Regulatory Data Protection in Switzerland

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Introduction

Pharmaceutical research and development is a complex, expensive, and risky process, often requiring years and substantial investment. Regulatory authorities evaluate a drug's quality, safety, and efficacy through extensive nonclinical and clinical trial data before granting approval. Given the high costs and risks, protections like patents and Regulatory Data Protection (RDP) are crucial to incentivise these investments. Patents alone may not be sufficient to encourage pharmaceutical innovation in a competitive market. Therefore, RDP was introduced to provide additional incentives for pharmaceutical companies. RDP consists of two main components: Data Exclusivity (DE) and Market Protection (MP). The DE period prevents generic drug manufacturers from referencing the innovator's clinical trial data to obtain marketing approval for a certain number of years. MP refers to the period during which a generic version of a drug cannot be marketed, even if it has received regulatory approval. This ensures that the innovator maintains market exclusivity and profitability for a specified time. These periods vary across countries but generally start from the market authorisation date of the original product.[1]

Patents alone may not be sufficient to encourage pharmaceutical innovation in a competitive market. Therefore, Regulatory Data Protection was introduced to provide additional incentives for pharmaceutical companies.

Ark Patent Intelligence provides the most up-to-date data on RDP for 41 countries (including 27 countries in the European Union) in its Regulatory Protection module, offering valuable insights into the varying protection periods and regulations across different jurisdictions.

Regulatory data protection in Switzerland

In Switzerland, Swissmedic, the national regulatory authority, oversees the approval and monitoring of drugs and pharmaceutical products through the Therapeutic Products Act (TPA). Swissmedic grants regular authorisation to medicinal products based on full documentation as per Art. 11 TPA. Prior to the TPA, the regulation for pharmaceutical products was fragmented across different pieces of legislation. Since its implementation, the TPA has undergone several revisions to improve and adapt the regulatory framework.

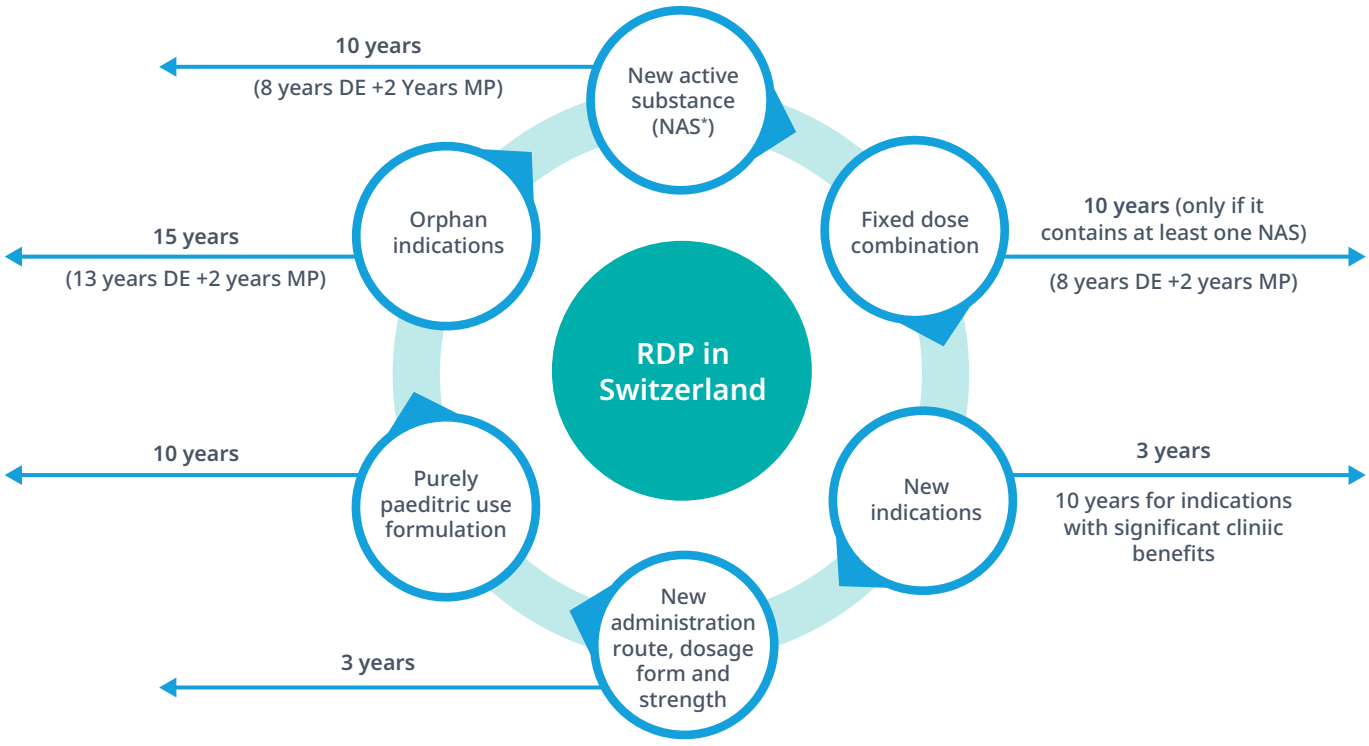
One of the key aspects of the TPA is the granting of RDP to pharmaceutical companies. RDP ensures that the data submitted during the drug approval process cannot be used by other companies to gain approval for generic versions of the drug for a specified period. The RDP provisions were revised and became effective from January 01, 2019, introducing the concept of document protection.[2]

