TRADE AND DISTRIBUTION OF THERAPEUTIC PRODUCTS (PHARMACEUTICALS/BIOLOGICS AND MEDICAL DEVICES)

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REGULATORY FRAMEWORK AND COMPETENT AUTHORITIES

1. What are the principal statutes, regulations, and competent authorities that govern the import, wholesale distribution, retail sale, and export of therapeutic products (ie, for pharmaceuticals/biologics and medical devices, noting any separate or overlapping regimes)? In the case of a federal state, what is the division of powers between the federal government and the states?

The principal statutes regulating therapeutics in Canada are the Food and Drugs Act (FDA) and the Controlled Drugs and Substances Act (CDSA), together with the Food and Drug Regulations (including Part C for drugs), the Medical Devices Regulations, and the Natural Health Products Regulations. The FDA bans the sale of unsafe or misrepresented drugs and devices and requires market authorisation; the CDSA regulates controlled substances (including import, export, distribution, sale, and production). Medical device rules cover licensing, import/sale, advertising, and safety reporting, including information requests and recall/foreign action reporting where risks arise.

Health Canada is the federal regulator of therapeutics. Within Health Canada, the Health Products and Food Branch (HPFB) grants marketing authorisations, licences establishments, and oversees import/export, quality, and post-market surveillance, including through the Pharmaceutical Drugs Directorate and the Biologic and Radiopharmaceutical Drugs Directorate.

Import, wholesale distribution, and export of drugs generally require a Drug Establishment Licence (DEL) and compliance with GMP requirements under the Food and Drug Regulations, with additional permits from Health Canada's Office of Controlled Substances for narcotics, controlled drugs, and precursors. Medical device importers and distributors generally require a Medical Device Establishment Licence (MDEL) and must meet complaint-handling, incident-reporting, and recall requirements.

Under the Constitution Act, 1867, the federal government (through Health Canada) regulates market authorisation, manufacturing standards, import/export, and post-market surveillance (primarily under criminal law and trade and commerce powers). Provinces and territories regulate healthcare delivery and retail distribution, including pharmacy licensing and professional practice, formularies, and reimbursement.

2. How are therapeutic products classified for regulatory purposes (eg, prescription-only, over-the-counter, hospital-use, risk classes for devices, etc.) and what legal consequences attach to each classification with respect to trade and distribution? In particular, is premarket review and approval required by a competent authority?

Drugs are classified federally as prescription or non-prescription through the Prescription Drug List under the Food and Drug Regulations (C.01.040.3). Controlled substances are further restricted under CDSA Schedules I–V. Conditions of sale at retail are also reflected in the National Drug Schedules maintained by the National Association of Pharmacy Regulatory Authorities (NAPRA) (Schedule I–III and Unscheduled). Commercial sale generally requires a Drug Identification Number (DIN) issued following Health Canada review (FDR C.01.014).

Medical devices are classified by risk (Classes I–IV) under Schedule 1 of the Medical Devices Regulations. Class I devices generally require only an MDEL (no device-specific review), while Classes II–IV require a Medical Device Licence (MDL) with increasing evidence requirements and mandatory premarket review.

Natural health products (NHPs) (eg, vitamins and herbal remedies) are regulated under the Natural Health Products Regulations and generally must be suitable for OTC use. Sale requires a Natural Product Number (NPN) (or DIN-HM for homeopathic medicines).

Selling drugs without DINs/NPNs or Class II–IV devices without MDLs contravenes the FDA and may lead to seizures, injunctions, licence action, or prosecution (ss 31–37 FDA). Health Canada conducts market surveillance federally; provinces regulate pharmacy operations and retail practice.

LICENSING, AUTHORISATIONS, AND DISTRIBUTION CHANNELS

3. Which licences, authorisations, registrations, or other official permissions are required for businesses to engage in wholesale distribution of therapeutic products, and what key conditions (such as Good Distribution Practice, facility standards, personnel, insurance, or financial guarantees) attach to them?

For drugs, wholesale distribution generally requires a Drug Establishment Licence (DEL) and compliance with GMP requirements that incorporate distribution practices (Part C, Division 1A, FDR; GUI-0001). Key requirements include a quality system, appropriate storage (including temperature controls), qualified personnel, traceable distribution records, and recall/complaint procedures. Foreign fabrication/packaging/labelling/testing sites must be listed on the DEL annex with supporting GMP evidence (eg, GUI-0080). DELs are subject to inspection and annual review.

DEL requirements apply to fabricators, packagers/labellers, importers, distributors, wholesalers, and testers unless an express exemption applies (eg, certain pharmacy and practitioner activities).

For NHPs, manufacturers/importers require site licences and products require product licences (NPNs), with facility and quality information provided to Health Canada.

Cannabis for medical purposes is licensed under the Cannabis Act and regulations.

