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Organisation of Pharmaceutical Producers of India



ADVANCING PHARMACEUTICAL INNOVATION IN INDIA THROUGH REGULATORY DATA PROTECTION (RDP)

INNOVATION AND PATIENT ACCESS

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India's ambition to lead pharmaceutical innovation requires an ecosystem that supports research, rewards investment and expands patient access to new therapies, strengthening health outcomes and national research capabilities.

Regulatory Data Protection (RDP) is one component of this ecosystem. Distinct from patents protecting inventions, it protects proprietary test and clinical trial data submitted to regulators to establish a medicine's safety and efficacy for marketing approval.

The FAQs examine RDP's rationale, relationship with patents and potential implications for clinical research, investment and innovative medicine availability. They consider international approaches, India's regulatory framework and pathways for generic and biosimilar entry, presenting the case for clear, predictable enforceable RDP aligned with global best practices.

Through these FAQs, the Organisation of Pharmaceutical Producers of India (OPPI) recommends for an innovation-led pharmaceutical sector, keeping patient access, regulatory oversight and the development of India's research capabilities central to policy discussions.

OPPI and its member companies remain committed to developing innovative, affordable, accessible and effective medicines and diagnostic solutions that improve quality of life and support the government's goal of healthcare access for all.

KEY TAKEAWAYS

- RDP protects confidential clinical data submitted for marketing approval, safeguarding the substantial investments required for drug development and providing originators with a predictable exclusivity window.
- Higher availability of innovative medicine (3.1-fold) in RDP markets (14.7%) compared with non RDP markets (4.8%).
- Markets with RDP conduct 8.2x more clinical trials per million population per year than markets without RDP (14.9 vs 1.8). India currently lags far behind (~0.7 clinical trials per million population per year).
- UK data showing USD 0.39-USD 0.64 generated per USD 1 invested in clinical trials through income, jobs, and capability gains.
- In India, RDP has the potential to boost pharmaceutical R&D investment by ~98%-179%.
- Adopting RDP could drive a multi fold increase (estimated to be 5x) in trial activity.
- For top innovative medicines, Indian patients face an average launch delay of ~3.95 years versus the first global launch (delay is as high as 13 years).
- RDP is expected to incentivise earlier filings and faster launches in India, with no discernible burden on public health budgets.

FAQs

Why are innovation and research and development (R&D) essential for advancing a country's healthcare system?

Innovation and R&D are fundamental to advancing medical science. They drive development of new therapies, improve patient outcomes, and strengthen health systems' ability to respond to emerging health challenges. Over time, sustained investment in healthcare R&D infrastructure, collaborative research networks, and innovative solutions contributes to healthier populations, improved quality of life, and more resilient and sustainable healthcare systems, while enhancing preparedness for future pandemics and other public health threats.

What is meant by Innovation and R&D in the Bio-Pharmaceutical sector?

In the bio-pharmaceutical sector, innovation and R&D cover a wide range of activities directed at discovering, developing and bringing new medicines, therapies and treatments to patients, with the aim of improving human health and quality of life.

What do Innovation and R&D in the Bio-Pharmaceutical entail?

Innovation and R&D in the biopharmaceutical sector transform scientific discoveries into new or improved treatments. The process involves identifying drug targets, selecting and optimizing candidates, developing formulations, and conducting preclinical studies. Clinical trials then assess safety and dosage (Phase 1), initial effectiveness and side effects (Phase 2), and treatment benefit and safety in larger groups (Phase 3), followed by regulatory review and post-approval safety monitoring.

What are the Drug Discovery and Development Timelines?

The development of new safe and effective medicines is an extremely time consuming, costly and complex process. Pharmaceutical companies examine thousands of molecules with the aim of developing new medicines with only a few of these molecules successfully reaching the stages of clinical trials. Eventually less than 12% of candidate medicines reaching clinical trials will be registered and approved for marketing[1].

