

## Publisher's Note

An Update has Arrived in Your Library for:

Please circulate this notice to anyone in your office who may be interested in this publication.  
*Distribution List*

### DRUG AND HEALTH PRODUCTS LAW IN CANADA

Mathieu Gagné

Release No. 1, November 2021

#### Publisher's Special Release Note 2020

The pages in this work were reissued in December 2020 and all the pages carry that date in the release line. Please note that we have not reviewed the content on every page of this work in this current release. We will continue to review and update the content according to the work's publication schedule. This will ensure that subscribers are reading commentary that incorporates developments in the law as soon as possible after they have happened or as the author deems them significant.

Changes to chapter and heading numbering may have occurred. Please refer to the Correlation Table in the front matter if you wish to confirm references.

THOMSON REUTERS CANADA®

#### Customer Support

1-416-609-3800 (Toronto & International)

1-800-387-5164 (Toll Free Canada & U.S.)

Fax 1-416-298-5082 (Toronto)

Fax 1-877-750-9041 (Toll Free Canada Only)

E-mail [CustomerSupport.LegalTaxCanada@TR.com](mailto:CustomerSupport.LegalTaxCanada@TR.com)

This publisher's note may be scanned electronically and photocopied for the purpose of circulating copies within your organization.

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 4 (Federal Penal Law) and Chapter 5 (Civil Law, Common Law, Law of Professions and Research Ethics).

### Chapter Highlights:

- **Chapter 4 — Federal Penal Law** — This chapter has been updated to take into account updated legislation such as Regulations Amending Certain Regulations Made under the *Food and Drugs Act* (Sale of a New Drug for Emergency Treatment) (the “New SAP Regulations”) and updated documents and guidance from Health Canada. Updated sections in this chapter include the discussion of **Section I New Drugs** with updated commentary on **Features of a New Drug System and Notice of Compliance**. In particular the following topics were updated: Prohibition against Selling or Advertising a New Drug; Emergency Treatment (Special Access Programme—SAP) Drug Submissions; and Issuance of Notice of Compliance. **Section III Drug for Use in a Clinical Trial** has also been updated with a discussion **The Sale or Importation of a Drug for the Purposes of a Clinical Trial** and **Conducting Clinical Trials**. In particular the following topics were updated: Content of a Clinical Trial Application; and Good Clinical Practices (for conducting clinical trials).
- **Chapter 5 — Civil Law, Common Law, Law of Professions and Research Ethics** — In Canada there is no overarching federal legislation governing biomedical research. Each province has its own normative framework comprised of various laws and regulations that touch, often in passing, on experimentation involving human subjects. In this chapter the author updates the discussion of provincial standards in Ontario, Alberta, Manitoba, Saskatchewan, British Columbia, Prince Edward Island, Newfoundland and Labrador, Yukon, and Northwest Territories. A new section on Nunavut has been added.

### ProView Developments

Your ProView edition of this product now has a new, modified layout:

- The opening page is now the title page of the book as you would see in the print work
- As with the print product, the front matter is in a different order than previously displayed
- The Table of Cases and Index are now in PDF with no searching and linking
- The Table of Contents now has internal links to every chapter and section of the book within ProView
- Images are generally greyscale and size is now adjustable
- Footnote text only appears in ProView-generated PDFs of entire sections and pages