



Canada's public drug plans spend over \$18 Billion¹ annually to provide comprehensive drug coverage for eligible Canadians. As it stands today, there is no preference in public drug plan formularies for Canadian-made medicines, even though governments at the federal, provincial and territorial level have all committed to "Buy Canadian".

Why not drugs too?

By directing procurement to domestic pharmaceuticals, the F/P/T drug budgets can ensure demand for Canadian-made medicines, particularly generic and biosimilar products. Harnessing their spending power, Canadian public payers can support local production and reduce dependency on imported medicines without incurring any additional cost.

Market-based policies to establish sustainable and reliable demand will give Canadian pharmaceutical manufacturers business confidence and predictability to justify investments in expanding production and improving productivity.

"Canada First" Formulary Exclusivity

When a new off-patent medicine is launched, a six-month period of exclusivity on provincial formularies will be provided for Canadian producers.

Price will be determined by the pCPA Tiered Pricing Framework (TPF)

- Price will be determined according to the total number of suppliers in the market, including importers
- This is completely cost neutral to payers - their cost is the same based on the total number of suppliers in the market – but only Canadian producers are listed for the first six months.

Definition of "Canadian Producer":

- At least 30% of manufacturer's gross revenue generated through the sale of drug products manufactured in Canada.
- For a DIN to contribute towards the value of gross sales manufactured in Canada, the finished goods must be manufactured in Canada, with substantial transformation of the product having occurred in Canada.
- Packaging of finished goods manufactured outside of Canada should not count towards the value of gross sales manufactured in Canada.

¹ [CIHI](#)

Verification:

- Manufacturers will be required to provide sales and manufacturing data as evidence satisfactory to the pCPA or Provincial Drug Plan Manager/Executive Officer
- May require minor amendments to provincial regulations including a definition of “Canadian manufacturer.” (see attached)

Impact on Canadian producers:

- A “Canada First” procurement policy will improve market conditions and reduce investment risk. Canadian pharmaceutical producers have been reluctant to build additional inventories and production capacity due to the extremely low margins for produce generic medicines and the unreliability imported supply.
- This policy also creates opportunity for Canadian Contract Manufacturers to pick up business from importers to qualify as “Canadian Producers”.

This is not a new idea; many government agencies in Canada already target procurement to Canadian suppliers of goods and services. The Ontario government has initiated a government procurement program specifically aimed at supporting domestic companies.

Other countries often use public procurement to support domestic industries and build resilience while lessened dependence on imports especially for critical products like pharmaceuticals. In this uncertain trade environment, having a stable and secure source of domestic pharmaceutical production is essential to national security.

APPENDIX

Regulatory Amendments to the Regulations under the Ontario Drug Benefit Act

The intent of the proposal is to grow and sustain domestic pharmaceutical manufacturing in Ontario, particularly in a time of global economic uncertainty, by providing a brief period of exclusivity on the formulary when listing generic products made by domestic manufacturers for newly launched generic categories.

Proposed amendments to the Regulations under the Ontario Drug Benefit Act, including a definition of “Canadian Manufacturer”, are provided below for the Government of Ontario’s consideration.

Proposed Regulatory Amendments

1. Subsection 11(1) of the Regulation is amended by adding the following paragraph:

5. The manufacturer of the product shall, if it seeks to be recognized as a Canadian Manufacturer, provide evidence satisfactory to the executive officer as to its operation of manufacturing facilities in Canada, its total revenue from the sale of drug products in Canada, and its total revenue from the sale of drug products in Canada fabricated in Canada.

2. The Regulation is amended by adding the following section:

11.1. (1) A strength and dosage form of a product submitted by a manufacturer other than a Canadian manufacturer shall not be designated as a listed drug product if there is a strength and dosage form of the product submitted for designation by a Canadian manufacturer prior to the submission by the manufacturer other than a Canadian manufacturer.

(2) For the purposes of subsection (1), a submission by a Canadian manufacturer shall be deemed to be submitted prior to a submission by a manufacturer other than a Canadian manufacturer in the event that both submissions are received in advance of a deadline established by the executive officer for the purposes of receiving such submissions, regardless of the order in which the submissions are received.

(3) Subsection (1) does not apply if,

i. six months have elapsed since the date that the strength and dosage form of the product of the Canadian manufacturer that was first designated as a listed drug product was designated;

ii. if the first designated strength and dosage form of the listed drug product is the product of a manufacturer other than a Canadian manufacturer; or

iii. the Canadian manufacturer ceases to supply the listed drug product or, if there is more than one prior Canadian manufacturer, each of the Canadian manufacturers ceases to supply the listed drug product.

(4) “Canadian manufacturer” means,

i. a manufacturer that operates one or more finished goods manufacturing facilities in Canada; and

ii. at least 30 percent of the manufacturer’s gross revenue from the sale of drug products in Canada is generated through the sale of drug products manufactured in Canada