Document Protection is a provision that safeguards data submitted by the innovator applicant in support of a marketing authorisation application, or for an extension or modification of indications or dosage recommendations, against use by third-party entities for a specified period, and is granted in accordance with Art. 11a and Art. 11b of the TPA. Generic applications can be submitted referencing the protected data up to two years before the protection period ends, but the authorisation will only be granted after the document protection expires. Swissmedic publishes the details and duration of the document protection for each pharmaceutical product.[3]

Temporary authorisation: Swissmedic may issue temporary authorisation for medicinal products with incomplete documentation under Art. 9a TPA for life-threatening or debilitating diseases if the products are compatible with health protection, are expected to provide significant therapeutic benefits, and if no authorised, alternative, or equivalent medicinal products are available in Switzerland. Temporary authorisation is granted under specific conditions that must be met within a certain timeframe. Once these conditions are fulfilled, the temporary authorisation can be converted into regular authorisation. Document protection is not granted to temporarily authorised products; relevant document protection is only granted upon the conversion of temporary authorisation to regular authorisation in Switzerland.[4]

Types and Duration of RDP in Switzerland (Figure 1) The 8+2 years rule of New Active Substance (NAS) is applicable for all reference products whose data protection expires on or after January 01, 2019.[5] For earlier authorised products, 10 years DE period was granted.[6] Document protection of 10 years for New Indications, 10 years for Paediatric Use Only, and 15 years for pharmaceutical products for Orphan Indications is granted on application provided the authorisation application was submitted to Swissmedic after January 01, 2019.

Figure 1: Types and duration of RDP in Switzerland



Source: Guidance on Document protection.[3]
NAS*- New active substance approved with a complete dossier in accordance with Art. 11 TPA, DE-Data exclusivity, MP-Market protection.

Comparison between RDP provisions of the European Union (EU) and Switzerland

RDP provisions in EU and Switzerland are designed to protect the investment of pharmaceutical companies in developing new drugs and to align with their regulatory framework. A comparison between the provisions in both the regions can be found below (Table 1).[1,3]

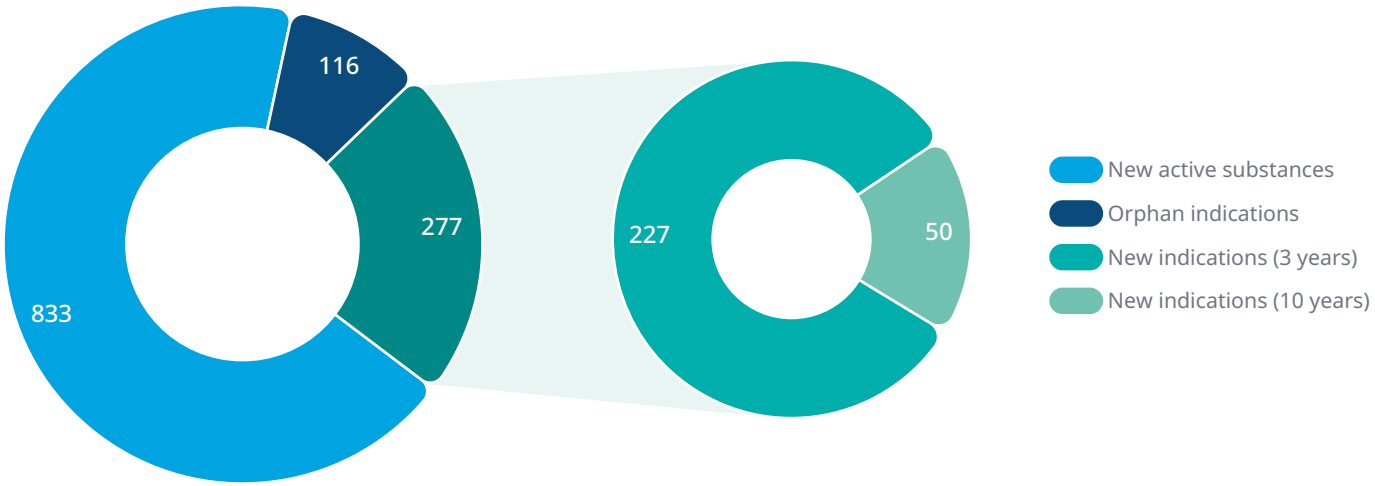
RDP in Switzerland in Ark Patent Intelligence:

