

Zometa benefits from secondary SPCs

Late July brings the loss of supplementary protection certificate (SPC) exclusivity for Novartis' blockbuster Zometa (zoledronic acid) in several European countries. These include France, Germany, Spain and the UK (see Figure 1). The SPCs are based on national versions of European patent EP0,258,618. However, points out patent intelligence expert GenericsWeb, SPCs based on Novartis' active pharmaceutical ingredient (API) patent – EP0,275,821 – are likely to prevent the launch of generics in major European markets well into next year.

Due to Novartis having completed an agreed paediatric investigation plan (PIP) for its Zometa osteoporosis and bone-cancer drug, the company obtained an additional six months of protection, extending SPC expiry from November 2012 until May 2013 in most key European countries. In Slovenia, Zometa's protection stretches until October 2013.

Looking beyond Europe, GenericsWeb observes that a national patent-term extension to Novartis' API patent conveys protection in Australia until November 2012. In the US, generic rivals to Zometa are expected to reach the market in March next year, as a six-month paediatric extension – on top of a 1,755-day patent-term extension – gives the brand protection until early March 2013.

Novartis said global sales of its Zometa 4mg/5ml formulation declined by 2% to US\$1.49 billion in 2011. The Swiss company also markets zoledronic acid as Aclasta/Reclast, a 5mg/100ml once-yearly

infusion therapy for treating osteoporosis. Global sales of Aclasta/Reclast increased by 6% to US\$613 million in 2011.

Several generics companies have prepared for expiries of API patents and extensions by securing marketing authorisations for both the 4mg/5ml concentrate and the 5mg/100 ml solution. Actavis, for example, recently obtained pan-European centralised clearance for the 4mg/5ml concentrate (**Generics bulletin**, 9 March 2012, page 18).

But there could be barriers to bringing the 5mg/100 ml solution to market. "Patents expiring in May 2021 that protect the dosage regime for Aclasta/Reclast may further prevent launches of generics to this product," GenericsWeb observes.

July also sees the end of data exclusivity for GlaxoSmithKline's Avodart (dutasteride) in those European countries offering 10 years of protection (see Figure 2). However, ongoing patent protection – extended by SPCs – will prevent generic competition in major European markets until 2017, GenericsWeb expects. **G**

SPC expiries in July	
INN	Country
Aspirin/Dipyridamole	Austria, Denmark, France, Germany, Greece, Ireland, Italy, Netherlands, Norway, Portugal, Romania, Spain, Switzerland, UK
Bemiparin sodium	Italy, UK
Carmustine	France, Luxembourg, Netherlands
Cetrorelix	Latvia
Cidofovir	Switzerland
Dtpa-Hb vaccine	Belgium, Germany*, Italy, Luxembourg, Sweden, UK*
Ethinylestradiol/gestodene	Austria, Belgium, France, Greece, Italy, Luxembourg, Netherlands, Spain, Switzerland
Grepafloxacin	Denmark, France, Germany, Italy, Netherlands, Spain, Sweden, UK
Insulin glargine	France, Italy
Pioglitazone	Hungary, Spain
Rivastigmine	Austria, Belgium, Denmark, Finland, France, Ireland, Switzerland
Trandolapril/Verapamil	Switzerland
Zoledronic acid	Austria, Belgium, Denmark, Finland, France, Germany, Hungary, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, Switzerland, UK

*indicates that the SPC remained an application at expiry, so never entered into force

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

Data exclusivity expiries in July	
INN	Country/Region
Aciclovir/Hydrocortisone	US
Antithrombin alfa	Turkey
Beclometasone/Formoterol	Austria, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, Greece, Hungary, Iceland, Ireland, Lithuania, Latvia, Malta, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Turkey
Canine coronavirus vaccine	Belgium, France, Germany, Italy, Luxembourg, Netherlands, Sweden, UK
Darunavir	Canada*
Dexrazoxane	Turkey
Dutasteride	Belgium, France, Germany, Italy, Luxembourg, Netherlands, Sweden, UK
Fibrinogen (125I)	Canada*
Fludeoxyglucose (18F)	Canada*
Human papillomavirus vaccine	Canada*
Lanreotide	Canada*
Metformin/pioglitazone	Turkey
MMR live vaccine	Austria, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, Greece, Hungary, Ireland, Iceland, Lithuania, Latvia, Malta, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Turkey
Sorafenib	Canada*, Turkey
Sunitinib	Turkey

* This will be followed by a no-marketing period of two years during which a notice of compliance will not be granted to a generic manufacturer. In addition, a further six months of data protection will be added to the eight-year term for studies of darunavir and human papillomavirus vaccine in paediatric populations

Figure 2: Molecules for which data exclusivity expires in certain markets during July 2012 (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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