Pharmaceutical Test Data Exclusivity

A Multi-Jurisdictional Survey

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Introduction & Contents/Subjects

Books in this series are developed within the framework of the International Association for the Protection of Intellectual Property (AIPPI), a non-affiliated non-profit organization dedicated to the development and improvement of legal regimes for the protection of intellectual property at both national and international levels.

Objective & Readership

The aim is to publish innovative work appealing to practitioners, other users of IP systems and academics.

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Switzerland

Simon Holzer

1. GENERAL LEGAL RULES AND REGULATORY DATA PROTECTION AVAILABILITY

Switzerland is an important research location for the pharmaceutical industry. It is therefore no surprise that Switzerland has set up a comprehensive system to protect the results of pharmaceutical research.

The basis of the Swiss efforts for the protection of data filed for the authorization of pharmaceutical products is Article 39(3) of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). The Swiss provisions on regulatory data protection go far beyond the TRIPS minimum requirements.

Specific regulations on providing regulatory data protection to the technical data generated by innovator companies for the marketing authorizations of their preparations, i.e., data generated by drug firms through preclinical and clinical trials to prove the efficacy and safety of their products, were introduced in the Federal Medicinal Products and Medical Devices Act of 15 December 2000.

On 1 January 2019, revised provisions for the protection of data filed in support of marketing authorization applications for pharmaceutical products came into force in Switzerland. In principle, these new provisions also apply to products that were already approved before 1 January 2019, except for the special rules on orphan drugs, pediatric uses and regulatory data protection for new indications with a significant clinical benefit proven by extensive clinical trials. These provisions only apply to products filed for registration after 1 January 2019.

a) Pharmaceutical Products

i) Chemical Products

Documents filed in support of marketing authorizations for human medicinal products comprising at least one new active substance or dossiers for new indications, new dosage recommendations, new modes of administration, orphan drugs or pediatric

uses, i.e., the pharmacological, toxicological and clinical trial data for such marketing authorizations, are protected from use and reference by third parties (regulatory data protection).

The following laws are relevant for the regulatory data protection of human health products in Switzerland:

- Federal Medicinal Products and Medical Devices Act of 15 December 2000 (Therapeutic Product Act, SR 812.21)
- Federal Ordinance on Medicinal Products of 21 September 2018 (Medicinal Products Ordinance, SR 812.212.21)

The Swiss regulatory data protection regulations provide for a total regulatory data protection period of ten years for data filed in support of marketing authorization applications for medicinal products for human health with at least one new active substance. According to the definition of the Therapeutic Product Act, a new active substance means an active substance which is authorized for the first time in Switzerland pursuant to an ordinary marketing authorization procedure under the Therapeutic Product Act. Active substances previously only authorized in medicinal products for human use shall be considered new active substances if they are used in products for veterinary use, and vice versa.

This ten-year regulatory data protection period for new active substances consists of an initial data exclusivity period of eight years and an additional market exclusivity of two years for the corresponding product.

During the initial data exclusivity period, the data submitted to the Swiss Agency for Therapeutic Products (Swissmedic) in support of a Swiss marketing authorization for a product comprising at least one new active substance is protected from being referenced by later filed marketing authorization applications (data exclusivity).

During the last two years of the regulatory data protection period, third parties might refer to the protected data submitted in support of older marketing authorizations for marketing authorization applications for generic products or biosimilars. However, Swissmedic may only grant a marketing authorization for the new generic product or biosimilar on the first day after the end of the total regulatory data protection period (market exclusivity).

The data filed in support of a Swiss marketing authorization for a medicinal product that contains no new active substance but concerns a new indication, new mode of administration, or new dosage form is protected for a separate period of three years after the grant of the new marketing authorization or the amendment of an existing marketing authorization. This regulatory data protection period for new indications, new modes of administration, or new dosage forms runs independently of the aforementioned ten-year protection for the main dossier that covers at least one new active substance.

For new indications of known active substances that are expected to bring a significant clinical benefit in comparison with existing therapies and that are based on extensive clinical trials, the regulatory data protection period will be extended by Swissmedic to up to ten years upon applicant's request.

In addition, Swissmedic grants, on the applicant's request, a total data protection period of ten years for medicinal products specifically and exclusively for pediatric use in accordance with the pediatric investigation plan of those products, provided

that no data protection exists for another medicinal product authorized by Swissmedic with the same active substance for the same specific pediatric use.

In summary, Swiss law provides for a general data protection period of 8 + 2 years following the grant of the marketing authorization for dossiers filed in support of marketing authorization applications for medicinal products with at least one new active substance (i.e. eight-year data exclusivity and two-year market exclusivity, similar to the solution of the EU). Apart from that, the regulatory data protection regime in Switzerland differs considerably from the EU regulations. In particular, dossiers for new indications, new modes of administration, new dosage forms or dosages, or new applications to new target animal species benefit from a separate data protection period that is independent from the data protection period for the data filed in support of the initial marketing authorization application.