Ark Patent Intelligence covers up-to-date RDP data for 833 New Active Substances (NAS), 277 New Indications, and 116 Orphan Indications in Switzerland, as of February 2025 (Figure 2). This data is accessible within the Regulatory Protection module under the country code CH and includes details such as marketing authorisation dates, expiry dates, trade names and indications.

Table 1: Comparison between EU and Switzerland data protection provisions

DATA PROTECTION PROVISIONS	EU	SWITZERLAND
Medicinal products submitted with complete dossier	10 years, including 8 years of DE and 2 years of MP. Applies to both new and known active substances (MA holder should be different) An additional 1-year MP extension is possible	10 years, including 8 years of DE and 2 years of MP. This applies only to NAS. No further extension on MP is available
Fixed dose combination	10 years	10 years, only if the combination contains at least one NAS
New indications	MP period can be extended by 1 year if, within the first 8 years, the MA holder obtains authorisation for new indications with significant clinical benefit in comparison with existing therapies	3 years/10 years for new indications with significant clinical benefit
Orphan indications	10 years, extension of 2 years is possible upon completion of the Paediatric Investigation Plan (PIP)	15 years, with no further extensions available
Paediatric incentives	PUMA (Paediatric Use Marketing Authorisation) exclusivity: 10 years 2 years extension on orphan exclusivity for completing the PIP	10 years

Figure 2: RDP in Switzerland



Source: Ark Patent Intelligence.

Case study 1

RDP of Semaglutide in Switzerland and EU

Switzerland: Semaglutide was first authorised in Switzerland under the trade name Ozempic® as an injection dosage form on July 02, 2018, and has received data protection for the NAS until July 02, 2028. Additionally, it received separate data protection for a new indication. Semaglutide was later authorised in tablet dosage form under the trade name Rybelsus® on March 24, 2020, and has received separate data protection for the NAS until March 24, 2030. Semaglutide has received two different periods of data protection as a NAS for Ozempic® and Rybelsus® due to some differences in the manufacturing process of Semaglutide used in both products based on section 1.1.1 of the guidance document Authorisation human medicinal product with NAS.[7] Semaglutide was also authorised under the trade name Wegovy® on February 15, 2022. Wegovy® did not receive any document protection for NAS but has been granted three separate periods of data protection for three new indications. These protections will expire on February 15, 2025, April 10, 2034, and December 2, 2034, respectively (Table 2).

EU: In the EU, Semaglutide was first authorised under the trade name Ozempic® as a subcutaneous injection solution on February 12, 2018, based on a complete dossier and as a NAS, receiving regulatory data protection until February 12, 2028. Subsequently, Rybelsus®, an oral tablet, was approved on April 7, 2020. At the time of dossier submission, although the applicant mentioned some process differences, they claimed Semaglutide to be a known active substance. Later, Wegovy® was authorised as a subcutaneous injection solution on January 7, 2022. In the dossier, the applicant claimed the active substance to be the same as that of Ozempic®. The Marketing authorisation holder for all the products is Novo Nordisk. Since Novo Nordisk is the marketing authorisation holder for all three products, and the applicant claimed the same active substance in all three products, Rybelsus® and Wegovy® fall under the global marketing authorisation of Ozempic® and no separate period of data protection could be granted to Rybelsus® and Wegovy®. Thus, the RDP period for all three products begins on the authorisation date of first authorised product (Ozempic®) i.e. on February 12, 2018, and ends on February 12, 2028 (Table 2).

