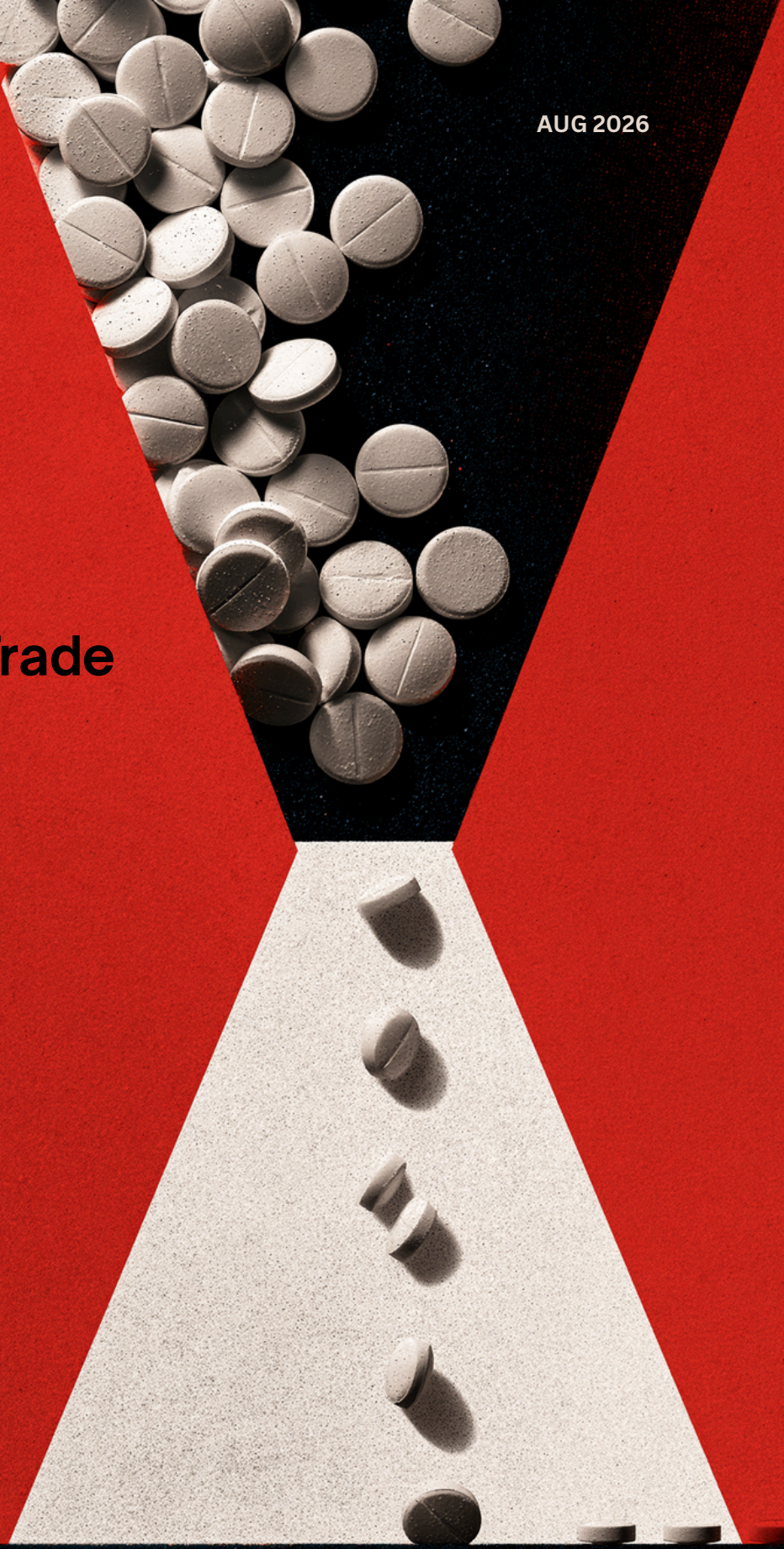
INDIA-CANADA RESEARCH INITIATIVE

AUG 2026

The Quiet Corridor

The Case for Deepening India-Canada Pharmaceutical Trade



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ABOUT THIS REPORT

This report makes the case for deepening India-Canada trade in finished pharmaceutical products and for institutionalizing it under the CEPA negotiations now targeted for conclusion by the end of 2026. Canada faces rising drug expenditure, an aging population and chronic shortages, and does not manufacture low-cost generics at scale; India, the world's third-largest pharmaceutical producer by volume, supplies exactly that capability. Compiled at HS heading 3004 from Statistics Canada microdata cross-checked against UN COMTRADE, the analysis shows Canada's imports of finished doses from India rising roughly seventy per cent between 2020 and 2025, to US$637.6 million, making India Canada's fourth-largest supplier. The report weighs the hard problems honestly, including the shared dependence on Chinese APIs and the uneven Indian quality record, and recommends a dedicated pharmaceutical annex within CEPA, joint upstream resilience, and regulatory cooperation on Good Manufacturing Practices. Its argument is redundancy alongside America and Europe, not replacement.

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AUTHOR

Noyonika Lahiri Singh

ABBREVIATIONS

6-APA	6-aminopenicillanic acid, the core penicillin intermediate
AIR	All India Radio
API	Active pharmaceutical ingredient
C-64	Bill C-64, An Act respecting pharmacare, Canada
CAD	Canadian dollar
CBSA	Canada Border Services Agency
CDA-AMC	Canada's Drug Agency, Agence des medicaments du Canada
CDSCO	Central Drugs Standard Control Organisation, India
CEPA	Comprehensive Economic Partnership Agreement, India and Canada
CETA	Comprehensive Economic and Trade Agreement, Canada and the European Union
COMTRADE	United Nations International Trade Statistics Database
DGCI&S	Directorate General of Commercial Intelligence and Statistics, India
DPT	Diphtheria, pertussis and tetanus vaccine
EEA	European Economic Area
EFTA	European Free Trade Association
EPTA	Early Progress Trade Agreement
FDA	Food and Drug Administration, United States; also written USFDA
FDI	Foreign direct investment
FPP	Finished pharmaceutical product
FY	Fiscal year, as in FY2024-25
GMP	Good manufacturing practice
HS	Harmonized Commodity Description and Coding System; HS-2 and HS-6 denote the two digit and six digit levels of it
HSN	Harmonized System of Nomenclature, the Indian tariff schedule built on the HS
IBEF	India Brand Equity Foundation
ICIS	Independent Commodity Intelligence Services
JSG	Joint Sectoral Group, the India-Canada officials' forum on trade
KSM	Key starting material
NAICS	North American Industry Classification System
NCD	Noncommunicable disease
NPDUIS	National Prescription Drug Utilization Information System, Canada
PIC/S	Pharmaceutical Inspection Co-operation Scheme
PLI	Production linked incentive, the Indian manufacturing subsidy scheme
PMPRB	Patented Medicine Prices Review Board, Canada
SHAKTI	India's Biopharma SHAKTI initiative; the sources used here do not state what the letters stand for
UNICEF	United Nations Children's Fund
USFDA	United States Food and Drug Administration
WHO	World Health Organization

EXECUTIVE SUMMARY

This report analyzes the structural imperatives and opportunities for deepening the pharmaceutical trade between India and Canada, specifically in Finished Pharmaceutical Products (FPPs). Canadian demand-side pressures and Indian supply-side capabilities show strong potential for a bilateral relationship that goes beyond trade, with the possibility of institutionalizing it under the ongoing Comprehensive Economic Partnership Agreement (CEPA) negotiations. The report separates downstream finished drugs from critical upstream chemical inputs, key starting materials (KSMs) and active pharmaceutical ingredients (APIs), because conflating them is the most common error in debates about the pharmaceutical supply chain.

Canada's need to diversify its pharmaceutical supply is driven by an aging population, rising expenditures on high-cost biologics, and chronic shortages of generic medications: 1,772 drug shortage reports were still active at the close of the 2024–25 fiscal year.[2] Canada lacks the manufacturing elasticity and cost competitiveness required to produce mass generic FPPs domestically. Bill C-64, or the 2024 Pharmacare Act, established the legislative architecture for universal coverage of contraceptives and diabetes medicines, but the rollout has stalled at four jurisdictions and federal funding is now being wound down.[3] The demand pressures set out in this report therefore do not depend on pharmacare expanding, and would intensify further if it resumed. India, on the other hand, is well positioned to fill this gap, offering manufacturing elasticity in large-scale generic production, cost competitiveness and mass production capacity. The CEPA negotiations, relaunched in November 2025 and now targeted for conclusion by the end of 2026, provide a narrow window to institutionalize this partnership.

