

Supplementary Protection Certificates in Europe

The SPC is not a patent extension, it is an IP right relating to the active substance of a medicinal or plant protection product regulated by EU regulation (1768/92 for medicinal products and 1610/96 for plant protection products) or by National laws. EU 1768/92 came into force:

- in January 1993 in Community member states,
- in July 1994 in Austria, Finland, Norway and Sweden,
- in January 1998 in Greece, Iceland, Portugal and Spain
- in May 2004 in new member states.

SPC were regulated by National laws before 1993 in France, and Italy, and before 1994 in Sweden.

SPC are regulated by National laws in Switzerland and until May 2004 in 7 of the new member states (Cyprus, Czech Republic, Estonia, Latvia, Lithuania, Slovenia, and Slovakia).

A SPC refers to:

- a patent which protects this active substance *per se*, a process to obtain it, or its application and
- a marketing authorisation for a formulation containing the active substance.

The SPC protects the active substance within the limits conferred by the patent.

The SPC has the effect to compensate for the reduction in the effective patent life of pharmaceuticals caused by the delays inherent in the process for the marketing authorisation.

The SPC comes into force at the patent term and extends the patent life for the product covered by the marketing authorisation. It has a maximum term of five years (or more for French or Italian SPC filed before January 1993).

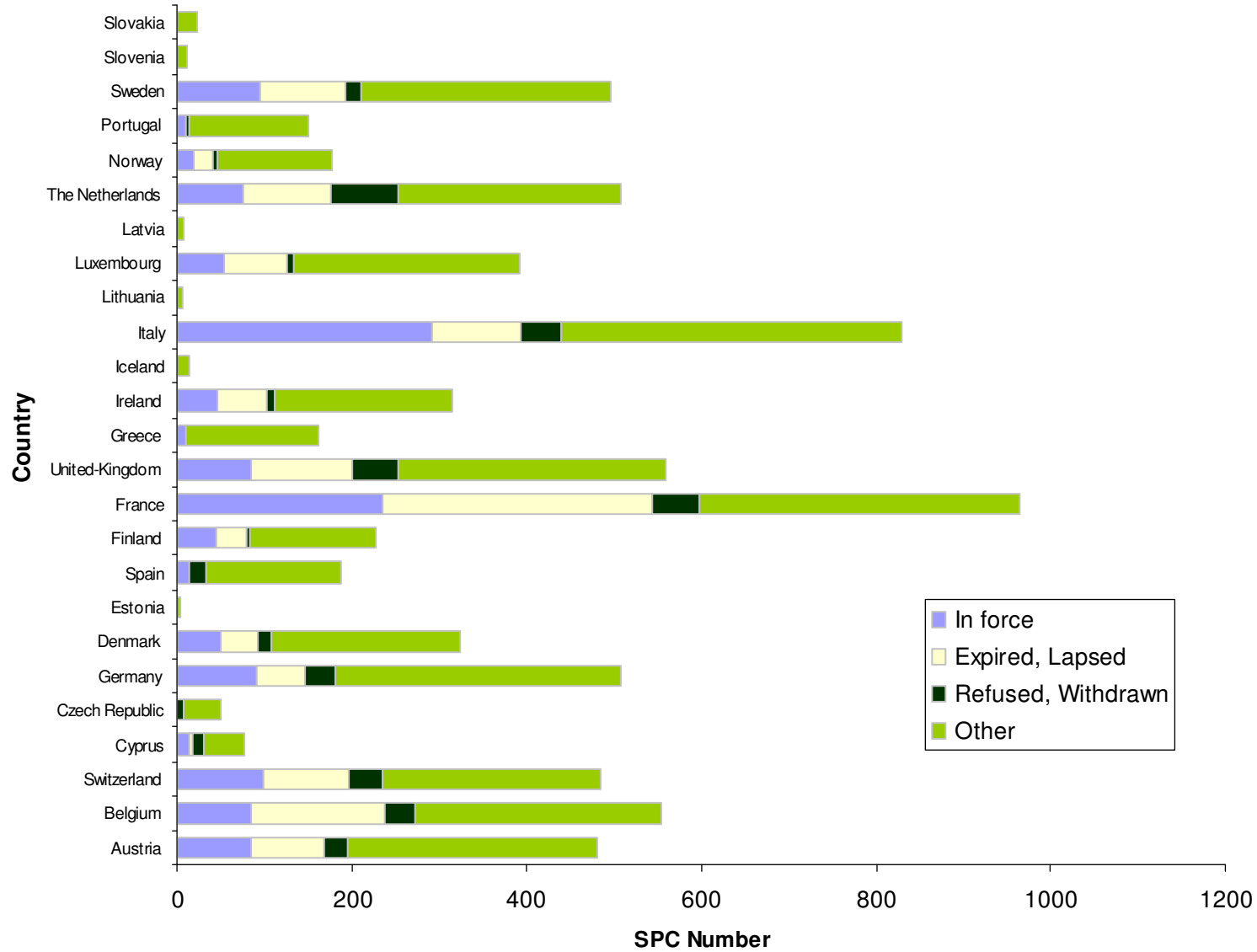
The SPC Regulation has direct effect throughout the EU but is administered by the different national patent offices, which can produce disparities in the application of the Regulation.

A major disparity in the economic effect comes from the transitional provisions, and from the National patent laws.

About 7,500 SPCs have been filed in Europe.

The figure below represents the number of SPCs sorted by country. For each country, is shown the number of SPCs, which were still in force, which were expired or lapsed, and which were withdrawn or rejected on January 1st 2004.

1991-2003 Medicinal Product SPCs



The figure below represents the number of SPCs sorted by country.
For each country is shown the number of SPCs regulated by National law and/or by EU regulation.

National and EU SPC 1991-2003

