

REGULATORY DATA PROTECTION OF MEDICINAL PRODUCTS FROM A SWISS PERSPECTIVE

DR SIMON HOLZER*

Partner, Meyerlustenberger Lachenal, Zurich

Introduction

Regulatory data protection in the pharmaceutical industry provides protection to the technical data generated by innovator companies for the authorisation of their preparations, that is, data generated by drug firms through preclinical and clinical trials to prove the efficacy and safety of the products concerned. By providing exclusive rights to this data, the relevant regulatory provisions prevent competitors from obtaining marketing licences for low-cost versions during this period of exclusivity.

As in other jurisdictions, ready-to-use medicinal products may only be put on the Swiss market if they have been authorised by the competent regulatory authorities. In Switzerland this is the Swiss Agency for Therapeutic

Products ('Swissmedic').¹ Producing data to demonstrate the quality, safety and efficacy of the products concerned has become a complex and expensive venture for pharmaceutical companies. Applicants applying for a marketing authorisation for a product with a new active substance have to provide Swissmedic with the results of preclinical and clinical testing data from pharmacological, toxicological, galenic, biological and clinical trials.² According to a report of the European Federation of Pharmaceutical Industries and Associations (EFPIA) from 2011,³ it takes approximately 12 to 13 years for a medicinal product to reach the market, and the average costs of researching and developing a new chemical entity exceed €1 billion.⁴ On the one hand, the increased cost of collecting regulatory data has also increased originators' need for protection, and on the other, a growing awareness has developed that, for economic and ethical reasons, repetitive testing on animals and patients should be avoided where this would not contribute to further knowledge regarding safety and efficacy or provide a positive risk-benefit balance.⁵ The legislator has to find a fair balance between these conflicting interests.

Current Swiss legislation on regulatory data protection is strongly influenced by the legislation of the European Union at the turn of the millennium when the current Swiss law was enacted.⁶ The European legislation has since been amended,⁷ which has led to discussions on possible follow-up adjustments in Switzerland.⁸

This article outlines the current framework for regulatory data protection in Switzerland and its connections to EU law. In particular, it provides an overview of recent case law in the field, shows the interfaces between the Swiss system and the regulatory framework in the EU, and outlines the planned amendments to the Swiss law.

* The author represented the originator company's interests before the Swiss regulatory authorities and in court in the *Swissmedic* case described in the article (see Note 29 below). The proceedings have been completed and this article reflects the author's personal opinion.

1) Article 9(g)(h) of the Federal Law on Medicinal Products and Medical Devices ('LTP', SR 812.21) dated 15 December 2000 (updated on 1 May 2007).

2) Article 11 LTP.

3) EFPIA, *The Pharmaceutical Industry in Figures 2011*, available at <http://www.efpia.eu/Content/Default.asp?PageID=559&DocID=11586> accessed on 20 June 2012.

4) See EFPIA report, at page 6 note 3, with reference to a study dating back to 2005.

5) Sally Shorthouse in *Guide to EU Pharmaceutical Regulatory Law* (ed. Sally Shorthouse) (2nd edn) 2011, at 215. Kluwer.

6) The Swiss regulatory data protection system is based on Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products, OJ 1965 L 22, at 369. For further details see the Federal Council's Dispatch on the Law of Therapeutic Products of 1 March 1999, at 3500 (BBl 1999 3453) (in German).

7) Codification Directive 2001/83/EC of the European Parliament and the Council of 6 November 2001 on the Community Code relating to medicinal products for human use (OJ 2001 L 311, at 67) brought 11 Directives on human medicinal products into one legislative text. It was amended by Regulation (EC) No. 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ 2006 L 378, at 1).

8) Federal Department of Home Affairs (FDHA), *The Report on the Ordinary Revision of the Law on Therapeutic Products* (Stage 2), October 2009, at 37 (in German), available at <http://www.admin.ch/ch/d/gg/pc/documents/1636/Bericht.pdf>, accessed on 20 June 2012.

Regulatory Data Protection in Switzerland

Article 39(3) TRIPs Agreement

The basis of the Swiss efforts concerning the protection of data filed for the authorisation of pharmaceutical products is Article 39(3) of the Agreement on Trade Related Aspects of Intellectual Property Rights ('TRIPs').⁹ This Article reads as follows:

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.

