

# Valsartan protection varies across EU

Managing complexity in the intellectual-property landscape has long been a key skill for generics players in the European Union (EU). For example, while Novartis' Diovan (valsartan) blockbuster faces competition throughout the continent this year, the potential entry dates for generic versions of the antihypertensive vary according to the duration of local protection for the brand.

Supplementary protection certificates (SPCs) for Diovan were due to expire during May this year. However, in several EU member states, Novartis applied for – and received – six-month paediatric SPC extensions, stretching protection to November 2011. As *Generics bulletin* went to press, patent intelligence expert GenericsWeb had identified paediatric SPC extensions for Diovan in most EU countries, with the exceptions of Greece, Hungary, Luxembourg, Norway, Romania, Spain and Switzerland.

Reporting its financial results for the first quarter of 2011 last month, Novartis said Diovan remained “the top-selling branded antihypertensive medication worldwide”, even though the brand now faced generic competition in Brazil, Canada and Spain.

Valsartan SPCs running until mid-November have also proved useful in protecting Novartis' CoDiovan combination of valsartan and hydrochlorothiazide. In Germany for example, a Düsseldorf district

court issued an injunction preventing Actavis from launching the combination (*Generics bulletin*, 8 April 2011, page 22).

Other commercially significant molecules that face SPC expiry this month include GlaxoSmithKline's analgesic Ultiva (remifentanyl) and Bristol-Myers Squibb's Zerit (stavudine) antiretroviral (see Figure 1).

This month sees the expiry of the Australian five-year data exclusivity for a number of products, including Genzyme's Mabcampath (alemtuzumab) leukaemia treatment; Abbott's blockbuster antiretroviral combination Kaletra (lopinavir/ ritonavir); and Pfizer's Tygacil (tigecycline) systemic antibiotic (see Figure 2). However, GenericsWeb notes that in all of these examples, Australian patent-term extensions provide protection until after the expiry of the data exclusivity.

In the US, the end of data exclusivities for Eisai's Aricept (donepezil) and Eli Lilly's Gemzar (gemcitabine) this month will have a limited commercial impact. Ranbaxy had already launched donepezil 5mg and 10mg tablets with sole 180-day exclusivity at the end of November last year. Hospira enjoyed 180-day exclusivity for gemcitabine 2g vials, while Teva earlier this year struck a supply deal with APP to ensure it made use of its 180-day exclusivity for the 200mg and 1g strengths (*Generics bulletin*, 11 February 2011, page 17).

In terms of molecules that are potential development targets, three Japanese patent-term extension applications have been filed for menthol as clear-spray solutions of 0.8% levomenthol (see Figure 3). **G**

## Potential launch opportunities for products whose SPC expires in May

INN	Country
Anastrozole	Switzerland
Ethinylestradiol/gestodene	Portugal
Gadoxetic acid	Germany, Netherlands, Sweden, Switzerland, UK
HVT IBD vaccine	France, Germany, Italy, Netherlands, UK
Remifentanyl	Austria, Belgium, Denmark, France, Germany, Ireland, Italy, Luxembourg, Netherlands, Romania, Spain, Sweden, UK
Sertindole	Austria, Belgium, Denmark, Germany, Italy
Stavudine	Austria, Belgium, France, Germany, Italy, Luxembourg, Netherlands, Spain, Sweden, UK
Valsartan	Luxembourg, Norway
Zaleplon	Denmark, Finland, Ireland

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

## Molecules in the spotlight

INN	Event
Fluocinolone acetonide; hydroquinone; tretinoin	Newly issued US patent listed in Orange Book for Tri-Luma topical cream formulation
Menthol	First extension applications published in Japan

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

## Potential filing opportunities for products whose data exclusivity expires in May

INN	Country/Region
Alemtuzumab	Australia
Apomorphine	European Union
Azacitidine	US
Betamethasone/calcipotriol	US
Decitabine	US
Desmopressin	US
Donepezil	US
Eptacog alfa (activated)	Canada*
Eptotermin alfa	European Union
Gemcitabine	US
Lopinavir/ritonavir	Australia
Mesalazine	US
Phentolamine	US
Rasagiline	US
Resocortol	Canada*
Rotavirus vaccine	Australia
Sertindole	Israel
Sunitinib	Canada*
Tigecycline	Australia
Tinidazole	US
Varenicline	US

\* In practice, Canada did not implement its previous data-protection legislation in a manner that prohibited reliance on proprietary data during the exclusivity term.

Figure 2: Molecules for which data exclusivities expire in certain markets during May 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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