



Date: September 19, 2019

# Life Sciences

The Canadian regulatory and business environment in which companies in the life sciences industry operate is very complex. We help our life sciences clients with all aspects of their business from regulatory compliance, market access and brand protection to financing, transactions and commercialization.

## Pharma, Medical Device and Natural Health Products

Our in-depth knowledge of the Canadian pharmaceutical, medical device and natural health products industry enables us to understand the business imperatives and issues facing our clients. Our clients benefit from a wide range of services including:

- Advice on regulatory compliance and market access issues, including:
  - Supporting our clients' regulatory affairs functions on regulatory interpretation and compliance projects
  - Health Canada (TPD, MDB, VDD) approval
  - Labeling, package inserts, audit procedures, Establishment Licence restrictions, export issues and recordkeeping obligations
  - Guidance on adverse incident reporting, recall management and positioning to defend against resulting lawsuits
- Dealing with the Patented Medicine Prices Review Board (PMPRB) and Canadian Association for Drugs and Technologies in Health (CADTH) Common Drug Review regimes
- Providing public policy advice through the entire continuum of the value chain
- Navigating provincial drug benefit legislation, provincial formulary listings and reimbursement issues, including reimbursement claims to private insurers and other third party payors under individual benefit plans
- Advising on the obligations and rights under applicable advertising and marketing regulations (*Food and Drugs Act*, Rx&D and MEDEC Codes of Conduct and professional standards) as well as pricing, volume discounts, rebates and advertising allowances
- Advising on procurement practices and responses from private sector suppliers, including compliance with OntarioBuys' Supply Chain Guideline

- Marketplace dispute strategy on complaints governed by the Advertising Standards Council of Canada and the Pharmaceutical Advertising Advisory Board
- Protection of intellectual property
- Licensing, outsourcing and distribution

## Biotechnology

Whether your company is a biotechnology start-up, at the initial stages of development and financing preclinical trials, or a company on the brink of commercialization, our lawyers understand the challenges you face in successfully bringing your products to market. We have the experience and network to advise you on the legal needs to support your business arrangements including:

- Health Canada (TPD, MDB, VDD, PMRA) approval
- Clinical trial agreements and approvals
- Protection of intellectual property
- Licensing and other outsourcing agreements
- Integration of Canadian and US regulatory processes

## Agriculture & Ag-Chem

- Navigating the registration and evaluation processes of pest control products under *Canada's Pest Control Products Act* and working with the PMRA
- Supporting our clients' regulatory affairs functions on regulatory interpretation and compliance projects
- Providing guidance on adverse incident reporting, recall management and positioning to defend against resulting lawsuits
- Advising on opportunities and challenges arising from the Growers Own Use (GROU) and the Protection of Proprietary Interests in Pesticide Data (PPIP) Programs
- Providing public relations advice at all levels of government
- Protecting intellectual property
- Licensing, outsourcing and distribution

## Food

From raw materials, processing, packaging and distribution to retail, the Canadian food industry is held to a high standard of quality in product and business practices. We advise our clients on a wide variety of legal issues including:

- Regulatory compliance such as labeling and packaging issues, ingredient specifications, storage and

display requirements

- Customer and competitor relations
- Distribution and supply agreements
- Managing product related incident reporting, managing recalls and positioning to defend against resulting lawsuits
- Advising on the obligations and rights under applicable advertising and marketing regulations
- Licensing, outsourcing and distribution
- Protection of intellectual property

## Complementary Services

Our Life Sciences clients benefit from our specialized expertise in a number of key areas:

- Financing — from early stage angel or venture capital investments to IPOs
- Privacy — managing the federal *Personal Information Protection and Electronic Documents Act* (PIPEDA) and provincial privacy laws
- Information Management — responding to federal and provincial freedom of information requests
- International Trade — managing the movement of goods, services, capital and intellectual property across international borders, including customs and tariff-related matters, trade cases and export and import controls
- Products liability — dealing with product complaints and risk management issues as well as defending product liability and class action claims
- Commercial — negotiating and drafting co-marketing agreements and other joint venture agreements
- Mergers & Acquisitions — advising and project management on all forms and sizes of transactions whether for buyer or seller
- Competition Law/Antitrust and Foreign Investment Review — advising on compliance with all applicable regulatory regimes and obtaining all necessary regulatory clearances
- Commercial litigation — bringing and defending litigation arising from commercial disputes