

How to Calculate Standard Patent Expiry Dates and Data Exclusivity in Key Territories

Patent Expiry Dates

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Data Exclusivity

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How to Calculate Standard Patent Expiry Dates

DISCLAIMER: All expiry dates in GenericsWeb products are shown as the maximum full-term expiry date as calculated according to our understanding of the patent term calculation rules, and do not account for any applicable disclaimer(s). The material in this guide is intended only to provide a summary and general overview for calculating the term of patent. It does not constitute legal advice. You should seek legal or other professional advice before acting or relying on any of the content. In no circumstances will GenericsWeb, its agents or employees be liable for any special, consequential or indirect loss or damage arising from any use of or reliance on any material appearing in this guide. The information in this guide is liable to change and we do not guarantee its currency.

Please Note: the expiry calculation methods described below assume that no extensions have been applied to the patent in question and that it is maintained to achieve maximum term by payment of all necessary maintenance fees. National patent registers should be checked to ensure that maintenance fees have been paid and that the patent has not been extended, withdrawn, amended or revoked during this period.

For clarity, the following methodology will refer to the INID codes, which are the small numbers found on the front page of the patent. You will need to click on the patent number in the Pipeline Developer.

N.B. where a patent application is a divisional of another application the expiry date of the divisional is based on the application date of the parent application.

Australia (AU)

Add 20 years to application date shown on front page of patent (INID code 22) to obtain full-term expiry date.

National Register:

<http://pericles.ipaustralia.gov.au/ols/auspat/>

Canada (CA)

For patents based on applications filed before 01/10/1989 (INID Code 22 or 86): Add 17 years to patent issue date shown on front page of patent (INID code 45) to obtain first date, then add 20 years to application date shown on front page of patent (INID code 22 or 86) to obtain second date. The later of these two dates is the full-term expiry date. N.B. This does not apply to patents with an issue date (INID code 45) prior to 12/07/1984, all of which have now expired.

For patents based on applications filed on or after 01/10/1989 (INID Code 22 or 86): Add 20 years to application date shown on front page of patent (INID code 22 or 86) to obtain full-term expiry date.

National Register: <http://patents.ic.gc.ca/opic-cipo/cpd/eng/search/number.html>

Germany (DD/DE/EP)

For DD patents applied for before 01/07/1990 (INID Code 22):

Add 18 years to application date shown on front page of patent (INID code 22) to obtain full-term expiry date.

For DD patents applied for on or after 1/7/1990 (INID Code 22) & all DE/EP patents:

Add 20 years plus one day to application date shown on front page of patent (INID code 22) to obtain full-term expiry date. N.B. DD or DE patents now apply to both former East Germany and West Germany.

N.B. to check the designated states of EP patents refer to the EPO patent register by clicking on the EP patent status from the Pipeline Developer 'patent detail' window.

National Register: https://dpinfo.dpma.de/index_e.html (Free registration required)

Spain (ES/EP)

For patents applied for before 26/06/1986 (INID Code 22):

Add 20 years to grant date shown on front page of patent (INID code 45) to obtain full-term expiry date.

For patents applied for on or after 26/06/1986 (INID Code 22):

Add 20 years to application date shown on front page of ES or EP patent (INID code 22) to obtain full-term expiry date.

N.B. to check the designated states of EP patents refer to the EPO patent register by clicking on the EP patent status from the Pipeline Developer 'patent detail' window.

National Register: <http://sitadex.oepm.es/ServCons/SitJurExpGra>

France (FR/EP)

Add 20 years to application date shown on front page of patent (INID code 22) to obtain full-term expiry date.

N.B. to check the designated states of EP patents refer to the EPO patent register by clicking on the EP patent status from the Pipeline Developer 'patent detail' window.

National Register: <http://regbrvfr.inpi.fr/portal/>

United Kingdom (UK/EP)

Add 20 years to application date shown on front page of patent (INID code 22) to obtain full-term expiry date.

Extensions (maximum 5 years) are allowed for pharmaceutical patents in this country.

N.B. to check the designated states of EP patents refer to the EPO patent register by clicking on the EP patent status from the Pipeline Developer 'patent detail' window.

