

Swiss exclusivities delay entry to market

Due to Switzerland's unique legal and regulatory position within Europe, a raft of pharmaceuticals will lose protection during December, significantly later than in most European Union (EU) member states. For example, supplementary protection certificates (SPCs) for Sanofi's blockbuster oncology agent Taxotere (docetaxel) in the EU expired in November 2010, whilst Sanofi enjoyed more than a year's extra protection – and the resulting sales – in Switzerland.

A similar situation, observes patent intelligence expert GenericsWeb, affects Roche's Rapilylin (reteplase) vials. In the EU, SPCs expired in more than a dozen member states around four months ago (*Generics bulletin*, 2 September 2011, page 23), but the antithrombic agent is only just losing its protection in Switzerland (see Figure 1).

In terms of data exclusivity, Switzerland is alone in seeing 10-year exclusivity end for both Pfizer's Zyvox (linezolid) antibiotic and Roche's Valcyte (valganciclovir) antiviral agent during December. But this month also brings the expiry of 10-year protection in several EU member states – as well as the end of similar protection in Switzerland (see Figure 2) – for Lundbeck's antidepressant CipraleX (escitalopram).

Lundbeck reported European sales of CipraleX down by 7% to

DKr872 million (US\$158 million) in the third quarter of this year. The Danish originator said brand sales had been depleted by generic escitalopram launches in Finland and Spain last year. Furthermore, sales of the antidepressant suffered when Lundbeck pulled out of the Germany's statutory healthcare market in July after a court upheld a decision to include CipraleX in a reference-price group with generic antidepressants (*Generics bulletin*, 15 July 2011, page 17).

CipraleX sales halved in Spain and Germany

"Lundbeck has now lost around 50% of CipraleX revenue in Spain and Germany," the company admitted.

Among the molecules for which GenericsWeb has now identified current EU orphan-drug exclusivity are anagrelide for treating essential thrombocythemia; laronidase as a treatment for treatment of type-I mucopolysaccharidosis; and stiripentol, which is used to combat severe myoclonic epilepsy in infants (see Figure 3).

The EU approval this year of Bayer Animal Health's Veraflox (pradofloxacin) anti-infective for cats and dogs has led to the filing of several SPC applications with potential expiry dates of February 2022, if granted. In the US, recent approvals of Fibrocell Technologies' cosmetic agent Laviv (azficel-T) and Seattle Genetics' Adcetris (brentuximab vedotin) oncology drug have triggered applications for patent-term extensions.

Molecules in the spotlight	
INN	Event
Anagrelide	European Union orphan-drug exclusivity as a treatment for essential thrombocythemia
Azacitidine	Patent family discloses processes for the preparation of azacitidine
Azficel-T	First extension application published in the US following approval of Laviv in June 2011
Brentuximab vedotin	First extension applications published in the US following approval of Adcetris in August 2011
Edoxaban	First extension applications published in Japan following approval of Lixiana in April 2011
Ibuprofen/ Scopolamine	First extension application published in Japan
Laronidase	European Union orphan-drug exclusivity as a treatment for type-I mucopolysaccharidosis
Methylnaltrexone	US patent listed in Orange Book.
Pradofloxacin	SPC applications published in Belgium, Czech Republic, Finland, Ireland, Italy, Netherlands, Norway and Sweden following European approval of Veraflox in April 2011.
Stiripentol	European Union orphan-drug exclusivity as a treatment for severe myoclonic epilepsy in infants
Thiotepa	Patent family discloses the thiotepa molecule and processes for its preparation

Figure 3: Molecules in the spotlight, based on recent regulatory or litigation events (Source – GenericsWeb)

SPC expiries in December	
INN	Country
Cilastatin	Latvia
Docetaxel	Switzerland
Econazole	Italy
Miconazole	Italy
Reteplase	Switzerland
Ropivacaine	Cyprus, Switzerland
Sibutramine	Belgium, Denmark, Finland, Greece, Italy, Luxembourg, Portugal, Spain, Sweden
Tazarotene	Austria, France, Germany, Greece, Ireland, Italy, Luxembourg, Sweden, UK

Figure 1: Molecules for which supplementary protection certificates (SPCs) expire in certain markets in December 2011 (Source – GenericsWeb)

Data exclusivity expiries in December	
INN	Country/Region
Agalsidase alfa	Switzerland
Darunavir	US
Escitalopram	Belgium, France, Germany, Italy, Luxembourg, Netherlands, Sweden, Switzerland, UK
Linezolid	Switzerland
Valganciclovir	Switzerland

Figure 2: Molecules for which data or market exclusivities expire in certain markets during December 2011 (Source – GenericsWeb)

Want more?

This data is extracted from the monthly update for Pipeline Scope, an online intelligence tool that provides fast access to reliable information on key patent, SPC and data-protection expiries, covering 44 countries and over 1,500 INNs.

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