Potential Increase to Canadian Biologic Drug Data Protection Scratched from USMCA Free Trade Deal

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It is important for innovative drug companies to take advantage of available exclusivities, to ensure that they can recoup investment from the costly drug development process. A recent analysis of a snapshot of the Canadian market showed that both patents and data exclusivity were important as the potential last line of defence against generic and biosimilar drug competition[1].

Canada presently 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 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.

As noted above, Canada currently provides eight years of data protection for a *biologic* innovator drug. The United States provides 12 years of data protection. The term of data protection for biologics has been a matter of debate during negotiations between the United States, Canada and Mexico to modernize the 24 year old North American Free Trade Agreement ("**NAFTA**").

A draft of the renegotiated NAFTA was published on October 1, 2018 under the new title of the United States-Mexico-Canada Agreement ("**USMCA**"; the "**Agreement**"). Article 20 of the draft agreement related to intellectual property matter and included a data protection period for a new pharmaceutical product containing a biologic of at least ten years (Article 20.49). Also provided was a minimum definition of biologics to include biotechnological products that are or contain a virus, therapeutic serum, toxin, antitoxin, vaccine, blood component or derivative, allergenic product, protein or analogous products.

Innovator companies were happy to see the proposed extension of the Canadian data protection term for biologics from 8 years to 10 years (the United States, which already has 12 years of protection would not be required to change their laws)[3].

However, following further negotiations in December of 2019, amendments to the Agreement were agreed to by the United States, Canada and Mexico. Among the amendments to the October 1, 2018 draft was a deletion of Article 20.49 (Biologics). The deletion removes any reference to the term of data protection from the Agreement. As such, no change to Canada's data protection regime will be required should the current version of the Agreement be ratified.

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1 Noel Courage and Phil Goldbach. "Identifying the Last Line of Defence for Innovative Canadian Drugs." Biotechnology Focus. June/July 2017.

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).

3 Mexico does not currently have any data protection for biologics.