# Publisher's Note

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# Drug and Health Products Law in Canada

This book provides a comprehensive guide to the legal and regulatory regimes — provincial and federal — governing the manufacture and sale of drugs and health products in Canada. It is a must-have resource for anyone involved in any aspect of the development, manufacture and distribution of drugs in Canada, and for lawyers who represent both those in the industry and those wishing to challenge industry practice or procedure. Written by one of Canada's experts in the field.

This release features updates to Chapter 13 (The Patented Medicine Prices Review Board) and the Words and Phrases section of the book.

### Highlights

- **The Patented Medicine Prices Review Board (PMPRB) — The PMPRB's Mandate —** The Federal Court has affirmed that while only the "merest slender thread" of nexus between a patent and a medicine will be required, the patent must still pertain to the particular medicine in question in order to fall under the PMPRB's jurisdiction. In this case, the court determined that a product that is

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outside the claims of a patent (*i.e.* a different concentration of the same medication) may be determined to "pertain to" a medicine only if it can be proven that the product is "intended or capable of being used" for the patented medicine; if this cannot be proven, the necessary link will not be established: *Galderma Canada Inc v Canada (Attorney General)*, 2017 FC 1023 (F.C.).

- **The Patented Medicine Prices Review Board (PMPRB) — The Sale of Patented Medicines at a Non-Excessive Price —** The PMPRB has adopted guidelines on excessive prices to provide parameters to set medicine prices at levels which PMPRB staff would not find excessive. Under these guidelines, a price may be deemed to be excessive by the Board if, among other things:

(a) it exceeds the price of medicines of the same category in Canada or in the comparator countries; or

(b) it exceeds the median price at which the medicine is sold in the comparator countries identified in the regulations.

- **The Patented Medicine Prices Review Board (PMPRB) — The Sale of Patented Medicines at a Non-Excessive Price —** On December 1, 2017, the Federal Government published proposed changes to the Patented Medicines Regulations which govern the PMPRB. According to the Regulatory Impact Analysis Statement which accompanied the proposed amendments, the Patented Medicines Regulations needed to be modernized to provide the PMPRB with more relevant and effective regulatory tools in light of increasing prices of patented drugs and drug cost containment measures taken by the provinces.