



# EGA *fact sheet* on generic medicines



## Generic Medicines, Data Exclusivity and Patents

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A generic medicine can only be marketed once the patents and the supplementary protection certificates (SPCs) covering the originator product have expired. Data exclusivity also limits the time when a generic manufacturer can make an application for a marketing authorisation based on demonstrating bioequivalence with the originator product.

Patents are used to protect a product, process, apparatus or use that has a practical purpose. Registration provides a patentee the right to prevent anyone making, using, selling, or importing the invention for 20 years. Any given pharmaceutical product is typically protected by 20-40 different patents on various aspects and properties of the product.

Supplementary protection certificates (SPCs) grant up to five years of additional patent protection to pharmaceutical products. Additional market protection for the originator product may be generated by data exclusivity which prevents the medicines regulators from accepting an application for a marketing authorisation based on bioequivalence during a defined period.

The diagram below shows the application of data exclusivity as introduced by Directive 2004/27/EC. The “8+2 +1” formula applies to all new medicinal products where the application was submitted after 31 October 2005. In these cases generic medicines companies can apply for a marketing authorisation based on bioequivalence only after the 8-year data exclusivity period has expired, and can only market their products two or three years after that. The effective period of marketing exclusivity is therefore 10 or 11 years. The extra year applies when new indications (which have significant clinical benefit) are added by the originator during the first eight years of marketing the product.

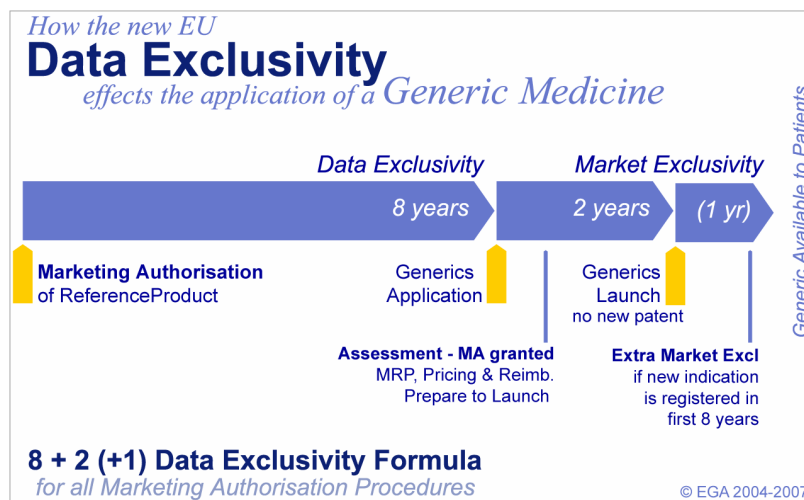
As this provision is prospective, these new data exclusivity provisions will not impact generic applications until after October 2013. Products for which the initial submission was made prior to transposition of the Directive (31 October 2005) continue to benefit from the previous periods of protection which are:

- **10 years** for national authorisations granted by: Belgium, Germany, France, Italy, the Netherlands, Sweden, United Kingdom, Luxembourg;
- **6 years** for national authorisations granted by: Austria, Denmark, Finland, Ireland, Portugal, Spain, Greece, Poland, Czech Republic, Hungary, Lithuania, Latvia, Slovenia, Slovakia, Malta, Estonia, Cyprus and also Norway, Liechtenstein and Iceland;
- **10 years** for all medicinal products authorised through the centralised procedure.

All combined, these measures give the EU the strongest IP protection for pharmaceuticals in the world.

### Pharmaceutical Properties Eligible for Patenting<sup>3</sup>

1980s	1990s
<ul style="list-style-type: none"> <li>■ Primary uses</li> <li>■ Processes and intermediates</li> <li>■ Bulk forms</li> <li>■ Simple formulations</li> <li>■ Composition of matter</li> </ul>	<ul style="list-style-type: none"> <li>■ Primary uses</li> <li>■ Processes and intermediates</li> <li>■ Bulk forms</li> <li>■ Simple formulations</li> <li>■ Composition of matter</li> <li>■ Expansive numbers of uses</li> <li>■ Methods of treatment</li> <li>■ Mechanism of action</li> <li>■ Packaging</li> <li>■ Delivery profiles</li> <li>■ Dosing regimen</li> <li>■ Dosing range</li> <li>■ Dosing route</li> <li>■ Combinations</li> <li>■ Screening methods</li> <li>■ Chemistry methods</li> <li>■ Biological target</li> <li>■ Field of use</li> </ul>



EU data exclusivity provisions affecting all applications for marketing authorisation submitted after 31 October 2005.

<sup>1</sup> Public Citizen, July 2001; The Lancet, vol. 358, 7 July 2001.

<sup>2</sup> According to the European Patent Office, in 2004 30% of all patents granted were totally revoked and 36.5% were “amended” (ie, partially revoked).

<sup>3</sup> “Evolution of IPR and Pharmaceutical Discovery and Development”, presentation by Eric Larson, Senior Director, Groton Site Head, Pfizer Global Research & Development (22 October 2001). Viewed on 24 May 2007 at: [www7.nationalacademies.org/step/Larson\\_ppt.ppt](http://www7.nationalacademies.org/step/Larson_ppt.ppt).

Formed in 1993, the EGA is the official representative body of the European generic pharmaceutical industry, which is at the forefront of providing high-quality affordable medicines to millions of Europeans and stimulating competitiveness and innovation in the global pharmaceutical sector.