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Tariffs, Pricing and Onshoring

The consequences of U.S. Section 232 pharmaceutical measures, most-favoured-nation pricing and onshoring agreements for Canadian and Quebec contract research and contract development and manufacturing organizations

100% Default Section 232 rate on Canadian-origin patented drugs and APIs

15% Negotiated rate for the EU, Japan, South Korea and Switzerland

0% Rate for the United Kingdom under its pricing arrangement

AUTHOR



Laurent Lecanu

POSITION

Head of Life Science Cluster North America, Leyton

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ABOUT THE AUTHOR

Laurent Lecanu

Head of Life Science Cluster North America, Leyton

OVERVIEW

/ Abstract

On 2 April 2026 the United States invoked Section 232 of the Trade Expansion Act of 1962 to impose tariffs of up to 100% on imported patented pharmaceuticals, their active pharmaceutical ingredients (APIs) and key starting materials. The measure became fully applicable to all importers on 29 September 2026. It operates alongside two company-level instruments: most-favoured-nation (MFN) drug pricing agreements negotiated with the Department of Health and Human Services, and onshoring agreements negotiated with the Department of Commerce. This paper examines how the three instruments, taken together, affect Canadian and particularly Quebec contract research organizations (CROs) and contract development and manufacturing organizations (CDMOs), now and over the period to 2030.

We find that **the immediate, direct impact on the sector is narrower than the headline 100% rate suggests**, because generics, clinical and research materials, products of companies holding MFN and onshoring agreements, and certain specialty products are exempt or zero-rated. However, Canada obtained none of the preferential treatment granted to the European Union, Japan, South Korea, Switzerland or the United Kingdom, and the U.S. rule that a drug's origin follows its API places Canadian API producers in the most exposed position. More importantly, **the combination of tariffs with MFN and onshoring commitments is redirecting future commercial manufacturing toward the United States** and is making Canada, a reference country in the U.S. MFN basket, a lower-priority launch market. These forces threaten the commercial pipeline on which the CDMO business model depends and, indirectly, the siting of late-phase clinical trials. **Generic manufacturing faces the most severe structural risk**: an announced, though not yet enacted, schedule of 100% tariffs from August 2028 rising to 200% in 2029 would be prohibitive for a low-margin sector that accounts for most Canadian drug exports to the United States.

KEY FINDINGS

/ Key findings

01 **Canada faces the default 100% Section 232 rate** on covered patented pharmaceuticals, with no CUSMA exemption and no negotiated reduced rate, unlike the EU, Japan, South Korea and Switzerland (15%) and the United Kingdom (0%).

02 Because U.S. customs practice **treats the country of the API as the origin of a finished drug**, a Quebec fill-finish CDMO using U.S. or EU API may face 0% or 15%, while Canadian-made API carries the full 100% rate wherever it is finished.

03 **CROs are largely shielded from direct effects**: services are not goods, and imports used solely for clinical trials, research and development are zero-rated. Their exposure is indirect, through the relocation of commercial manufacturing and the deprioritization of Canada as a launch market.

04 The zero rate enjoyed by large pharmaceutical companies with MFN and onshoring agreements is **a transition period rather than a shelter**: it expires on 20 January 2029 and is conditional on audited commitments to increase U.S. production.

05 MFN pricing, which benchmarks U.S. prices against a basket that includes Canada, **creates incentives to delay or forgo Canadian launches**; industry surveys report cancelled and delayed launches in 2026, although Canadian regulators had not yet observed the effect in their statistics.

06 Generics, currently exempt and representing roughly four-fifths of Canadian-made drugs exported to the United States, **face an announced 100% tariff from August 2028 and 200% from August 2029**. Reshoring timelines of five to ten years make this schedule impossible to meet through new construction.

07 Canada's most plausible path to tariff relief **may run through drug-pricing concessions** of the kind made by the United Kingdom, placing the interests of Quebec's life sciences sector and its public drug budget in tension.

KEY TAKEAWAY

The combination of tariffs with MFN and onshoring commitments is redirecting future commercial manufacturing toward the United States.

SECTION 1

/ 1. Introduction

Medicines were historically spared from tariffs on public health grounds. **That norm ended in 2026.** Following an investigation launched in April 2025, the U.S. administration concluded that reliance on imported patented pharmaceuticals and their ingredients threatens national security, and imposed a tiered tariff regime under Proclamation 11020 [1][2]. Canada had argued in its submission to the investigation that its exports reinforce, rather than impair, North American supply security [35]. The argument did not secure an exemption.