If, exceptionally, the separate data protection period for the data that supports a marketing application for a new indication, new mode of administration, new dosage form or dosage, or an application for a new target animal species expires before the regulatory data protection period of the documents filed for the initial marketing authorization, third parties cannot simply make use of or refer to the data filed in support of the new indication, etc., immediately but only after the expiry of the 8 + 2 regulatory data protection period of the data for the initial marketing authorization (provided that the initial marketing authorization enjoyed a ten-year regulatory data protection period). This is because a reference to the documents filed in support of the new indication, etc., is not sufficient for the grant of a marketing authorization but it also requires a reference to the dossier of the basic application.

ii) Biological Products

Swiss regulatory data protection as described above for chemical compounds also applies to biological products. The ten-year standard regulatory data protection is only available to new biological products that are authorized based on a complete dossier. Similar to chemical compounds, the data filed in support of a new indication, new mode of administration, new dosage form or dosage of a biological product enjoys a separate data protection period that runs independently from the data exclusivity period for the main dossier.

iii) Orphan Drugs

The new provisions of the Therapeutic Product Act on regulatory data protection in force since 2019 provide fifteen years of regulatory data protection for medicinal products with orphan drug status or 'minor use or minor species'. This regulatory data protection is only available if these marketing authorization applications were received by Swissmedic on or after 1 January 2019.

iv) New Uses or Formulations

As explained above, Swiss regulatory data protection also applies to new uses of previously approved drugs. The data filed in support of a Swiss marketing authorization

for a human health or animal health medicinal product that contains no new active substances is still protected for a period of three years, if the data are filed in support of a new indication, new mode of administration, new dosage form or dosage, or an application to a new target animal species.

For new indications that are expected to bring a significant clinical benefit in comparison with existing therapies and that are based on extensive clinical trials, the regulatory data protection period is ten years.

v) Product Combinations

Generally, regulatory data protection only applies to medicinal products with at least one new active substance.

If a combination product does not contain at least one new active substance, it only benefits from regulatory data protection if the combination concerns a new indication, new mode of administration, or new dosage form or dosage or if the medicinal product is specifically and exclusively for pediatric use or an orphan drug.

vi) Approvals or Testing for Pediatrics Products

Swissmedic grants, on the applicant's request, a data protection period of ten years for the data of medicinal products specifically and exclusively for pediatric use in accordance with the pediatric investigation plan of those products, provided that no data protection exists for another medicinal product authorized by Swissmedic with the same active substance(s) for the same pediatric use.

A product for purely pediatric use can also be an essentially identical medicinal product (for example a known active substance or biosimilar) and still enjoy ten years of regulatory data protection. However, Swissmedic only grants the ten-year regulatory data protection for pediatric uses if the submitted studies / investigations in relation to the product correspond with the pertinent pediatric investigation plan.

Pharmaceutical companies should note that this type of regulatory data protection is granted only for medicinal products that are intended specifically and exclusively for pediatric use. The medicinal product may not have an additional indication for adults. If a pharmaceutical company plans to use the same active substance in adults, it must do so with a separate medicinal product (separate product name, separate authorization, etc.) if it does not want to jeopardize the regulatory data protection for its pediatric product in Switzerland.

b) Other Products (Agricultural, Animal Health)

The regulatory data protection described above also applies to animal health products. This means that there is a ten-year data protection period (eight years of data exclusivity and another two years of market exclusivity) for animal health products and a three- to ten-year regulatory data protection period for new indications, new modes of administration, or new dosage forms or dosages. Furthermore, there is a three-year regulatory data protection period for the dossier of an application to new target animal species.

The Swiss Federal Ordinance on the Placing of Plant Protection Products on the Market (Ordinance on Plant Protection Products, SR 916.161) further stipulates that tests and study reports on the active substance of plant protection products (pesticides), safeners or synergists, additives or on the concerned plant protection product submitted to the Swiss Federal Office of Agriculture for the authorization of a plant protection product cannot be used for the grant of an authorization or amendment for another product for a period of ten years from the date of the first authorization of the plant protection product. This period is extended to thirteen years for tests and study reports filed in support of authorizations for low-risk plant protection products. The Ordinance on Plant Protection Products provides for additional extensions and exceptions. The total period of protection for normal plant protection products shall in no case exceed thirteen years; for low-risk plant protection products, the total term of protection shall not exceed fifteen years. Subject to certain exceptions, experimental dossiers and study reports that are required for the renewal or review of an existing authorization are normally protected for a period of thirty months. Special provisions apply to data concerning tests on vertebrate animals. Generally, the applicant of a later filed marketing authorization can refer to such data but must pay a reasonable royalty so that the animal experiments do not have to be carried out at all, if possible. If the parties cannot agree on the royalty rate, the Federal Office of Agriculture takes a decision and fixes the royalty rate.