For medical devices, importers and distributors generally require an MDEL (MDR ss 44–51.1) and must maintain procedures for complaints, mandatory incident reporting, distribution records/traceability, and recalls, with senior-official attestation. Class II–IV manufacturers must hold Medical Device Single Audit Program (MDSAP) certification (ISO 13485-based).

4. Are there distinct licensing or notification requirements for businesses that provide therapeutic products directly to consumers (including community pharmacies, internet pharmacies, or other retailers), and what key conditions attach to them?

Therapeutic products sold in Canada generally require federal authorisation (eg, DIN/NPN/MDL, as applicable). Retail supply is primarily provincial/territorial: community and internet pharmacies must be licensed by the provincial pharmacy regulatory authority and operate under a designated manager (licensed pharmacist). Retailers of pre-packaged, authorised NHPs do not require a federal site licence (site licences apply to manufacturers/packagers/labellers/importers). Medical device retailers selling directly to end-users for personal use are generally MDEL-exempt (GUI-0016; MDR s 44).

5. What rules govern the sale of therapeutic products to consumers over the internet (including social-media and marketplace platforms)?

Online sales (including via social media and marketplace platforms) are governed by the same federal rules as offline sales, principally the FDA and associated regulations (and, for certain products, the Canada Consumer Product Safety Act). Online pharmacies must be provincially licensed, operate from Canadian premises, employ Canadian-licensed pharmacists, and dispense prescription drugs only on valid prescriptions from Canadian-licensed practitioners. Unauthorised health products ordered online may be refused entry or seized at the border (GUI-0116).

Advertising rules apply equally online: Health Canada bans false or misleading advertising and distinguishes advertising from informational content in guidance. Consumer-directed prescription drug promotion is limited (eg, reminder and help-seeking messages, subject to strict criteria).

Some marketplaces have made voluntary commitments (eg, the September 2023 Canadian Product Safety Pledge) to detect and remove unsafe products; enforcement authority remains with Health Canada under the CCPSA and FDA.

IMPORT

6. What is the import-control framework for therapeutic products (eg, import licences, product registration or listing prerequisites, customs classification, tariff rates, national or regional exemptions, and routine or risk-based border inspections)?

Therapeutic product imports are regulated under the FDA/FDR and customs law. Importing drugs for sale generally requires a DEL, with foreign manufacturing sites listed on the importer's annex and supported by GMP evidence.

Commercial imports generally require product authorisation (DINs for drugs; NPNs for NHPs) and importer licensing (DEL for drugs and MDEL for devices). CBSA and Health Canada coordinate border controls (including through risk-based inspections). CBSA may detain shipments under the Customs Act, and Health Canada may refuse entry, seize, or order removal of non-compliant products (FDA, s 23; Customs Act, s 101; GUI-0116).

7. To what extent may consumers import therapeutic products for personal use (whether by taking the products across the border or receiving them by mail), and what quantitative limits, prescription requirements, customs declarations, duties, or other restrictions apply?

For prescription drugs, personal importation is limited: travellers entering Canada may generally bring the lesser of a single course of treatment or a 90-day supply, in pharmacy/hospital-dispensed packaging that permits identification as personal-use (GUI-0116).

Mail/courier importation of prescription drugs by Canadian residents is generally not permitted, subject to narrow exceptions (eg, returning residents with Canadian prescriptions and certain visitor scenarios). For OTC drugs, NHPs, and devices, 90-day personal-use supplies are generally permitted. Controlled substances must be carried by the traveller (no mail/courier), declared at the border, and are subject to the same 'single course/90-day' limit (GUI-0116; CDSA class exemptions).

8. May foreign suppliers ship therapeutic products directly to consumers via e-commerce or mail order, and what local presence, platform registration, verification, or labelling obligations - if any - must they satisfy?

Foreign suppliers generally cannot ship therapeutic products directly to Canadian consumers for commercial sale. Imports for sale must be made through a Canadian licence holder (eg, DEL/MDEL, as applicable), and products must be authorised (eg, DIN/NPN/MDL).

Prescription drug importation is restricted (eg, FDR C.01.045), and Canadian consumers generally cannot legally purchase prescription drugs from foreign sources by mail/internet. Foreign manufacturers typically partner with Canadian-licensed importers (DEL holders) and must provide GMP evidence for foreign sites. For devices, foreign manufacturers may hold MDLs, but import/distribution generally requires an MDEL holder with complaint/recall systems. Practitioners may access non-marketed drugs for urgent needs via the Special Access Programme (FDR C.08.010–C.08.011).

9. How is parallel importation (ie, of products licensed and sold in other jurisdictions) of therapeutic products by businesses regulated, particularly with respect to intellectual property rights, product re-labelling or re-packaging, and requirements to maintain original quality, safety, and traceability?