The pharmaceutical industry in Canada represents roughly C$74 billion in revenue and 81,000 jobs [35]. Canadian pharmaceutical exports reached approximately C$14.5 billion in 2025, about 70% of which went to the United States, according to federal data reported in the press [27]. Montreal, Laval and the broader Quebec ecosystem host **a dense network of CROs and CDMOs** serving international sponsors across early-phase clinical research, bioanalysis, process development, sterile manufacturing, biologics and advanced therapies. This paper asks how the U.S. measures affect these organizations. It proceeds in eight parts: the U.S. policy framework; Canada's specific position; the rules of origin that determine actual exposure; a segment-by-segment assessment; the combined effect of tariffs with MFN pricing and onshoring; the particular threat to generic production; an outlook to 2030 with scenarios; and strategic implications for firms and policymakers.

C$74B

Pharmaceutical industry revenue in Canada

81,000

Jobs in Canada's pharmaceutical industry

C$14.5B

Canadian pharmaceutical exports, 2025

~70%

Share of those exports bound for the United States

SECTION 2

/ 2. The U.S. policy framework

Table 1. Section 232 pharmaceutical rate structure (as of October 2026)

CATEGORY	ADDITIONAL RATE	CONDITIONS AND DURATION
Default: covered patented drugs, APIs, key starting materials	**100%**	Applies absent any other pathway; **includes products of Canada**
Products of the EU, Japan, South Korea, Switzerland, Liechtenstein	**15%**	Total rate inclusive of ordinary duty
Products of the United Kingdom	**0%**	Under the U.S.-UK pharmaceutical pricing arrangement, effective 31 July 2026
Company with approved onshoring plan	**20%**	Rises to 100% on 2 April 2030
Company with onshoring plan and MFN pricing agreement	**0%**	Until 20 January 2029
Generic pharmaceuticals, biosimilars and their ingredients	**0%**	Excluded at this time; Commerce review due within one year of the proclamation
Specialty products (orphan, cell and gene therapy, ADCs, plasma-derived, nuclear medicine, fertility, CBRN countermeasures, animal health)	**0%**	Only if from an eligible jurisdiction or approved for an urgent U.S. health need
U.S.-origin products, including U.S. API packaged in dosage form abroad	**0%**	Origin documentation required
Articles used solely for clinical trials, R&D or non-commercial purposes	**0%**	Heading 9903.04.70, effective 29 September 2026

Sources: Proclamation 11020 and CBP and Commerce implementing guidance as summarized in [2], [3] and [4].

2.1 The Section 232 tariff regime

Proclamation 11020 imposes a default 100% ad valorem duty on patented pharmaceutical articles listed in its Annex I, together with the APIs and key starting materials used to make them. Duties began on 31 July 2026 for the products of seventeen large companies named in Annex III and on 29 September 2026 for all other importers [2][3]. Where more than one rate could apply, the lowest governs. Excipients and inactive ingredients are not treated as pharmaceutical articles [2].

The 100% figure is a ceiling rather than a uniform rate. Actual exposure depends on the product, the country of origin and the commercial agreements held by the company concerned. Table 1 summarizes the structure.

Three operational features matter for contract organizations. First, **duty drawback is expressly available**, so duties can be recovered when imported goods are re-exported or destroyed; unlike most earlier Section 232 actions, this preserves a relief valve for globally distributed products, although substitution drawback does not extend to exports to Canada or Mexico [3][34]. Second, the ability to use U.S. foreign trade zones to lock in favourable status is restricted [3]. Third, for goods eligible for free-trade-agreement preferences, the Section 232 duty is collected in addition to the preferential rate [2].

2.2 Most-favoured-nation pricing agreements

MFN agreements are voluntary, company-level commitments to align U.S. drug prices with those paid in other high-income countries. Under the framework described by the White House Council of Economic Advisers, signatories commit to launch all new medicines in the United States at prices comparable to those in a reference group, and **the policy is explicitly designed to combine lower U.S. prices with higher prices elsewhere** [13]. The benchmark is the second-lowest price within a basket of eight countries: Canada, Denmark, France, Germany, Italy, Japan, Switzerland and the United Kingdom [14].

By September 2026, the administration had extended the framework to all state Medicaid programs and reached pricing agreements with 26 manufacturers representing roughly 89% of the branded drug market [15]. The Council of Economic Advisers projects US$529 billion in U.S. savings over ten years and expects most makers of sole-source brand drugs to sign similar agreements [13].

