patents Act,

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[17] Brook K. Baker, *Ending Drug Registration Apartheid: Taming Data Exclusivity*, 34 Am. J.L. & Med. 303 (2008).

[18] Drugs & Cosmetics Act, No. 23 of 1940, INDIA CODE (1940)

[20] (2013) 6 SCC 1 (India)

1970, the reasoning reflects judicial caution against mechanisms (like DE) that might indirectly extend monopolies and restrict generic entry.

## INTERNATIONAL PRESSURE

India's stance has faced sustained pressure in bilateral and multilateral negotiations. During discussions on a proposed India-EU Free Trade Agreement, the European Union repeatedly demanded DE provisions similar to its "8+2+1" model.[21]The United States Trade Representative has also criticized India's refusal to adopt DE, citing it as a barrier to protecting innovators' interests. [22]

At the multilateral level, the TRIPS Agreement under the WTO obliges member states to protect undisclosed test data against "unfair commercial use."[23]However, TRIPS do not mandate exclusive rights[24] over such data, leaving members free to design regimes consistent with public health needs.

India has used this flexibility to reject exclusivity while still protecting against outright misappropriation.[25]

India thus remains at a policy crossroads. On one hand, refusing DE safeguards its role as the "pharmacy of the developing world." On the other hand, the absence of DE fuels criticism about drug quality, innovation disincentives, and trade friction. The ongoing debate raises the question of whether India can devise a hybrid framework protecting innovation where necessary without undermining its public health commitments.

[21] Press Release, European Commission, EU-India Free Trade Negotiations (2011)

[22] office of the U.S. Trade Representative, 2023 Special 301 Report (Apr. 2023)

[23] Agreement on Trade-Related Aspects of Intellectual Property Rights art. 39.3, Apr. 15, 1994, 1869 U.N.T.S. 299.

[24] *Canada – Patent Protection of Pharmaceutical Products* WT/DS114/R (2000) WTO Panel Report.

[25] Shamnad Basheer, Data Exclusivity in India: TRIPS Compliance, TRIPS-Plus Pressure, 8 J. WORLD INTELL. PROP. 5, 8–9 (2005).

# GENERICS, REGULATORY FAILURES, AND THE DEBATE ON DRUG QUALITY

India has earned the title of the "pharmacy of the developing world" for its robust generic drug industry, which supplies affordable medicines across Asia, Africa, and Latin America. Generics play a critical role in ensuring widespread access by providing low-cost alternatives once patents expire. However, affordability cannot be the sole measure of success. Growing concerns over the quality and safety of Indian-manufactured generics have triggered both domestic debate and international scrutiny[26].

## THE PROMISE OF GENERICS[27]

Generic medicines are bioequivalent versions of originator drugs, produced after patents lapse or where no patent protection exists. Their primary advantage lies in cost reduction, enabling millions to access essential treatments[28]. In India, generic penetration is exceptionally high due to price-sensitive markets and government procurement policies. By bypassing the need for costly original R&D, generic manufacturers can offer the same therapeutic effect at a fraction of the cost.

## RECENT REGULATORY FAILURES AND INTERNATIONAL CONTROVERSIES

Despite these advantages, multiple international incidents have raised alarm over the safety and regulatory oversight of Indian generics. In 2022 and 2023, the World Health Organization (WHO)[29] issued global medical alerts linking Indian-manufactured cough syrups to child deaths in The Gambia, Uzbekistan, and Cameroon. Investigations revealed unacceptable levels of diethylene glycol and ethylene glycol, contaminants with lethal effects when ingested. The New York Times

[26] *F Hoffmann-La Roche Ltd v Cipla Ltd* (2015) 225 DLT 391 (Del).
[27] Henry Grabowski, Iain Cockburn and Genia Long, 'The Market for Follow-On Drugs: How Generics Compete' (2006) 7(3) *Pharmacoeconomics* 199.
[28] Amir Attaran, 'How Do Patents and Economic Policies Affect Access to Essential Medicines in Developing Countries?' (2004) 23 *Health Affairs* 155.
[29] Sundaram (n 3).

reported that these deaths "shook confidence in India's drug exports and revealed systemic regulatory gaps," casting doubt on India's ability to ensure basic safety standards[30].