Article 39(3) TRIPs offers considerable room for interpretation. The provision does not provide for a fixed period of protection for the first applicants' data, so that the national laws of the WTO member states apply different time limits.¹⁰ In addition, it does not specify the term 'new chemical entities' ('NCE') and therefore opens the door to different views regarding the scope of protection of this particular provision.

It is important to keep in mind that Article 39(3) TRIPs only establishes a minimal standard for regulatory data protection. According to Article 1 TRIPs, '*... Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement.*'

Implementation of Article 39(3) TRIPs Agreement in Switzerland

Although Article 39(3) of the TRIPs Agreement has required the WTO member states to implement the aforementioned minimum standard of protection for regulatory data produced by pharmaceutical originators since 1995¹¹ and the transitional period for adopting the TRIPs minimum standard ended in 1996,¹² Switzerland did not implement its first federal statutory provisions for the protection of regulatory data, the Federal Law on Medicinal Products and Medical Devices (Law on Therapeutic Products ('LTP')), until 1 January 2002.¹³

Prior to the implementation of the LTP on a federal level, the cantons of the Swiss Confederation entered into the Intercantonal Convention on the Control of Therapeutic Products to implement Article 39(3) TRIPs in 1998. Before 1998, regulatory data was protected by the Unfair Competition Act¹⁴ and other provisions protecting trade secrets only.

Current Legal Framework

Ten years of data exclusivity for original preparations

The legal framework for regulatory data protection in Switzerland is structured as follows. According to Article 11 LTP:

... the application for authorisation of a medicinal product must contain the following documentation:

...

(g) the results of physical, chemical, galenic, biological or microbiological as well as pharmacological and toxicological tests;

(h) the results of clinical trials.

9) See Trevor Cook, 'Regulatory Data Protection in Pharmaceuticals and Other Sectors' in Krattiger, Mahoney, Nelson *et al.* (eds), *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practice* (MIHR: Oxford, UK, 2007 and PIPRA: Davis, USA., 2007) available online at www.ipHandbook.org; Ingo Meitinger, 'Commentary on Art. 39 TRIPs', in Thomas Cottier and Pierre Véron (eds), *Concise International and European IP Law; TRIPs, Paris Convention, European Enforcement and Transfer of Technology* (Kluwer Law International 2008) at 112; Stefan Kohler and Christa Pfister, 'Erstanmelderschutz für Arzneimittel in der Schweiz', *sic!* 5/2008, at 396; Dominik Bachmann, 'Der Erstanmelderschutz in der Schweiz und in der EU', *Schweizerische Zeitung für Gesundheitsrecht*, 32 2004; Peter Mosimann and Markus Schott, 'Commentary on Art. 12 LTP, note 4', in Thomas Eichenberger, Urs Jaisli and Paul Richli (eds), *Commentary on Therapeutic Products Act (Basel Commentary)* (Basel: Helbling & Lichtenhahn Verlag, 2006); Alesch Staehelin, *Das TRIPs-Abkommen* (2nd edn) (Bern: Stämpfli Verlag AG, 1999) at 169.

10) The period of protection ranged from six years in the European Union (now revised) to ten years, for example in Switzerland; for a good overview see Shorthouse, Note 5 above, at 224.

11) Date of entry into force.

12) Article 65(1) TRIPs.

13) Federal Law on Medicinal Products and Medical Devices (Law on Therapeutic Products, ('LTP')), dated 15 December 2000, enacted 1 January 2002 (SR 812.21).

14) Federal Act against Unfair Competition ('UCA'), dated 19 December 1986, enacted 1 March 1988 (SR 241).

An exemption to this rule arises out of Article 12 LTP, which, under specific circumstances, provides for facilitations of the requirements laid down in Article 11 LTP:

An application for a marketing authorisation for a medicinal product which is essentially the same as a medicinal product already authorised (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 authorised medicinal product if:

(a) the applicant for the original preparation provides written permission; or

(b) the protection period [of ten years] for the original preparation has expired.¹⁵

Thus, according to Article 12 LTP, subsequent applicants who are not in possession of written permission issued by the holder of the marketing authorisation for the original preparation may apply for a marketing authorisation relying on the data submitted by the first applicant but not earlier than ten years after the marketing authorisation was first granted. Once the ten-year period has expired, it is assumed that the pharmaceutical companies have recouped their investments in connection with the marketing approval procedure. In this situation, it would be of no specific use to repeat the complex preclinical and clinical studies often combined with tests on humans and animals, as the safety and efficacy of a medicinal product have already been confirmed and approved by the first applicant. The limitation of the scope of data protection not only considers the interests of the second applicants in an abridged authorisation procedure, but is also justified on ethical grounds and for economic reasons.¹⁶

Similar to the old six- to ten-year data protection period under Directive 65/65/EEC¹⁷ in Europe, Swissmedic only starts examining an application relying on the data of the first

applicant when the protection period of ten years has expired.¹⁸ In other words, the Swiss law (still) offers a ten-year data exclusivity period and not only a ten-year marketing exclusivity period.