2.3 Onshoring agreements

Commerce opened a company-specific application process for onshoring agreements in May 2026 [10]. Applicants must submit detailed, multi-year plans to move production of patented products, APIs and upstream ingredients to the United States, including the percentage of U.S. production, capital expenditure and timelines, and **must identify the parts of their patented portfolio they do not intend to onshore** [10][12].

Approved companies file audited progress reports at least semi-annually; relief applies only to the products and importers named in the approval; and **misrepresentation may lead to retroactive reimposition of tariffs** [11][12].

MFN PRICING AT A GLANCE

26
Manufacturers with MFN pricing agreements by September 2026

~89%
Share of the branded drug market they represent

US$529B
Projected U.S. savings over ten years

8
Countries in the reference basket, Canada included

ONE SYSTEM, THREE INSTRUMENTS

The tariff is the penalty; onshoring and MFN commitments are the price of avoiding it.

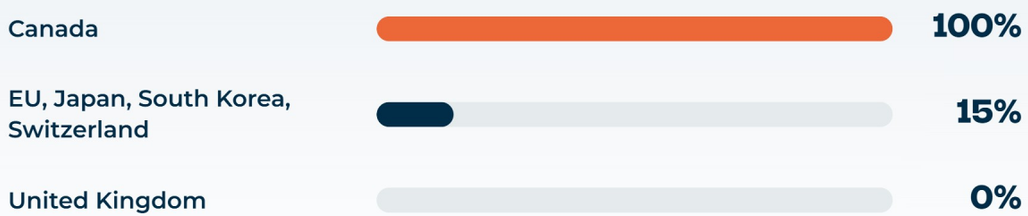
Combined, the three instruments form a single system. A company with both agreements pays nothing until January 2029, but only by committing to produce more in the United States and to price globally in a way that limits the influence of low-price markets on U.S. revenue.

2. THE U.S. POLICY FRAMEWORK · CONTINUED

2.4 Related measures

Several parallel measures shape the environment. A U.S. Section 301 duty of 10% or 12.5% on products of sixty economies, linked to forced-labour import practices, took effect on 24 July 2026; **CUSMA-compliant Canadian goods are exempt** [5][6]. A separate 50% tariff on a range of Canadian products under Section 338 of the Tariff Act of 1930 took effect on 22 August 2026; products subject to Section 232, including patented pharmaceuticals, were excluded from it [9][5]. Finally, on 21 July 2026 the President announced that **imported generic drugs would remain tariff-free for two years** from 1 August 2026, then face 100% for one year from August 2028 and 200% thereafter; a White House official indicated that Section 232 would be the legal basis, but no proclamation had been issued as of this writing [20][24].

Section 232 rate on covered patented pharmaceuticals, by origin



Additional rate absent company-level agreements or product exemptions. Canada has no CUSMA exemption.

SECTION 3

/ 3. Canada's position

Canada's treatment is distinctive in three respects. First, **there is no CUSMA exemption from the pharmaceutical tariff**: a Canadian medicine can satisfy North American rules of origin and still be fully dutiable [5][27]. Second, Canada was not among the jurisdictions granted the 15% rate, nor did it secure an arrangement comparable to the United Kingdom's 0% [2][27]. Third, Canada does not appear on the list of jurisdictions eligible for the 0% specialty-product rate, which includes the EU, the United Kingdom, Japan, South Korea, Switzerland, India, Taiwan and others [2]. Canadian-origin specialty products must therefore seek relief product by product under the urgent-health-need procedure.

Canada-U.S. negotiations failed to produce an agreement in August 2026 [29], and Quebec's own budget projections assume a new equilibrium characterized by persistent tariffs [31]. Canada's pharmaceutical exposure is nonetheless uneven. Before the proclamation, analysts noted that the impact would hinge on the treatment of generics, which make up **about 79% of Canadian drug exports to the United States** [28][21]. The generic exclusion has, for now, limited the damage.

SECTION 4

/ 4. Rules of origin: why the API matters most

The Section 232 rate depends on the country of origin of the imported article, and that determination follows U.S. customs rules rather than CUSMA rules [6]. For pharmaceuticals, U.S. Customs and Border Protection (CBP) has long held that converting a bulk API into finished dosage form, whether by tableting, encapsulating or otherwise dividing it into doses, does not substantially transform the product; **origin generally follows the API** [7][8]. CBP has recognized substantial transformation only in fact-specific cases involving chemically complex processing, such as combining two APIs into a new therapeutic product [7].