The report argues that CEPA could feature a dedicated pharmaceutical annex focusing on regulatory cooperation, good manufacturing practice (GMP), and mutual recognition agreements (MRAs). This framework would allow Canada to secure a stable, reliable supply chain with Indian manufacturers of FPPs, while creating a route for technology transfer and joint ventures in biologics and blood-derived products (HS 3002) and higher-value finished therapeutics (HS 3004). Whatever form the deepened relationship takes, resilience requires confronting both nations' dependency on Chinese APIs and KSMs. To ensure a long-term, mutually beneficial supply chain regardless of sudden political shocks, the proposed bilateral corridor must incorporate institutional mechanisms alongside a coordinated long-term strategy for joint upstream resilience.

Unless otherwise stated, trade figures are for calendar years with Canada as the reporting country; they cover HS heading 3004, the finished dose heading, rather than the whole of HS Chapter 30, and all money values are given in US dollars. Trade values are the US dollar series published by the United Nations COMTRADE database, cross-checked against Statistics Canada's Canadian dollar series. Where a source publishes only Canadian dollars or Indian rupees, the figure has been converted at the 2025 calendar year averages of 1.3978 Canadian dollars and 87.1661 rupees to the US dollar, with the figure as published retained in parentheses.[1] The evidence base closes on 12 August 2026.

INTRODUCTION

This report addresses a crucial question: should India and Canada deepen their pharmaceutical trade and, if so, on what basis and in whose interest? The pharmaceutical trade remains small relative to Canada's overall import bill, though section II shows it is no longer nascent, and an analysis of Canada's structural needs and India's capacity suggests that deepening it would be mutually beneficial and strategically sensible.

Canada's structural vulnerabilities, the cost pressures, chronic drug shortages, and concentration risks of its public healthcare system, will persist regardless of political intervention. India's industrial identity as the "pharmacy of the world",[4] its manufacturing scale for mass generic products, its cost advantages, and a quality record that is strong in aggregate though uneven across firms, position it as a strategic diversification partner.[5] The institutionalization of this bilateral trade in finished pharmaceutical products can be built into CEPA, and this report argues that the relationship can grow beyond trade into a long-term strategic partnership. The distinction between FPPs and upstream inputs, such as active pharmaceutical ingredients (APIs) and key starting materials (KSMs), matters throughout, because the global pharmaceutical chain functions as a series of sequential dependencies, and policy that ignores that sequence misjudges where the risks lie.

India excels at large-scale FPP manufacturing, with affordable labor costs and strong economic competitiveness, especially for chemically synthesized small-molecule drugs.[6] Canada, meanwhile, needs generic tablets at scale as shortages recur and FPP prices rise, and the match between that need and this capacity is central to the case for deepening India-Canada pharmaceutical trade.[7]

An honest assessment must also acknowledge a shared vulnerability: no surge in Indian FPP exports or Canadian procurement can, by itself, sever the deeper, structural reliance on Chinese upstream inputs (APIs and KSMs) that underpins both economies. This dependency is particularly prominent in India. China accounted for about 73.7 percent by value of India's imports across 200 specified categories of APIs, bulk drugs and drug intermediates in FY2024–25, some US$3.2 billion of a US$4.35 billion total, and for roughly 94 to 96 percent of India's imports of 6-aminopenicillanic acid (6-APA), the core penicillin intermediate.[8] Official figures show that dependence is rising rather than falling. Diversification in FPPs would therefore reinforce resilience downstream while leaving upstream concentration risks intact.

This report analyzes the India-Canada pharmaceutical relationship through five pillars:

First, Canada's structural need: an urgent demand-side crisis driven by chronic drug shortages, severe supply-chain concentration risks, and the unfinished legislative mandate of Bill C-64.[9] Canada needs a secure, reliable supply chain regardless of domestic political shifts.

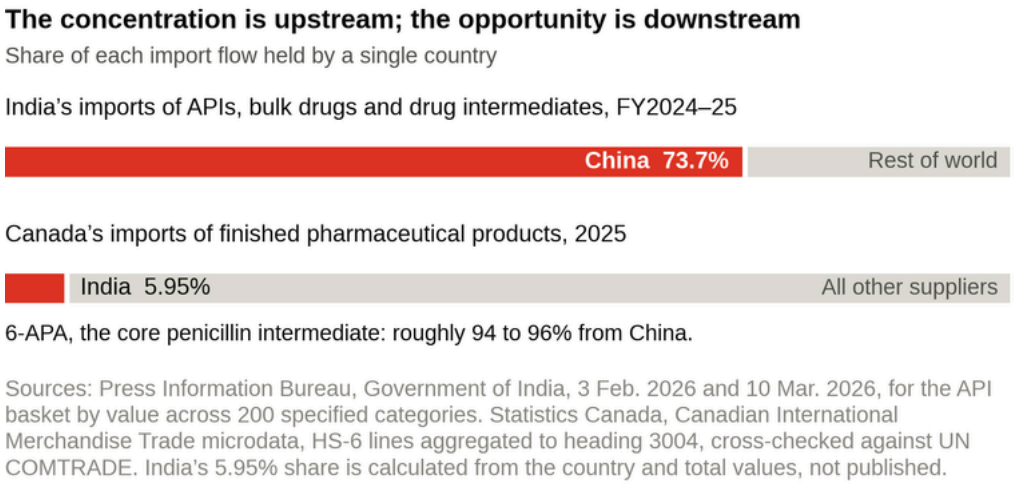
Second, India's supply-side capacity: manufacturing scale, cost advantages, and a strong aggregate compliance record, which together position it to serve as a leading diversification partner and build a long-

term institutional partnership.

Third, the mutual benefits: low-cost generics protect Canadian healthcare budgets while Indian manufacturers gain market access and exposure to advanced segments, and the corridor opens routes to technological transfer, joint ventures in biologics and blood-derived products, and collaborative research.

Fourth, the upstream vulnerability: the core risk in FPP production lies in procuring APIs and KSMs, a shared exposure that demands joint resilience.

Fifth, CEPA could provide the institutional framework to address non-tariff barriers through instruments such as Mutual Recognition Agreements (MRAs) and joint manufacturing initiatives, and to anchor collaboration on the joint procurement of APIs and KSMs.



THE BASELINE: WHERE THE TRADE ACTUALLY STANDS

To understand the dynamics of the India-Canada pharmaceutical trade, this report uses the Harmonized Commodity Description and Coding System (HS), the international classification created and maintained by the World Customs Organization.[10] Chapter 30 covers pharmaceutical products, including vaccines, immunological products, medicaments, and human blood and blood products. Finished pharmaceutical products correspond to HS heading 3004, which covers medicaments consisting of mixed or unmixed products for therapeutic or prophylactic use, put up in measured doses, including transdermal systems, or in forms or packings for retail sale, and which excludes the goods of headings 3002, 3005 and 3006 by its own terms.[11] Trade figures cited in this report use Canada as the reporting country unless stated otherwise; where figures for India's total exports are given, they are India-reported, are compiled on a different basis, and run consistently higher than the Canada-reported values, with which they are not directly comparable.

The trade figures and both tables in this report are therefore compiled at heading 3004 rather than at chapter level, and the distinction is not just cosmetic: in 2025, heading 3004 accounted for 56.7 percent of Canada's Chapter 30 imports, so chapter-level data roughly double the apparent size of the finished dose market. They also understate India's place within it, because Chapter 30 is padded by the blood products, vaccines, and immunological goods of heading 3002, in which India is a marginal supplier: on the chapter measure, India ranked ninth among Canada's suppliers in 2025, whereas in finished dose it ranked fourth.

Just as important is what Chapter 30 excludes: upstream pharmaceutical inputs, the APIs and KSMs, are recorded under HS Chapter 29 as organic chemicals, so this report measures the movement of finished products rather than the chemical inputs used in their production. Those inputs are nonetheless analyzed throughout as a dependency affecting trade, and the second recommendation addresses them directly.