The investments and resources required from innovators for approval of new medicines for marketing is constantly increasing. On average, it takes 10 to 15 years and $2.6 billion to develop and win approval for a new medicine[2]. In newer areas of medicine such as gene therapy, the path from the underlying scientific discovery to an approved product can stretch to thirty (30) years.

Also, it has been estimated that more than 60% of the total cost of bringing a new medicine to market arises from clinical trials, including trials for medicines that are ultimately not approved[3].

What is proprietary clinical data?

It is the undisclosed or otherwise confidential and other data that is provided to health regulators to gain marketing approval of pharmaceutical products. Such data may include but is not limited to, the originator's laboratory, pre-clinical and clinical data, such as: information regarding product indications, efficacy, tolerability and safety, pharmaco-kinetics, drug interactions, side effects, contra-indications, precautions, warnings, adverse effects, dosage and product administration.

What are some specific examples of outcomes of Innovation/R&D in countries across globe?

As per the 15th Annual Report, titled, 'Advancing Health Through Innovation: New Drug Therapy Approvals 2025[4]', by the Center for Drug Evaluation and Research (CDER), the USFDA approved 46 "novel" drugs in 2025, either as new molecular entities (NMEs) under New Drug Applications (NDAs) or as new therapeutic biologics under Biologics License Applications (BLAs). Of these, 23 (50%) received orphan drug designation because they target rare diseases, 20 (43%) were identified as first-in-class.

Further, although the count of novel drugs that received market authorisation in Europe (by the EMA and the MHRA) or in the US (by the FDA) was lower than in 2024 (53) and 2023 (70), the quality of innovation remained high: twenty-five (25) of these drugs, i.e., 54% were categorised as "first-in-class" (FIC), and proteins and antibodies continued to make up roughly a quarter of all new approvals.

The innovation index in India is also rising. CDSCO approved 28 new drugs of r-DNA origin for manufacturing and marketing in India in 2025, and a further 44 r-DNA origin new drugs for import and marketing, up from 26 in 2024[5]. In cell and gene therapy, India now has 2 approved, domestically manufactured CAR-T products: NexCAR19, developed at IIT Bombay with Tata Memorial Centre and approved in October 2023 as the country's first CAR-T therapy, and Qartemi, approved by CDSCO in January 2025 for relapsed or refractory B-cell non-Hodgkin lymphoma[6].

What is the importance of research and innovation for sustainable growth of the pharmaceutical sector in any country? Will India gain from policies that promote research and innovation?

Research and innovation are fundamental to the sustainable growth of the pharmaceutical sector and contribute to broader economic development. By fostering a culture of innovation, countries can strengthen their healthcare systems, enhance global competitiveness, create jobs, and improve public health outcomes, all while driving economic prosperity and sustainability. A larger share of global value capture (40% of a market of 6.65 trillion USD) in the pharmaceutical sector lies in innovation- based products.

Government of India's Amrit Kaal blueprint - Vision Pharma 2047 – envisages India as 'Vishwaguru' (global leader) in innovation and research. The 'National Policy on Research & Development and Innovation in the Pharma-Med Tech Sector in India'[1] dated August 16, 2023 along with recently released government policies such as Research, Development and Innovation (RDI) Scheme 2025 and Biopharma SHAKTI initiative that support and promote drug discovery and innovation along with other policy initiatives to incentivize innovation, can potentially unlock this value and also enhance the industry's contribution to Indian economy and create a large pool of white-collar jobs to enhance India's differentiation vis-a-vis other developing economies.

What are other factors needed for a Sustainable Innovation Ecosystem?

For incentivizing an innovative bio-pharmaceutical industry in India, a sustainable innovation ecosystem is required which must include effective and enforceable intellectual property rights regime and introduce RDP.

How can Innovation and R&D be incentivized?

Drug Discovery and the development of innovative remedies, therapies and diagnostics require substantial upfront and continuing investments of capital, research, and other resources into investigating several therapeutic pathways for treating any particular disease of ailment.

