

Reteplase loses protection from SPCs

August brought the expiry of European supplementary protection certificates (SPCs) for two major recombinant biologic drugs – the thrombolytic product Rapilysin (reteplase), as well as Novo Nordisk’s fast-acting diabetic treatment NovoLog/NovoRapid (insulin aspart), which achieved 2010 worldwide sales of around US\$2 billion.

However, patent protection remains in force for Novo Nordisk’s other formulations containing insulin aspart, notes patent intelligence expert GenericsWeb, including for the company’s NovoMix preparations.

GenericsWeb also highlights the expiry of the Swiss SPC for Novartis’ Diovan (valsartan) blockbuster antihypertensive (see Figure 1). “As Swiss SPCs are governed by national law, the Swiss SPC has not benefited from a six-month paediatric SPC extension, in contrast to other European territories,” it points out.

In the US, AstraZeneca’s blockbuster Nexium (esomeprazole) recently lost its ‘new patient population’ exclusivity, which had been increased to three-and-a-half years by a paediatric extension. In several European countries, drospirenone and ethinylestradiol – both of which are used in many leading oral contraceptives – also lost exclusivity during August (see Figure 2).

GenericsWeb has also identified potential targets for future generic development: extension applications have been filed in Japan for Chugai and Taisho’s osteoporosis vitamin D3 analogue eldcalcitol (see Figure 3); and in Europe new SPC applications have been identified for two veterinary drugs – tildipirosin, indicated for treating bacterial respiratory disease in cattle and swine; and Du Pont’s pesticide indoxacarb for preventing and treating fleas in cats and dogs.

Potential launch opportunities for products whose SPC expires in August	
INN	Country
Dorzolamide	Cyprus
DTPA vaccine; DTPA-HB vaccine	France
Etoposide	Switzerland
Florfenicol	Hungary
Insulin Aspart	Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, UK
Lamivudine	Denmark, Finland, France, Italy, Luxembourg, Netherlands, Sweden
Mizolastine	Switzerland
Olive Oil/Soybean Oil	Netherlands
Pegfilgrastim	Norway
Reteplase	Austria, Belgium, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, Netherlands, Norway, Sweden, UK
Valsartan	Switzerland

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

Molecules in the spotlight	
INN	Event
Eldcalcitol	First extension applications published in Japan
Indoxacarb	First patent family for this molecule has been identified as ‘key’ following publication of SPC applications in Bulgaria and Italy
Tildipirosin	First patent family for this molecule has been identified as ‘key’ following publication of an SPC application in the Netherlands

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

Potential filing opportunities for products whose data or market exclusivity expires in August	
INN	Country/Region
Agalsidase alfa	European Union
Agalsidase beta	European Union
Agalsidase alfa/beta	European Union
Conjugated oestrogens/ drospirenone	Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Greece, Hungary, Iceland, Ireland, Latvia, Lithuania, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain
Drospirenone	Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, Greece, Hungary, Iceland, Ireland, Latvia, Lithuania, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain
Ethinylestradiol	Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, Greece, Hungary, Iceland, Ireland, Latvia, Lithuania, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain
Gadofosveset	Australia
Human papillomavirus vaccine	Australia
Nitric oxide	European Union
Solifenacin	Australia
Valganciclovir	Belgium, France, Germany, Italy, Luxembourg, Netherlands, Sweden, UK

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

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