National Register: <http://www.ipo.gov.uk/patent/p-find/p-find-number.htm>

United States of America (US)

For patents based on applications filed before 08/06/1995 (INID Code 22):

Add 17 years to patent issue date shown on front page of patent (INID code 45) to obtain first date (take note of any terminal disclaimer or extension or adjustment to the patent term denoted by an asterisk and also published below the 'Assignee' information (INID code 73); for reissued patents see below). Next add 20 years to the application date of the earliest related application shown on the front page of patent (INID codes 62 or 63) to obtain second date (note provisional applications (INID code 60) are disregarded in the calculation). The later of these two dates is the expiry date. Add any applicable extensions or adjustments to the patent term, and then account for any terminal disclaimers to obtain the full-term expiry.

For patents based on applications filed on or after 08/06/1995 (INID Code 22):

Add 20 years to the date of the earliest related application shown on front page of patent (INID codes 62 or 63) to obtain the expiry date (note provisional applications (INID code 60) are disregarded in the calculation). Add any applicable extensions or adjustments to the patent term, and then account for any terminal disclaimers to obtain the full-term expiry.

National Register: <http://portal.uspto.gov/external/portal/pair>

For a more detailed description of how to calculating US expiry dates [click here](#).

How to Calculate Data Exclusivity

How to Calculate Data Exclusivity Periods in Australia

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, in Australia a 5 year data exclusivity period for new products containing pharmaceutical actives approved after 17 April 1998 was established by the Therapeutic Goods Amendment Act 1998. The data exclusivity period begins on the date of marketing approval and extends for five years, during which time the TGA may not accept applications for approval of generics that rely on these data.

Data exclusivity is only provided in relation to new active components that have not previously been included in the Australian Register of Therapeutic Goods. Data exclusivity is not provided for new dosage forms, routes of administration, indications or combinations with other active ingredients.

To calculate the expiry of the data exclusivity period in Australia, add 5 years to the corresponding Australian First Marketing Authorisation Date.

How to Calculate Data Exclusivity Periods in Canada

An application for approval of a New Chemical Entity must include evidence 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.

In Canada a 5-year data exclusivity period for new products containing pharmaceutical actives was introduced in 1995 through amendments to the Food and Drug Regulations. However, on 5th October 2006 new regulations were introduced to extend this period of data exclusivity. As such the data exclusivity periods that apply to a particular pharmaceutical active ingredient in Canada depend on the Canadian first authorisation (NOC) date of a product containing it.

Active Ingredients Contained in Products First Authorised prior to 17th June 2006

For these products, the data exclusivity period begins on the date of marketing approval and extends for five years, during which time Health Canada will not issue a notice of compliance to a generic product that relies on these data.

Data exclusivity is only provided in relation to approval of new active components that have not previously been approved by Health Canada. Data exclusivity is not provided for new dosage forms, routes of administration, indications or combinations with other active ingredients.

To calculate the expiry of the data exclusivity period for products authorised prior to 17th June 2006 in Canada, add 5 years to the corresponding Canadian First Marketing Authorisation Date.

N.B. In practice, Canada had not implemented its previous data protection legislation in a manner that automatically prohibits this type of reliance for a minimum period of time. Data protection does not arise where bioequivalence forms the basis of a generic submission and data protection under previous legislation is rarely, if ever, triggered. As a result, drugs in Canada sometimes receive less than five years of data exclusivity under the old legislation, as affirmed by the Federal Court of Appeal in Bayer Inc. v. Canada (Attorney General), 87 C.P.R. (3d) 293.

Active Ingredients Contained in Products First Authorised on or after 17th June 2006

For these products Canada provides for a six-year period where applications for authorisation of a generic are not permitted to be submitted*. This will be followed by a no-marketing period of two years during which a notice of compliance will not be granted to the generic manufacturer. In addition, a further six months of data exclusivity will be added to the 8-year term for active ingredients that have been the subject of paediatric studies designed and conducted with the purpose of increasing knowledge about the use of the drug in paediatric populations.[†]

Additional terms of data protection are not available for salts, esters, enantiomers, solvates or polymorphs of a previously authorised active ingredient, or combinations thereof with other active ingredients.

To calculate the earliest authorisation date based on expiry of the data exclusivity period for products authorised on or after 17th June 2006 in Canada, add 8 years to the corresponding Canadian First Marketing Authorisation Date, plus another 6 months if paediatric extension has been granted. To calculate the earliest date for filing a generic application, add 6 years to the corresponding Canadian First Marketing Authorisation Date.