Since most of the substantial costs incurred is in discovery, research, and development costs, apart from Government policies to promote drug discovery and innovation, it is critical that innovations are protected through grant of Intellectual Property Rights (IPR) to the innovators including RDP, so as to enable the innovators to recoup the investments and also to prevent the infringement of the IPRs.

Further, an effective, predictable, and meaningful intellectual property system provides the certainty necessary to build confidence for investments in research and innovation.

What is RDP?

RDP is an independent form of intellectual property (IP) right and an international obligation found in Article 39.3 of the TRIPS Agreement. It provides time-limited protection against disclosure and unfair commercial reliance on the confidential pre-clinical, clinical and quality data or other data generated to secure approval for new medicines, biologics and vaccines; it complements patents without extending patent life or preventing competitors from generating their own data.

The obligation is derived from the “considerable effort” needed to demonstrate safety, quality and efficacy of an innovative drug to regulatory authorities, who require the submission of such data as a condition for gaining marketing approval.

How does India's R&D expenditure compare with OECD economies, and what is the government doing to close the gap?

India's gross expenditure on R&D rose to 0.84% of GDP in 2023-24 from 0.64% in 2020-21 and is projected to reach 0.90% in 2025-26, with private industry now accounting for just over half of the total[7]. The gap with advanced economies is nonetheless wide: the OECD average has stood at 2.7% of GDP since 2020[8], and innovation-led countries such as the United States, China, South Korea and Israel spend between 2.5% and more than 6% of GDP[9].

The Government of India has committed to bridge this gap through several large commitments including setting up of Anusandhan National Research Foundation and approval of Research, Development and Innovation (RDI) Scheme 2025 with a budget allocation of INR 1 lakh crore to be extended to private enterprises in sunrise and strategic sectors over six (6) years, with a further allocation of INR 20,000 in 2025-26[10].

Where does India stand in terms of it's clinical trial frequency when compared with the global average?

Currently, India's clinical trial frequency is among the lowest globally:

An analysis of the clinical trial data for Phases I-III (excluding devices) from 2015 to 2025 indicates that India only has 0.7 clinical trials per million population per year a number far below the global average of 11.2.

Countries such as Australia, Switzerland, and Canada conduct nearly over 30 times more clinical trials per million population than India.

Why does RDP exist, and what purposes does it serve?

Originators' regulatory data are generated over many years at substantial cost, effort, and risk. RDP exists to prevent unfair commercial use and incentivize drug development, i.e. to provide incentives to conduct the clinical trials necessary to bring a substance to market in the form of a drug.

RDP is particularly important, given that clinical trials account for nearly two-thirds of the total investment in bringing an innovative drug to market.

RDP also provides a defined window to monitor and refine real world safety and efficacy outcomes before generic entry, strengthening overall regulatory oversight of new medicines.

Competitors are allowed to rely on originator data once the RDP term expires, enabling predictable and orderly generic entry.

When did India provide for product patent protection for bio-pharmaceuticals?

India re-introduced product patent protection for bio-pharmaceuticals w.e.f., January 1, 2005, a regime that was removed in 1970.

What does a patent grant provide?

Patent allows the inventor the right to exclude others from five disparate rights i.e., making, using, offering for sale, selling or importing for those purposes the patented product in India for a period of twenty (20) years from the date of first filing of the patent application.

What is the difference between patents and RDP?

Patent protection and RDP are two (2) independent and separate forms of protection , both of which are required of WTO Members under the TRIPS Agreement. Unlike patent rights, which are enforced by the right holder through the courts, WTO member governments are affirmatively obligated to enforce data exclusivity.

RDP protects the investment made by the innovator in the generation of regulatory dossier required for regulatory submissions/approval. It is independent of patent protection.

Both forms of protection are vital for the biotech and pharmaceutical industries and relate to the two essential steps in bringing an innovative drug to market: the discovery of the new invention, where patent protection is essential, and the demonstration to regulatory authorities of the safety, quality and efficacy of the innovative drug containing that active ingredient, where effective RDP is essential. Both steps are necessary; neither is sufficient by itself with the patients reaping the benefits of new therapies after both steps are completed.