INDIA-CANADA PHARMACEUTICAL TRADE, 2020–2025

Canada's imports of finished pharmaceutical products from India rose by roughly 70 percent between 2020 and 2025, from US$377.6 million to US$637.6 million.[12] In the US dollar series, the increase is uninterrupted year after year; in the Canadian dollar series, which Statistics Canada publishes, there is a marginal fall of 0.7 percent in 2021, a currency effect rather than a change in volume. India's total merchandise exports to Canada were US$4.48 billion in 2025 on India-reported figures; Canada, compiling on a different basis, recorded merchandise imports from India of some US$7.0 billion in the same year, an increase of 18.9 percent.[13] The flow in the other direction is very small by comparison: Canada exported US$11.3 million of finished pharmaceutical products to India in 2025, its twenty-eighth largest destination under the heading, so the finished dose trade runs at about fifty-seven to one in India's favor.[14]

Table 1: Canada's imports of finished pharmaceutical products from India, 2020 to 2025

Year	Imports from India	Canada's total imports	India's share	India's rank
2020	377.6	8,488.5	4.45%	7
2021	401.0	9,347.1	4.29%	7
2022	448.2	10,101.7	4.44%	8
2023	491.7	9,545.5	5.15%	6
2024	573.6	10,395.9	5.52%	6
2025	637.6	10,706.8	5.95%	4

HS heading 3004, Canada reporting, imports by country of origin, US$ millions. Compiled from Statistics Canada's Canadian International Merchandise Trade microdata and the United Nations COMTRADE series for the same heading; the two agree on every share to within 0.01 percentage points. The share column is calculated from the two value columns.

India's position in the Canadian market is stronger in finished dose than chapter-level figures suggest, and it has improved sharply. The US remains dominant at US$3.78 billion, or 35.3 percent of Canada's imports under the heading in 2025, followed by Germany at US$894.4 million and Denmark at US$687.8 million. India ranked fourth at US$637.6 million, up from seventh in 2020 and eighth in 2022.[15] Canada's total imports under the heading were US$10.71 billion in 2025, and India's share rose from 4.45 percent in 2020 to 5.95 percent in 2025.[16] India is now within US$50 million of Denmark, and one further year of growth at the 2025 rate would put it third. The movement is not India's alone: Switzerland fell from second place in 2020 to fifth, Germany's share nearly halved, and the United Kingdom slipped from fourth to tenth, a reminder that supplier rankings in this market can shift quickly in both directions.

The bilateral pharmaceutical trade between India and Canada is therefore lopsided, and in finished dose it is larger than chapter-level figures suggest. It flows almost entirely in one direction, from Indian generic manufacturers into the Canadian market, while Canada's much smaller exports are concentrated in high-value patented medicines and biologics. The place of generics in this picture needs stating precisely, because trade statistics do not record a generic-or-branded split. Generics dominate Canadian prescribing rather than Canadian imports: they accounted for about 81 percent of units dispensed in Canada in 2024, but only 23 percent of sales by value, and roughly 56 percent of the finished generic medicines consumed in Canada are imported.[17] Therefore, the strategic question facing both nations is not whether to rebalance an existing relationship, but whether to deepen a thin one.

Table 2: Canada's ten largest suppliers of finished pharmaceutical products, 2025

Rank	Supplier	2025 value	Share
1	United States	3,784.1	35.34%
2	Germany	894.4	8.35%
3	Denmark	687.8	6.42%
4	India	637.6	5.95%
5	Switzerland	617.3	5.77%
6	Ireland	613.6	5.73%
7	Italy	455.5	4.24%
8	Sweden	430.1	4.02%
9	France	428.8	4.01%
10	United Kingdom	317.3	2.96%

HS heading 3004, Canada reporting, US$ millions. Shares are of Canada's total imports under the heading. Belgium, eighth on a Chapter 30 basis, ranks thirteenth in finished dose at US$245.0 million.

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WHY CANADA MUST DIVERSIFY

Canada's pharmaceutical supply is highly dependent on imports and on supply chains that have proved fragile, a problem faced by many nations worldwide.[18] The need to diversify stems from rising expenditure, demographic aging, growing use of high-cost medicines, shortages, and dependence on imported products. Together, these factors drive demand for reliable and affordable FPPs. Diversification is hence not just a trade objective for Canada but a means to preserve the financial sustainability of Canadian healthcare.

The immediate pressure lies in rising expenditure, as according to the Patented Medicine Prices Review Board (PMPRB) in its CompassRx analysis, prescription drug expenditure across public plans rose 7.4% in 2022–23, reaching more than US$10.09 billion (CAD 14.1 billion). PMPRB reports that spending across these plans grew by US$2.43 billion (CAD 3.4 billion) between 2017–18 and 2022–23, from US$7.73 billion (CAD 10.8 billion), a compound annual growth rate of 5.9 percent.[19] These remain the most recent public-plan figures available, because PMPRB publishes with a lag of roughly three years. The PMPRB has noted an overall growth in prescription drug expenditure due to sustained increases in the use of modern, costlier drugs, alongside a post-pandemic recovery in the number of active beneficiaries.

The composition of that spending is as telling as its level: medicines costing more than US$7,150 a year (CAD 10,000) were used by fewer than 3% of beneficiaries yet accounted for more than 37% of public-plan drug costs. Medicines costing more than US$17,890 a year (CAD 25,000) were used by less than 1% of beneficiaries yet accounted for more than 20% of public costs. The concentration at the high-cost end also shows in a second dataset, and the change of basis is worth marking: the figures above are for the NPDUIS public drug plans in fiscal 2022–23, whereas patented medicines accounted for 47 percent of all medicine sales in Canada in calendar 2024, with the value of those sales rising 10.9 percent in a single year to US$15.81 billion (CAD 22.1 billion).[20]

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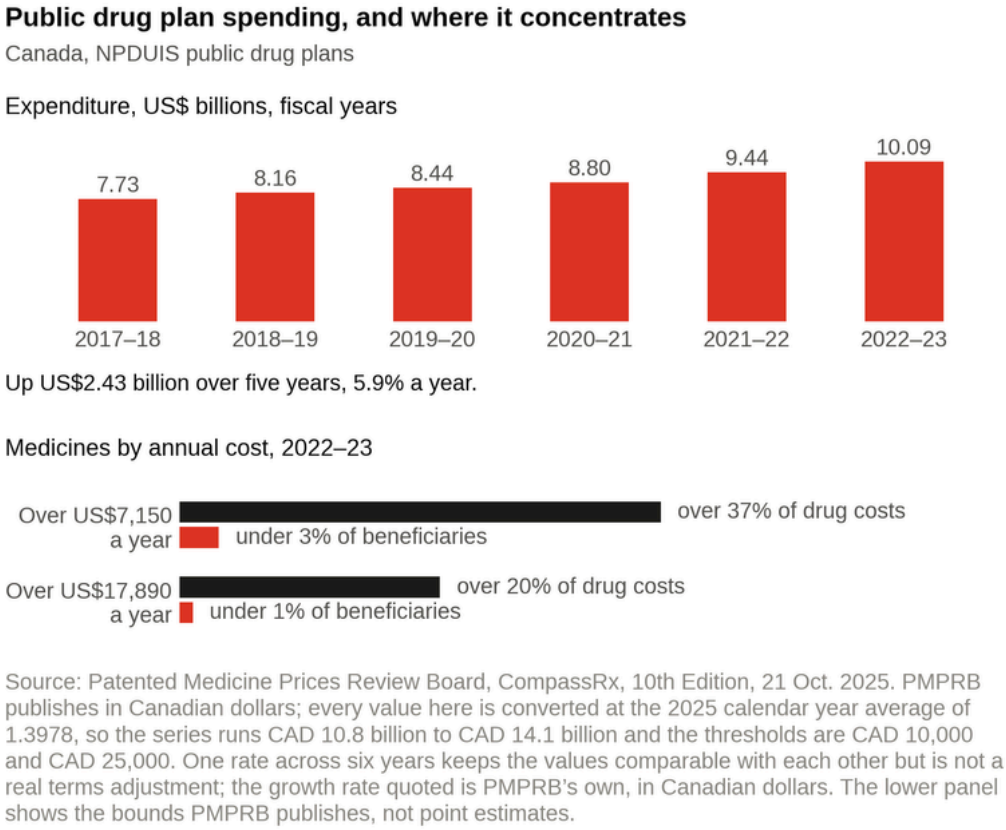


Source: Patented Medicine Prices Review Board, CompassRx, 10th Edition, 21 Oct. 2025. PMPRB publishes in Canadian dollars; every value here is converted at the 2025 calendar year average of 1.3978, so the series runs CAD 10.8 billion to CAD 14.1 billion and the thresholds are CAD 10,000 and CAD 25,000. One rate across six years keeps the values comparable with each other but is not a real terms adjustment; the growth rate quoted is PMPRB's own, in Canadian dollars. The lower panel shows the bounds PMPRB publishes, not point estimates.

