

Aricept alternatives are set to abound

In several western European countries, February brings the expiry of supplementary protection certificates (SPCs) for Eisai and Pfizer's blockbuster Aricept (donepezil), the market-leading treatment for Alzheimer's disease (see Figure 1).

In western Europe and Scandinavia – where Pfizer markets Aricept under licence from Japan's Eisai – the US originator's sales of the brand stalled last year at US\$229 million. Pfizer's total Aricept sales, down by 1% to US\$450 million, did not include any contribution from the US, where it co-markets the brand with Eisai.

Ranbaxy launched the first generic rival to Aricept in the US with 180-day exclusivity late in 2010, although Pfizer responded by introducing an authorised generic through its Greenstone operation (*Generics bulletin*, 14 January 2011, page 24). When Ranbaxy's 180-day exclusivity ended in May 2011, more than a dozen generic competitors flooded into the US market (*Generics bulletin*, 10 June 2011, page 25).

This intense competition led Eisai to report a 93% slump in US Aricept sales to US\$119 million in the nine months to December 2011. That total included US\$36 million from Greenstone's authorised generic.

As a number of generics firms already hold marketing authorisations for donepezil in several major European countries, patent-intelligence expert GenericsWeb believes fierce generic competition immediately upon SPC expiry is extremely likely. While this will potentially bring

a swift decline in sales of Aricept, GenericsWeb points out that Eisai has spent "a reasonable amount of resources" laying down patent barriers to hinder generic competition, including several patent families that cover polymorphic forms or other formulations of donepezil.

However, GenericsWeb does not consider such patents to be a constraint to generic competition, as the protected technology could be circumvented through generic re-formulation, such as by employing alternative routes of synthesis or using different molecular forms and/or salts. It appears that Pfizer is anticipating imminent generic competition to Aricept in major markets, having already in Germany introduced its own generic donepezil tablets ahead of SPC expiry at "clearly reduced" prices compared to Aricept.

In terms of data exclusivity (see Figure 2), February sees the expiry of 10-year protection in the majority of European Union member states for Gilead's antiviral agent Viread (tenofovir), a key component of several top-selling HIV treatments. Several SPCs protect certain combination drugs containing tenofovir. However, GenericsWeb notes, the validity of these SPCs remains in doubt following the recent European Court of Justice decisions concerning combination SPCs.

Among future generic development targets, the US Food and Drug Administration's approval of Pacira's Exparel (bupivacaine) analgesic has led a patent-term extension application to be submitted (see Figure 3). **G**

SPC expiries in February	
INN	Country
Antitrypsin alpha-1 human	France
Barnidipine	Spain
Cefditoren	Spain
Donepezil	Austria, Belgium, Denmark, Finland, France, Germany, Greece, Italy, Luxembourg, Norway, Portugal, Spain, Sweden, UK
Dtpa-Hb Vaccine	Switzerland
Eptifibatide	Austria, Belgium, Denmark, Finland, France, Germany, Italy, Luxembourg, Netherlands, Norway, Spain, Switzerland, UK
Felbamate	Switzerland
Losartan/hydrochlorothiazide	Switzerland
Letrozole	Switzerland
Levetiracetam	Spain
Mometasone	Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Spain, Sweden, UK
Sumatriptan	Switzerland
Tolcapone	France, Ireland, Luxembourg, Sweden, Switzerland, UK

Figure 1: Molecules for which supplementary protection certificates (SPCs) expire in certain markets during February 2012 (Source – GenericsWeb)

Data exclusivity expiries in February	
INN	Country/Region
Avian influenza vaccine	Austria, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, Greece, Hungary, Iceland, Ireland, Latvia, Lithuania, Malta, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Turkey
Bosentan	Switzerland
Dibotermin alfa	European Union
Etoricoxib	Belgium, France, Germany, Italy, Luxembourg, Netherlands, Sweden, UK
Lisdexamfetamine	US
Rotigotine	Turkey
Tenofovir	European Union
Varenicline	Australia

Figure 2: Molecules for which data exclusivity expires in certain markets during February 2012 (Source – GenericsWeb)

Molecules in the spotlight	
INN	Event
Bupivacaine	First extension application published in the US following approval of Exparel in October 2011
Mirabegron	First extension applications published in Japan
Myxoma Rhd Virus Strain 009	First SPC application published in France following European Union approval of Mobivac Myxo-RHD in September 2011

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

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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.

For further information, visit www.genericsweb.com, or contact:

Europe: +44 870 879 0081 North America: +1 704 665 1986

Or e-mail: info@genericsweb.com

