OPPI
Organisation of Pharmaceutical Producers of India

भारत के लिए

VALUE OF INNOVATION

Organisation of Pharmaceutical Producers of India

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Value of Innovation

OPPI, and its member companies, are committed to innovating for developing **affordable**, **accessible,** and **effective medicines and diagnostic remedies** for diseases, and thus, improving people's quality of life. This is also aligned with the Indian government's objectives of expanding healthcare access for all.

FAQs

1. Why are Innovation and Research & Development(R&D) indispensable?

Innovation and R&D are indispensable for advancing medical science, developing new treatments, improving patient outcomes, and addressing emerging health challenges. These efforts ultimately contribute to healthier populations, enhanced quality of life, and sustainable healthcare systems worldwide. It highlighted the necessity for sustained investment in healthcare R&D infrastructure, collaborative research networks, and innovative solutions to prepare for and respond to future pandemics effectively.

2. What do Innovation and R&D in the Bio-Pharmaceutical area mean?

In bio-pharmaceutical area, R&D and innovation encompass a broad spectrum of activities aimed at discovering, developing, and delivering new drugs, therapies, and treatments to improve human health and quality of life.

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

Innovation and R&D in the bio-pharmaceutical sector refer to the continuous pursuit towards discovery and development of newer treatments and outcomes and entails identifying potential drug targets, extensive preclinical research involving laboratory studies and animal testing to assess the safety, efficacy etc. of potential drug candidates, clinical trials conducted in phases (Phase 1 to Phase 3) to evaluate the safety, dosing, and efficacy and the subsequent regulatory approval process.

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

In 2023, seventy (70) novel drugs received market authorization for the first time in either Europe (by the EMA and the MHRA) or in the United States (by the FDA). More than half of these drugs target rare diseases or intractable forms of cancer. Thirty (30) drugs were categorized as "first-in-class" (FIC), illustrating the quality of research and innovation that drives new chemical entity discovery and development.

As per the 13th Annual Report titled 'Advancing Health Through Innovation: New Drug Therapy Approvals'[1] by the Center for Drug Evaluation and Research (CDER), the USFDA approved 55 "novel" drugs either as new molecular entities (NMEs) under New Drug Applications (NDAs), or as new therapeutic biologics under Biologics License Applications (BLAs). Out of the said 55 novel drugs, 28 (51%) received orphan drug designation because they target rare diseases.

There is a shift in the innovative index of the industry in India as well. Reportedly, as many as fifty-eight (58) biotherapeutics, biosimilars, monoclonal antibodies-based drugs, and m-RNA vaccines were approved by CDSCO in the last couple of years. Nine (9) cell and gene therapy products were approved and in October 2023, the first indigenous CAR – T Therapy for leukemia developed at the IIT Bombay was approved.

5. What are the Drug Discovery and Development Timelines?

Drug discovery is a long, expensive, and risky path. It is estimated that fewer than 14% of all drug candidates entering Phase 1 clinical trials (the first human trial) gain FDA approval, and the successful ones take, on average, 10-15 years and a $2.5 billion investment to get market authorization[2]. In newer areas of medicine, like gene therapy, it may take up to thirty (30) years[3].

[1] FDA Approves Many New Drugs in 2023 that Will Benefit Patients and Consumers | FDA
[2] https://www.cas.org/resources/cas-insights/dealing-challenges-drug-discovery#:~:text=Drug%20discovery%20is%20a%20risky,billion%20investment%20to%20get%20there.
[3] https://www.biostock.se/en/2023/01/drug-development-the-four-phases/#:~:text=On%20average%2C%20the%20journey%20from,take%20up%20to%2030%20years.- BioStock is Scandinavia's leading digital news and analysis service with an exclusive focus on companies in the Life Science sector.

6. What is the average cost incurred in drug development?

A 2023 published Report titled 'Seize the Digital Momentum Measuring the Return from Pharmaceutical Innovation 2022[4]' reveals that the average cost of developing a new drug among the top 20 global bio-pharmaceutical companies rose 15% ($298 million) to approximately $2.3 billion.

