In a joint statement on September 30, 2018, the United States and Canadian Governments announced that they reached an agreement, alongside Mexico, on a new, modernized trade agreement for the 21st century. The pending trilateral deal, called the United States-Mexico-Canada Agreement (USMCA), is intended to replace the North American Free Trade Agreement (NAFTA) currently in force.

The text of the USMCA was published on the Office of the United States Trade Representative website shortly after the formal agreement was announced. The deal includes updated provisions governing the protection and enforcement of intellectual property (IP) rights which, if ratified, will modify the legal and regulatory landscape for the pharmaceutical industry in Canada, notably in the field of biologics. The following is a summary of what is new and what will likely remain the same after the USMCA comes into force.

**What's new?**

**Data Protection - Biologics**

*Current Data Protection Regime*

The current data protection regime in Canada provides legal protection to "innovative drugs" from generic competition for a period of eight years though the protection of innovator data.
Canadian law currently defines an "innovative drug" as one that contains a new medicinal ingredient not previously approved in a drug by the Minister and that is not a variation of a previously approved medicinal ingredient (e.g. a salt, ester, enantiomer, solvate, or polymorph).

This definition of innovative drugs includes both biologic and non-biologic drugs.

In the first six years of data protection, a generic manufacture cannot file a drug submission making a direct or indirect comparison to the innovator's data. In the last two years, a drug submission may be filed but the approval cannot issue until the expiry of the eight-year term. Drugs that qualify for data protection are listed on Health Canada's Register of Innovative Drugs.

Data Protection for Biologics under the USMCA

Under the USMCA, Canada has agreed to extend the term for data protection for new pharmaceutical products that contain a biologic from eight years to at least ten years. The text of the USMCA defines a biologic as a product that, at minimum, is "produced using biotechnology processes and that is, or, alternatively, contains, a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, for use in human beings for the prevention, treatment, or cure of a disease or condition".

The minimum ten-year period will run from the date of first marketing approval of that product in the relevant country.

Patent Term Extension - Patent Granting Authority Delays

The patent term extension provisions of the USMCA provide for an adjustment to a patent term for delays owing to the patent granting authority. However, Canada does not currently provide for patent term adjustment for "unreasonable" delays in the issuance of a patent by the Patent Office. At this time there is no indication of how long the patent term will be extended over such delays.

What will likely remain the same?

Data Protection - Non-Biologics

i. New Pharmaceutical Products
The USMCA prohibits generic manufacturers from referencing undisclosed test or other data concerning safety and efficacy of "new pharmaceutical products" for at least five years from the date marketing approval was first granted. Canada's existing regime appears to surpass the minimum outcomes agreed to under the USMCA.

ii. Previously Approved Pharmaceutical Products

The USMCA also contains a provision for at least three years of data protection for new clinical information submitted for a previously approved pharmaceutical product covering a new indication, formulation, or method of administration. However, in a footnote the USMCA provides that if a Party already provides eight years of data protection pursuant to a new pharmaceutical product, which Canada offers, such data protection is optional.

**Patent Term Extensions - Regulatory or Marketing Approval for Pharmaceutical Patent Delays**

The patent term extension provisions of the USMCA also provide for an adjustment due to "unreasonable curtailment" of a patent term for regulatory or marketing approval for pharmaceutical patents. Since the implementation of the Canada-European Union Comprehensive Economic and Trade Agreement (CETA), Canada already provides up to two years of patent term adjustment as a result of the pharmaceutical marketing approval process.

**Patentable Subject Matter**

According to the text of the USMCA, patents must be granted for inventions that are new, non-obvious, and useful. Eligible exclusions for patentable subject matter are: (1) diagnostic, therapeutic, and surgical methods of treatment in humans or animals; (2) animals and plants, other than microorganisms; and, (3) essentially biological processes for the production of plants or animals.

**Patent Linkage and Early Working Exception**

The USMCA includes provisions analogous to Canada's early working exception and regulatory regime for challenging pharmaceutical patents under the Patented Medicines (Notice of Compliance) Regulations. However, no major changes to the Regulations are expected as a
result of the USMCA.

**When can we expect these changes?**

The USMCA does not yet have the force of law. Before coming into force, the agreement will have to be ratified by each country.

Once the USMCA is in force, Canada will have five years to implement its obligations with respect to the ten-year data protection term for biologics and four and a half years to implement its obligations with respect to patent term adjustments for unreasonable granting authority delays.[17]


[5] USMCA, supra note 2, Art 20.F.14.1 (a new pharmaceutical product is defined as a pharmaceutical product that does not contain a chemical entity that has been previously approved in the applicable country).


[8] Ibid, Art 20.F.9 (under the USMCA, unreasonable delays are defined as more than five years from the date of filing of the application or three years after a request for examination of the application has been made, whichever is later).

[9] Ibid, Art 20.F.13.1 (the USMCA defines a "new pharmaceutical product" at Art 20.F.15 as a pharmaceutical product that does not contain a chemical entity that has been previously approved in the applicable country).

[10] Since the USMCA defines a "new pharmaceutical" product as one that does not contain a chemical entity that has been previously approved in the applicable country, these products appear to fall within the definition of "innovative drug" in Canada.
Certificate of Supplementary Protection Regulations, SOR/2017-165 (Canada has implemented this commitment by introducing Certificates of Supplementary Protection (CSPs) for medicinal ingredients, applicable for Canadian pharmaceuticals, biologics, and veterinary drugs).

USMCA, supra note 2, Art 20.F.1.1.

Ibid, Art 20.F.1.3.