For Canadian contract manufacturers this rule is decisive. Table 2 illustrates the effect on a patented, single-API finished product manufactured in Quebec.

Table 2. Likely Section 232 treatment of a patented finished drug manufactured in Quebec, by API source

API SOURCE	LIKELY ORIGIN FOR SECTION 232	LIKELY ADDITIONAL RATE
United States	United States	**0%** (U.S.-origin API in dosage form)
EU, Switzerland, Japan, South Korea	Country of API	**15%**
United Kingdom	United Kingdom	**0%**
Canada	**Canada**	**100%** (default)
India, China or other non-preferred countries	Country of API	**100%** (default)

Illustrative only, absent company-level agreements or product exemptions. Multi-API and complex products may differ and may warrant a CBP ruling.

THE PARADOX

The most vertically integrated Canadian operation, one that makes both the API and the finished product, is the most exposed, while a firm finishing imported U.S. or EU API may be largely shielded. Canadian API and intermediate producers carry their Canadian origin, and the default rate, into every product made from their output, wherever it is finished. Analysts expect origin to be a focus of CBP enforcement given the large rate differentials [7].

SECTION 5

/ 5. Exposure by segment

Exposure depends less on geography than on business model. Table 3 summarizes our assessment.

Table 3. Exposure of Canadian and Quebec contract organizations, by segment

SEGMENT	EXPOSURE NOW (2026-2027)	EXPOSURE 2028 AND BEYOND
CRO services (Phase I, bioanalysis, clinical operations)	LOW Services are not goods; trial supplies are zero-rated	LOW DIRECT MEDIUM INDIRECT
Clinical-stage CDMO (process development, clinical batches)	LOW Clinical and R&D heading at 0%	HIGH Clients select commercial sites elsewhere
Commercial CDMO, patented products, large pharma clients	LOW Client agreements give 0%	MEDIUM TO HIGH Zero rate expires January 2029
Commercial CDMO, patented products, small and mid-size biotech clients	HIGH 100% default	HIGH
Canadian API and key starting material producers (patented)	VERY HIGH Canadian origin means 100%	VERY HIGH
Specialty modalities (ADCs, cell and gene therapy, orphan)	MEDIUM Canada not an eligible jurisdiction	MEDIUM
Generic finished dose and generic CDMO	LOW Possibly advantaged (see Section 7)	VERY HIGH If the 2028 schedule is enacted

Exposure scale LOW MEDIUM HIGH VERY HIGH

5.1 Contract research organizations

CRO revenue is predominantly derived from services, which are not subject to customs duties. Materials imported solely for clinical trials, research and development or other non-commercial purposes are zero-rated under a heading added in September 2026, and investigational products that are not yet approved generally fall outside the definition of a covered patented article in any case [2][26]. Logistics providers serving clinical research have concluded that importers of investigational products are unlikely to be affected.

The exposure of CROs is therefore second-order. Chemistry, manufacturing and controls (CMC) work, stability programs and release testing tend to follow commercial manufacturing: when a sponsor relocates commercial supply to the United States, associated analytical work often moves with it. Sponsors facing MFN price compression and tariff costs are also likely to tighten research budgets, and outsourced spending is typically the first to be cut. Finally, as discussed in Section 6.2, the deprioritization of Canada as a launch market may erode Canada's share of late-phase trials. **Early-phase clinical research and bioanalysis**, which are chosen on cost, speed and expertise rather than launch strategy, **remain comparatively resilient**. U.S. pressure on Chinese contract providers may also direct some sponsors toward trusted North American alternatives.

5.2 Clinical-stage CDMOs and the pipeline effect

The typical CDMO growth model involves winning clients at the clinical stage and following them into commercial supply, where volumes and margins are highest. **The current regime leaves the clinical stage untouched while steering the commercial stage away from Canada.** A sponsor without a U.S. agreement choosing a commercial site for U.S. supply faces roughly 100% for Canada, 15% for an EU site and 0% for a U.S. or UK site. Proximity, cost competitiveness, regulatory track record and talent, Canada's traditional advantages, cannot offset a differential of that magnitude.

The consequences are unlikely to appear in current revenue. They will appear in the 2027-2029 order book, through earlier exercise of technology-transfer clauses, demands for U.S. dual sourcing and pressure to share duty costs. Biotech companies have been advised to review importer-of-record and duty-allocation provisions in their CDMO and supply agreements [26].

