

Topotecan SPCs tumble in much of EU

In certain western European Union (EU) member states, October brings the expiry of supplementary protection certificates (SPCs) for GlaxoSmithKline's Hycamtin (topotecan) treatment for ovarian, small-cell lung and cervical cancers (see Figure 1). The October expiry dates of these SPCs are based on the first marketing authorisation having been in Switzerland. However, notes patent intelligence expert GenericsWeb, authorities in Denmark, France and Italy based the local SPC durations on a later European centralised authorisation, pushing back SPC expiry dates in those countries to November 2011.

Having faced competition from generic topotecan in the US since the end of last year (**Generics bulletin**, 11 December 2010, page 16), GlaxoSmithKline said Europe had generated more than three-quarters of Hycamtin brand sales totalling £27 million (US\$42 million) in the first half of this year. Thus, one month of additional SPC protection

in Denmark, France and Italy will prove lucrative for the brand firm.

Other commercially significant molecules facing SPC expiry this month include Roche's HIV-1 protease inhibitor Invirase (saquinavir) and Schering-Plough's veterinary antibiotic Orbox (orbifloxacin).

In terms of data exclusivity, Merck & Co's blockbuster antifungal agent Cancidas (caspofungin) sees the expiry of 10-year protection in several European Union member states (see Figure 2).

In the US, Merck also sees expiry on 16 October of its five-year new chemical entity (NCE) exclusivity for the Januvia (sitagliptin) diabetes treatment, as well as for the sitagliptin/metformin combination that it markets under the Janumet brand name. In the cases of both sitagliptin and caspofungin, however, GenericsWeb says molecule-patent protection extends beyond the exclusivity period, and, as such, must be considered the main barrier to generic competition.

Meanwhile, the antibiotic gatifloxacin and the bronchodilator tiotropium bromide also lose exclusivity in several of the larger EU member states during October. And in Turkey, exclusivity terms end during October for gadofosveset, ivabradine and omalizumab, as well as for palifermin, posaconazole, sodium oxybate and tipranavir.

Among recent regulatory and litigation events, several patents were listed by the US Food and Drug Administration (FDA) in its Orange Book following recent agency approvals. These included patent listings against Pfizer's Xalkori (crizotinib) treatment for non-small-cell lung cancer; Optimer's macrolide antibiotic Dificid (fidaxomicin); and the Zelboraf (vemurafenib), melanoma brand marketed by Roche's Genentech (see Figure 3).

SPCs expiries in October	
INN	Country
Clofarabine	France, Germany, UK
Flumethrin	Italy
Orbifloxacin	Austria, Belgium, Finland, France, Germany, Greece, Luxembourg, Netherlands, Portugal, UK
Saquinavir	Austria, Belgium, France, Germany, Ireland, Italy, Luxembourg, Netherlands, Sweden
Topotecan	Austria, Belgium, Germany, Finland, Ireland, Luxembourg, Netherlands, Norway, Sweden, Switzerland, UK
Tropisetron	Austria

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

Molecules in the spotlight	
INN	Event
Crizotinib	First US Orange Book patents listed following FDA approval of Xalkori in August 2011
Fidaxomicin	First US Orange Book patents listed following FDA approval of Dificid in May 2011
Retigabine	First extension application published in US following FDA approval of Potiga (USAN:ezogabine) in June 2011
Tetrachlorodecaoxide	US patent-inventorship suit filed by Nuvo Research
Tylvalosin	First patent listed in Health Canada Patent Register following approval of Aivlosin Water Soluble Granules in September 2011
Vemurafenib	First US Orange Book patents listed following FDA approval of Zelboraf in August 2011

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

Data exclusivity expiries in October	
INN	Country/Region
Caspofungin	European Union (10-year countries)
Ciclesonide	US
Gadofosveset	Turkey
Gatifloxacin	Belgium, France, Germany, Italy, Luxembourg, Netherlands, Sweden, UK
Ivabradine	Australia, Turkey
Metformin/Sitagliptin	US
Omalizumab	Turkey
Palifermin	Turkey
Posaconazole	Turkey
Sitagliptin	US
Sodium oxybate	Turkey
Tegaserod	Switzerland
Telbivudine	US
Temoporfin	European Union
Tiotropium bromide	Belgium, France, Germany, Italy, Luxembourg, Netherlands, Sweden, UK
Tipranavir	Turkey
Vorinostat	US

Figure 2: Molecules for which data or market exclusivities expire in certain markets during October 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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