Table 2: RDP data for Semaglutide in Switzerland and EU

INN	REGION	TRADE NAME	APPROVAL DATE	EXCLUSIVITY TYPE	EXCLUSIVITY EXPIRY
Semaglutide	Switzerland	Ozempic®	Jul 2018	NCE	Jul 2026
				MP	Jul 2028
			Mar 2020	Indication 1#	Mar 2023
		Rybelsus®	Mar 2020	NCE	Mar 2028
				MP	Mar 2030
		Wegovy®	Feb 2022	Indication 1*	Feb 2025
			Apr 2024	Indication 2*	Apr 2034
			Dec 2024	Indication 3*	Dec 2034
	EU	Ozempic®	Feb 2018	NCE	Feb 2026
		Rybelsus®	Apr 2020		
		Wegovy®	Jan 2022	MP	Feb 2028

Source: Ark Patent Intelligence

Indication 1# – To treat adults with inadequately controlled type 2 diabetes mellitus in combination with SGLT-2 inhibitor.
Indication 1* – For weight reduction. Indication 2* – For weight management in adolescent population (12 years and older).
Indication 3* – Reduction of the risk of serious cardiovascular events. NCE — New chemical entity data exclusivity. MP — Market protection.

Case study 2

RDP for fixed dose combinations in Switzerland and EU

INNs: “Empagliflozin”, “Empagliflozin, Linagliptin”, and “Empagliflozin, Metformin”

Switzerland: Empagliflozin was authorised in Switzerland on November 12, 2014, under the trade name Jardiance®, with data protection until November 12, 2024. Additionally, it received separate data protection for four new indications. The combination of Empagliflozin, Metformin was authorised on November 12, 2015, under the trade name Jardiance Met®. Since Metformin has been a known active substance since the 1960s and Empagliflozin was a NAS at the time of authorisation of Jardiance Met®, data protection for this combination also runs until November 12, 2024. Jardiance Met® also received a separate period of data protection for a new indication. The combination of Empagliflozin, Linagliptin was authorised under the trade name Glyxambi® on March 29, 2017. In this combination, both active substances were new. Linagliptin was authorised on March 8, 2012, with data protection until March 8, 2022, while Empagliflozin had data protection until November 12, 2024. Thus, data protection for Glyxambi® runs until November 12, 2024, based on the later expiry of data protection for Empagliflozin (Table 3).

EU: Empagliflozin was authorised in EU on May 27, 2014, under the trade name Jardiance® and has received 8 years of data protection, 2 years of market protection, and an additional year of market protection for the treatment of symptomatic chronic heart failure, which is expiring on May 27, 2025. The combination of Empagliflozin and Metformin was authorised on May 29, 2015, under the trade name Synjardy® and has received 8 years of data protection, 2 years of market protection until May 29, 2025, for the new fixed combination. The combination of Empagliflozin, Linagliptin was authorised on November 15, 2016, under the trade name Glyxambi® and has received 8 years of data protection, 2 years of market protection until November 15, 2026, for the new fixed combination (Table 3).

Table 3: RDP data for Empagliflozin, Empagliflozin, Metformin and Empagliflozin, Linagliptin in Switzerland and EU

INN	REGION	TRADE NAME	APPROVAL DATE	EXCLUSIVITY TYPE	EXCLUSIVITY EXPIRY
Empagliflozin	Switzerland	Jardiance®	Nov 2014	NCE	Nov 2022
				MP	Nov 2024
			Sep 2021	Indication 1*	Sep 2024
			Jun 2022	Indication 2*	Jun 2025
			Oct 2023	Indication 3*	Oct 2026
			Dec 2023	Indication 4*	Dec 2026
	EU		May 2014	NCE	May 2022
				MP	May 2024
				MP-I	May 2025
Empagliflozin, Metformin	Switzerland	Jardiance Met®	Nov 2015	NCE	Nov 2022
				MP	Nov 2024
			Jul 2024	Indication 1#	Jul 2027
	EU	Synjardy®	May 2015	NC	May 2023
				MP	May 2025
Empagliflozin, Linagliptin	Switzerland	Glyxambi®	Mar 2017	NCE	Nov 2022
				MP	Nov 2024
	EU		Nov 2016	NC	Nov 2024
				MP	Nov 2026

Source: Ark Patent Intelligence

Indication 1* — Heart failure. Indication 2* — Chronic symptomatic left ventricular heart failure. Indication 3* — Treatment of type II diabetes in children aged ≥ 10. Indication 4* — Chronic kidney disease. Indication 1# — Treatment of type 2 diabetes mellitus in children aged ≥ 10. NCE — New chemical entity data exclusivity, MP — Market protection. MP-I — Additional year of market protection. NC — New combination data exclusivity.