5.3 Commercial CDMOs

For commercial manufacturers, exposure is determined by client status. Companies holding both MFN and onshoring agreements, including the seventeen named in Annex III and nine others, are exempt until 20 January 2029 [5][37]. Volume produced in Quebec for these clients is currently protected. Small and mid-size biotech sponsors without agreements, by contrast, face the default rate on Canadian-origin product and have little leverage to negotiate company-specific relief. **Exposure is thus concentrated precisely in the emerging-company segment that many Quebec CDMOs target.**

5.4 API and key starting material producers

As explained in Section 4, **Canadian producers of APIs and key starting materials for patented products are the most exposed group in the sector.** Their output confers Canadian origin on downstream products wherever those are finished, and therefore attracts the default rate unless the purchasing company holds an agreement. A negotiated Canadian rate would benefit this group more than any other.

5.5 Specialty modalities

Quebec has built capabilities in antibody-drug conjugates, rare diseases and cell and gene therapy; a Montreal-based cell-therapy CDMO, for example, has manufactured clinical product for European sites [36]. These categories qualify for a 0% rate only when they originate from an eligible jurisdiction or meet an urgent U.S. health need [2]. Because Canada is not on the eligible list, **Canadian-origin commercial specialty products must pursue single-product applications to Commerce**, a burden that competitors in the EU, the United Kingdom or Japan do not bear.

> *Exposure is concentrated precisely in the emerging-company segment that many Quebec CDMOs target.*



Laurent Lecanu
HEAD OF LIFE SCIENCE CLUSTER NORTH AMERICA — LEYTON

SECTION 6

/ 6. The combined effect of tariffs, MFN pricing and onshoring

The tariff alone understates the challenge. Combined with MFN pricing and onshoring commitments, it affects Canadian contract organizations through two channels simultaneously: **where medicines are made, and where they are launched and studied.**

6.1 The manufacturing channel

The zero rate is a transition, not a shelter.

A Quebec CDMO producing for a client with both agreements pays no tariff today. But that client has signed an audited, portfolio-wide commitment to raise the share of U.S. production [10][11]. Every Canadian contract not on the client's declared list of products that will not be onshored is, implicitly, a candidate for migration. **The tariff protects current volume while the agreements commit future volume to the United States.**

U.S. contract manufacturers are the structural beneficiaries.

Companies lacking sufficient in-house U.S. capacity are likely to meet onshoring milestones in part through U.S. CDMOs, shifting demand away from Canadian sites even for clients that never pay a tariff. This is an inference; the treatment of contracted U.S. capacity within specific approved plans has not been published.

The residual portfolio is the competitive opening.

Because companies must declare what they will not onshore, a residual portfolio will remain abroad. It is likely to include low-volume and niche products, mature brands approaching patent expiry, complex modalities that are difficult to transfer, and supply for non-U.S. markets.

Margin pressure compounds volume pressure.

Projected U.S. savings from MFN pricing represent lost revenue for the branded industry [13]. The industry typically responds by pressing suppliers on price, payment terms and risk sharing. A partial offset is that firms under cost pressure sometimes increase outsourcing to convert fixed costs into variable ones.

6.2 The launch and trial channel

This channel is specific to MFN pricing and has no counterpart for EU or Japanese competitors that benefit from a 15% tariff. Because the U.S. benchmark is the second-lowest net price in a basket that includes Canada, **a low Canadian price can depress U.S. revenue many times larger than the Canadian market itself** [14]. Manufacturers may respond by seeking higher Canadian prices, reducing discounts, or delaying launches in Canada [16].

Industry data suggest the effect has begun. A survey of 31 member companies conducted for Innovative Medicines Canada reported 16 launches cancelled and 32 delayed in Canada as a result of MFN [17], and the association's September 2026 pre-budget submission reported more than 30 delays in 2026 [18]. These figures come from an interested party; the heads of Canada's Drug Agency and the pan-Canadian Pharmaceutical Alliance have stated that they had not yet seen the effect in their statistics and that approvals remained historically strong [15].

The relevance for CROs lies in **the link between launch strategy and trial siting**. Sponsors tend to place late-phase trials in markets where they intend to launch and seek reimbursement, and observers have noted that MFN affects clinical trial investment and launch sequencing as well as prices [15]. A decline in Canada's launch priority would weaken Phase II and III site selection, affecting Quebec's hospital research centres and CRO clinical operations. Medicines that are not launched in Canada also generate no Canadian commercial packaging, labelling or release testing, removing a niche on which domestic contract manufacturers and packagers rely.

