

GSK Public policy positions

Regulatory Data Protection

The Issue

Regulatory Data Protection (RDP)¹ confers on the holder of a pharmaceutical marketing application, for a set period of time, the exclusive use of the proprietary pre-clinical and clinical data that it generated at significant cost and submitted to the applicable regulatory authority to obtain approval of its product. After the set period of time, generic pharmaceutical companies are then permitted to rely upon the data to obtain approval of their "abbreviated" applications.

Some ask why RDP is needed if patents exist. Others see it as a brake on competition and market access. This paper provides some background on the evolution of RDP and explains why it is so important to the pharmaceutical industry. It also sets out the rationale for why the Trade Related Aspects of Intellectual Property Rights (TRIPs) RDP provisions should be interpreted in a robust way and demonstrates how, by protecting the substantial financial investment involved in drug discovery and development, RDP provides incentives to undertake research which is particularly important where patent protection is weak or non-existent.

GSK's Position

- The pharmaceutical industry is virtually unique in its obligation to generate, at the cost and risk of individual companies, a substantial body of data and submit those confidential data to regulatory authorities as part of the product registration process. Pharmaceutical companies submit the data to enable their products to be approved for sale. Governments, therefore, have a responsibility to regulate use of the data in a fair and effective way via strong RDP laws.
- Unlike with patents, enforcement of RDP is the responsibility of governments, not the originators of the data. This obligation represents an important commitment from governments to support innovation in a spirit of partnership with medical researchers.
- RDP recognises the value and proprietary nature of data submitted to regulatory authorities as part of, and solely for the purpose of, product registration. It also protects (and thus provides incentives for) the substantial financial investment involved in drug discovery and development.
- RDP and patents are two distinct and separate forms of intellectual property protection. A country's intellectual property framework should ensure strong protection for both in order to provide incentives for pharmaceutical research and development.
- RDP is of particular significance where strong patent protection for a particular product or indication may not be available, where the patent term has been eroded by a long development phase or where patent enforcement systems are inadequate. Without RDP research might focus only on patentable compounds and not other compounds which could be beneficial to public health.
- GSK accepts that, in the interest of facilitating market access of generics at an appropriate time, and the need to avoid repetitive animal testing and human clinical trials, competitors should be able to rely upon the originator's proprietary data for obtaining approval of equivalent products. However, such reference to the originator's data should, in fairness, only be permitted after expiration of a reasonable period of protection. Direct or indirect reliance upon data during the period of protection should be prohibited.
- GSK supports greater transparency of clinical data and has made important commitments in this area. See GSK's Public Policy Position on Public Disclosure of Clinical Research. However, it is important that this enhanced transparency does not undermine RDP. Clinical and other data submitted to regulatory authorities should not be used by third parties to gain a license to market a copy of the originator's product.

¹ Some refer to RDP as "data exclusivity". RDP should not be confused with protection of personal data under data privacy laws. RDP protects the data generated by the pharmaceutical and agro-chemical industries and is submitted to government authorities in order to obtain marketing approvals for their products. Data *privacy* protects individuals from wrongful disclosure of data relating to them.

- TRIPs requires that unpublished data provided to a regulatory authority in order to obtain approval for marketing a pharmaceutical product should be protected against disclosure and unfair commercial use. It does not specify any minimum period of RDP. Many countries offer between 5 and 10 years protection from local approval for new chemical entities (NCEs). We believe this range of exclusivity is generally appropriate for all new products; however, we welcome the 12 year period recently extended to biologicals in the US.
- There is no obligation within TRIPs to offer RDP to new indications or formulations for an approved product. However, both the US and EU recognise that RDP is one way of providing incentives for the significant cost and risk involved in the development of new indications for existing compounds. GSK welcomes this recognition. We would like to see it applied globally to all indications, as well as extended to formulations that require a significant investment in additional clinical studies. However, off-label prescribing means that RDP alone may not be an adequate incentive for the development of new indications.