Isn't RDP really "Double Protection," given that India provides patent protection?

No. RDP is not "double protection" - fundamentally, the 2 forms of IPRs are like different elements of a house, which needs both a strong foundation and a roof to protect its inhabitants. In line with India's WTO obligation, India provided product patents for bio-pharmaceutical w.e.f. January 1, 2005. Similarly, the bio- pharmaceutical industry needs RDP as well to thrive in the knowledge intensive 21st century.

Moreover, more often than not, both the RDP period and patent terms run concurrently.

Does RDP extend patent life or enable 'evergreening'?

Evidence[11] confirms that RDP runs concurrently with a drug product's patent life and does not extend it. As per the recent study, out of the top 50 innovative medicines launched globally (40 launched in India) from 1998 to 2025, the average remaining patent life at regulatory approval was ~15 years globally versus ~8.6 years in India. Thus, except in rare cases, a standard RDP term, starting at local approval would typically operate within an existing patent duration.

Does the Indian new drug approval process provide for a level-playing field for all new drug applicants?

No. There is a lack of a level playing field in the new drug approval process in India.

The New Drugs & Clinical Trials Rules 2019 (NDCT) requires a new drug applicant to submit the complete pre-clinical and clinical dossier to establish safety and efficacy of the drugs that are proposed to be marketed for the first time in India. On the other hand, any subsequent new drug applicant can obtain the approval for the same new drug by simply undertaking a BA/BE study only. This results in lack of level playing field between the first applicant and the subsequent applicant.

Has the existence of the lack of level playing field in the new drug approval process ever recognized in India?

Yes. In its notice[12] dated October 8, 2025, the CDSCO did acknowledge that first applicants bears the cost and risk of generating local clinical-trial data, while subsequent applicants obtains approval with substantially lower data requirements thereby creating an uneven playing field. In order to remove the discrepancy and to encourage the development of new drug, the CDSCO decided to deliberate on the issue.

How can level playing field in the drug approval process in India be ensured?

India should consider adopting a clear, meaningful, effective and enforceable Regulatory Data Protection framework. When implemented effectively, RDP can support a level-playing field in the new drug approval process.

RDP should be extended for products requiring generation of clinical test data to demonstrate the safety and efficacy of that product, including small molecules, biologics, vaccines, combination products and qualifying new indications or formulations/ line extensions for the existing products/drugs with protection running from Indian marketing approval, and regard to the 2007 Inter-Ministerial Inter-Ministerial (Reddy) Committee's[13] proposed progression towards a finite non-reliance period.

Why is a defined exclusivity period important for investment decisions in the pharmaceutical sector?

Exclusivity is a necessary incentive. The anticipated date of loss of exclusivity is central to investment decision making across the pharmaceutical value chain, from funding new clinical trials and engaging in collaboration with local partner companies to licensing and acquisitions.

Doesn't India already provide remedies for breach of confidentiality?

No. The confidentiality requirements and remedies provided in India is under the Official Secrets Act, 1923 (OSA). The obligation to provide RDP is distinct from that provided under the OSA.

Does the TRIPS Agreement require any particular period for provision of RDP?

While the TRIPS Agreement does not specify a minimum time period, WTO member practice is converging on a period of between five (5) and ten (10) years from the time that the originator's product is approved for sale in a specific market. Examples include the U.S. [four (4) years for small molecules under the Hatch Waxman Act, 1984 and registration in the Orange Book | for Biologics, twelve (12) years under Biologics Price Competition and Innovation Act 2009]; the EU and UK [eleven (11) years (8+2+1) as per Article 10 (1)(a)(iii) of EC Directive 2001/83] - ten (10) year to be extended by one (1) more year if during the first eight (8) years, the marketing authorization holder obtains an authorization for a new therapeutic indications; Canada [eight (8) years for all drugs]; Australia [five (5) years for all drugs under Australian Government Department of Foreign Affairs and Trade, 2016], China [Six (6) years as per Implementing Measures for Pharmaceutical Test Data Protection 2026 etc.