These incidents are not isolated. Earlier quality-control failures involving Indian generics in the U.S. and Europe have resulted in recalls, import bans, and erosion of trust. Taken together, these events point to a deeper regulatory problem: India's heavy reliance on self-certification, underfunded regulators, and weak enforcement mechanisms.[31]

## LINKING QUALITY FAILURES TO THE DE DEBATE

The absence of data exclusivity in India exacerbates regulatory vulnerabilities. Since generic manufacturers can rely on originator data indirectly without conducting their own extensive clinical trials, there is limited incentive to maintain rigorous pharmacovigilance or invest in data quality.[32] The recent controversies highlight how a system designed to maximize affordability may inadvertently compromise safety.

Supporters of DE argue that a limited form of exclusivity could improve accountability. If certain categories of drugs required fresh clinical or bioequivalence data submissions, rather than simple reference to originator data, manufacturers would be forced to adopt stricter testing and compliance. This, in turn, could strengthen the credibility of India's pharmaceutical exports while safeguarding domestic patients.

## COUNTERARGUMENTS: COST AND ACCESS CONCERNS

Opponents caution that introducing DE may delay the entry of generics and inflate drug prices, disproportionately affecting poor and rural populations. India's generic dominance has been a global lifeline for low-income countries[33], particularly in areas such as antiretroviral (ARV)

[30] 'Indian Drugs, Sold Worldwide, Sometimes Deadly - The New York Times' <https://www.nytimes.com/2022/11/03/world/asia/india-gambia-cough-syrup.html> accessed 8 September 2025.
[31] www.ETGovernment.com (n 8).
[32] Baker (n 6).
[33] Warren Kaplan and Richard Laing, 'The 1 Billion People with No Access to Medicines: Generics and International Trade Agreements' (2005) *Health Economics, Policy and Law* 1(1).

treatment for HIV/AIDS. Any policy shift that curtails this advantage must therefore be carefully designed to avoid undermining access.[34]

## TOWARDS REGULATORY REFORM

The debate should not be framed as generics versus innovation, but rather as quality and access working together. India requires a dual approach:

1. Stronger regulatory infrastructure- with more inspectors, transparent trial data, and international quality harmonization.
2. Calibrated exclusivity measures- where DE is introduced selectively to improve accountability without restricting affordable generics in life-saving categories.

By linking DE to improved drug quality rather than pure market control, India can preserve its role as the global pharmacy while addressing valid concerns over safety and credibility.

# RECOMMENDATION – TOWARDS A HYBRID FRAMEWORK FOR INDIA

The debate over data exclusivity in India cannot be resolved through the binary of adoption or rejection. A more balanced approach is necessary, one that protects the public health mandate of affordable access while addressing legitimate concerns about regulatory quality, innovation incentives, and India's global credibility. This chapter proposes a hybrid framework designed to reconcile these competing imperatives.

## LIMITED DATA EXCLUSIVITY FOR SELECT CATEGORIES

India should consider introducing tiered data exclusivity in narrowly defined circumstances:

- Biologics and biosimilars, where clinical data is inherently complex and costly.
- Drugs addressing rare or neglected diseases, which otherwise attract limited private investment.

[34] 'Pharma's Influence on India's Global Health Engagement | Think Global Health' (n 2).

- Innovations developed under public–private partnerships (PPPs), where DE could incentivize collaboration without surrendering public interest.

Such targeted exclusivity would avoid blanket restrictions on generics, focusing instead on areas where innovation needs the greatest support.

## COMPULSORY LICENSING SAFEGUARDS DURING DE

To ensure that DE does not create an unyielding monopoly, compulsory licensing provisions[35] should be extended to regulatory data in situations of public health emergencies. Comparable mechanisms exist in the United States and Japan, where governmental override powers ensure that exclusivity does not block patient access to life-saving drugs.

## STRENGTHENING REGULATORY OVERSIGHT OF GENERICS

DE alone cannot guarantee safety; India must also upgrade its drug regulatory infrastructure. Recommendations include:

- Increasing funding and staffing for the Central Drugs Standard Control Organization (CDSCO)[36].
- Establishing mandatory, transparent bioequivalence testing for all generics.
- Expanding pharmacovigilance databases to monitor adverse drug reactions.
- Harmonizing standards with the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

These reforms would address criticisms that India's reliance on generics sacrifices quality for affordability.

## STATE-SUPPORTED ACCESS MECHANISMS

Introducing DE without social protection could exacerbate inequities. To mitigate this, the government should expand public insurance programs such as Ayushman Bharat, alongside

[35] Sec 84 of The Patent Act, 1970
[36] Satwant Reddy Committee Report, *Data Protection for Pharmaceuticals in India* (2007)

targeted subsidies for high-cost drugs under exclusivity. This approach balances innovation incentives with affordability, ensuring no patient is priced out of essential treatment.