Case study 3

RDP of Trastuzumab deruxtecan in Switzerland and EU

Switzerland: On August 14, 2020, Daiichi Sankyo submitted a marketing authorisation application for Trastuzumab deruxtecan in Switzerland, requesting the status of a new active entity and marketing authorisation in accordance with Art. 9, para. 1 TPA. Due to incomplete clinical data and in line with the guidance document "Authorisation procedures for COVID-19 medicinal products during a pandemic, HMV4," Swissmedic granted a temporary authorisation under Art. 9a TPA on November 29, 2021, under the trade name Enhertu®. On January 01, 2023, the marketing authorisation for Trastuzumab deruxtecan was converted to regular authorisation and hence, the document protection period for the NAS starts from January 01, 2023, the date of regular authorisation, rather than the initial temporary authorisation date. Additionally, Trastuzumab deruxtecan received two separate periods of data protection for two new indications, expiring on March 06, 2026, and November 23, 2026, respectively (Table 4). However, it is important to note here that for calculating the term of supplementary protection certificates (SPCs), the Swiss Federal Institute of Intellectual Property considers the temporary authorisation date as the first authorisation date. For instance, in this case, the basic molecule patent was filed on January 28, 2015, with the 20-year term expiring on January 28, 2035, but for the purpose of calculating the SPC, the temporary authorisation date (November 29, 2021) was considered the first authorisation date, resulting in the product being granted an SPC until November 28, 2036.

EU: Trastuzumab deruxtecan was granted conditional marketing authorisation under the trade name Enhertu® on January 20, 2021. The product received 8 years of data protection, 2 years of market protection, and an additional 1 year of market protection for the treatment of unresectable or metastatic HER2-positive breast cancer in patients who have received one or more prior anti-HER2-based regimens, due to its significant clinical benefit over existing therapies. This protection is expiring on January 20, 2032 (Table 4).

Table 4: RDP data for Trastuzumab deruxtecan in Switzerland and EU

INN	REGION	TRADE NAME	APPROVAL DATE	EXCLUSIVITY TYPE	EXCLUSIVITY EXPIRY
Trastuzumab deruxtecan	Switzerland	Enhertu®	Nov 2021 (Temp. auth.) Jan 2023 (Regular auth.)	NCE	Jan 2031
				MP	Jan 2033
			Mar 2023	Indication 1*	Mar 2026
			Nov 2023	Indication 2*	Nov 2026
	EU		Jan 2021	NCE	Jan 2029
				MP	Jan 2031
				MP-I	Jan 2032

Source: Ark Patent Intelligence.
Indication 1* — HER2-low expressing breast cancer. Indication 2* — Unresectable or metastatic HER2-positive breast cancer.
NCE — New chemical entity data exclusivity. MP — Market protection. MP-I — Additional year of market protection.

Conclusion

Swissmedic has established a robust system for governing RDP in Switzerland, ensuring that innovator data is safeguarded from generic competition for a specified period, thereby fostering innovation. The 2019 revisions to Switzerland's TPA and introduction to document protection have brought about substantial enhancements in regulatory data protection. While Switzerland's RDP provisions are comparable to those elsewhere in Europe, there are notable differences in certain aspects and the duration of the protection period. These differences highlight the unique regulatory environment in Switzerland, which, while aligned with EU standards, maintains its distinct approach. As the regulatory landscape continues to evolve, it will be interesting to observe how pharmaceutical companies strategically leverage these provisions in Switzerland. The future of document protection in Switzerland will undoubtedly play a pivotal role in shaping the country's pharmaceutical framework.

References

1. https://www.ema.europa.eu/en/documents/presentation/presentation-data-exclusivity-market-protection-orphan-and-paediatric-rewards-s-ribeiro_en.pdf
2. Therapeutic Products Act, TPA (status as of 1 January 2025)
3. Guidance document on Document protection
4. Guidance document on temporary authorisation of human medicinal products
5. Questions and answers on document protection
6. Therapeutic Products Act, TPA (status as of 1 January 2018)
7. Guidance document on human medicinal products with new active substance

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