REPORTED LAUNCH EFFECTS IN CANADA

31
Member companies surveyed for Innovative Medicines Canada

16
Launches cancelled in Canada as a result of MFN

32
Launches delayed in Canada as a result of MFN

30+
Delays in 2026, per the September 2026 pre-budget submission

Industry-association figures [17][18]. Canadian regulators had not yet observed the effect in their statistics [15].

6.3 A policy collision in Canada

Canadian policy is moving in the opposite direction. New guidelines of the Patented Medicine Prices Review Board (PMPRB), in force since 1 January 2026, benchmark Canadian prices against eleven countries and exclude the United States [19]. The U.S. Trade Representative argued in an April 2026 report that excluding Switzerland and the United States from the comparator basket undervalues innovative medicines in Canada [18].

The United Kingdom provides a template for resolution. In exchange for its pharmaceutical arrangement, the United Kingdom agreed to adopt a higher cost-effectiveness threshold and to reduce the rebate its National Health Service claws back from manufacturers [20]; UK patented products now face a 0% tariff [2]. **Canada's most plausible route to tariff relief may therefore involve pricing concessions**, such as changes to the PMPRB basket, cost-effectiveness thresholds or national price negotiations. Such concessions would support CDMO demand, API producers, launch timing and trial siting simultaneously, but would raise costs for provincial drug plans. Quebec, which operates its own universal drug insurance regime, would feel this directly. The province's life sciences sector and its drug budget would sit on opposite sides of the same negotiation.

TWO BASKETS, OPPOSITE DIRECTIONS

8

Countries in the U.S. MFN basket, Canada included

11

Countries in the PMPRB basket, U.S. excluded

> *The province's life sciences sector and its drug budget would sit on opposite sides of the same negotiation.*



Laurent Lecanu
HEAD OF LIFE SCIENCE CLUSTER NORTH AMERICA — LEYTON

Table 4. Combined effect of tariffs, onshoring and MFN pricing, by client type

CLIENT OR COMPANY TYPE	TARIFF TODAY	ONSHORING AND MFN EFFECT	NET EFFECT ON CANADIAN CDMOS AND CROS
Large pharma with both agreements	**0%** until January 2029	Audited commitment to raise U.S. production share; caution on Canadian launches	Gradual erosion of commercial volume; fewer Canadian launches and trials
Mid-size pharma with onshoring plan only	**20%** until 2030	Must build or contract U.S. capacity	Faster migration; Canada retained mainly for non-U.S. supply
Small and mid-size biotech without agreements	**100%**	Limited leverage to negotiate	Canada unlikely to be chosen for U.S. commercial supply; clinical work unaffected
EU, Swiss or Japanese company manufacturing at home	**15%**	Little incentive to use a Canadian site	Canada loses as an alternative location
Generic manufacturers	**0%** for now	MFN not applicable; 2028 tariff announced	Separate cliff (Section 7)

SECTION 7

/ 7. Generics: the structural threat

7.1 Why generics matter

Generics currently insulate the Canadian sector. Canada exported around US$6.75 billion of pharmaceuticals to the United States in 2023, of which about 79% of Canadian-made exports were generics [21]. Exposure is concentrated among a few large manufacturers. Apotex, the country's largest generic producer, which fills roughly one-fifth of generic prescriptions in Canada, derived about 46% of its fiscal 2026 sales from the United States [22], and analysts identified it as the most exposed generic company because it has no U.S. manufacturing [23]. In Quebec, Pharmascience is the principal player and has also built a CDMO unit focused on sterile injectables at its Candiac site, so generic and contract manufacturing risks converge within the same organization [32].

7.2 Why a generic tariff would be prohibitive

Patented products carry margins that can partly absorb a duty or that can be protected through company agreements. Generics operate on thin margins in tender-driven markets. Even a 10-15% duty can render a product uneconomic; **rates of 100% and 200% would mean withdrawal from the U.S. market**, product by product, rather than a higher cost of doing business.

7.3 The timeline problem

A new pharmaceutical manufacturing facility can cost up to US$2 billion and take five to ten years to build, according to the U.S. biotechnology industry association [26]. **Canadian generic manufacturers cannot build their way to compliance by August 2028.** Their realistic options are to acquire or lease existing U.S. capacity, to contract with U.S. CDMOs (diverting volume from Quebec contract manufacturers), or to secure a negotiated Canadian carve-out.

