The Pharma Legal Handbook

Canada

Regulatory, Pricing and Reimbursement Overview · Preclinical and Clinical Trial Requirements · Marketing, Manufacturing, Packaging and Labeling Advertising · Traditional Medicines and OTC Products · Product Liability · Patents and Trademarks · Regulatory Reforms · Cannabinoid Drugs, Medicinal Cannabis and Opioid Drugs · Orphan Drugs and Rare Diseases · Localization · Biosimilars and Biologics

PHARMA BOARDROOM

Canada

The Pharma Legal Handbook answers essential questions about this environment for pharmaceuticals in Canada.
It is a must have for any company operating in the country or looking to enter the market.

Prepared in association with FASKEN, a leading international law firm, it should answer any questions linked to Regulation, Pricing, Clinical and Preclinical Trials, Marketing, Manufacturing, Trademarks and Patents.

FASKEN

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THE AUTHORS

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Dara Jospé practises law in the area of life sciences, health and food regulation. She advises manufacturers on all stages of the lifecycle of a pharmaceutical product, from conception until it reaches the consumer. In all cases, Dara develops low-risk and creative ways to adjust to the legal prohibitions and policy restrictions while keeping business interests and the safety of patients in mind.

She regularly assists companies with their regulatory and compliance responsibilities, including advising on the launch of a new health product in Canada, reviewing advertising material, developing patient support programs involving healthcare professionals, opining on bribery and corruption concerns and drafting standard operating procedures, among others.

In addition, she provides advice on all drug and medical device pricing and reimbursement questions, including assisting with PMPRB investigations, negotiating and drafting product listing agreements in various provinces and providing public procurement assistance.

Dara also advises clients in the context of health product advertising complaints before Health Canada as well as the Pharmaceutical Advertising Acceptance Board and Advertising Standards Canada.

She is frequently involved in Health Canada investigations and recalls. She helps to guide companies through field actions and provides strategic advice to save time, effort and costs for her clients.

Languages:
· French · English

JEAN-RAPHAËL CHAMPAGNE

Jean-Raphaël Champagne advises clients on issues related to commercial and regulatory law in the technology and life sciences sectors. He has extensive experience drafting legal opinions on regulatory compliance with Health Canada, the rules governing advertising and the ethical standards applicable to the pharmaceutical industry. He also counsels clients on cannabis-related issues.

Jean-Raphaël advises clients on the complex regulatory framework applicable to the cannabis market. Mr. Champagne is often asked by the press to comment on various aspects of cannabis law.

He has participated in many start-ups in several high-technology sectors. Jean-Raphaël has also participated in purchase and sale transactions involving private financings and technology transfers.

A published author, he contributes to updating the Drug and Health Products Law in Canada by Mathieu Gagné, an indispensable health law tool.

Languages:
· French · English

MARIE LAFLEUR

Marie Lafleur is a seasoned intellectual property litigator. She regularly appears before the courts in proceedings under the Patented Medicines (Notice of Compliance) Regulations and litigation concerning pharmaceutical patent infringement or invalidity. Her expertise encompasses biologicals and biosimilars.

Marie has represented numerous companies in proceedings to prevent the Minister of Health from issuing Notices of Compliance that would allow generic versions of patented drugs to be sold, including citalopram, escitalopram, doxylamine/pyridoxine, cyclosporin, omeprazole, diltiazem, divalproex and terazosin.

She has also successfully filed numerous applications to add or remove patents from the Health Canada register. She was involved in many applications for judicial review of various decisions by provincial and federal health ministers.

Marie's expertise covers every extraordinary remedy, particularly seizures before judgment and injunctions, and she fully masters the range of alternative dispute resolution mechanisms available.

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01 REGULATORY, PRICING, AND REIMBURSEMENT OVERVIEW

1. What are the regulatory authorities with jurisdiction over drugs, biologicals, and medical devices in your country?

Health Canada is the federal authority responsible for regulating pharmaceutical drugs, biologicals, and medical devices for human use. Health Canada's Health Products and Food Branch (**"HPFB"**) is the body responsible for reviewing, assessing, regulating and monitoring health products in Canada.

2. What is the regulatory framework for the authorization, pricing, and reimbursement of drugs, biologicals, and medical devices?

(a) AUTHORIZATION

The Food and Drugs Act forms the legislative framework for the marketing and manufacture of drugs, biologicals, and medical devices in Canada. The Food and Drug Regulations, Natural Health Products Regulations, and Medical Devices Regulations make up the general regulatory framework. The law and its regulations are supplemented by policies and guidelines published by Health Canada.

(B) PRICING

Price regulation in Canada occurs at both the federal and provincial levels. The price of patented medicines is reviewed at the federal level through the Patented Medicine Prices Review Board ("PMPRB"). The PMPRB seeks to ensure that the prices of patented medicines are not excessive.

The provinces and territories employ various mechanisms to regulate the price at which both innovative and generic drugs are sold and reimbursed, as further described below.