Assuming a typical review period of 330 days¹⁹ plus the time the applicant needs to answer Swissmedic's List of Questions and the duration of other correspondence between the applicant and Swissmedic, the marketing exclusivity period in Switzerland comes to more than eleven and a half years. Compared with the protection systems in other jurisdictions, in particular the 8+2 regulatory data protection system in the EU, this is a rather long period of exclusivity for original preparations. As a consequence, generic products normally appear later on the Swiss market than on other markets and patent litigation usually also begins later in Switzerland.²⁰

Original preparations

The Swiss legislator chose to grant the ten-year period of data exclusivity only for what are termed 'original preparations'. Unfortunately, the Law on Therapeutic Products does not define the term 'original preparation', which has led to several disputes between applicants for a marketing authorisation and Swissmedic.²¹

According to the current practice of Swissmedic, the term 'original preparations' only encompasses pharmaceuticals comprising at least one new active substance that has never before been authorised in Switzerland. It is irrelevant whether or not the holder of the marketing authorisation for the preparation concerned was required to compile and submit a full dossier.²²

In contrast to the EU regime, not every full dossier submitted to support an application for a marketing authorisation with the regulatory authorities enjoys regulatory data protection in Switzerland. Recent Swiss case law supports the narrow definition of the term 'original preparation' applied by Swissmedic.²³

15) Article 12 LTP.

16) Mark Schweizer, *Drittbeschwerde gegen arzneimittelrechtliche Zulassungen*, AJP 2005, at 797, 800; Bachmann, Note 9 above, at 34.

17) See Note 6 above.

18) Schweizer, Note 6 above, at 801; Swiss Federal Supreme Court, Decision 2C_208/2010 of 17 June 2011, paragraph 4.

19) See Swissmedic's guideline for the deadlines and time limits of the approval procedure of 24 November 2011, para. 6.2. (QM-Ident no. ZL000_00_004d_RL). If the authorisation holder submits an application based on the evaluations of foreign regulatory authorities in accordance with Article 13 LTP, and if the corresponding requirements are met, Swissmedic's decision

can be entirely based on the results of the reference authority's evaluation, which reduces the target processing time by one third (see Swissmedic's instructions for the authorization of medicinal products already authorised in foreign countries (QM-Ident no. ZL000_00_001e)).

20) Kohler and Pfister, Note 9 above, at 400; see also Bachmann, Note 9 above, at 37.

21) Swissmedic Journal 01/2010, at 4.

22) Swissmedic Journal 07/2003, at 556; see also Mosimann and Schott, Note 9 above, Commentary on Art. 12 LTP, note 8.

23) See Note 29 below.

Three to five years of data exclusivity for new indications, new modes of administration, new preparation forms, or new dosages of a known substance

According to Article 39(3) TRIPs, WTO members are merely obliged to adequately protect the data submitted to the authorities in the authorisation proceedings for new chemical entities. However, the Swiss law goes further and provides for additional data protection for new indications, new modes of administration, new preparation forms, and new dosages of an old substance.

Under Swiss law, data filed in support of authorisation for new indications, new modes of administration, new preparation forms, and new dosages of a known substance are protected for three years. If the applicant proves that the new product brings significant clinical benefits compared to existing therapies, Swissmedic might extend the data exclusivity period for up to five years.²⁴

Although the Swiss law does not contain explicit language, Swissmedic takes the view that only the first applicant, that is, only the holder of the first marketing authorisation for the relevant chemical entity, is entitled to data exclusivity of three to five years for new indications, new modes of administration, new preparation forms, or new dosages. Second applicants, even if they apply for new indications, new modes of administration, new preparation forms, or new dosages of a known substance, do not benefit from regulatory data protection.