GENERICS BY THE NUMBERS

US$6.75B
Canadian pharmaceutical exports to the U.S. in 2023

~79%
Share of Canadian-made exports that were generics

~46%
Apotex fiscal 2026 sales derived from the U.S.

5–10 yrs
To build a new plant, at up to US$2 billion

7.4 The domestic supply risk

The most serious second-order effect concerns Canada's own drug supply. The president of the Canadian Generic Pharmaceutical Association has warned that, without access to the U.S. market, some Canadian production for the domestic market may cease to be viable [25]. U.S. volumes underwrite plant scale; without them, some molecules manufactured in Quebec for Quebec patients could become uneconomic, raising shortage risks for public drug plans and hospital procurement. **For Canada, the generic question is therefore a health-policy issue as well as a trade issue.**

7.5 Canada's current advantage, and an origin twist

For the moment, Canadian generics may hold an advantage. The Section 301 pharmaceutical exemption is built around ingredients rather than finished drugs, leaving generic finished products from covered economies exposed to the 10-12.5% duty [7]. CUSMA-compliant Canadian goods are exempt from that duty [6]. Because formulating imported API into finished dosage form typically satisfies the applicable CUSMA rule of origin, **a qualifying Canadian generic can currently undercut competitors finished in covered economies**. Qualification should be confirmed product by product.

The advantage has a limit. For Section 232 purposes, origin follows the API rather than CUSMA rules. If a future generic tariff differentiates by country, a Canadian generic made with Indian or Chinese API would likely be treated as a product of the API country, and Canadian finishing alone would not secure any rate Canada negotiates. **This strengthens the case for North American or allied API supply chains.**

Biosimilars are also currently exempt. The July 2026 announcement referred only to generics, leaving their future treatment, and its implications for Quebec's biologics ambitions, uncertain.

7.6 Uncertainty

The generic schedule remains an announcement rather than an enforceable instrument; it requires a proclamation with annexes and tariff classifications [24]. Commerce must also advise the President within one year of the April proclamation on whether to extend tariffs to generics [4]. The schedule could be delayed, softened or traded in negotiations. **Yet the planning horizon for site decisions is long enough that the announcement is already shaping investment.**

SECTION 8

/ 8. Outlook to 2030

Table 5. Key dates

29 September 2026

Section 232 duties apply to all importers

Default 100% now applies to non-agreement companies

About April 2027

Commerce advice on extending tariffs to generics

First formal signal on the generic schedule

1 August 2028

Announced start of 100% tariff on generics (not yet enacted)

Potential loss of U.S. generic market from Canada

20 January 2029

Expiry of 0% rate for companies with MFN and onshoring agreements; end of current U.S. presidential term

Large-pharma protection lapses unless extended

August 2029

Announced increase of generic tariff to 200%

Prohibitive for remaining exports

2 April 2030

Onshoring-only rate rises from 20% to 100%

Pressure on mid-size companies to complete U.S. relocation

Three scenarios bracket the outlook.

BASE CASE

The patented regime persists and the generic tariff is formalized, possibly with agreement-based reduced rates. **Canadian commercial manufacturing for the U.S. market contracts gradually**, while firms pivot toward clinical work, Canadian and European supply, and U.S. footprints.

NEGOTIATED SCENARIO

Canada obtains a rate comparable to the EU's 15% or better, probably as part of a broader settlement that may include pricing concessions; this is the single largest upside variable and would particularly benefit API producers.

ESCALATION SCENARIO

Pharmaceuticals become entangled in the wider trade dispute; **this appears less likely given U.S. supply-security concerns**, but cannot be excluded.

SECTION 9

/ 9. Strategic implications

9.1 For CDMOs

- Segment the client portfolio by agreement status (MFN and onshoring, onshoring only, none) and by product origin, and identify which products appear on clients' declared lists of products that will not be onshored.
- Favour U.S. or EU API sourcing where technically and commercially feasible to reduce the rate applicable to U.S.-bound product.
- Consider a U.S. footprint, through partnership or acquisition, so that clients can meet onshoring commitments without leaving the relationship.
- Position Canadian sites for ex-U.S. supply, complex residual products and clinical-stage work, and pursue urgent-health-need applications for eligible specialty products.
- Revisit supply agreements on importer of record, duty allocation, drawback and technology transfer.

9.2 For CROs

- Emphasize the zero-rated clinical, research and development segment and early-phase and bioanalytical services, where Canada's cost and speed advantages persist.
- Monitor launch-delay data as a leading indicator of late-phase trial siting, and diversify Canadian late-phase exposure.
- Position as a trusted, non-Chinese North American provider.