These pressures have been reinforced by Canada's aging population. As of July 1, 2025, 8,108,467 Canadians were aged 65 or older, or 19.5 percent of the population.[21] Life expectancy at age 65 stood at a further 19.43 years for males and 22.15 years for females in the preliminary 2022–2024 estimates.[22] An older population generally needs longer treatment periods and regular pharmaceutical care, especially for chronic diseases, thereby increasing demand.

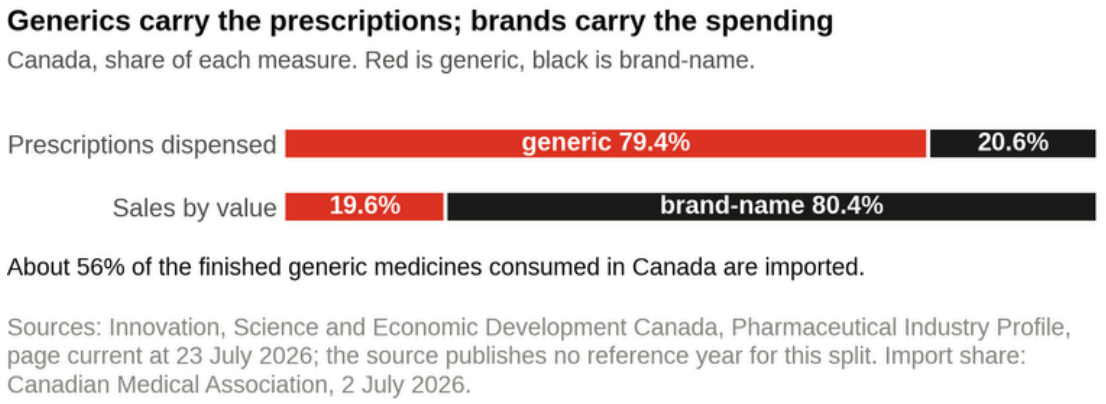
Brand-name products account for 80.4% of Canadian pharmaceutical sales in value but only 20.6% of prescriptions by quantity. Generics account for 19.6% of sales by value and supply 79.4% of prescriptions, according to industry data.[23] Hence, generics account for most prescriptions by volume while consuming a considerably smaller share of total spending, making them essential to maintaining the affordability and sustainability of Canada's public drug plans. The Competition Bureau noted in its 2007 generic drug sector study that generics play an important role in keeping health costs down by competing with brand drugs after they lose patent protection;[24] this holds even though Canada's generic pricing framework has been rebuilt since 2010.

The PMPRB's more recent analysis of Canada's generic drug market demonstrates why affordable medicines matter for healthcare payers. On PMPRB's separate figures for 2018 to 2024, inflation-adjusted generic sales increased by 20.2%, with Canadian per capita spending on generics reaching US$148 (CAD 207) in 2024, the second highest among the countries examined at market exchange

rates and the third highest at purchasing power parity, behind Spain and the US. As a cost-control and access tool, generics allow both public and private payers to meet rising demand for affordable, high-volume medicines while limiting the financial burden on the broader pharmaceutical system.[25]

The first phase of the Pharmacare Act (Bill C-64) established a framework for bilateral agreements with provinces to provide universal, single-payer, first-dollar coverage for selected diabetes and contraceptive medications. The Act also requires the Minister of Health to ask Canada's Drug Agency to prepare a list of essential medicines to inform a national formulary, and to develop a national bulk purchasing strategy alongside a pan-Canadian strategy for the appropriate use of prescription medicines. While broader public coverage can improve access, it also requires purchasing medicines at sustainable prices and maintaining a secure supply chain.[26]

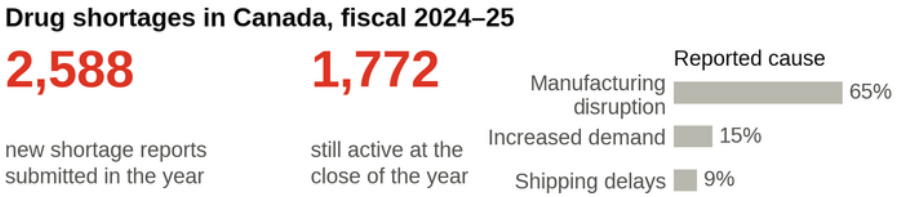
As of mid-2026, however, the rollout has stalled, and only Manitoba, British Columbia, Prince Edward Island and Yukon have signed bilateral agreements, all four before the April 2025 general election, and no further jurisdiction has signed since.[27] The federal position has been inconsistent rather than simply negative: the Prime Minister said in September 2025 that the government remained committed to reaching agreements with the outstanding provinces,[28] while bilateral health funding is scheduled to fall from US$3.08 billion (CAD 4.3 billion) in 2025–26 to US$2.22 billion (CAD 3.1 billion) in 2027– 28, no new federal money has been allocated for further pharmacare deals, and the four existing agreements are set to expire without renewal.[29] For this report, the practical consequence is that the demand expansion Bill C-64 was designed to produce has not arrived, and the pressures described above rest on demography and drug prices rather than on any widening of public coverage.



Canada's domestic pharmaceutical industry, for its part, cannot resolve these challenges without imports. While Canada succeeds in research and development, biopharmaceutical innovation, patented therapies, and specialized manufacturing, its structure is not organized around the mass production of low-margin, high-volume generic medicines. Affordable imports are therefore a rational component of Canada's strategy, working alongside the domestic capacity building set out in its Biomanufacturing and Life Sciences Strategy rather than as a substitute for it. Between 2021 and 2025, Canadian pharmaceutical exports to the world increased by 9.4% while imports increased by 9.2%. The US remains Canada's

main partner in the sector, accounting for 70.4% of pharmaceutical exports and 32.4% of pharmaceutical imports in 2025, with a further 43.7% of imports originating in the European Union. These are figures for pharmaceutical and medicine manufacturing (NAICS 3254) and should not be confused with Canada's all-merchandise trade shares, which are similar for exports but very different for imports.[30]

Compared with patented drugs, essential generic medicines are commercially unattractive since low prices discourage manufacturers from maintaining production lines or redundant capacity. When a small number of firms supply a medicine, a single quality failure or delay in obtaining raw materials can lead to a wider shortage, and that pattern dominates the Canadian record: in the most recent period for which PMPRB has published a breakdown, 91 percent of shortage reports concerned non-patented drugs with multiple manufacturers, against 7 percent for patented medicines.[31] Therefore, while diversification cannot eliminate these domestic hurdles faced by the Canadian pharmaceutical sector, it can reduce dependency on individual firms by broadening the international supply base.



Source: Health Canada, Health Product Shortages in Canada: Fiscal Year 2024 to 2025 in Review, 26 Jan. 2026. The three causes shown are those the review reports; they do not sum to 100%.

Recent changes in US trade policy have made the case for diversification considerably more urgent. In April 2026, the US issued a Section 232 proclamation imposing tariffs of up to 100% on imported patented pharmaceuticals and their upstream inputs, taking effect from 31 July 2026 for seventeen named large manufacturers and from 29 September 2026 for all others.[32] The headline rate is the top of a tiered structure: 20% for companies with onshoring plans approved by the Department of Commerce, zero until January 2029 for those that also agree to most-favored-nation pricing with the Department of Health and Human Services, 15% for the European Union, Japan, South Korea and Switzerland, and zero for the United Kingdom following an amendment effective 31 July 2026. Orphan drugs, plasma therapies, nuclear medicines and cell and gene therapies are excluded outright; there is no carve-out for Canada or India.