## TRIPS COMPLIANCE AND POLICY SPACE

The TRIPS Agreement requires protection of undisclosed data against "unfair commercial use" but does not mandate exclusive rights[37]. India retains discretion to design a sui generis DE regime that grants limited exclusivity in specific cases while upholding its constitutional duty to safeguard public health. By adopting a hybrid model, India can demonstrate leadership in reconciling international intellectual property obligations with domestic healthcare needs.

## CRITICISMS OF THE HYBRID PROPOSAL

While the hybrid framework seeks to balance access with innovation, several criticisms merit consideration.

First, regulatory complexity. Introducing tiered data exclusivity for select categories of drugs, such as biologics, rare disease treatments, and public–private partnership (PPP) innovations, may create confusion and administrative burdens. Determining eligibility could lead to disputes, inconsistent application, and potential litigation from pharmaceutical companies.

Second, exposure to trade disputes. Although the TRIPS Agreement requires only protection against "unfair commercial use" of test data, multinational corporations and their home governments have historically lobbied for stronger forms of DE. A sui generis Indian model could therefore be challenged at the World Trade Organization (WTO), particularly by the United States or the European Union, on grounds of insufficient protection.

Third, concerns of affordability. Even selective DE will delay generic entry for certain high-cost drugs, particularly biologics, resulting in higher treatment costs during the exclusivity period. Unless India simultaneously expands state-backed insurance schemes, such as Ayushman Bharat,

[37] *Canada – Patent Protection of Pharmaceutical Products* WT/DS114/R (2000) WTO Panel Report.

the proposal risks exacerbating inequalities by privileging insured or urban populations over poor and rural patients.

Fourth, risks to India's generic industry. India's reputation as the "pharmacy of the Global South" rests upon its ability to manufacture and export affordable generics. Any movement toward exclusivity, however limited, may signal a shift toward innovator-friendly policies, discouraging domestic manufacturers and raising concerns among partner countries dependent on Indian generics for essential medicines.

Finally, enforcement challenges. India's regulatory infrastructure remains underfunded and overstretched. The Central Drugs Standard Control Organization (CDSCO) struggles with staff shortages, inadequate laboratories, and limited pharmacovigilance capacity. Without parallel institutional reforms, a hybrid framework risks being ineffective in practice, or worse, susceptible to manipulation by dominant market players.

Taken together, these criticisms highlight that the hybrid model, while normatively appealing, may face practical and political challenges in implementation.

## CONCLUSION

India's drug regulatory framework sits at the intersection of two pressing imperatives: ensuring access to affordable medicines for its population and safeguarding the integrity of its pharmaceutical exports in the global marketplace. While the country has historically prioritized access, cementing its reputation as the "pharmacy of the developing world" recent controversies surrounding the quality of generics have exposed vulnerabilities in the system. These challenges highlight the urgent need for reforms that not only preserve affordability but also elevate regulatory standards and innovation incentives.

The debate over data exclusivity underscores this tension. Developed jurisdictions treat DE as a core incentive for pharmaceutical innovation, but India has resisted adoption, citing constitutional commitments to health and socio-economic realities. However, complete rejection of DE risks reinforcing perceptions of regulatory laxity and discouraging high-value innovation. Conversely,

wholesale adoption of Western-style exclusivity would erode the affordability lifeline that Indian generics provide to millions worldwide.

A hybrid framework offers a pragmatic middle ground. By introducing limited data exclusivity for select categories of drugs, biologics, rare disease treatments, and public–private innovations, India can create targeted incentives without undermining the availability of essential generics. Complementing this with stronger regulatory oversight, compulsory licensing safeguards, and expanded state-backed insurance schemes would ensure that exclusivity enhances rather than restricts access.

The broader lesson is that access and innovation need not be mutually exclusive. India can, and must, design a sui generis framework that aligns with TRIPS flexibilities while fulfilling its constitutional duty to protect public health. In doing so, it can retain its role as the world's leading supplier of affordable generics while simultaneously emerging as a credible hub of pharmaceutical innovation.

The choice before India is therefore not a binary one but a balancing act, between protecting patients and respecting patents, between ensuring affordability and fostering quality, and between serving domestic priorities and meeting global expectations. Rethinking data exclusivity within a carefully tailored, hybrid framework may provide the balance India needs to secure both the health of its citizens and the strength of its pharmaceutical future