Data Exclusivity for Drugs in Canada, the U.S. and Europe

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Data exclusivity (also called data protection) protects an innovative company that first developed a drug and spent a lot of money on clinical trials and regulatory approvals. The exclusivity blocks subsequent drug developers from referencing (comparing to) the innovative drug’s data in order to take a shortcut to get marketing authorization. The subsequent drug developers are generic drug manufacturers or biosimilar manufacturers. Without data exclusivity, a subsequent developer could potentially get its marketing approval on the heels of the initial drug approval, and undercut on price because it didn’t have to undergo R&D or significant clinical trial expenses\(^1\). Protecting the innovative company allows it to recoup drug development expenses, and hopefully put part of its profit back into more innovative research. Data exclusivity is time limited, and varies between countries. This article compares data exclusivity in Canada, the U.S. and Europe.

**Canada**

Canada currently provides eight years of data protection for an innovator drug\(^2\). This data exclusivity period applies to both biologics and conventional small molecule pharmaceuticals. A manufacturer may not file a drug submission

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\(^1\) Patents are another important protection for innovator drugs against competition, but they are a statutory monopoly to make, use and sell an invention, not a regulatory exclusivity. Another exclusivity is orphan drug exclusivity, in the U.S. and Europe, for rare diseases, which will not be addressed in this article.

\(^2\) *Food and Drug Regulations*, section C.08.004.1, C.R.C., c. 870. Drug products authorized prior to June 17, 2006 receive a five-year data exclusivity period (*Food and Drug Regulations*, section C.08.004.1(1), C.R.C. 1978, c. 870).
referencing an innovator drug within six years of the initial authorization of the innovator drug. This completely blocks comparisons to the innovator drug. Comparisons may be made in a drug submission after six years. However, there remains an additional two-year period that applies before generic or biosimilar marketing authorization can be granted. Where clinical trials relating to the use of the drug in pediatric populations have been conducted, an additional six months of exclusivity may be added to the eight-year term.

A biosimilar drug or generic drug does not qualify as an “innovator drug” and therefore cannot itself benefit from data protection or other regulatory exclusivity against other subsequent products. There is also no market exclusivity for the first approved generic drug or biologic drug against subsequent drugs.

**Europe**

Current European regulations provide eight years of data exclusivity for drugs, running from the first marketing authorization date. No biosimilar or generic drug submission for marketing authorization may be submitted during this time. This means that no regulatory review may be conducted during the eight year data exclusivity period. Data exclusivity is followed by a two year market exclusivity period\(^3\). This is similar in principle to the Canadian system, although the

\(^3\) Directive 2001/83/EC, as amended by Directive 2004/27/EC, Art. 10.1. See also, EMEA, EMA procedural advice for users of the centralized procedure for generic/hybrid applications (EMEA/CHMP/225411/2006), Jan. 2011 at page 17. This harmonized regulatory exclusivity applies to reference products applying for marketing authorization since November 2005 and to all member states unless the member state has been granted derogation. Formerly, products approved through the centralized procedure received 10 years of data exclusivity (Directive 2001/83/EC).
terminology and time periods are different. The cumulative ten-year period may be extended for an additional year with respect to certain new indications that have significant clinical benefit over prior indications. Regardless of when the subsequent drug is approvable, it cannot be marketed until after year 10 or 11.

Europe does not provide data protection or other regulatory exclusivity for approved biosimilars or generic drugs to block subsequent drugs.

**United States**

There is U.S. data exclusivity for the first approved, innovator biologic drug. As in Canada and the EU, a biosimilar or generic drug will typically not be approved on an abbreviated basis unless the FDA can access the innovator’s data. For biologics, the exclusivity term provided by the *Biologics Price Competition and Innovation Act* (*BPCI Act*) is 12 years from the date the reference product was first licensed\(^4\,\,^5\). An additional 6 months of exclusivity may apply to biologics for use in

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\(^4\) Approval of a biosimilar application is not effective until 12 years after the date on which the reference product was first licensed. In addition, an application under the *BPCI Act* may not be submitted until 4 years after the date on which the reference product was first licensed. *Public Health Service Act*, § 351 (k)(7), as added by the *BPCI Act*.

pediatric populations. By comparison, under the Hatch-Waxman Act, a five-year data exclusivity period applies to conventional small-molecule generic drugs. The five-year term may be extendable by six months where pediatric studies have been conducted.

The U.S. also has special market exclusivity provisions for the first approved interchangeable biological product, to block future subsequent products. This is intended as an incentive for subsequent product manufacturers to try to get their products approved as soon as possible. No data protection is available for a biosimilar or generic drug.

Conclusion

Data protection can be a very important protection for innovator drug manufacturers to maintain market exclusivity. It should be used in conjunction with patents, with a particular focus on which exclusivity can last longest.

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6 Public Health Service Act, § 351 (m)(2).
8 The length of market exclusivity varies between 12 and 42 months, depending on factors such as whether or not patent litigation is ongoing. Public Health Service Act, § 351(k)(6).