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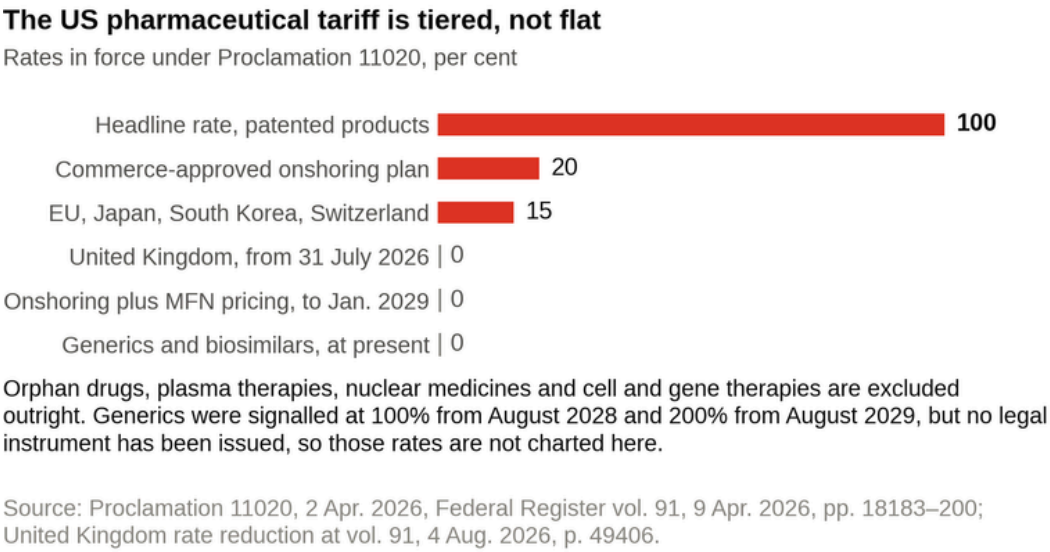
Two aspects of the new US policy have direct implications for the arguments in this report. First, the distribution of the tariff matters more than its headline rate: because European rates are capped at 15% and British products now enter free, the shock falls unevenly across precisely those suppliers on which Canada depends most. Second, generic medicines and biosimilars are exempt for now, so the measure does not yet affect the Indian trade; that exemption, however, is explicitly provisional. The proclamation requires the Secretary of Commerce to advise the President on generics within a year, and in July 2026 the President signaled an intention to tariff generic imports at 100% from August 2028 and 200% from August 2029, although no legal instrument has been issued and the authority for the higher rate has not been stated.[33]



Further, Proclamation 11020 taxes imports into the US and does not tax what Canada buys from Germany or Ireland. The expectation is that American and European producers reallocate capacity towards the protected US market, or reshore into it, and that Canadian orders become a lower priority. That is an expectation rather than an observed effect, and Canadian order lead times and shortage reports for European-sourced products over the next two years would confirm or refute it. Even as an expectation, however, it would act on a very large concentration: in 2025 the US and the European Union together supplied 77.2 percent of Canada's finished dose imports, with the European Union accounting for 41.9 percent and the US 35.3 percent.[34] What India offers is therefore redundancy rather than replacement, a parallel source of supply alongside, not instead of, America and Europe.

Access to FPPs improves affordability and addresses the demand-side problem; it does not, however, solve the upstream dependence on APIs and KSMs, whose production remains concentrated in China. Diversifying FPPs is therefore necessary but not sufficient: it strengthens the final manufacturing stage while leaving the upstream challenge unresolved.

WHAT INDIA OFFERS

India is the world's third-largest pharmaceutical producer by volume and one of the largest suppliers of generic medications.[35] Canada's pharmaceutical constraints lie in affordability, large-scale manufacturing, and long-term supply-chain resilience, making India's pharmaceutical industry a natural supply-side response. Canada's pharmaceutical sector focuses primarily on research and biologics; in contrast, India's comparative advantage lies in its large-scale production of affordable FPPs. India has developed an industrial framework that is capable of manufacturing large volumes of generic medicines at internationally competitive prices.[36]

India's pharmaceutical framework aligns with Canadian demand for high-volume, cost-efficient FPPs. The Government of India puts the country's share of global generic medicine supply at around 20 percent, and the India Brand Equity Foundation gives the same figure for India's share of global generic exports by volume. India is also the largest single source of the vaccines procured by UNICEF, supplying 55 to 60 percent of that agency's requirement, and it meets 99 percent of World Health Organization demand for DPT vaccine, though the measles figure is 45 percent, so the position varies sharply by antigen.[37] Taken together, these figures describe a manufacturing base capable of supplying essential generic medicines, reliably and at scale, to healthcare systems worldwide. Canada's challenge is not only to procure medicines but to secure a reliable supply chain for large quantities of affordable FPPs that can support domestic public drug plans over the long term.[38]

Indian pharmaceutical firms have built their competitiveness on manufacturing efficiency and economies of scale rather than on proprietary innovation, although, as the biosimilar discussion below shows, that is beginning to change.[39] Foreign direct investment into Indian drugs and pharmaceuticals was US$891 million in FY2024–25, against cumulative inflows of US$24.62 billion since 2000. The sector ranks eighth among recipients of Indian foreign investment at about 3 percent of total equity inflow, which measures investor appetite rather than manufacturing capability. The annual figure was down 16 percent from the previous year and the lowest in five years, and that caution applies to everything that follows: the capacity described below exists, but its expansion is not automatic.[40]

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India's manufacturing capabilities become important during sudden increases in demand, supply-chain disruptions, or healthcare emergencies, where production capacity is the determining factor. Indian manufacturers have built deep experience with the most demanding single regulator: 499 Indian sites were approved under the US Food and Drug Administration's generic drug user fee program as at March 2025, out of 2,013 worldwide, second only to the 530 sites in the US itself.[41] India's industrial capabilities make it one of the few countries that can meet Canada's future requirements for FPPs at the scale and consistency the Canadian healthcare system requires. Access to competitively priced finished pharmaceutical products thus becomes a matter of long-term fiscal sustainability and not just trade.[42]

> Going beyond conventional generic medicines, India's expanding biosimilar industry is another important area for future India-Canada pharmaceutical cooperation.

Going beyond conventional generic medicines, India's expanding biosimilar industry is another important area for future India-Canada pharmaceutical cooperation. While India's leadership was built on affordable generic medicines, the global landscape is now shifting towards biosimilars, biologics, and specialty medicines. The Biopharma SHAKTI initiative, announced in the 2026–27 Union Budget with an outlay of US$1.15 billion (₹10,000 crore) over five years, is intended to build capability across biologics and biosimilars, add three new National Institutes of Pharmaceutical Education and Research and upgrade seven existing ones, expand accredited clinical trial capacity, and strengthen the regulatory capacity of the Central Drugs Standard Control Organisation (CDSCO).[43] India has invested significantly in developing domestic biosimilar capabilities and hosts one of the world's largest portfolios of approved biosimilars, which the India Brand Equity Foundation puts at more than 135.[44]

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On the Canadian side, all ten provinces and two of the three territories now operate biosimilar transition policies, requiring patients on certain biologics to move to biosimilar versions in order to retain public drug coverage; Manitoba was the last province to do so, closing its transition window in January 2025.[45] Canadian pharmaceutical research capacity is concentrated in two provinces: Ontario and Quebec together accounted for 71.6 percent of the sector's in-house research and development

expenditure in 2023, at 36.1 and 35.4 percent respectively.[46] While generic medicines remain the immediate foundation of bilateral trade, biosimilars present the next stage for cooperation as Canadian healthcare systems continue to balance rising expenditures with the need to maintain patient access.[47]

Health Canada's regulatory standards are among the world's most stringent, and in August 2025 the World Health Organization designated it a WHO-Listed Authority alongside the regulators of Japan and the United Kingdom.[48] Successful market authorization therefore gives Indian pharmaceutical manufacturers international credibility. Access to Canada helps India achieve its export goals while signaling compliance with high regulatory and quality standards to other advanced pharmaceutical markets. This trust factor improves the global competitiveness of Indian manufacturers and eases entry into other developed markets. It also explains why cooperation under a future CEPA framework offers long-term gains for both countries, a case the remainder of this report sets out.

Successful market authorization therefore gives Indian pharmaceutical manufacturers international credibility. Access to Canada helps India achieve its export goals while signaling compliance with high regulatory and quality standards to other advanced pharmaceutical markets.

WHO GAINS WHAT?

The benefits of deeper India-Canada pharmaceutical cooperation fall to different groups in each country. For India, the principal gains lie in export diversification, industrial and technological advancement, and international credibility in highly regulated markets. In Canada, the gains go beyond cheaper drug procurement: patients gain reliability of supply, and the pharmaceutical sector becomes more resilient through diversified partnerships.

