



Regulatory Data Protection

Regulatory data protection (RDP) is an intellectual property right available for a limited duration which protects an innovator's proprietary safety and efficacy data for its innovative product. This prevents any other party, during the RDP term, from relying on the innovator's proprietary data in order to obtain marketing authorizations and market follow-on generic products

Marketing authorizations of medicines

National regulatory legislations stipulate that medicines can only be introduced into a market by holders of a marketing authorization. The development and submission of extensive data relating to the drug's safety and efficacy, as well as its physical and chemical characteristics, is a requirement to obtain marketing approval.

Innovator products versus generic products

Innovator products are novel drug products that have not previously received a marketing authorization from a regulatory authority, and are being evaluated for the first time. An innovator's proprietary safety and efficacy data are submitted to the regulatory authorities to support the company's marketing authorization application on an innovator product.

Generic products are copies of innovator products which have been previously approved by a regulatory authority. A company wishing to obtain a marketing authorization for a generic version of an innovator product can either 1) generate and rely on its own regulatory data to demonstrate safety and efficacy of its generic product, or 2) rely on regulatory data submitted to the regulatory authority for the innovator product. When the generics company relies on the innovator's regulatory data, it must demonstrate that its generic product is medically equivalent to the innovator product, under the laws and regulations governing the relevant regulatory authority.

The ability of generics manufacturers to rely on the innovator's safety and efficacy data for generic drug approval provides them with significant commercial and economic benefits. In particular, generics companies are able to bring their product to the market faster, with far

less risk and uncertainty, and at a significantly lower cost compared to the innovator company.

Merck's position on RDP

Merck considers RDP to be an essential means of protecting an innovator company's proprietary data and of rewarding the innovator company for its significant investment in the generation of this proprietary data. This position has been recognized by the World Trade Organization's (WTO) Trade Related Aspect of Intellectual Property Agreement (TRIPs) in Article 39.3, requiring that all WTO members protect the data submitted to regulatory authorities against unfair commercial use and disclosure.

RDP helps innovator companies recover the financial investment made during the development of innovator products and prevents generics manufacturers from gaining an unfair commercial advantage from an innovator's investment.

RDP provides an incentive for innovator companies to continue to fund research and development on new innovative products to the benefit and well-being of society. This paves the way for more affordable generic drugs to enter the market at a later date, without incurring the risks and costs undertaken by the innovator.

RDP does not prevent generics companies from generating their own safety and efficacy data for a generic product and submitting it for regulatory authority review while the innovator's RDP period is still in effect. However, in practice, generics companies usually rely on the innovator's previously submitted data to establish safety and efficacy. Thus, it is important to stipulate circumstances in which generics companies can rely on an innovator company's proprietary data. To this end, Merck supports the use of a limited RDP period, allowing generics companies to rely on innovator data after a certain time period has elapsed from the date of approval of an innovator product.

Merck believes that the term of RDP should be for a duration which provides an adequate reward and incentive for innovators. For example, Merck supports a 12 year period of data protection for biologics drugs.

RDP and patents

Merck supports RDP as an independent intellectual property right, separate and apart from patent protection. The requirement of WTO members under TRIPs to protect regulatory data in Article 39.3 is separate from the requirement under Article 27(1) to provide patent protection for innovations in all areas of technology. Thus, to comply with TRIPs, member countries must provide for both types of rights.

Importantly, each right is available for an independent and finite duration, and the two rights run concurrently rather than sequentially.

For a variety of reasons, innovator companies are not always able to rely on patents to recover the financial investment made in bringing a medicine to the market. Irrespective of whether or not the relevant product is eligible for patent protection, innovator companies are required to generate and submit to the regulatory authorities extensive data to demonstrate safety and efficacy of a drug. In these circumstances, RDP is able to offset the limits of patent protection and enable innovator companies to recover their development costs. For example, legal standards governing patentability of biotechnology inventions have become significantly more stringent. It has become increasingly difficult to obtain patents which adequately cover biological products. This can lead to a lack of patent exclusivity for a biological product which has been developed by an innovator company through significant financial investment and resources.

Finally, medicinal products which require investigation over a long duration may not be approved for a significant amount of time following the filing of a patent application that covers the product. For such products, the period elapsing between the filing of a patent application and issuance of a marketing authorization makes the period of patent exclusivity insufficient to recover the investment put into research and development. This is especially true in countries where patent term extensions or supplementary protection certificates are unavailable.

Conclusion

Merck believes that RDP is an important intellectual property right, that is necessary to encourage innovation in the pharmaceutical industry. Merck calls on all countries to comply with TRIPS, by establishing national laws and regulations and laws to adequately protect RDP.