REGULATORY DATA PROTECTION PROMOTES BIOPHARMACEUTICAL INNOVATION AND PATIENT ACCESS

The biopharmaceutical industry uses its scientific and technical expertise to research, develop, manufacture and distribute safe and effective treatments and vaccines to patients around the world. On average, it takes **10-15 years** and costs **$2.6 billion** to develop one new medicine, when taking into account medicines that do not make it through approvals. Even when biopharmaceutical companies are successful in developing a new product, only **two out of ten** marketed medicines achieve returns that match or exceed average research and development costs.

The intellectual property (IP) system enables this investment and supports competition by facilitating development of generic and biosimilar products and encourages post-approval research into other approaches for treating a disease. Regulatory data protection (RDP) is a critical element of effective IP systems and is a critical component of international IP rules. RDP provides a period of protection for clinical trial and other test data that biopharmaceutical innovators must submit to governments when applying for regulatory approval to prove a new medicine is safe and effective.

RDP protects against disclosure of test data and, for a limited time, third-party reliance on that data for regulatory review. Upon termination of the period of protection, generic and biosimilar manufacturers are able to rely on the original innovator's regulatory data to secure marketing approval for their follow-on product.

Why is RDP important?

RDP represents a carefully balanced mechanism which allows innovators to invest in the development of safe and effective medicines, while also permitting follow-on companies to eventually rely on the originator's proprietary data by foregoing their own clinical studies. Also, RDP complements patents on innovative medicines and runs concurrently with the patent terms. RDP is particularly critical for biologic molecules (e.g., complex IV infusion products), which may not be adequately protected by patents alone given their complexities.

RDP is important for any regulated industry that requires extensive testing to ensure the safety and efficacy of the products involved; especially the biopharmaceutical industry. Best in class RDP standards include twelve years of protection for biologic medicines, and ten years of protection for small molecule drugs, typically pills and capsules.

Experience shows that a strong RDP framework and adequate enforcement mechanisms are vital components to innovative ecosystems.

Reasons to Support Regulatory Data Protection

The development of new safe and effective medicines is an extremely **risky, time-consuming, costly** and **complex process**. Less than 12% of medicines that reach clinical trials will be approved. Providing temporary protection of the data and information biopharmaceutical innovators must submit to regulatory authorities for approvals, through RDP, incentivizes and protects the value of the R&D of new safe and effective medicines. Here are four reasons to support RDP:

1. **RDP improves the availability of medicines worldwide.**
   Without adequate RDP, the high cost of investment can be a barrier for development of new and improved medicines, including those for rare diseases and pediatrics. Markets with RDP have an average of 31.5% of innovative medicines available, compared to just 11.1% in markets without RDP. One study found that extending RDP for small molecules from 5 years to 12 years in the United States would yield an additional 228 medicines approved from 2020 through 2060. Furthermore, another study confirmed that with more innovative medicines available, the number of generic and biosimilar products also increases. Simply put, strong IP rights, like RDP, promote innovation and help ensure timely patient access to medicines of all kinds.

2. **RDP attracts more clinical trials.**
   Clinical trials, required to demonstrate a medicine is safe and effective, are both risky and expensive. Estimates show that more than 60% of the total cost of bringing a new medicine to market comes from clinical trials, including those for medicines that are ultimately not approved. Protecting test data from unfair commercial use make countries with robust protections more attractive locations for R&D.

3. **Global rules require countries to implement RDP.**
   The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) requires most members to protect regulatory test data submitted against both unfair commercial use and disclosure. Many bilateral and regional trade agreements expand upon the minimum regulatory data protections required by the TRIPS Agreement.

4. **RDP plays an important role in enabling generic and biosimilar competition.**
   After the expiration of the RDP period, generic and biosimilar companies are able to rely on an innovator's proprietary data and forego (in full or in part) costly independent clinical studies. In this way, RDP systems balance and advance both the development and testing of new medicines and enable availability of lower-cost alternatives. In Brazil, for instance, 3.17 generic or biosimilar medicines could become available for every innovative medicine on the market if RDP protection was available for biopharmaceutical products.

The lessons are clear. Policymakers should support robust regulatory data protection and enforcement to the benefit of patients and economies worldwide.