CANADIAN GAINS

Federal and provincial healthcare payers stand to gain most directly, because public drug plans finance a large share of prescription medicine spending in Canada, with private insurance and households covering the remainder. However, reductions in the cost of generic medicines will not benefit everyone equally. The government, which purchases medicines through public drug plans, stands to gain most financially from lower costs and diversification. As pharmaceutical expenditures rise due to demographic aging and increased demand for medications, preserving financial capacity for other healthcare priorities, such as primary care and specialized treatments, is important.[49] Canada's Drug Agency has worked to expand pharmaceutical procurement to further reinforce reliable, competitively priced suppliers for essential medicines.[50]

While the government benefits, patients also benefit, primarily through improved supply to meet demand. Canada's pharmaceutical framework is structured so that many generic medications are reimbursed through public or private drug plans. Affordability alone is not enough if medicines are not available to the public when required, as recurrent shortages of medicines for chronic conditions have shown.[51] Diversifying Canada's supplier base to include Indian manufacturers not only provides supply-chain security but also reduces dependence on a concentrated group of suppliers.[52]

Increased redundancy within pharmaceutical supply chains reduces the risk of manufacturing disruptions or geopolitical shocks that could translate into nationwide shortages. For patients with chronic illnesses, continuity of treatment matters more than reductions in medicine prices alone. Drug security, therefore, becomes an important factor in healthcare quality alongside affordability.[53]

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The Canadian healthcare system itself is also one of the biggest beneficiaries, because diversification improves resilience by reducing concentration rather than by replacing existing suppliers. Canada continues to rely heavily on the US and Europe for biologics and specialized therapeutics, so expanding trade with India for high-volume FPPs adds a protective layer against future geopolitical disruption,[54] reducing systemic vulnerability by allowing essential medicines to be procured through more than one international route. Pharmaceutical procurement is therefore not only a health policy question but a matter of national resilience, as Canada's own Biomanufacturing and Life Sciences Strategy frames it.[55] Finally, companies that specialize in biologics, biosimilars, and high-technology medicines would gain a larger market as bilateral trade expands. While India's advantage lies in large-scale production of generic medicines, Canada excels in advanced biologics, research and development (R&D), and specialized therapeutics.[56] Pharmaceutical cooperation under CEPA could support joint ventures and technology partnerships between manufacturers in both countries. Canadian companies could benefit from India's manufacturing ecosystem while maintaining their focus on specialized medicines and technology. This corridor therefore opens ties beyond FPP trade and creates new opportunities across research and manufacturing capability.

INDIAN GAINS

With increased access to Canadian markets, India's comparative advantage in manufacturing affordable FPPs generates benefits that go beyond export revenue.[57] Indian generic manufacturers would gain access to a stable, high-income market with considerable demand, long-term purchasing intentions, and transparent regulation.[58] Diversification into Canada reduces commercial concentration and adds a more stable export partner. Increased pharmaceutical exports generate foreign exchange that helps support manufacturing investment and advances India's objective of expanding high-value pharmaceutical exports. The benefits also extend to employment and industrial capability. Together, these strengthen India's pharmaceutical industry and reinforce the country's role as one of the world's leading suppliers of affordable generics.

Canadian demand also brings with it higher-value pharmaceutical products, especially biosimilars.[59] As Canadian provinces continue implementing biosimilar substitution policies to contain rising pharmaceutical expenditure, demand is shifting towards complex specialized medicines.[60] India's investment in biopharmaceutical manufacturing in recent years is encouraging manufacturers to grow in this market.[61] Cooperation under CEPA could also lead to technological partnerships, joint research and investment in biologics and biosimilars. This diversification would help India move up the pharmaceutical supply chain while supporting Canada's efforts to improve the affordability of such medicines.[62]

Health Canada operates one of the world's most respected and stringent regulatory systems, a status the World Health Organization recognized in 2025;[63] successful authorization under such conditions demonstrates compliance with internationally recognized standards of safety and quality. For Indian manufacturers, Canadian approval widens market access and strengthens India's credibility when

seeking entry into other advanced markets. In this respect, Canada offers India a platform for improving its reputation as a trusted global pharmaceutical supplier. For Canada, deepening pharmaceutical trade with India supports the objective of reducing dependency on concentrated supply chains. Shortages of essential medicines since the COVID-19 pandemic, and more recent geopolitical uncertainty including US tariff action, demonstrate the importance of pharmaceutical supply chains that can withstand external political shocks. An institutionalized pharmaceutical corridor with India therefore strengthens Canada's long-term health security by expanding the range of reliable suppliers. Analyses of pharmaceutical security make the same point: resilient health systems depend on diversification and a secure supply chain for essential medicines.[64]

Canada needs reliable access to affordable FPPs,[65] and India seeks to expand its biopharmaceutical capabilities, making the exchange mutually beneficial. Pharmaceutical cooperation would then be more than a commercial arrangement; it would become one of the larger building blocks of the wider India-Canada relationship.

> Canada needs reliable access to affordable FPPs, and India seeks to expand its biopharmaceutical capabilities, making the exchange mutually beneficial.

Three limitations qualify that conclusion, and the following section examines each in turn. Firstly, dependence on Chinese APIs and KSMs is the sector's most significant constraint, affecting India directly and Canada indirectly; expanding India-Canada FPP trade does not address upstream concentration risk, and reducing that vulnerability requires investment in domestic API production and joint manufacturing initiatives that go beyond FPP trade. Secondly, Canada's domestic pharmaceutical industry would face greater competitive pressure, since domestic manufacturers cannot match the cost of Indian imports. Canada remains internationally competitive in biotechnology, biosimilars and pharmaceutical innovation,[66] but expanded generic imports could reduce the incentive to build domestic generic manufacturing capability over the long run. That trade-off between cheaper imports and domestic capacity is real and unresolved here. It turns on Canadian industrial policy choices that lie outside a report on bilateral trade, and the recommendations below do not address it. Finally, deepening the India-Canada pharmaceutical corridor should form one part of a broader supply-chain resilience strategy: it strengthens diversification and healthcare security without resolving the structural concentration of the global industry in the US and China.

HOW THEY CAN WORK TOGETHER, AND WHY NOW

During Prime Minister Mark Carney's visit to India from 27 February to 2 March 2026, both governments signed the Terms of Reference for the Comprehensive Economic Partnership Agreement (CEPA) and committed to concluding negotiations before the end of 2026.[67] By July 2026, three negotiating rounds had been completed, the third in Ottawa, covering goods market access, rules of origin, services, intellectual property, sanitary and phytosanitary measures, technical barriers to trade, critical minerals, clean technology, and agriculture.[68] Pharmaceuticals are not among the named negotiating tracks, and appear in the published outcome documents only within the descriptive list of Indian exports. What follows is therefore an intervention in the negotiation rather than a description of it.

Unlike the earlier Early Progress Trade Agreement (EPTA), which was narrower and more of a stepping stone towards a broader agreement,[69] CEPA provides a stage to address investment and regulatory barriers that have constrained bilateral trade in the past. Canada needs a reliable diversification partner capable of large-scale manufacturing and affordable FPPs,[70] while India seeks to expand its exports,[71] strengthen its position as a trusted global pharmaceutical supplier, and advance its technology and biopharmaceutical capability; these needs are complementary.

Unlike the earlier Early Progress Trade Agreement (EPTA), which was narrower and more of a stepping stone towards a broader agreement, CEPA provides a stage to address investment and regulatory barriers that have constrained bilateral trade in the past.

For pharmaceuticals, tariffs are not the main problem; the binding constraints are the regulatory systems that control market access, licensing, inspections, and quality assurance.[72] The timing matters because the current CEPA negotiations offer an opportunity to institutionalize pharmaceutical cooperation rather than treat it as another chapter of a conventional free trade agreement. Most pharmaceutical products already face comparatively low tariffs, small against the cost of regulatory compliance. To enter the Canadian market, manufacturers must meet all of Health Canada's requirements on Good Manufacturing Practices (GMP), product safety and quality, and regulatory compliance.[73] Reducing tariffs would therefore do little for pharmaceutical trade while long regulatory processes remain. The aim of this cooperation should not be to reduce tariffs but to lower regulatory transaction costs while maintaining Canada's standards. Establishing a dedicated pharmaceutical annex within CEPA, centered on

regulatory cooperation, would help both nations. It could include regulatory dialogues, greater transparency in the approval process, and mechanisms for improving inspection outcomes. Such a framework would not lower Canadian standards; it would enable closer working between Health Canada and India's Central Drugs Standard Control Organisation (CDSCO).