Canada does not provide a simplified 'parallel import' pathway: drugs generally require independent Canadian market authorisation (DIN) even if approved elsewhere. A limited exception exists for critical shortages, where Health Canada may permit temporary importation of certain foreign-authorised drugs under the exceptional importation framework (FDR C.10.004–C.10.011), with conditions and modified labelling.

For standard importation, drugs must hold a DIN, NHPs an NPN, and Class II–IV devices an MDL. Importers require establishment licences (DEL for drugs; MDEL for devices) with foreign sites listed (for drugs). Relabelling of non-compliant products may be permitted on notice to Health Canada within prescribed time limits (FDR A.01.044; MDR s 21.1), and labelling must meet Canadian requirements (including bilingual requirements where applicable).

Importers must maintain distribution records for traceability, manage recalls/complaints, and meet reporting obligations (including adverse reactions/incidents) under the applicable regulations. Health Canada and CBSA may refuse entry, seize, or order destruction of non-compliant products (FDA, s 23).

EXPORT

10. Are there quantitative quotas, permits, or other measures that restrict or condition the export of therapeutic products (eg, to mitigate shortages or address public health emergencies), and how are such measures administered and enforced?

Canada does not generally impose export quotas, but shortages are managed through mandatory reporting and restrictions on exporting drugs intended for the Canadian market.

FDR C.01.014.9 requires reporting actual and anticipated drug shortages/discontinuations within five days. Shortages are classified through a multi-stakeholder tiering process; Tier 3 shortages may trigger exceptional importation of certain foreign-authorised drugs (FDR C.10.004–C.10.011).

Since 27 November 2021, DEL holders may not distribute drugs intended for the Canadian market for use outside Canada unless they have reasonable grounds to believe this will not cause or worsen a shortage (FDR C.01.014.13; GUI-0145).

11. Is there any form of 'export-only' or 'dual-labelling' authorisation that permits the manufacture and export of therapeutic products not approved for domestic marketing, and if so, what standards, labelling, or record-keeping obligations apply?

Canada permits manufacture and export of drugs not approved for domestic marketing through the section 37 exemption under the FDA, where the drug is made in Canada solely for export (not Canadian consumption) and is accompanied by an export certificate meeting the destination country attestation requirements (s 37(1)(c) FDA; Appendix III FDR).

Amendments effective 8 December 2022 extended DEL and GMP requirements to export-only drugs (FDR A.01.048), and export certificates must generally be retained for five years (A.01.046 FDR). Export-only drugs remain subject to prohibitions on adulteration, unsanitary conditions, and misleading packaging (s. 37(1.1) FDA).

Export documentation typically includes certificates/declarations confirming the product is not for Canadian consumption and addressing destination-country requirements, with supporting records retained to substantiate compliance.

For medical devices, FDA, s 37(1.1)(d) requires that export-only devices not cause injury when used as directed/customarily used and not be labelled or packaged in a misleading manner, but they are otherwise exempt from domestic licensing requirements.

LABELLING, TRACEBILITY, AND PRODUCT INFORMATION

12. What local language labelling, patient information, unique device identification, serialisation, anti-counterfeiting, or traceability requirements must be met before imported therapeutic products may circulate domestically or before therapeutic products may be exported?

For drugs, non-prescription products sold in open self-selection areas must be labelled in English and French (FDR A.01.015(2)) and include required information such as a Drug Facts Table, DIN, lot number, and expiry date (eg, C.01.004; C.01.004.02 FDR). Prescription drugs and hospital/clinic-only products may generally be labelled in either official language.

For medical devices, labelling must be in English or French at minimum, with the other language provided on request; devices sold to the general public require specified information in both languages (MDR s 23). Labels must also include core product and safe-use information (eg, manufacturer, identifiers/control numbers where applicable, contents, directions, storage conditions, expiry date, and sterility/investigational statements where relevant).

Canada does not currently mandate unique device identification, pharmaceutical serialisation, or a general track-and-trace regime. Anti-counterfeiting relies mainly on establishment licensing, GMP controls, and Health Canada's counterfeit health product policy (POL-0048).

PRICING, REIMBURSEMENT, AND MARKET ACCESS

13. Are there any price-control, reimbursement, public procurement, or stock/ supply-obligation regimes that (while not trade measures per se) materially influence the distribution channels or availability of therapeutic products?

The Patented Medicine Prices Review Board (PMPRB) reviews prices of patented medicines to ensure they are not excessive (Patent Act ss 79–103). Amendments in force since 1 July 2022 updated the comparator 'PMPRB11' countries. Final PMPRB Guidelines published 30 June 2025 take effect 1 January 2026 and use a two-step review, including comparison to the highest international price among PMPRB11 countries.

The pan-Canadian Pharmaceutical Alliance (pCPA) conducts joint price negotiations for public drug plans after health technology assessment. Provinces/territories make final formulary decisions, and generics are subject to tiered pricing frameworks.