(C) REIMBURSEMENT

In Canada, reimbursements of drugs, biologicals and medical devices are governed under federal and provincial jurisdiction and also provided for by the private sector. Under the Health Act, all necessary drug therapy administered within a Canadian hospital setting is insured and publicly funded. Outside the hospital setting, provincial and territorial governments are responsible for the administration of their own publicly funded prescription benefit programs. Provincial drug benefit plans are not harmonized, and a miscellany of different private and public drug plans for reimbursement are available across Canada. To be reimbursed by one or more provincial drug insurance plans, manufacturers will have to ensure that their drugs appear on the provincial formulary list.

Certain eligible groups are also covered under specific federal or provincial drug benefit programs. First Nations and Inuit, members of the military, veterans, members of the Royal Canadian Mounted Police, and inmates in federal penitentiaries are covered by federal programs. Seniors, recipients of social assistance, and individuals with diseases or conditions that are associated

with high drug costs are covered by provincial programs. Some provinces include income-based universal programs.

3. What are the steps to obtaining authorization to develop, test, and market a product?

(A) NEW DRUGS

New drugs cannot be marketed unless they have been granted authorization. Applicants must submit a New Drug Submission (**"NDS"**) that demonstrates the new drug's safety and efficacy. The NDS includes the results of the pre-clinical and clinical studies regarding the production of the drug, packaging and labelling details, and information regarding therapeutic claims and side effects. The drug's name must be provided and approved to ensure that drug names are not similar and thus likely to be confused with one another. Applicants must then submit a Drug Identification Number (**"DIN"**) application. The applicant further submits specimens of the labelling to be used for the new drug as well as a statement indicating the proposed date on which those labels will first be used. Once authorized, the new drug is issued a Notice of Compliance (**"NOC"**) and a DIN.

Additionally, no Canadian pharmaceutical establishment may manufacture, fabricate, perform any tests on, package, label, distribute, import, or sell a drug without a Drug Establishment Licence (**"DEL"**). To acquire a DEL, applicants must provide information concerning their activities and each category of drug for which the licence is requested. The application must also include information about the building in which the activities will be performed, as well as evidence that these buildings, equipment and proposed practices and procedures meet applicable Good Manufacturing Practices (**"GMP"**) requirements.

(B) MEDICAL DEVICES

Medical devices are categorized in one of four categories (Class I, II, III or IV) depending on their level of risk. Class II, III and IV medical devices require pre-market approval to be commercialized in Canada. A manufacturer of a Class II, III or IV device must submit an application attesting to, among other things, the safety and efficacy of the device and must also submit labelling information.

Although certain exemptions may apply, the importer and the distributor of a device normally needs a Medical Device Establishment Licence ("MDEL") to perform their activities in connection with medical devices. For instance, while they do not need a product licence, Class I medical devices can only be imported, sold and distributed by companies that hold MDELs delivered by Health Canada.

Class I medical devices also remain subject to and must comply with any requests of the Minister of Health (the "Minister") to submit safety and efficacy information.

(C) NATURAL HEALTH PRODUCTS

Under the Natural Health Products Regulations, applicants must submit applications demonstrating safety and efficacy of the Natural Health Product

(**"NHP"**) to acquire a Product Licence, and must also apply for a Site Licence instead of a DEL. For further information on NHPs, see **Chapter 4.**

(D) EXCEPTIONS: EMERGENCIES AND ORPHAN DRUGS

As an exception, practitioners can obtain authorization for new drugs and medical devices intended for medical emergencies through the Special Access Program (**"SAP"**) even if a NOC has not yet been issued. Applications for Orphan Drugs are often processed under SAP. Applicants must provide information about the medical emergency, the names of all institutions that will use the drug, any possessed data regarding the drug's use, safety and efficacy, and any other requested data. Practitioners must agree to inform the Minister and manufacturer of results as well as any adverse reactions. They must also agree to account, on the Minister's request, for all drug quantities. Once approved, a formal letter of authorization is issued, indicating the practitioner's name, the medical emergency, and the quantity of the drug. The manufacturer may then sell the new drug to the practitioner on the terms and conditions stated in the letter of authorization, up to a maximum quantity equivalent to a six-month supply.

4. What are the approximate fees for each authorization?

The Fees in Respect of Drugs and Medical Devices Regulations, established under the *Financial Administration* Act, set out authorization fees for most drugs and medical devices. Fees are payable by the person who files the submission or supplement or who makes the application.

As at April 2018, the current approximate fees for the examination of a drug submissions and their supplements vary depending on the submission's content, ranging in Canadian dollars from $350,000 for submissions concerning new active substances, and for submissions concerning previously approved drugs or medicinal ingredients that contain only:

- Clinical or non-clinical, chemistry and manufacturing data: $170,000;
- Clinical or non-clinical data: $80,000;
- Comparative studies: $50,000;
- Chemistry and manufacturing data: $23,000;
- Published data: $19,000; and,
- Labelling material: $3,000.

The approximate fees payable for the examination of a DEL application or for its annual review vary depending on the area of activity, and contain the following basic fees as well as additional fees for each additional category of drug for:

- Drug fabrication: $17,000, plus $4,500 per category;
- Packaging and labelling: $12,000, plus $3,000 per category;
- Importing and distributing: $7,500, plus $3,000 per category;
- Distribution and wholesale: $4,500;
- Testing: $3,000; and,
- Drug analysis: from $0 to $30,000, depending on the drug classification.