Health Canada is party to four Mutual Recognition Agreements covering Good Manufacturing Practices, with Australia, Switzerland, the EEA EFTA states and the European Union member states under the CETA Protocol on Pharmaceuticals, together with a post-Brexit arrangement with the United Kingdom; these show how regulatory cooperation can facilitate trade without compromising safety standards.[74] India is not among them. Health Canada's list of regulatory authorities recognized for the purposes of section C.01A.019 of the Food and Drug Regulations contains thirty-two authorities, all Australian, Swiss, British or European.[75]

Indian manufacturing buildings are listed on Canadian importers' drug establishment licenses, and their GMP compliance is demonstrated overwhelmingly by documentary assessment of inspection reports issued by other regulators, principally members of the Pharmaceutical Inspection Co-operation Scheme and the US Food and Drug Administration.[76] Of the 729 Indian buildings recorded on Health Canada's drug and health product inspections database, 681 currently hold a compliant rating, making India Canada's largest foreign source of drug manufacturing after the US; but fewer than one in five of those buildings have ever been inspected on site by Health Canada.[77] On the database's own record types, then, a mutual recognition arrangement with India would formalize a reliance that already exists in practice rather than create a new one. That reading is the author's; no regulator has put it that way. It would nonetheless be a first for a jurisdiction Canada has not previously treated as a regulatory equivalent, and it should be argued on that basis, with the sequencing and safeguards such a step requires. If comparable cooperation were extended to India, it would accelerate market access and strengthen supply-chain resilience while preserving Health Canada's independent regulatory authority.

Canada maintains internationally competitive strengths in biotechnology, biologics, specialized therapeutics, and pharmaceutical research, while India possesses large-scale manufacturing capability. A dedicated pharmaceutical framework within CEPA could therefore enable joint partnerships, collaborative clinical research, and investment in advanced pharmaceutical manufacturing. Such collaboration would give Canadian firms access to India's manufacturing ecosystem while helping Indian companies extend their capabilities in technology and innovation. India, for its part, has a clear trade interest in expanded exports of affordable FPPs to Canada. Pharmaceuticals are also a less politically sensitive concession for Canada than agriculture, where supply management makes market opening far more costly, and India's negotiators have signaled that the most sensitive files should be left outside the agreement. Pharmaceutical cooperation could therefore deliver comparatively low-cost concessions that generate mutual gains, while Canada continues to pursue its research and development objectives.[78]

The diplomatic rupture that began in 2023[79] is itself an argument for institutionalizing the pharmaceutical corridor under CEPA, so that it can operate independently of the political weather. Trade proved more durable than diplomacy, and the finished dose data make the point more precisely than chapter-level figures do. Across 2022 and 2023, the year that sits wholly inside the diplomatic freeze, Canada's Chapter 30 imports from India fell 6.2 percent while its imports under heading 3004 rose 9.7 percent. The commerce this report is concerned with continued through the rupture; what fell was the biologics and blood products in which India is a marginal supplier. Canadian merchandise imports from India then rose 18.9 percent in 2025 as the relationship began to recover.[80]

A dedicated pharmaceutical framework within CEPA could therefore enable joint partnerships, collaborative clinical research, and investment in advanced pharmaceutical manufacturing.

Integrating the pharmaceutical sector within CEPA would establish a working dialogue, joint review mechanisms, and formal dispute-resolution frameworks to help preserve cooperation during future periods of political tension. This framework should sustain long-term cooperation, as structural demand will persist with Canada's aging population and rising pharmaceutical expenditures. India's pharmaceutical industry will continue seeking access to advanced biotechnology markets. Hence, CEPA is a core mechanism that can be used strategically to create such an alliance, further strengthening India-Canada bilateral relations.

THE HARD PROBLEMS

While the proposed India–Canada pharmaceutical corridor has strong economic reasons for deepening cooperation, several structural hurdles need to be addressed: the shared dependency on Chinese upstream pharmaceutical inputs such as APIs and KSMs,[81] the shifting geopolitical relationship between Canada and China, regulatory quality and confidence in Indian manufacturers, and the political durability of India–Canada relations after the rupture that began in 2023. These issues shape the conditions under which any cooperation would have to be designed. The aim is not to eliminate the vulnerabilities but to build institutions capable of managing them over time.

First, the upstream concentration of the global pharmaceutical supply chain remains the most significant limitation. Throughout this report, a clear distinction was maintained between FPPs and the APIs and KSMs required to manufacture them. Deepening pharmaceutical trade between India and Canada improves supply-chain resilience at the downstream level;[82] it does not change where the upstream chemical inputs originate. India's Department of Pharmaceuticals has reported that China accounted for about 73.7 percent by value of India's imports across 200 specified categories of APIs, bulk drugs and drug intermediates in FY2024–25.[83] Any disruption to Chinese API manufacturing would therefore affect India's capacity to make FPPs, harming Indian manufacturers directly and, indirectly, the Canadian system that relies on them. Deepening this bilateral relationship therefore reduces downstream concentration risk while leaving upstream risk untouched, and pharmaceutical resilience requires parallel investment in domestic API manufacturing and diversification of raw-material suppliers. Joint strategies for upstream resilience are the key hurdle to overcome.

> Deepening pharmaceutical trade between India and Canada improves supply-chain resilience at the downstream level; it does not change where the upstream chemical inputs originate.

Secondly, the reset in Canada-China economic relations during 2026 presents a new challenge to the argument. In January 2026, Ottawa and Beijing issued a Canada-China Economic and Trade Cooperation Roadmap alongside a Preliminary Joint Arrangement on bilateral economic and trade issues.[84] Canada granted an initial quota of 49,000 Chinese electric vehicles a year at a 6.1 percent tariff in place of a 100 percent surtax, extended remission on certain Chinese steel and aluminum products, and undertook not to tariff certain solar products and semiconductors; China in turn cut canola seed tariffs to about 15 percent from 84 percent and exempted canola meal, peas, lobster and crab.[85] Neither instrument mentions pharmaceuticals or active pharmaceutical ingredients, so the reset reflects political direction rather than medicine supply chains. The objection it raises is nonetheless real: if relations with

China are stabilizing, why invest in alternative sources of upstream inputs? The answer is that resilience depends on concentration, not goodwill. Renewed engagement with Beijing does not reduce the concentration of global API production, nor does it assure future stability in the face of public health emergencies or export restrictions. Multiple supply routes make a country more resilient than relying on a single dominant supplier, regardless of the political agreements in force at any given moment.

A third concern is India's pharmaceutical quality and the regulatory confidence it commands. The record is genuinely mixed, and this report's argument is not helped by minimizing it. Between 2022 and May 2025, the US Food and Drug Administration issued 33 warning letters to Indian manufacturing sites, most commonly for failures of quality and purity control, documentation discipline, and hygiene, and 108 of the entries on the FDA's import alert for firms that have not met drug good manufacturing practice requirements are Indian addresses, second in number only to China.[86] More seriously, contaminated pediatric syrups made in India have been implicated in mass child fatalities abroad. The World Health Organization issued an alert in October 2022 concerning four products made by Maiden Pharmaceuticals,[87] and the US Centers for Disease Control and Prevention documented 78 suspected acute kidney injury cases and 66 deaths in The Gambia, three-quarters of them in children under two.[88] Further alerts during 2023 named three other Indian manufacturers, and a domestic cluster in October 2025 involving diethylene glycol in the syrup Coldrif killed more than twenty children in Madhya Pradesh and Rajasthan.[89]

Resilience depends on concentration, not goodwill. Renewed engagement with Beijing does not reduce the concentration of global API production, nor does it assure future stability in the face of public health emergencies or export restrictions.