ENFORCEMENT, COMPLIANCE, AND RECENT DEVELOPMENTS

14. What investigative powers, sanctions, and remedial measures (administrative, civil, or criminal) are available to regulators when they detect non-compliance with trade and distribution rules for therapeutic products, and how are these powers used in practice?

Health Canada inspectors may enter premises, examine products, take samples, copy records, and seize or detain non-compliant goods (FDA s 23). The Regulatory Operations and Enforcement Branch applies a graduated compliance approach, including compliance promotion, licence action (DEL/MDEL), seizures, and referrals for prosecution. The Minister may also order a recall where a product presents a serious or imminent risk of injury to health (s 21.3 FDA).

The Protecting Canadians from Unsafe Drugs Act expanded ministerial powers (eg, recalls, label changes, and requiring tests/studies) (ss 21.1–21.32 FDA). Contraventions can result in

significant fines (including up to CAD5m for certain offences) and imprisonment, with higher penalties where conduct is knowing/reckless or involves false or misleading statements to regulators (eg, ss 31.2–31.4 FDA).

15. Is there recent case law, legislative or policy developments, noteworthy enforcement trends, or anticipated reforms that may significantly alter the regulation of trade, distribution, or cross-border movement of therapeutic products in the future?

Recent federal reforms include the Agile Licensing amendments (SOR/2024-238, registered 29 November 2024), which expand terms-and-conditions authority for DINs (C.01.014.21 FDR) and introduce new risk management plan requirements for certain submissions (in force 1 April 2027; Division C.01.700–704). The Budget Implementation Act, 2024, No. 1 (S.C. 2024, c. 17) created new FDA regulation-making authorities, including foreign regulatory authority reliance (s. 30.06). Medical device amendments (SOR/2024-136, in force 14 December 2024) include 24-hour recall reporting, terms-and-conditions authority for MDELs, and expanded adverse event reporting; terms-and-conditions authority for Class II–IV MDLs effective as of 1 January 2026.

Protecting Canadians from Unsafe Drugs Act powers were extended to natural health products on 22 June 2023 (S.C. 2023, c. 26). Sale restrictions for NHPs containing ephedrine and pseudoephedrine were finalised in SOR/2025-93 (effective 18 May 2025), including pharmacist oversight for certain online fulfilment. Planned NHP cost recovery (previously scheduled for 1 December 2025) was paused in 2025.

Protecting Canadians from Unsafe Drugs Act was extended to natural health products effective 22 June 2023 (S.C. 2023, c. 26), authorising Health Canada to order recalls and label changes with penalties up to CAD5m for non-compliance. Sale restrictions for NHPs containing ephedrine and pseudoephedrine were finalised through SOR/2025-93 (effective 18 May 2025), extending retail restrictions to combination products and requiring pharmacist approval for online sales fulfilment. NHP cost recovery, originally scheduled for 1 December 2025, was paused following the spring 2025 federal election.

In *Pharmascience Inc v Janssen Inc*, 2024 FCA 23, the Federal Court of Appeal upheld patent claims for dosing regimens, holding that patentable subject matter is assessed by examining ‘how to use’ rather than ‘whether to use’ an invention. The Supreme Court of Canada granted leave to appeal, and the appeal was heard 9 October 2025. A decision has not yet been released.

In *Galderma Canada Inc v Canada* (Attorney General), 2024 FCA 208, the Federal Court of Appeal held that the Patented Medicine Prices Review Board exceeded its jurisdiction in regulating prices of unpatented medicines based on clinical similarity to patented drugs.

The Patented Medicine Prices Review Board released final Guidelines on 30 June 2025, effective 1 January 2026 (PMPRB Guidelines 2025), establishing a two-step price review: Initial Review comparing Canadian list prices to the Highest International Price among 11

comparator countries (Australia, Belgium, France, Germany, Italy, Japan, Netherlands, Norway, Spain, Sweden, United Kingdom), followed by In-Depth Review for prices exceeding benchmarks. Complaints triggering In-Depth Review are limited to federal, provincial, and territorial health ministers and public drug plan representatives.

Foreign site GMP requirements (GUI-0080, updated December 2024) ended Covid-19 temporary 'new evidence required by' (NERBY) date extensions as of 31 December 2024, requiring DEL holders to submit current GMP evidence for foreign buildings. SOR/2024-136 introduced ambulatory incorporation by reference for designated regulatory authority recognition. MDEL modernisation proposed by Health Canada proposes removing MDEL requirements for foreign distributors selling solely through Canadian importers, while mandating supplier list disclosure and standard operating procedure requirements.

Health Canada's Forward Regulatory Plan 2025–2027 outlines potential initiatives such as clinical trials modernisation and drug scheduling amendments, with an emphasis on risk-proportionate oversight and international alignment.