

DATA PROTECTION IN CANADA: THE SIX-MONTH PEDIATRIC EXTENSION

16 April 2019

Innovative drugs in Canada are granted data protection, preventing generic competition for a period of eight years following their initial approval. This period can be extended for an additional six months if the innovative drug manufacturer generates data related to the drug's use in a pediatric population prior to the fifth anniversary of the initial drug approval.

It is prudent to consider conducting pediatric studies with respect to innovative medicines as part of lifecycle planning.

Data protection in Canada

Innovative drugs are drugs that contain a new medicinal ingredient not previously approved and which is not a variation of a previously approved medicinal ingredient (e.g. a salt, ester, enantiomer, solvate, or polymorph).^[1]

As part of any new drug submission, undisclosed clinical and non-clinical data must be submitted to Health Canada. Innovative drugs are granted data protection, which prevents generic drug manufacturers from relying on this undisclosed data.

Innovative drugs are listed on the Register for Innovative Drugs, maintained by the Minister of Health (the "Minister").^[2] Data protection applies to both biologic and conventional small molecule drugs.^[3]

Once registered, generic manufacturers are prevented from filing a drug submission that makes a direct or indirect comparison to the innovator's undisclosed data for a period of six years (the "no file" period). Following the 6-year "no file" period, generic manufacturers are precluded from receiving drug approval for an additional 2 years (the "no approval"

period), culminating in eight years of data protection.

The six-month pediatric data extension

In addition to the eight-year data protection period, a six-month pediatric extension may be available.

The pediatric data extension can be obtained through inclusion of pediatric data as part of a new drug submission or any supplement to the new drug submission, to update the Product Monograph. An update to the product's indication is not necessarily required. To qualify, the innovative drug manufacturer must apply for the six-month extension prior to the fifth anniversary from the initial approval.

Requirements to obtain the pediatric extension

The innovator must submit the description and results of clinical trials relating to the use of the innovative drug that were "designed and conducted for the purpose of increasing knowledge about the use of the drug" in relevant pediatric populations and which would provide a "health benefit" for children.^[4]

Relevant Populations

The clinical trials must have been conducted in at least one three groups: (1) premature babies (born prior to 37th week of gestation); (2) full-term babies (age 0-27 days); and (3) children (28 days – 18 years of age). However, to obtain the six-month extension, a clinical trial does not need to involve patients whose ages span the entire group. For example, the innovator may only choose to study patients between the ages of 10 and 18.

The Type of Data Required for the Pediatric Extension

There is no requirement that the clinical trials submitted for the pediatric extension be a certain phase study or include a particular number of patients.

The Food and Drug Regulations, considers a "clinical trial" an "investigation in respect of the drug for use in humans that involves human subjects and that is intended to discover or verify the clinical, pharmacological or pharmacodynamic effects of the drug, identify any adverse events in respect of the drug, study the absorption, distribution, metabolism and excretion of the drug, or ascertain the safety or efficacy of the drug".^[5]

Designed and conducted for the purpose of increasing knowledge

The six-month extension is intended to encourage innovative drug manufacturers to submit clinical trial data pertaining to the use of the drug in pediatric populations in order to maximize the information available for the benefit of children.

For the purpose of receiving the six-month extension, pediatric studies must result in increased knowledge that can assist individuals in making informed choices about drug therapy. It is not necessary that the published information results in an indication in the population studied. For example, the addition of contraindications and/or other warning statements may be sufficient to warrant the granting of the six-month pediatric extension. The knowledge generated must however be publically available to provide a health benefit, such as through the approved labelling or the Product Monograph.

A number of products listed on the Register of Innovative Drugs have obtained the pediatric extension (even those with limited pediatric data). For example:

- TOVIAZ is not indicated nor contraindicated for use in pediatric patients. TOVIAZ was studied in one Phase II study with 21 patients aged 9-17.
- JEVTANA is not indicated nor contraindicated for use in pediatric patients. JEVTANA was studied in one Phase I/II study with 39 patients aged 3-18.
- TREANDA is not indicated nor contraindicated for use in pediatric patients. TREANDA was studied in one Phase I/II study with 42 patients aged 1-19.
- DOTAREM is indicated for use in pediatric patients. DOTAREM was studied in 185 patients aged 0 months-17 years old in Phase III and IV studies.

As of March 2019, nearly one third of the 269 drugs with active data protection periods on the Register of Innovative Medicines have been granted the six-month pediatric extension.

Pediatric extensions in foreign jurisdictions

Obtaining a pediatric extension in Canada can be contrasted to obtaining it in Europe and the US.

In Europe, applicants must include in their marketing authorization application, data on their product's use in children resulting from an agreed-upon pediatric investigation plan. However, orphan-designated medicines (medicines intended for the diagnosis, prevention or treatment of very serious conditions that affect no more than 5 in 10,000 people) that are studied in pediatric populations can obtain an additional two year extension for data protection in Europe. In Canada there is no additional data protection for orphan-designated medicines.

To qualify for a six-month pediatric extension in the US, a sponsor with an approved New Drug Application for a particular "active moiety" must conduct a pediatric study in response to a "Written Request" from the Food and Drug Administration for a study to evaluate the pediatric effectiveness and safety of the active moiety. The Written Request describes in detail the studies needed and the time frame for their completion. Similar to Canada, the six month exclusivity takes on characteristics of the existing exclusivity.

Conclusion

Drug manufacturers should be cognizant of the 5-year horizon for any pediatric data submission in relation to an innovative drug listed on the Register.

While the requirements to obtain a pediatric data extension in Canada differ than the EU and US, the 5-year time horizon can at times be an impediment to obtaining the extension even if large-scale clinical trials are planned. When manufacturers are planning globally to generate data for pediatric use, and potentially obtaining a pediatric data protection extension, manufacturers should plan to have data available prior to the fifth year anniversary.

Footnotes

[1] Food and Drug Regulations, CRC c 870, C.08.004.1.

[2] Health Canada, Register of Innovative Drugs, online: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/register-innovative-drugs/register.html>.

[3] Once the United States-Mexico-Canada Agreement is in force, Canada will extend the term for data protection for new pharmaceutical products that contain a biologic from eight years to at least ten years which will run from the date of first marketing approval of that product in Canada.

[4] Food and Drug Regulations, CRC c 870, C.08.004.1(4).

[5] Food and Drug Regulations, CRC c 870, C.05.001.


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Related Life Sciences, Intellectual Property

Authors

Cole Meagher

Associate - Ottawa

 Email

cole.meagher@gowlingwlg.com

 Phone


+1 613-786-3248

 vCard

Cole Meagher

Jenny Thistle

Associate - Ottawa

 Email

jenny.thistle@gowlingwlg.com

 Phone

+1 613-786-0272

 vCard

Jenny Thistle