In contrast to the 8+2(+1) system in the EU (which lumps together the data protection periods for the initial application and the subsequent application for new indications, new modes of administration, new preparation forms, or new dosages), the additional three- to five-year period of data exclusivity for data submitted in connection with new indications, new modes of administration, new preparation forms, or new dosages of known substances in Switzerland does not depend on the ten-year protection period for the first application and does not affect said ten-year period either. Both periods exist independently of each other and only encompass the corresponding data. This means, *inter alia*, that it is irrelevant for the three- to five-year data protection period whether the ten-year period for the first application is

still running or has expired. In addition, the three- to five-year period of protection only applies to the data submitted in support of the application for the new indications, new modes of administration, new preparation forms, or new dosages, and does not extend the ten-year period of protection for the data filed in support of the first application.²⁵

No Linkage Between Patent System and Regulatory Regime for Authorisation of Pharmaceutical Products in Switzerland

In Switzerland, as in the EU and contrary to the approach of the United States and other jurisdictions influenced by the United States, the regulatory provisions dealing with the authorisation of a pharmaceutical product and the patent protection system do not interlock. This means that there is no linkage between patent protection and the regulatory regime concerning market access in the pharmaceutical sector in Switzerland.²⁶

The last such linkage between the patent system and regulatory regime was abandoned on 1 July 2009. Prior to that date, the simplified and shortened authorisation procedure for pharmaceutical products that had been authorised in a country with an equivalent authorisation system, that satisfies the same requirements as a product that had been already authorised in Switzerland, was not available if the product of the first applicant in Switzerland, which the second applicant referred to, was protected by a patent.²⁷ However, since 1 July 2009, Swissmedic has no longer considered patent protection when assessing applications for a marketing authorisation.²⁸

Recent Case Law

Definition of Term 'Original Preparation'

As mentioned above, Swiss law grants regulatory data protection only for data submitted in support of an application for an 'original preparation'. The narrow interpretation of the term 'original preparation' by Swissmedic led to a decision by the Federal Administrative Court in May 2009,²⁹ the facts of which can be summarised as follows.

24) Article 17(2) Ordinance of 17 October 2001 concerning Medicinal Products (Medicinal Products Ordinance, VAM), SR 812.212.21.

25) Kohler and Pfister, Note 9 above, at 398; Mosimann and Schott, Note 9 above, Commentary on Art. 12 LTP, note 22; Bachmann, Note 9 above, at 33.

26) See Bachmann, Note 9 above, at 34.

27) See the former Article 14(3) LTP (Official Compilation of Federal Legislation AS 2001 2796).

28) Swissmedic Journal 04/2009, at 354.

29) Federal Administrative Court, Decision C-7020/2007 of 6 May 2009, published in *sic!* 9/2009, at 816; see also Swissmedic Journal 01/2010, at 4. The author of this article represented the originator company's interests in court. The proceedings have been completed and the present contribution reflects the author's own personal opinion. The article is based on publicly available information.

The Swiss holder of a marketing authorisation for an analgesic and Swissmedic could not reach agreement on whether or not the data filed in support of said analgesic some years ago should benefit from a ten-year data protection period.

The pharmaceutical product in dispute contained an analgesic developed in the early 20th century as one of several new semi-synthetic active agents in an attempt to improve on existing opiates like morphine. In Switzerland, the first pharmaceutical containing said analgesic was authorised in the first half of the 20th century. The owner of the licence for that product was a pharmacist who ran his own drugstore in a small town in the Eastern part of Switzerland. The product that was first licensed was an injection solution containing a combination of three active agents, including the analgesic medication in dispute.

Said analgesic, like any other product licensed in the first half of the 20th century, was authorised without any study proving its safety and efficacy. In the late 1980s, the owner withdrew his licence for the analgesic due to lack of demand. Therefore, the pharmaceutical company that was in conflict with Swissmedic had to file a full dossier in support of its application since the old file was out of date and, as already mentioned, did not contain any clinical studies.

Nevertheless, Swissmedic refused to grant the company a ten-year period of protection for the data submitted in support of the new application, although there was no other product with the same active agent licensed at the time when the new application was filed and granted and there was no product which the company could refer to in order to minimise the amount of data that was necessary to support its application.