India's regulatory response has been substantial: mandatory government laboratory testing before the export of cough syrups from June 2023, license cancellations and criminal proceedings, risk-based inspections of some 400 premises resulting in more than 300 enforcement actions,[90] and a revised Schedule M of the Drugs and Cosmetics Rules, notified in December 2023, which introduces a pharmaceutical quality system, quality risk management and annual product quality review, with compliance required of all manufacturers from January 2026.[91] A study published in 2025 found that generic drugs manufactured in India were associated with significantly more serious adverse events than equivalent generics made in the US, an effect concentrated in mature products subject to sustained cost reduction. That finding rests on a passive adverse-event reporting system and does not establish causation, but it is the most substantial published challenge to the quality case and is better met than ignored.[92]

Against that, the aggregate regulatory data do not mark Indian sites out as outliers. In the FDA's own fiscal 2025 inspection results, 17.9 percent of inspections of Indian sites produced an official action indicated classification, against a global average of 18 percent; the only statistically significant deviations the agency identified were China, with fewer such outcomes, and the US itself, with more.[93] Hundreds of Indian facilities continue to manufacture medicines that satisfy regulatory requirements in the US, the European Union, Australia, Japan, and Canada, and Health Canada, relying largely on those same PIC/S and FDA reports, currently rates 681 of the 729 Indian buildings on its inspection database as compliant.[94] That is not an independent Canadian judgment and should not be presented as one. It shows that no regulator with access to the underlying inspection reports has concluded that Indian sites, as a class, fail to meet requirements. Quality failures are therefore not representative of the Indian industry as a whole; they reflect uneven performance across a very large manufacturing base, and that unevenness is precisely what a regulatory cooperation framework exists to address. Canada's framework already limits the risk, because every medicine entering the Canadian market is subject to Health Canada's independent assessment of safety and quality irrespective of its country of origin. What cooperation under CEPA should deliver is not a lower bar, but a faster and better-informed way of applying it. Regulatory cooperation, good manufacturing practice alignment and market authorization are the right subjects for the pharmaceutical annex.

Hundreds of Indian facilities continue to manufacture medicines that satisfy regulatory requirements in the US, the European Union, Australia, Japan, and Canada, and Health Canada, relying largely on those same PIC/S and FDA reports, currently rates 681 of the 729 Indian buildings on its inspection database as compliant.

This report has assumed a degree of continuity in the bilateral relationship between India and Canada, which cannot be taken for granted. Following the tensions that began in 2023, diplomatic engagement largely froze, and trade negotiations were suspended. The sequence is worth stating precisely, because it is often reversed: Canada paused negotiations on the Early Progress Trade Agreement in early September 2023, shortly before the allegations concerning the killing of Hardeep Singh Nijjar were put to Parliament, and the deepest rupture, the reciprocal expulsion of senior diplomats, came in October 2024. Relations have improved since, and the current negotiations aim to conclude CEPA by the end of 2026, but history has shown how readily political disagreement disrupts economic cooperation. Should Canada then increase its reliance on FPP imports from India, and should India commit to a partner with whom tensions have only recently settled? The framework's design, rather than

forecasts about the relationship, answers both questions. Pharmaceutical supply chains depend on stable regulation, predictable procurement, and confidence that they will hold during periods of diplomatic disagreement. These challenges therefore reinforce the central argument of this paper. China continues to dominate API and KSM manufacturing, and the political relationship between India and Canada cannot be assumed to remain permanently stable; that is precisely why any institutionalization of a pharmaceutical corridor between them must be built on diversified supply chains and regulatory cooperation.

> Pharmaceutical supply chains depend on stable regulation, predictable procurement, and confidence that they will hold during periods of diplomatic disagreement.

RECOMMENDATIONS

The goal for India-Canada is a resilient bilateral relationship that improves supply-chain security despite geopolitical uncertainty. Pharmaceuticals are not currently among CEPA's named negotiating tracks, so the three recommendations below are proposals for the negotiation rather than commentary on it. Taken up during the current round, they would change how India and Canada treat pharmaceuticals.

A pharmaceutical annex within CEPA

The annex would deepen cooperation on information sharing, resolving regulatory issues, innovation, and biotechnology. An institutional framework would strengthen resilience and hold through temporary diplomatic tension or geopolitical shock. Institutionalizing cooperation would reduce uncertainty for both governments, healthcare providers, and pharmaceutical manufacturers, and would provide the confidence long-term investment requires.

Joint upstream API and KSM resilience, and joint research and development

Reducing the shared dependency on Chinese APIs and KSMs would build long-term resilience for both countries.[95] India is already expanding domestic API capacity through its production-linked incentive (PLI) scheme for critical key starting materials, drug intermediates, and APIs, which carries an outlay of US$796 million (₹6,940 crore) and has approved 48 projects covering 33 drugs, establishing roughly 55,100 tonnes a year of capacity across 26 critical APIs and KSMs.[96] The results so far are modest against the scale of the problem: cumulative sales under the scheme reached about US$265 million (₹2,313 crore) by early 2026, while China's share of India's API and intermediate imports rose rather than fell over the same period. That gap argues for cooperation, not against it. With Canada's advanced biotechnology, biologics, and pharmaceutical research and India's manufacturing scale and cost competitiveness, both countries stand to gain from acting together. Canada can finance projects and generate new technology, and India intends to expand its presence in pharmaceutical biotechnology, so joint research and development could sustain a pharmaceutical chapter in its own right. A bilateral science and technology cooperation framework already exists and offers a route to do this without building new machinery.[97]

Regulatory cooperation and Good Manufacturing Practices

Canada should maintain its regulatory standards while expanding cooperation with Indian authorities on Good Manufacturing Practices: joint or observed inspections, structured pre-submission dialogue, and a defined route for Indian manufacturers to remediate identified gaps. The purpose is quality assurance before it is trade facilitation: shared inspection outcomes give Health Canada more information about Indian sites than documentary assessment alone provides, and a defined remediation route gives manufacturers a reason to close gaps rather than leave the market. Shorter approval times during shortages and improved market access would follow from that foundation rather than substitute for it.[98]

The practical first step is narrower than a full mutual recognition agreement. A confidentiality arrangement and information-sharing protocol between Health Canada and CDSCO, followed by a pilot covering a defined class of products, would build the inspection record on which any later recognition decision would have to rest.

CONCLUSION

Canadian demand-side vulnerabilities and Indian supply-side capabilities together present a compelling case for deepening pharmaceutical trade. Canada's healthcare system faces persistent pressure from an aging population, rising expenditure on high-cost biologics, and chronic drug shortages. The Pharmacare Act created the architecture for universal coverage of contraceptives and diabetes medicines, but its rollout has stalled, and federal funding is being withdrawn, so these pressures rest on demography and drug prices rather than on any widening of public coverage. As Canada lacks the domestic manufacturing elasticity and cost competitiveness required for mass generic production, importing FPPs is economically rational. As the world's third-largest pharmaceutical producer by volume, India offers the manufacturing scale, cost efficiency, and regulatory compliance record, strong in aggregate though uneven across firms, to act as a leading diversification partner, though it is not the only candidate: China competes at comparable scale and dominates the upstream inputs; the established European manufacturers already supply two-fifths of Canada's finished dose imports; and Canada's own Biomanufacturing and Life Sciences Strategy contemplates building domestic capacity. What distinguishes India is that it supplies the particular capability Canada lacks: high-volume, low-margin finished dose, at a scale and price none of those alternatives offers on the same terms.

However, both nations remain heavily dependent on Chinese upstream chemical inputs (APIs and KSMs) and on the concentration risk that comes with them, so sustaining FPP manufacturing means addressing those vulnerabilities. Supply-chain security also requires a long-term strategic framework combining the expansion of downstream pharmaceutical trade with joint upstream resilience. The Comprehensive Economic Partnership Agreement (CEPA) negotiations, expected to conclude by the end of 2026, provide the best available opportunity to institutionalize India-Canada pharmaceutical cooperation. A dedicated pharmaceutical annex focused on Good Manufacturing Practice alignment, mutual recognition, and wider regulatory cooperation could lower the non-tariff barriers that matter most in this sector. Such a framework would help keep the pharmaceutical relationship insulated from diplomatic tension. Through joint research and development, joint upstream API and KSM resilience, and regulatory cooperation on Good Manufacturing Practices, India and Canada can turn pharmaceuticals from one more traded commodity into a strategic partnership of mutual benefit.

ENDNOTES

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ENDNOTES

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[15] Statistics Canada, Canadian International Merchandise Trade Database. India's rank among Canada's suppliers of heading 3004 ran seventh in 2020 and 2021, eighth in 2022, sixth in 2023 and 2024, and fourth in 2025. On the Chapter 30 measure the same series runs ninth, tenth, eleventh, tenth, eighth and ninth, so the "eleventh to eighth" formulation used in earlier drafts was a two-year window on the broader measure and its endpoint no longer holds. Top suppliers in 2020 were the United States, Switzerland, Germany, the United Kingdom and Italy; in 2022, the United States, Germany, Ireland, Switzerland and Denmark.
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