


Atorvastatin arrives in EU as SPCs expire

Early May brought the loss of supplementary protection certificate (SPC) exclusivity in Europe for Pfizer's blockbuster cholesterol-lowering agent Lipitor (atorvastatin), following the expiry of six-month paediatric extensions (see pages 1 and 21). Patent-intelligence expert GenericsWeb notes that SPC expiries have opened the door for generic launches not only in western Europe's largest markets – France, Germany and the UK – but also also in several smaller European Union (EU) markets (see Figure 1). According to IMS Health, the brand's 2011 sales in France, Germany and the UK were €937 million (US\$1.21 billion).

Global Lipitor sales declined by 11% to US\$9.58 billion in 2011, due to the presence of generics on the markets of Brazil, Canada, Mexico, Spain and the US. Ranbaxy launched the first generic rival to Lipitor in the US on 30 November last year with 180-day market exclusivity, although it faced competition from Watson's authorised generic as well as Pfizer's aggressive discounting tactics aimed at clinging onto Lipitor's market share. In the US, increased market pressure is expected when Ranbaxy loses its 180-day exclusivity later this month, enabling rivals to launch atorvastatin tablets.

In terms of data exclusivity (see Figure 2), May brings the end of 10-year protection in the majority of European Union member states for Ebixa (memantine), Lundbeck's top-selling treatment for Alzheimer's disease. In 2011, Ebixa had a 20.3% value share of the European Alzheimer's disease market, as brand sales rose by 14% to DKr2.75 billion (US\$479 million). GenericsWeb points out that key patent protection for the use of memantine has expired in certain European countries due to the SPCs being found invalid. Thus, it notes, expiry of data exclusivity could allow companies to submit market-authorisation applications for rivals to Ebixa, and then launch upon approval in those European markets where SPCs have been invalidated.

Among future generic-development targets (see Figure 3), the US Food and Drug Administration (FDA's) approval of Mobius Therap's Mitosol (mitomycin) topical ophthalmic formulation in February this year has led to the agency listing a patent against the brand in its Orange Book. GenericsWeb observes that Mitosol has been awarded seven years of US data exclusivity to 2019 as an orphan drug for topical application to the surgical site of glaucoma-filtration surgery. 

| SPC expiries in May | |
|---|---|
| INN | Country |
| Amphotericin B | Switzerland |
| Atorvastatin | Austria*, Belgium*, Denmark*, France*, Germany*, Ireland*, Italy*, Luxembourg*, Netherlands*, Sweden*, Switzerland, UK* |
| Dalfopristin/ quinupristin | Belgium, Denmark, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, UK |
| Dofetilide | Ireland |
| Donepezil | Switzerland |
| Losartan/ hydrochlorothiazide | Cyprus |
| Mangafodipir | Austria, Finland, France, Germany, Ireland, Italy, Norway, Spain, Sweden, UK |
| Olanzapine | Cyprus |
| Pneumococcal saacharide conjugated vaccine | Austria, Belgium, Denmark, Germany**, Ireland, Italy, Luxembourg, Spain, Sweden |
| Quinupristin | Austria, Finland, UK |
| Tepoxalin | Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, UK |

* indicates expiry of six-month paediatric extension to SPC
** 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 May 2012 (Source – GenericsWeb)

| Data exclusivity expiries in May | |
|----------------------------------|--|
| INN | Country/Region |
| Amotosalen/platelets | Belgium, France, Germany, Italy, Luxembourg, Netherlands, Sweden, UK |
| Bimatoprost | Switzerland |
| Bimatoprost/timolol | Turkey |
| Bosentan | European Union |
| Clofarabine | Turkey |
| Estradiol/nomegestrol | Belgium, France, Germany, Italy, Luxembourg, Netherlands, Sweden, UK |
| Human papillomavirus vaccine | Australia |
| Insulin glargine | Switzerland |
| Memantine | European Union |
| Olopatadine | European Union |
| Rotigotine | US |
| Varicella-zoster live vaccine | Turkey |

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

| Molecules in the spotlight | |
|-----------------------------|--|
| INN | Event |
| Acetylcysteine | First US patent listed in Orange Book |
| Mareks disease virus type-1 | First extension applications published in Japan |
| Methadone | First Canadian patent listed in Health Canada's Patent Register |
| Mitomycin | First US Orange Book patent listed following approval of Mitosol topical ophthalmic product on 7 February 2012 |

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