This number includes the cost of the thousands of failures starting with 10,000 drug candidates and ending up with just one new, approved medicine.

7. 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. As per the 'National Policy on Research & Development and Innovation in the Pharma-Med Tech Sector in India'[5] dated August 16, 2023 as released by the Department of Pharmaceuticals, Government policies that promote drug discovery and 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.

[4] file:///C:/Users/91817/Downloads/deloitte-ch-en-lshc-seize-digital-momentum-rd-roi-2022.pdf

[5] chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://pharmaceuticals.gov.in/sites/default/files/Notification%20-%20R%26D%20Policy.pdf

8. 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 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.

9. 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 patents** and introduce **Regulatory Data Protection (RDP)**.

10. 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.

11. What does a patent grant provide?

When a product patent is granted by the government, it 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 filing of the patent application.

12. What is RDP?

RDP is an independent form of intellectual property right and an international obligation found in Article 39.3 of the TRIPS Agreement that requires WTO members to provide a period of protection during which the undisclosed proprietary test and clinical trial data that is provided to health regulators to gain marketing approval of pharmaceutical products by one company may not be used or relied upon directly or indirectly by another company to obtain a marketing approval of the same drug. 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.

13. In addition to patents, is RDP required to protect innovation?

Yes. RDP protects investment in product development. Both forms of protection are vital for the bio-pharmaceutical innovation and relate to the two essential steps in bringing an innovative drug to market - 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 regulatory data protection is essential. Both steps are necessary; neither is sufficient by itself.

14. What is proprietary or confidential clinical data?

It is this undisclosed or otherwise confidential 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.

15. What is the difference between patents and RDP?

Patent protection and RDP are two independent and separate forms of protection (see above), 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.

16. Why is RDP important?

In addition to respecting the proprietary nature of the clinical data, which represents a major investment of time and money for the originator, RDP provides incentives in the small number of cases when innovative pharmaceutical products are not covered by patents. Without RDP, research would be skewed in favor of patentable products and away from new uses or indications of non-patentable products. In addition, RDP ensures that the regulators receive the detailed product information for new products that they need to ensure the safety and efficacy of drugs before approval.

17. Why is Regulatory Data Protection 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.

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

No. RDP is not "double protection" - fundamentally, the two 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. For example, pharmaceutical products generally reach the market in the 10th year (on average) of the twenty (20) year patent term. Thus, assuming a five (5) year period of RDP, it would cover years ten (10) through fifteen (15), leaving five (5) more years of patent protection.

19. 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] etc.

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

20. 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 FTA drafts such as India-UK FTA, EU-India FTA etc.

The recently signed TEPA between India and EFTA dated March 10, 2024 with provision on 'undisclosed information' *pari materia* to TRIPS Article 39.3 underscores the relevance of India's commitments in 2024.

It is to be noted that Article 15 of Chapter 8A of the TEPA with EFTA signed on March 10, 2024 includes the language of TRIPS Article 39.3 and the 'Record of Understanding' relating to the annex on IPRs states that the Governments of the EFTA States and India confirm and agree to enter into consultations, 1 year after entry into force of TEPA to discuss issues relating to protection of undisclosed information from unfair commercial use.

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

While the data does not become public after the expiration of the fixed RDP, the competitors would be allowed to reference the proprietary data which remains on file with regulatory authorities after the expiration of the said RDP period. At that point, generics would need 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.

On the other hand, clinical trials may be performed by competitors during the period of non-reliance, and, if there are no patents involved, the generic product may be approved on the basis of its own, independent clinical dossier.

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.

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

RDP will be 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.

23. 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.

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

The Report on Steps to be taken by Government of India in the context of Data Protection Provisions of Article 39.3 of the TRIPS Agreement (Satwant Committee Report) dated May 31, 2007, recommended five (5) years of RDP for pharmaceuticals after a transition period. The recommendations made by the Satwant Committee have not been implemented as yet.

25. How can RDP be provided in India?

A *sui generis* law may be enacted, or suitable amendments may be brought in the Drugs and Cosmetics Act 1940 (DCA) to provide for RDP for a minimum of 5 years for small molecules and 8 years for biologics.