*An exception to this provision is required to allow for the filing of drug submissions within the framework of the Jean Chrétien Pledge to Africa Act ("JCPA Act")

† In November 2006, Canada's Generic Pharmaceutical Association launched a legal action challenging these amendments. In July 2009, a decision on this matter was handed down in the Federal Court of Canada which upheld the constitutional validity of the new Data Protection Regulations. See <http://www.canadiangenerics.ca>.

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.

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.

| 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) Bulgaria (BG) Cyprus (CY) Czech Republic (CZ) Denmark (DK) Estonia (EE) Finland (FI) Greece (GR) Hungary (HU) Iceland (IS) Ireland (IRL) Latvia (LV) Lithuania (LT) Malta (MT) Norway (NO) Poland (PL)* Portugal (PT) Romania (RO) Slovakia (SK) Slovenia (SI) Spain (ES) |

* Poland has a data exclusivity period of 3 years for approvals prior to 1/5/2004 and 6 years thereafter.

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.

To calculate the earliest authorisation date based on expiry of the data exclusivity period for products submitted for approval after 20th November 2005 in Europe, add 10 years to the corresponding European First Marketing Authorisation Date, plus another 1 year if a new indication has been approved. To calculate the earliest date for filing a generic application, add 8 years to the corresponding European First Marketing Authorisation Date.

How to Calculate Data Exclusivity Periods in the USA

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, on 24th September 1984 the Hatch-Waxman Act established a 5 year data exclusivity period in the USA for new drug applications for products containing chemical entities never previously approved by FDA either alone or in combination with other chemical entities.

The data exclusivity period begins on the date of marketing approval and extends for five years, unless the application contains a certification of patent invalidity or non-infringement (Paragraph IV filing), in which case it extends for four years. During this period the FDA may not accept 505(b)2 applications or ANDAs for approval of drug products that rely on these data. To calculate the expiry of the NCE data exclusivity period in the USA, add 5 years to the corresponding USA First Marketing Authorisation Date.

In addition to the above exclusivity provisions, a 3 year data exclusivity period was also established by the Hatch-Waxman Act for supplementary applications in relation to a chemical entity that has been previously approved, where the application contains reports of new clinical investigations (excluding bioavailability studies). Effectively, changes in an approved drug product that affect its active ingredient(s), strength, dosage form, route of administration or conditions of use may be granted this exclusivity if they meet the clinical investigations criteria of a) having not been previously relied upon by the FDA for approval of a product and b) do not duplicate the results of such an investigation. To calculate the expiry of the supplementary data exclusivity period(s) in the USA, use the dates shown in the FDA Orange Book website for the originator product available at <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>.

In addition to the above exclusivity provisions, the Food and Drug Administration Modernization Act (FDAMA) was legislated on 21st November 1997, and introduced a 6 month period that can be added to any existing data exclusivity or patent protection on a drug for which FDA has requested paediatric studies and the manufacturer has conducted such studies in accordance with the requirements of the Act. This period would usually be added to the patent term as this is likely to afford more significant benefits to the manufacturer, but should be considered as a possibility when calculating exclusivity periods.

In addition to the above exclusivity provisions, the Hatch-Waxman act provides an incentive of 180 days of market exclusivity to the "first" generic applicant to challenge an Orange Book listed patent by filing a substantially complete ANDA containing a paragraph IV certification and running the risk of having to defend a patent infringement suit. The beginning of this period is difficult to determine in advance due to the possibility of it being 'triggered' by the first of two events, being the first commercial marketing of the generic product or the date of a court decision finding the patent invalid, unenforceable or not infringed.

Source FDA: www.fda.gov

Please contact GenericsWeb if you have any questions in using this guide, or would like to speak to a representative about purchasing our products, in which all patent, SPC and data exclusivity calculations have been calculated for you.

Asia-Pacific:

Genericsweb Pty Ltd

Level 7, 503-505 Kent Street
Sydney NSW 2000
Australia

T: +61 (0)2 9262 7696

F: +61 (0)2 9262 7636

E: info@genericsweb.com

Europe:

Genericsweb (Europe) Ltd

The Oriel, 185 Bath Road
Slough SL1 OEY
United Kingdom

T: +44 (0)870 879 0081

F: +44 (0)870 879 0082

E: info-eu@genericsweb.com

North America:

Genericsweb (North America) Inc

55 Madison Avenue – Suite 400
Morristown, NJ 07960
USA

T: +1 (888) 3100774

F: +1 (888) 3100775

E: info-us@genericsweb.com