

Novartis Position on Regulatory Data Protection

Governments around the world rightly demand that biopharmaceutical manufacturers demonstrate the safety, efficacy and quality of their medicines before they are made available to patients. In most countries, this is done as a prerequisite to regulatory approval, a requirement which must be met by the submission of comprehensive test data from all phases of the pharmaceutical research and development (R&D) process. For innovative medicines, this regulatory data does not yet exist, and must be generated through extensive research and scientific study over a period that typically spans many years at substantial cost, effort and risk. In recognition of these costs and risks, and of the proprietary nature of the generated data, many governments have established laws that for a set time period prevent the disclosure of the data to others, and/or prevent others from using or relying on that data to obtain authorization to market a generic version of the medicine to which the data relates. These types of legal mechanisms, which operate in a variety of different ways depending on the country, are known as “regulatory data protection” (RDP).

RDP helps to incentivize both the development of new drugs and the rigorous study of their safety, efficacy and quality. Moreover, evidence shows that countries that have introduced RDP terms for the first time, or that have increased existing RDP terms, have not experienced meaningful increases in expenditures on medicines.¹ In fact, as part of a balanced regulatory system, RDP plays an important role in enabling lower-cost generic medicines by preserving an incentive for innovators to generate safety, efficacy and quality data, while allowing generic companies to refer to and rely on that data in seeking approval once the RDP period expires.

RDP and the patent system are distinct legal mechanisms that operate independently of each other. The two systems run in parallel, playing different—though complementary—roles in incentivizing innovative biopharmaceutical R&D. Patents are available only for previously unknown inventions that meet certain technical criteria, while RDP may be available for data pertaining to a broader range of substances, so long as they have not been previously approved for use as a medicine. The way terms are measured is also different, with patent term running for 20 years from the time a patent application is filed (which usually occurs 10-15 years before any medicine is marketed), while RDP term ranges from 3 to 12 years from the time that a medicine is approved. In practice, these differences mean that RDP helps to fill gaps in incentives in two major areas: situations where patents may not be available due to the nature of a new medicine, and situations where the time needed to develop, test and secure approval for a finished medicine is so long that

¹ See, e.g., Philip Stevens, "Will increasing the term of data exclusivity for biologic drugs in the TPP reduce access to medicines?," Geneva Network, July 2015 (https://geneva-network.com/wp-content/uploads/2015/07/RDP_biologics_TPP.pdf)

little or no patent term remains. In both cases, RDP may provide an incentive to develop new medicines that, due to the limitations of the patent system, might otherwise never exist. At the same time, where both patents and RDP are available for a new medicine, their terms run concurrently, with neither extending the term of the other.

Novartis Position

Novartis supports the implementation of RDP systems in all countries because RDP strikes a proper balance between incentivizing the continued development of new medicines and serving a variety of public interests. Specifically:

- RDP helps to incentivize innovation in areas where patents may not work to do so, such as previously known substances where patents are not available, but where an innovator is first to demonstrate the safety and efficacy of such a substance as a medicine.
- RDP helps to improve patient safety when new medicines enter the market, by providing a window during which safety can be further studied in real-world conditions and suitable adjustments made before generic versions enter the market.²
- RDP helps to accelerate and increase access to new medicines. Given the substantial investment required to introduce a new medicine, where other factors are equal, innovators are more likely to prioritize those markets with RDP systems in place that prevent a new medicine from being immediately copied, resulting in the introduction of a new medicine in those markets sooner.
- RDP may bring additional benefits to countries that adopt such systems locally. For instance, RDP has the potential to incentivize the development of new medicines tailored to local populations and local social and environmental conditions, and to incentivize R&D activities and research directions that may be especially feasible for early-stage companies in developing countries to embrace.

As not all countries have adopted RDP systems, and implementation varies in those that have, stakeholders may have different views on various aspects of RDP. Following are Novartis' views on selected issues:

- 1. RDP and the TRIPS Agreement:** Article 39.3 of the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) requires WTO Members to protect confidential regulatory data against both disclosure and “unfair commercial use.” Novartis believes that this provision imposes an obligation on all Members to implement RDP regimes that prevent competitors from relying on an originator's regulatory data for approval of a competing product for a set period. This includes a competitor's reliance on that data in seeking or securing approval of a competing medicine without the prior application of a reasonable period of protection. Reliance, moreover, must generally be implied and prevented for a period whenever a competitor seeks approval of a competing medicine without submitting its own data, even if it does not explicitly refer to the originator's data in its application. Were reliance deemed absent in such cases, the competing medicine would effectively be approved without any safety or efficacy data, a result which society could not accept.
- 2. Term of RDP:** While TRIPS does not specify a minimum term of RDP, and national laws and treaties vary, Novartis believes that in order to be effective

² This patient safety element is the primary concern upon which RDP systems like Japan's are built.

and serve its intended purpose, any national RDP regime must provide for a fixed RDP term of at least 5 years for new active substances, measured from the time of local product approval. A longer term as in the EU (overall exclusivity of 10 years) is strongly preferred, because longer terms increase the incentive to develop, test, and launch new medicines in new markets. Novartis also supports implementation of RDP globally for new forms and uses of existing substances whenever additional clinical studies are required to support their approval. The term in such cases should be at least 3 years or follow the EU model where the full dossier receives an additional 1 year of RDP upon demonstration of a “substantial clinical benefit.” However, where approval of a stand-alone dossier concerning a new indication is clearly and by necessity independent of an existing dossier, Novartis believes that the term of RDP should be the same as for new active substances.

- 3. RDP for Biologics:** All countries should recognize RDP for both traditional chemical entities (also known as “small molecules”) and new biologic medicines (also known as “biologics” or “large molecules”), because the sound public policies that justify RDP apply equally to both. Some countries currently offer a longer term of RDP for biologics than they do for small molecules (e.g., 12 years in the United States for biologics vs. 5 years for small molecules), while others offer a uniform term for both (e.g., the EU’s 10-year term). Where countries offer an RDP term of sufficient duration (e.g., the 10-year EU term), Novartis believes that small molecules and new biologics should be treated equally and given the same RDP term.

Application to “New” Substances: In Novartis’ view, when assessing whether a substance, use or formulation is sufficiently “new” to be eligible for RDP, the term “new” must be interpreted as new to the particular country (or region) in which the application for marketing authorization is filed. An active substance should not have to be “new to the world” (i.e. the first registration worldwide) in order to benefit from RDP in a locale or region where authorization to market that substance has not been previously sought. A “new to the world” standard would limit the value of RDP as an incentive for the development of new medicines and would remove an important incentive to launch those medicines in new markets after the original RDP term expires.

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