Background

Definition

The rationale for providing RDP is that governments and regulators should not allow unfair commercial advantage to be taken of the data which a company generates and submits in order to obtain and maintain marketing approval. It prevents competitors or governments, for a period of time, from using the originator's data by relying on it when seeking or granting approval for a generic copy and thus taking commercial advantage of the expensive investment undertaken by the originator. In this way, it protects (and thus provides incentives for) the substantial financial investment involved in drug discovery, development and regulatory approval.

The data which a company generates and submits to regulatory authorities and to which protection should be extended may include the originator's underlying laboratory, pre-clinical and clinical data, including information regarding product indications, efficacy, tolerability, pharmaco-kinetics, drug interactions, side effects, contra-indications, precautions, warnings, adverse effects, dosage and product administration.

The generation of registration data involves a substantial amount of time and expense for the originator. The entire drug development process from discovery to marketing can take as long as fifteen years and costs on average £1.15 billion per product. If data could immediately be shared with or relied upon by third parties, there would be no incentive for a company to generate it in the first instance.

RDP is Distinct from Patent Protection

RDP and patents are two critical intellectual property rights for the pharmaceutical industry; however, they are distinct and separate forms of protection. Patents protect inventions that meet the criteria for patentability – novelty, utility and inventive step. Making an invention, however, is distinct from the enormous scientific work and financial investment to generate the data for a pharmaceutical product to demonstrate quality, safety and efficacy to regulatory authorities. This proprietary data is worthy of protection in itself, regardless of whether the product is patentable. It costs no less to develop a non-patented product than a patented one.

RDP is of particular significance where patent protection may not be available, where patent enforcement systems are inadequate, where the patent is proven to be invalid² or where the patent term has been eroded by a long development phase. This may only become clear well into the development phase or after launch of the product. RDP is, therefore, an incentive for innovation where there is little or no patent protection.

² **Judgment of Jacob J of the English Patents Court in *Teva v Merck*, 21 January 2003**

"I accordingly hold both patents invalid. I do so with some regret. Merck have only had a few years' exclusive exploitation of alendronate. They must surely have had to make a very considerable investment and incurred considerable risk in bringing it to market. And mankind is better off as a result. But the patent system does not confer monopolies on those who develop obvious or old products, even if they have never been exploited. A workable system for that might be a good idea, particularly in the field of medicines and analogous fields."

Implementation of TRIPS Article 39.3

Article 39.3 of TRIPs requires a WTO Member State to protect unpublished data relating to pharmaceutical products containing new chemical entities (NCEs)³. An NCE is a regulatory concept and should not be confused with the “novelty” requirement of a patent. Any compound, or combination of compounds, which is approved/ marketed as a pharmaceutical for the first time in the country concerned is a “new chemical entity” for the purpose of protection under TRIPs Article 39.3, irrespective of whether it is “novel” under patent law.

Since January 2000 all WTO member countries – with the exception of Least Developed Countries – have been required not only to have TRIPs-compliant RDP but also effectively to enforce this protection. Unlike with patents, enforcement of RDP is the responsibility of governments, not the originators of the data. So, even in situations where a patent may exist, during the RDP period, governments must take responsibility for protecting the data by not granting applications for approval which directly or indirectly rely on the originator’s data.

Article 39.9 of TRIPs prohibits unfair commercial use of unpublished regulatory data. If a third party seeks to rely on an originator’s confidential data in obtaining approval to market its product, it makes commercial use of the originator’s data. It is necessary to provide for a period during which this is not permitted to prevent free-riding by the third party, which is unfair commercial use. Therefore, marketing approval applications for a product which refer directly or indirectly to the originator’s safety and efficacy data should not (for a fixed period of time) be granted by regulatory authorities.

Indirect Reliance

Where an originator does not file a full data package with local authorities, some argue there is no data to protect and it is, therefore, acceptable to allow a generic company to enter the market immediately by showing that its product is equivalent to the originator’s. This can happen where, for example, in order to obtain local marketing approval, the originator only needs to show that it has approval to market in another specified country. It can also happen where an originator has not obtained a local approval and the generic company seeks to show that its product is equivalent to the originator’s product approved in another country.

