

How to Calculate Data Exclusivity Periods in Europe

An application for approval of a New Chemical Entity must contain data to allow assessment of the safety and efficacy profile. These data include pharmacological and toxicological tests and the results of clinical trials.

To avoid repeating such tests and trials, applications for generic pharmaceutical substances are not required to include these data; instead they may rely on the data provided in relation to the NCE application. However, EC directive 2001/83/EC prevents regulatory authorities from accepting applications for approval of generics that rely on this data until a data exclusivity period has expired. This period starts on the day of the first marketing authorisation in the European Community (including Liechtenstein/Switzerland), and expires either six or ten years thereafter, depending on the country in which the application is to be filed and the procedure used to file it.

Data exclusivity relates to the active ingredient per se, new periods of data exclusivity are not applied to later approval of new dosage forms, routes of administration or indications.

1) To calculate the expiry of the data exclusivity period for **centralised applications** add 10 years to the corresponding European First Marketing Authorisation Date shown in the Pipeline Selector Report.

2) To calculate the expiry of the data exclusivity period for **national or mutual recognition procedure** applications, add the term from the following table to the corresponding European First Marketing Authorisation Date shown in the Pipeline Selector Report.

Exclusivity Period	Country
10 Years	Belgium (BE) France (FR) Germany (DE) Italy (IT) Luxembourg (LU) Netherlands (NL) Sweden (SE) United Kingdom (UK)
6 years	Austria (AT) Denmark (DK) Finland (FI) Greece (GR) Iceland (IS) Ireland (IRL) Norway (NO) Portugal (PT) Spain (ES) Other, acceding countries*

* Poland has a data exclusivity period of 3 years for approvals prior to 1/5/2004 and 6 years thereafter. Hungary, Slovenia, Slovakia and Malta have requested transitional data exclusivity periods.

New Data Exclusivity Provisions for Europe

A New Data protection directive (2004/27/EC) has been introduced in Europe, which provides eight years of protection from the first European Community marketing authorisation date, after which a European regulatory body may accept an application for approval of a generic. However, the product may not be marketed within ten years of the first European Community marketing authorisation date. An additional one year period of data exclusivity is allowed in respect of new indications with 'significant clinical benefit' over the existing indications. Approvals for other product line extensions, including different pharmaceutical forms, are regarded as a bundle of approvals for which only one data exclusivity period is available.

This new directive applies only to data relating to NCE products submitted for approval after 31 October 2005, hence do not affect any of the current Pipeline Patent Intelligence products.

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