Developing Countries that provide RDP for biopharmaceuticals are: Vietnam, Malaysia, Mexico, Jordan, Bahrain, Chile, Columbia, South Korea, Oman, Morocco, Panama, Peru, Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras and Nicaragua.

Do markets with RDP conduct more clinical trials than markets without RDP?

Yes. Markets with RDP conduct substantially more clinical trials. As per the data[16] from 2015-2025, on an average, markets with RDP report 14.9 clinical trials per million population annually compared with just 1.8 in markets without RDP - an 8.2 - fold difference. For example, evidence shows that there was meaningful gains in clinical trials per million capita in Japan only after 2007 when the RDP duration was extended to 8 years.

How is RDP viewed by other similarly placed countries as India?

Many of India's regional comparators, including China, Japan, South Korea, Malaysia, Singapore, and Taiwan, recognize the importance of RDP in supporting innovation and attracting investments, and have implemented RDP.

Malaysia introduced RDP effective March 1, 2011, via Directive No. 2 of 2011 issued by the National Pharmaceutical Regulatory Agency and Taiwan amended its Pharmaceutical Affairs Act on December 29, 2017, introducing patent linkage and data exclusivity for new drugs.

South Korea introduced a standalone statutory RDP framework from February 21, 2025, replacing rules previously tied to its post-marketing re-examination system.

Most recently, China[14] made RDP enforceable from May 15, 2026, when the NMPA's Implementation Measures granting a tiered RDP regime on May 15, 2026, granting six (6) years for qualifying innovative drugs, four (4) years for eligible modified new drugs and three (3) years for specified first-approved generics.

What is the estimated extent of the result of RDP implementation on clinical trials in India?

The number of clinical trials in India has been increasing but has remained much below the RDP markets. It is estimated that RDP implementation in India could potentially result in a significant increase (even five-fold) in the number of clinical trials per million population by 2.8 to reach 3.5 clinical trials per million population per year.

How are countries like China and South Korea building their bio-pharmaceutical innovation ecosystems, and what has it delivered?

Countries like China and South Korea have converted manufacturing capability into globally relevant innovation by aligning public funding, specialist capital, clinical trial infrastructure, regulatory reform, IP protection, including RDP, and outward-facing licensing into one integrated pathway from patent to approval to global licensing.

These measures resulted in the rise of out-licensing deals in China and South Korea. As compared to 94 transactions worth USD 51.9 billion in 2024, there were 157 transactions worth USD 135.7 billion in 2025. Licensing agreements involving South Korean innovator drugs too reached approximately USD 7.86 billion by July 2025, including USD 5.1 billion in international out-licensing.

What has been the impact of RDP in the USA?

The Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Act, was enacted in 1984 in the USA. One of its most transformative features was the introduction of regulatory data protection, or 'data exclusivity.'

Under this provision, originator companies were granted a period, typically five (5) years, during which the clinical trial data they submitted to the FDA could not be used by generic manufacturers to support their own applications, regardless of the patent status. The Hatch-Waxman Act's data protection provisions have dramatically increased the availability of generic medicines, reduced healthcare costs, and expanded patient access, while maintaining strong incentives for pharmaceutical innovation.

Do investments in clinical trials generate economic return in a country?

Yes. Clinical trial investments in any country yield significant socioeconomic multipliers. For example, evidence from the UK shows that per USD invested in clinical trials, generated an additional economic return of USD 0.39-USD 0.64 generated through employment and capability-building.

What are the potential investment benefits that may accrue to India from the introduction of RDP?

RDP implementation in India could increase pharmaceutical R&D investment by 98%-179%, strengthening research infrastructure and creating high-value jobs.

Does RDP impact innovative medicine availability in a country?

Yes. RDP accounts for almost half of the difference (45%) in the availability of the innovative medicines in the average market, with or without RDP.

Between 2015 and 2025[17], markets with RDP experienced 3.1x higher innovative medicine availability than markets without RDP (14.7% vs. 4.8%). Evidence confirms increased availability with RDP implementation. For example, introduction of RDP in Taiwan in 2017 boosted availability of innovative medicines by nearly 8 per cent points in 2020.