This argument is incorrect. In cases such as these, although the local regulatory authority does not examine the originator’s data, it relies on the approval by the regulatory authority in another country which has examined the originator’s data. This is “indirect reliance” on the innovator’s data, and it should not be permitted during the RDP period.

Transparency of Data

Recent transparency initiatives from the EU and elsewhere aimed at increasing access to clinical trial and other data should not undermine RDP. Clinical trial data stored in public databases or published in journals provide a valuable resource for researchers, medical professionals and the public. However, while GSK supports greater transparency of clinical data and has made important commitments in this area, it is important that this enhanced transparency does not undermine RDP. Clinical and other data submitted to regulatory authorities must not be used by third parties to gain a license to market a copy of the originator’s product.

RDP Periods

Unlike for patents, the period of RDP is not fixed by the TRIPs Agreement. However, most countries which have introduced RDP into their law offer between 5 and 10 years protection from local approval for NCEs.

³ “Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.”

The EU has a period of 10 years, during which third parties cannot receive authorisation to market a product for which the marketing approval was obtained by relying on the originator's data. The EU has also allowed for the possibility of an extra year's protection for a new use considered to be of significant clinical benefit in comparison with existing therapies.

The US has introduced a period of 12 years for biological products but only has 5 years for other pharmaceuticals. Recognising the key role that RDP plays in incentivising innovation and thereby supporting public health, GSK would like to see the US increase this 5 year term to at least match the 12-year period for biological products.

A country's intellectual property framework should provide for both strong patent protection and strong RDP. In this respect, the 5 years basic exclusivity offered in the US for non-biological products is a good example of how an imbalance between patent protection and RDP can work to the possible detriment of innovation and public health. If key patents are challenged after grant and held invalid, the effective period of exclusivity afforded by the US system can be as low as 5 years, substantially less than in the EU. This not only weakens overall incentives to innovate, but also has the potential to focus investment into research areas where commercial risk is lowest, rather than where medical need is greatest.

New Indications and Formulations

Improvements on patented or patent-expired products may not always qualify for patent protection and when they do, that protection may not provide effective commercial protection. In the absence of some other form of protection, research might, therefore, only be undertaken into "patentable" inventions, rather than into further valuable research on existing products.

Both the US and EU increasingly recognise that RDP is one way of providing incentives for the considerable effort involved in the development of new indications for existing compounds. The US, for example, provides 3 years exclusivity for a new indication (but not **all** indications for the product). Meanwhile, the EU will provide 1 year for **all** uses of a product - but only when the new indication is deemed to be of "significant clinical benefit".

As knowledge of biological pathways improves, it is becoming clear that existing products may be suitable for more uses than originally thought. Although RDP may provide some degree of incentive to develop the product for these new uses, off-label prescribing means that incentives beyond RDP may be needed. Therefore while GSK welcomes the EU and US's extended exclusivity policy for new indications and, in the case of the US, for new formulations, and would encourage other countries to follow their lead, further debate is needed to identify additional incentives to drive innovation in the new indications' area.

Self-medication / "Switch" Products

Governments and associated funding groups are increasingly considering mechanisms to empower greater patient involvement and self-care within the overall healthcare system. More widespread availability of non-prescription products and, in particular, "switching" from prescription to non-prescription status can be an important tool in this process. However, the investment required to "switch" products (in terms of safety assessment, and scientific and educational programmes required by agencies) can be significant.

In order to stimulate innovation and investment in the self-medication area, some form of RDP should be extended to the "switch" process. The EU recognised the importance of self-medication within the G10 framework (Recommendation V) and has introduced a 1 year protection period for switches. While GSK welcomes this initiative, we believe further developments are needed. The US, in comparison, currently offers up to 3 years RDP for switches. We will, therefore, continue to encourage further efforts in this area, both in the EU and elsewhere.

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