The company therefore appealed Swissmedic's decision to the Federal Administrative Court, which rejected the appeal and confirmed Swissmedic's decision. The court held that the term 'original preparation' enjoying regulatory data protection only encompassed active substances approved for the first time within the regulatory framework of Switzerland. It was irrelevant whether or not the older product with the same active agent allowed the second applicant to reduce the amount of studies that had to be filed in support of its application.³⁰

Innovative pharmaceutical companies criticise this decision since it leaves a harmful gap. The problem is that on the one hand pharmaceutical companies must submit a complete file including all relevant studies proving the safety and efficacy of their products in order to obtain a marketing authorisation, but on the other hand, the same companies are unable to protect the submitted information from free-riding by competitors for a reasonable period of time.

It is this author's opinion that the Federal Administrative Court failed to recognise that Article 39(3) TRIPs Agreement only requires a minimum standard of protection and that the member states of the WTO are free to go beyond that standard. Switzerland clearly intends to go beyond the minimum standard of the TRIPs Agreement in many ways and there is no reason to assume that the Swiss legislator wanted to create a harmful blank for innovative companies when it introduced the term 'original preparation'.

Since 1 October 2006, the Swiss law has explicitly provided that it does not matter whether a chemical entity is still licensed or whether a marketing authorisation has been withdrawn or has lapsed. In both constellations the data filed in support of the approval for a later product is excluded from the ten-year data exclusivity period.³¹ This corresponds to the previous practice of Swissmedic.

Uncertainty about Regulatory Data Protection Concerns Second Applicant

During the aforementioned dispute between Swissmedic and the applicant about data exclusivity before the Federal Administrative Court, at least three generic companies filed applications for bioequivalent products containing the same active agent. All three applications referred to the data filed in support of the appellant's application. Even though Swissmedic was of the opinion that the appellant's product (that is, the corresponding data) should not enjoy data exclusivity, it suspended the three generic companies' applications until the Swiss Administrative Court rendered a binding decision in this matter.

Two of the three generic companies appealed Swissmedic's stay of their approval procedures to the Federal Administrative Court. The Federal Administrative Court³² rejected the appeals on formal grounds, as did the Federal Supreme Court.³³

30) Ibid., at paragraph 4.2.

31) See Article 12 of the Federal Regulation of 22 June 2006 concerning the simplified authorisation of medicinal products as per 1 October 2006 (VAZY, SR 812.212.23).

32) Federal Administrative Court, Decision C-8074/2007 of 25 March 2008.

33) Federal Supreme Court, Decision 2C_318/2008 of 17 September 2008, paragraph 5.

As a result, the three generic application proceedings remained suspended until the Federal Administrative Court had decided on the disputed data exclusivity for the analgesic product that the three generic applications referred to. In effect, Swissmedic, the Federal Administrative Court and the Swiss Supreme Court granted the appellant factual exclusivity for its data for at least the duration of the proceedings.

This shows that if there is a dispute about the exclusivity of specific data between an applicant and Swissmedic, the uncertainty is likely to harm the position of possible second applicants who wish to refer to the first applicant's data. With regard to third parties, Swissmedic handled the data as if it were protected, although it had a different opinion *vis-à-vis* the alleged first applicant.

No Participation Rights for the Second Applicant in Administrative Proceedings between Swissmedic and the First Applicant (and Vice Versa)

Another interesting question the Federal Supreme Court had to decide was whether the generic companies concerned were entitled to participate in the proceedings between the first applicant and Swissmedic.

The Federal Supreme Court denied the generic companies the right to participate in the said proceedings, holding that a generic company which is, at the same time, the first applicant's competitor is not a party to the dispute regarding the data exclusivity of the data filed by the first applicant against Swissmedic.³⁴

Regulatory Data Protection for Combination Products?

In the European Union, Article 10b of Directive 2001/83/EC on the Community Code in Regard to Medicinal Products for Human Use as Amended by Directive 2004/27/EC applies to medicinal products containing active substances used in the composition of authorised medicinal products but not hitherto used in combination for therapeutic purposes.³⁵

The matter has not been the subject of litigation, but it has been generally accepted that, by virtue of this provision, a new combination has its own period of data protection calculated from the date of the first marketing authorisation for that particular combination in the Community, as if that new combination were a new active substance.³⁶

Since 2003, the Swiss approach has been different and less advantageous for innovators. Swissmedic changed its standing practice with regard to regulatory data protection for combination products. A new combination of two or more known and formerly approved substances is not deemed to be an original preparation and, therefore, does not enjoy a ten-year period of data exclusivity.³⁷

Following this new doctrine, Swissmedic denied in a specific case that a new combination of already approved substances can be treated as a new original preparation and, therefore, rejected a ten-year protection period. However, it granted a three-year period of regulatory data protection for the combination product, arguing that the applicant who filed the application for the new combination was also the owner of the marketing authorisation for the already approved substances.

