
Swiss Controversies over RDP for Pharmaceutical Products

The Regulatory Data Protection for Pharmaceuticals

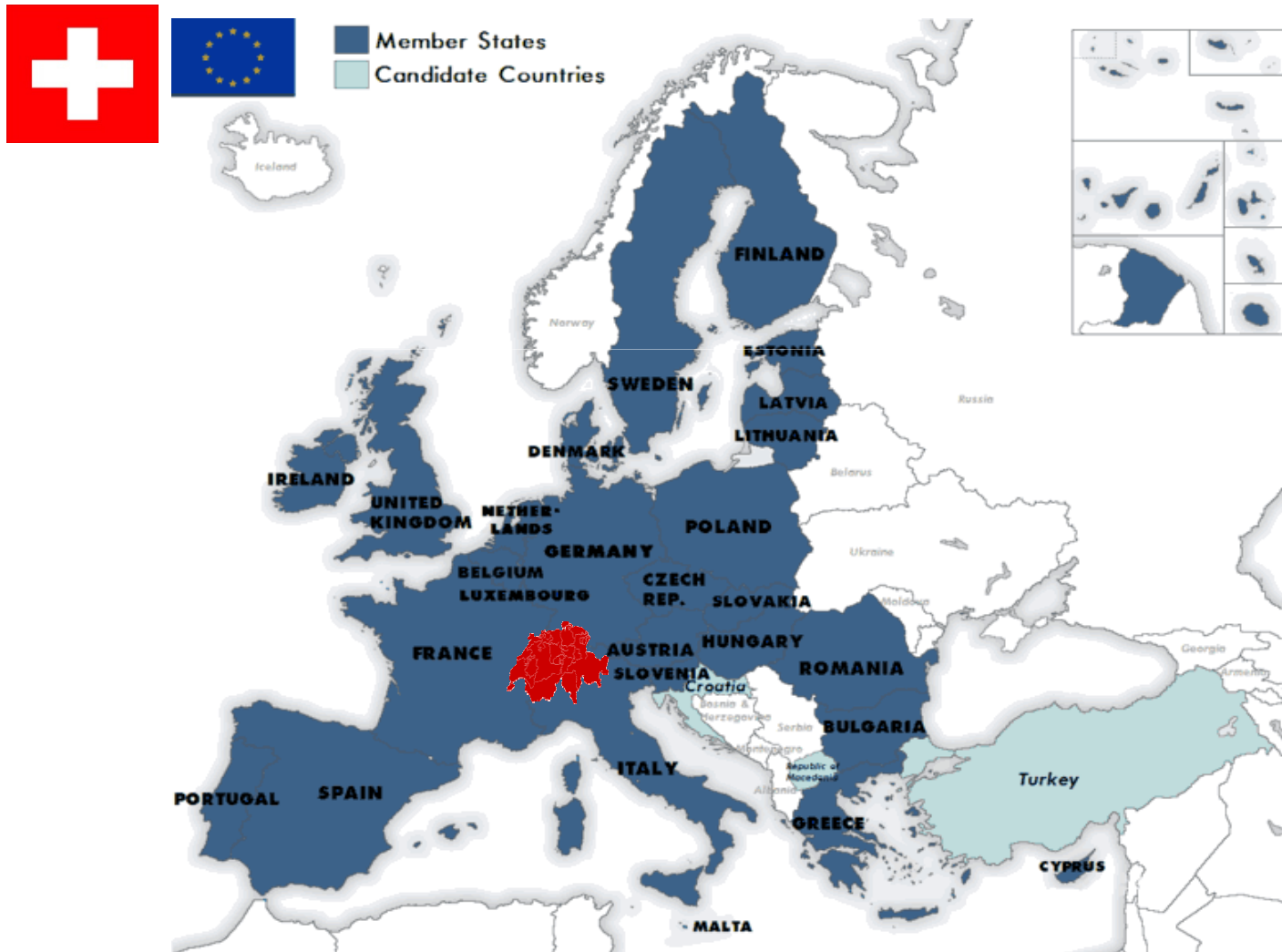
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I. The Swiss RDP System



I. The Swiss RDP System

- Statutory Regulatory Data Protection provisions in Switzerland since 1998.
- Before 1998: Protection under the Unfair Competition Act.
- New Federal Act on Medicinal Products and Medical Devices as per January 1, 2002.
- Swissmedic, the Swiss Agency for the Authorization and Supervision of Therapeutic Products.



I. The Swiss RDP System

Regulatory Data Protection and Patent Protection

- **No linkage between patent system and regulatory regime in Switzerland.**
- **Broad safe harbour exemption under the Swiss Patent Act.**
(including the submission of samples to the regulatory authorities)

I. The Swiss RDP System

Regulatory Data Protection and Patent Protection

- Patent right does not empower the patent holder to stop or delay authorization procedure.
- Marketing authorization does not empower its holder to infringe third parties' rights.

I. The Swiss RDP System

The Implementation of Article 39(3) TRIPS in Switzerland



I. The Swiss RDP System

10 Years of Data Exclusivity for Original Preparations

Article 12 Federal Law on Therapeutic Products

An application for a marketing authorization for a medicinal product which is essentially the same as an already authorized medicinal product (original preparation) and is intended for the same use, may be based on the results of the pharmacological, toxicological and clinical tests of the already authorized medicinal product if:

- a. the applicant for the original preparation provides written permission; or
- b. the protection period of 10 years for the original preparation has expired.

I. The Swiss RDP System

3-5 years of protection for data filed in support of an authorization for:

- **new indications,**
- **new modes of administration,**
- **new preparation forms, or**
- **new dosages of an old substance.**

II. Recent Case Law

How to define the Term “Original Preparation”?

Swiss Federal Administrative Court of Mai 6, 2009
(C-7020/2007):

Active substances approved for the first time in the regulatory framework of Switzerland.



II. Recent Case Law

Presumption of Regulatory Data Protection for clinical studies, whose data exclusivity is in dispute?

Right to participate in disputes regarding Regulatory Data Protection between Swissmedic and a competitor?

Swiss Federal Supreme Court of September 19, 2008
(2C_318/2008)

II. Recent Case Law

RDP for New Combinations?

Swiss Federal Administrative Court of November 7, 2007 (C-2263/2006):

Combinations of old substances $\neq$ original preparation.

Protection – 3 years.



II. Conclusions

- Regulatory data protection as an incentive to invest in clinical studies proving the safety and efficacy of pharmaceutical products.
- Deficiencies of the Swiss Regulatory Data System:
 - 10 years of data exclusivity only for “original preparations”.
 - No protection for new combinations.
- Art. 39(3) TRIPS = minimum standard of protection

Thank you!

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