Has the availability of innovative medicines been impacted on account of non-implementation of RDP in India?

India's innovative medicine presence is lower than the markets with RDP. Markets with RDP offer 3 times higher availability of innovative medicines.

As per the available data[18], between 2015 and 2025, the average innovative medicine share available in India was only 0.5 per cent of the total medicines available globally.

What would be the potential impact of RDP on the availability of innovative medicines in India?

Data[19] suggests that implementing RDP could potentially increase the availability of innovative medicines in India by up to 156 percent.

Does the existence of RDP impact timely access to top innovative medicines?

Yes. Countries lacking RDP often fall lower on the priority list for new product launches, potentially delaying patient access to innovative therapies and widening global health disparities.

RDP, on the other hand, incentivizes innovators, accelerates regulatory filing and medicine launches. Innovators prioritize countries with RDP in the global launch sequencing. Analysis of data between 2015-2025 across 14 markets indicates that the average percentage of innovative medicine in markets with RDP was nearly 3 times higher as compared to markets without RDP.

How does the absence of RDP affect patient access to new therapies?

Expeditious launch of drugs results in faster access of medicines for the patients of a country. Markets without RDP experience extended medicine launch gaps. Data comparing the launch timelines of the top 40 innovative medicines launched in India (out of the top 50 medicines launched globally between 1998-2025 indicates that the said medicines were first launched in global markets with RDP.

Will RDP benefit Indian patients in terms of early access to innovative medicines?

Yes. On an average, Indian patients typically have to wait between 3.95 (3.4 years in case of small molecules and 4.4 years for biologics) for accessing breakthrough medicines compared with global markets. Implementing RDP will significantly increase availability of innovative medicines in India.

Note: these timelines may be impacted by the regulatory approval timelines.

Why is RDP necessary for Biologics?

While RDP is important for all drugs, it is absolutely necessary for biologics. As understanding of genetics and molecular biology grew, scientists were able to start manufacturing biologic agents (such as antibodies, DNA, peptides etc.) as therapeutics, which differ from small molecules in terms of their size. They also differ in how they are made-small molecules are generally made through well-established synthetic pathways. Biologics, however, are derived from less well-defined biosynthetic pathways by molecular biologists, using living cells or other materials derived from living organisms that may introduce a significant amount of variability into the final biologic product.

Because of the complexity of biologics, it is possible to synthesize a generic biologic agent that is different enough structurally from the original that it would not infringe a patent on the original biologic while still being comparably effective as a therapeutic agent. Biologics are also much more expensive to develop and manufacture than small molecules.

Does RDP play a role in patient safety?

Yes. Absence of RDP has practical implications for patient safety. Without a defined RDP period, an originator company's ability to adequately monitor real-world outcomes, refine clinical use, or address emerging safety signals before generic versions enter the market may be limited. This constrains proactive pharmacovigilance and evidence-based regulatory decisions impacting patient safety.

If India adopts RDP, how will generic drugs enter the market?

RDP creates significant opportunities for generics or biosimilar manufacturers to expand their portfolios and introduce more generic drugs once the RDP term expires. After the expiration of the fixed RDP period for innovative medicines, generics are required to only show bioequivalence (BE) of their product to the originator's drug. As a result, the cost of generics is lowered, while the proprietary nature of the originator's data is respected.

By providing RDP and consequently increasing the total number of innovative medicines available in India, significant opportunities for generics and biosimilars will be created.

It is to be noted that in the U.S., which has a long-standing RDP regime, the market penetration for generics is among the highest in the world and stands at nearly half of all prescriptions. Indian generic companies are very successful in navigating the U.S. regulatory system and, in some cases, have filed for their own periods of exclusivity in the U.S. market.

What is the potential impact of RDP on public health expenditure?

None. Empirical evidence confirms that introducing RDP has no discernible impact on overall public healthcare expenditure[15].