The applicant filed an appeal with the Federal Administrative Court and asked for a regulatory data protection period of ten years. The court rejected the appeal and confirmed that only medicinal products with at least one new active substance were considered to be original preparations as defined by Article 12 LTP. A medicinal product consisting of a combination of chemical entities already known and formerly approved in Switzerland does not satisfy the requirements set out in Article 12 LTP.

Comparisons with European Law³⁸

Although Switzerland is not a Member State of the European Union, it has a similar system for the protection of data filed with regulatory authorities in support of marketing authorisations for pharmaceutical products. However, and especially since the enactment of Directive 2001/83, more differences between the European Union system and the Swiss regulatory data protection system have appeared.

34) Ibid., paragraph 6.

35) Swissmedic Journal 7/2003, at 556.

36) See Cook, Note 9 above, at 451.

37) Swissmedic Journal 7/2003, at 556.

38) For the details of European law see: Trevor Cook, 'The current status of regulatory data protection for medicinal products in the EU', BSLR Vol. 12 issue 2, at 50. Ulrich M. Gassner, 'Unterlagenschutz im Europäischen Arzneimittelrecht', GRUR Int 2004, at 983; Bachmann, Note 9 above, at 36; Shorthouse, Note 5 above, at 219 onward.

Present European legislation distinguishes between an eight-year period of data protection and an additional two-year period of marketing exclusivity. In contrast, Swiss law provides for ten-year data protection and the second applicant is not entitled to submit its application prior to the expiration of this period.³⁹

Like the European law, the Swiss regime also grants additional protection for specific new uses of known substances.⁴⁰ However, in contrast to European law, in Switzerland this exclusivity only applies to data produced in support of the specific innovation and does not extend the protection period of the original set of data. On the other hand, the period of protection in Switzerland for new indications, new modes of administration, new preparation forms, and new dosages of a known substance is three to five years.⁴¹

Another important difference between the two systems is that while data protection in the EU applies to 'reference medicinal products',⁴² Swiss legislation refers to 'original preparations'.⁴³ This distinction can be relevant to the question of whether it is also possible to protect data that does not refer to medicinal products consisting of new chemical entities (such as combinations of old substances) but the compiling of which also involves considerable effort. In Switzerland, the ten-year data protection period for such combinations has been denied by the authorities⁴⁴ while in the European Union, a new combination has its own period of data protection calculated from the date of the first marketing authorisation for that particular combination in the Community, as if that new combination were a new active substance.⁴⁵

Swiss Marketing Authorisations do not Trigger EU's 8+2 Data Protection Period

Liechtenstein and Switzerland co-operate closely in many ways. After the Court of Justice of the European Union's attention-getting decision of 21 April 2005, *In re Novartis et al. v Comptroller et al.*, in which the CJEU held that authorisation to place a medicinal product on the market issued by the

Swiss regulatory authorities and automatically recognised by Liechtenstein constituted the first authorisation to place the product on the market as defined in Article 13 of Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, one could ask whether Swiss marketing authorisations recognised by Liechtenstein also trigger 8+2-year regulatory data protection in the EU. However, this is not the case and the reasons are twofold:

First, marketing authorisations issued by Swissmedic for pharmaceutical products with new chemical entities are no longer automatically recognised in Liechtenstein. Today, NCE products with a Swiss marketing authorisation are only recognised in Liechtenstein after a marketing authorisation has been granted in an EU or EEA Member State for the same NCE product. After the aforementioned decision of the CJEU, Switzerland and Liechtenstein concluded an agreement that became effective on 1 June 2005.⁴⁶ This agreement has been regularly extended.⁴⁷ This provides that all medicinal products with new chemical entities authorised by Swissmedic should be reported to the medical agency of Liechtenstein and be put on an NCE list in Liechtenstein. As long as the products are included in this NCE list they are not authorised in Liechtenstein.