2. REQUIREMENTS FOR PROTECTION

a) Substantive Requirements

As mentioned above, specific regulatory data protection periods are available for (i) new active substances, (ii) new indications of known active substances, (iii) new modes of administration, (iv) new dosage forms or dosages, (v) applications to a new target animal species, (vi) orphan drugs and minor use or minor species status products, (vii) pediatric use products, and (viii) certain data filed in support of plant protection products.

b) Formal Requirements

The ten-year regulatory data protection period for medicinal products with new active substances and the three-year regulatory data protection period for new indications, new modes of administration, new dosage forms or dosages, or applications to new target animal species is automatically taken into account and granted by Swissmedic and does not require an application or specific evidence.

Additional regulatory data protection for the data filed in support of a special marketing authorization application is only available upon explicit request of the applicant and requires the submission of pertinent evidence or at least arguments.

If a product qualifies for regulatory data protection, then Swissmedic explicitly mentions the total duration of the regulatory data protection period in each new marketing authorization or in the amendment of an existing marketing authorization.

There are no specific preconditions to be observed if an applicant wants to obtain regulatory data protection. For example, Swiss regulatory data exclusivity is not dependent on filing for marketing approval within a certain time period relative to filing for marketing approval abroad.

3. SCOPE OF PROTECTION

a) Confidentiality

Generally, no data submitted to Swissmedic for obtaining a marketing authorization for a medicinal product will be disclosed to third parties.

The Swiss provisions concerning regulatory data protection regulate at what point in time third parties wishing to authorize a generic or biosimilar product may refer to the data submitted in support of an older marketing authorization application of an original product or reference product.

In addition, Swiss law not only stipulates when such reference is possible, but also the earliest point in time when Swissmedic may grant a marketing authorization for a product that makes reference to the dossier of another product.

According to the practice of the Swiss Federal Data Protection and Information Commissioner, under certain circumstances third parties may have a right to access the documents filed in support of a marketing authorization for a medicinal product under the Swiss Freedom to Information Act (see for example the recommendation of the Swiss Federal Data Protection and Information Commissioner dated 30 March 2010). However, trade secrets and manufacturing secrets are not to be disclosed. Since most of the studies submitted to Swissmedic concern trade secrets and/or manufacturing secrets, large parts of a dossier submitted to Swissmedic will therefore not be available to third parties even under the Freedom of Information Act.

b) Prevention to Reference or Rely on Data

As mentioned above, it is not possible to make reference to data that still enjoys data exclusivity. According to Swiss law, the data exclusivity period ends two years prior to the total regulatory data protection period. If a third party files a marketing authorization application with Swissmedic prior to the expiry of the data exclusivity period, then Swissmedic dismisses such application without prejudice and the application must be refiled at a later date.

c) Market Exclusivity or Other Rights

During the last two years of the total regulatory data protection period, Swissmedic may examine new applications that refer to protected data but the marketing authorization for the new product may only be granted after the expiry of the total regulatory data protection period. This means that during the last two years of the total regulatory data protection period, the protected data and dossiers no longer benefit from strict data exclusivity, but from market exclusivity only.

According to Swissmedic, the distinction between the data exclusivity period and the two-year market exclusivity period at the end of the total regulatory data protection period only applies to regulatory data protection periods of ten years and longer. This means, for example, that according to Swissmedic, a marketing authorization application for an indication of a known active substance that still enjoys separate regulatory data protection (e.g., three years for a new indication) can only be filed on the first day after the total regulatory data protection period has expired. This practice seems to conflict with the clear language of the law that says that an application for marketing authorization may be submitted two years before the end of the term of the regulatory data protection period. There is no case law available at this stage that would clarify this issue.

4. REGULATORY DATA PROTECTION GRANT AND ENFORCEMENT IN PRACTICE

The regulatory data protection period for a veterinary or human medicinal product is mentioned in the grant of the marketing authorization for the concerned product.

If the applicant that filed the marketing authorization application disagrees with the duration or refusal of the regulatory data protection period by Swissmedic, this part of Swissmedic's marketing authorization can be appealed to the Swiss Federal Administrative Court.

Swissmedic publishes a list with all veterinary and human medicinal products that enjoy regulatory data protection in Switzerland. This list has just under 800 entries (as of April 2022) including new active substances, new indications, new modes of administration, new dosage forms or dosages, new applications to a new target animal species, new orphan drugs, and new pediatric uses.