If India adopts RDP, how will it impact innovation in AYUSH, Phyto-products?

RDP will particularly help in spurring innovation in AYUSH, Phyto-products that are not permitted patent protection under the Patents Act, 1970 and investments in development of products that do not otherwise qualify for patents but can benefit from market exclusivity for a certain period. Developing proprietary medicines based on the raw materials described in the classical texts, improving their efficacy and finding new uses will require innovation, investments and therefore incentives.

What did the 2007 Satwant Committee Report recommend about India providing RDP for Pharmaceuticals?

The Report of the Interministerial Committee to examine the Steps to be taken in the context of Article 39.3 of TRIPS Agreement dated May 31, 2007, had recommended a calibrated data protection for pharmaceuticals - unauthorized disclosure and unauthorized use of regulatory data followed by higher standards of data protections, i.e., RDP for five (5) years with non-reliance of the data submitted by Originator to the Drug Regulator. The recommendations made by the Satwant Committee have not been implemented as yet.

How can RDP be provided in India?

A sui generis law may be enacted, or suitable amendments may be brought in the New Drugs and Clinical Trials Rules 2019 to provide an automatic RDP for a clearly defined minimum period separately for small molecule and for biologics starting from the date of approval of a new drug in India. Once the law is enacted, the same can be implemented by establishing clear rules for CDSCO and state authorities to enforce RDP.

What has been Government of India's stand on RDP in the context of several ongoing Free Trade Agreements (FTA) negotiations?

India is currently negotiating a number of FTAs with EU, UK, Trade Policy Forum discussions with US and Trade and Economic Partnership Agreement (TEPA) with the European Free Trade Association (EFTA) comprising Switzerland, Iceland, Norway & Liechtenstein.

RDP | 'Undisclosed Information' forms part of several FTAs. The TEPA between India and EFTA that came into effect on October 1, 2025 has provisions on 'undisclosed information' pari materia to TRIPS Article 39.3. Further, the India EU FTA, likely to be signed by the end of 2026, has similar provision.

While hither to India's stand on RDP has been that it is TRIPS plus, the Government of India has been deliberating on the implications of RDP in view of the ongoing various FTA negotiations.

RECOMMENDATIONS ON RDP

- Introduction of RDP for all pharmaceutical products for which marketing authorization requires the generation of new clinical test data to demonstrate the safety and efficacy of that product, including small molecules, biologics, combination products containing a chemical entity not previously approved in India and new uses of known active substances, i.e., new therapeutic indications/line extensions for the existing products/drugs.
- Any RDP law should protect the confidential clinical trial and other information submitted by an innovator to demonstrate the safety and efficacy of a medicine against disclosure, AND, for a defined term, should prevent reference to or reliance on that data and the resulting marketing approval by manufacturers of follow-on products;
- RDP terms should be competitive with global best practices. RDP should protect against disclosure and third-party reliance on innovator data.
- Begin the RDP term from the date of marketing approval in India.
- Establish clear rules for CDSCO and state authorities to enforce RDP.

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POWER OF PARTNERSHIP

About Power of Partnership

2025-26 marks a defining chapter for the Organisation of Pharmaceutical Producers of India (OPPI) – our Diamond Jubilee. Since its inception in 1965, OPPI has been the voice of the research based global pharmaceutical companies in India, advocating policies that encourage scientific innovation while ensuring that the patients are always at the centre of all decisions.

For six decades, OPPI has been at the forefront of shaping the Indian pharmaceutical landscape, fostering a patient-centric ecosystem grounded in innovation, ethics, access, and collaboration.

OPPI's journey has been defined not only by scientific and industrial progress but by the Power of Partnership.

Our legacy is rooted in partnerships with multiple stakeholders, i.e., with policymakers to drive regulatory clarity, with academia to nurture innovation, with the media to promote public understanding, and with our member companies to maintain the highest standards of ethics and compliance. This landmark is a reaffirmation of our commitment to India's future in healthcare.

#BharatKeLiye #PowerofPartnership

OPPI

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