Second, the CJEU made clear in the *Generics v MHRA* decision⁴⁸ that a medicinal product that has not been authorised in accordance with current EU pharmaceutical legislation cannot be considered a 'reference medicinal product' as defined by Article 10(2)(a) of the relevant Directive and, therefore, does not trigger the 8+2 regulatory data protection period. Medicinal products licensed in Switzerland, even if they are automatically recognised in Liechtenstein, do not qualify as reference products.

Plans to Amend Swiss Law

The Federal Office of Public Health has issued a preliminary draft amendment to the Swiss regulatory data protection system. The plan is to implement the amendment in the course of the current revision of the Law on Therapeutic Products.

39) See above, page 3.

40) See above, page 4.

41) See above, page 4; Bachmann, Note 9 above, at 37; Kohler and Pfister, Note 9 above, at 400.

42) Article 10(1) Directive 2001/83/EC.

43) Article 12 LTP.

44) See above, page 5.

45) Kohler and Pfister, Note 9 above, at 400 onward.

46) See Systematic Compendium of Federal Law SR 0.812.101.951. 41.

47) See Official Chronological Compilation of Federal Law AS 2009 3931.

48) CJEU Case no C-527/07, *Generics (UK) Ltd v The Licensing Authority (acting via the Medicines and Healthcare Products Regulatory Agency)*, judgment of 18 June 2009.

Based on the results of the consultation with the interested stakeholders, the Federal Council charged the Federal Department of Home Affairs (FDHA) with drafting a new Bill that could be presented to the Federal Parliament by 2012.

The published preliminary draft (PD) of the new Swiss regulatory data protection system is intended to implement the EU's 8+2(+1) system.⁴⁹

As a general rule, Article 11a(1) PD-LTP provides that data regarding medicinal products consisting of *at least one new active agent* and authorised on the basis of complete documentation in ordinary proceedings (original preparation) are protected for a period of ten years. Unlike today, the ten-year period does not provide full data exclusivity, at least not for ten but only for eight years. According to Article 12 PD-LTP, an application for a marketing authorisation for a medicinal product that is essentially the same as an already authorised medicinal product, the documentation of which is protected, may be based on the results of the pharmacological, toxicological and clinical tests of the already authorised medicinal product if the holder of the authorisation for the protected medicinal product provides written permission, or the protection period for the original preparation will *expire in less than two years*.

The preliminary draft legislation no longer provides for an additional independent period of protection from three to five years for new indications, new modes of administration, new preparation forms, or new dosages of an already registered

substance. However, Article 11a(2) PD-LTP provides that, under specific circumstances, the full set of data will be protected for 11 years if, during the first eight years, the holder of the marketing authorisation obtains authorisation for one or more *new indications* that are held to bring significant clinical benefits compared to existing therapies.

A significantly longer period of data exclusivity, that is, 10 and 12 years respectively, will only apply for new paediatric indications developed in accordance with a paediatric investigation plan approved by Swissmedic⁵⁰ and orphan medicinal products developed in accordance with an approved paediatric investigation as well.⁵¹

Even though the revised Swiss regulatory data protection system is intended to introduce harmonisation with the EU system, the new Swiss regime would fall behind and leave noteworthy loopholes. For example, compared to the European law, the proposed revision does not consider the required data protection for new combinations⁵² or in cases of a change of classification of a medicinal product.⁵³ In addition, the definition of the term 'original preparation' by Swissmedic is still much stricter than the reference products that enjoy regulatory data protection under the relevant EU Directive. The planned revision of the Swiss regulatory data protection system seems to be a half-hearted approach and should implement the complete set of EU provisions protecting the data submitted in support of an application for a new product.

49) See preliminary draft of the amended Therapeutic Products Act of October 2009, available online at <http://www.admin.ch/ch/d/gg/pc/documents/1636/Vorlage.pdf>, accessed on 20 June 2012.

50) Article 11b (2) PD-LTP; see also Article 38 Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 20 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004, OJ 2006 L378.

51) Article 11b (3) PD-LTP. The European law provides for general data exclusivity for orphan medicinal products, see Article 8 Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products, OJ 2000 L18.

52) Article 10b Directive 2001/83/EC.

53) Article 74a Directive 2001/83/EC provides that where a change of classification of a medicinal product has been authorised on the basis of significant pre-clinical tests or clinical trials, the competent authority will not refer to the results of those tests or trials for one year after the initial change was authorised.