9.3 For generic manufacturers and their contract partners

- Plan for the August 2028 schedule as if it will be enacted, including U.S. capacity options.
- Secure CUSMA origin documentation to preserve the current Section 301 advantage.
- Build the case for domestic supply security with federal and Quebec authorities.

9.4 For policymakers

Quebec has deployed liquidity support through the FORCE program, administered by Investissement Québec for manufacturers whose sales are substantially reduced by U.S. tariffs of 25% or more [29], and its 2025-2028 life sciences strategy provides roughly C$271.5 million, including support for new production capacity [30].

At the federal level, **the principal instrument is the Regional Tariff Response Initiative (RTRI)**, delivered by the regional development agencies, in Quebec by Canada Economic Development for Quebec Regions (CED). Announced in March 2025 with C$450 million, the program was raised to C$1 billion over three years in September 2025, of which C$197 million was allocated to Quebec [38]. By May 2026, CED had supported 260 Quebec projects worth more than C$179.5 million, leveraging C$518.1 million in total investment and committing nearly all of its available funds; demand under its grant call exceeded the funding available more than threefold [38]. Sector-specific envelopes followed, including C$150 million for steel, a C$150 million food security fund and up to C$100 million for automotive manufacturing [38].

Following the breakdown of Canada-U.S. negotiations, the federal government announced on 25 August 2026 an additional C$1.5 billion for the RTRI as part of a C$7.5 billion package of measures for workers and businesses, bringing the program to C$3.45 billion over four years. **Eligible businesses may now receive up to C$3 million in non-repayable support**, comprising up to C$2 million for liquidity needs and up to C$1 million for pivot projects, with repayable contributions available for larger transformation projects [39]. In Quebec, eligibility generally targets manufacturing SMEs with fewer than 500 employees, at least three years of operation and at least C$2 million in annual revenue, which must demonstrate concrete tariff impacts and propose projects that improve productivity, competitiveness or market diversification [40].

SUPPORT PROGRAMS AT A GLANCE

C$3.45B
RTRI envelope over four years, after the August 2026 top-up

Up to C$3M
Non-repayable support per eligible business

260
Quebec projects supported by CED by May 2026

C$271.5M
Quebec life sciences strategy, 2025-2028

9.4 FOR POLICYMAKERS · CONTINUED

Program materials do not single out pharmaceuticals or life sciences. Smaller CDMOs and API producers with demonstrable exposure to the Section 232 tariff could in principle qualify, and the liquidity component is relevant to firms facing lost U.S. commercial volume. However, the SME focus excludes the larger generic manufacturers and multinational sites most exposed to the 2028 schedule, and the amounts available are small relative to the capital needed to acquire U.S. capacity, re-source APIs or absorb a 100-percentage-point duty differential. Provincial and federal measures can cushion firms but cannot offset the tariff itself. **The decisive variable is whether Canada negotiates a preferential rate, and on what terms.** Because pricing concessions are the most likely currency of such a deal, federal and provincial authorities face an explicit trade-off between industrial and health-budget objectives that deserves open deliberation, informed by sector organizations such as Montréal InVivo and BIOQuébec.

SECTION 10

/ 10. Conclusion

The U.S. Section 232 pharmaceutical tariff, read in isolation, has a narrower immediate effect on Canadian and Quebec contract organizations than its 100% headline suggests. Read together with MFN pricing and onshoring agreements, **it represents a structural reorientation of where patented medicines will be made, launched and studied, with Canada disadvantaged on each count.**

The near-term risk is concentrated in Canadian API production and in commercial manufacturing for sponsors without U.S. agreements. The medium-term risk lies in the erosion of the commercial pipeline that sustains the CDMO model and, through launch deprioritization, in late-phase clinical research. The most acute structural threat is to generic manufacturing, where an announced tariff schedule, if enacted, would collide with reshoring timelines that cannot be compressed.

How Canada chooses to negotiate, and in particular whether it is prepared to trade pricing concessions for tariff relief, will shape the sector's trajectory more than any single support program.

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NOTE ON SOURCES AND LIMITATIONS

This analysis reflects publicly available information as of mid-October 2026. Several elements remain fluid: the terms of individual MFN and onshoring agreements are largely confidential; the generic tariff has been announced but not enacted; and origin and classification outcomes are product-specific. Some figures, including launch-delay data, originate from industry associations. **The paper does not constitute legal, customs or trade-compliance advice.**

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