

LIFE SCIENCES
INDUSTRY GROUP



CASSELS BROCK
LAWYERS



WE UNDERSTAND HOW YOU DO BUSINESS.

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.

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 IP
- Licensing, outsourcing and distribution

**PHARMA, MEDICAL DEVICE AND
NATURAL HEALTH PRODUCTS**



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 IP
- Licensing and other outsourcing agreements
- Integration of Canadian and US regulatory processes

AGRICULTURE & AG-CHEM

Canada's agriculture and agricultural chemical industry is subject to significant regulatory oversight from the federal Pest Management Regulatory Agency (PMRA) as well as provincial and local governments. We support our clients on a broad range of issues, including by:

- 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 IP
- Licensing, outsourcing and distribution

TO LEARN MORE ABOUT HOW YOU CAN BENEFIT FROM OUR SERVICES

CONTACT DAVID BUTLER AT 416 860 6449
EMILY LAROSE AT 416 860 5217

OR ANY MEMBER OF THE LIFE SCIENCES TEAM



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 IP

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



YOUR TEAM

PRODUCT LIABILITY & CLASS ACTION DEFENCE/LITIGATION

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REGULATORY & PUBLIC POLICY

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PRIVACY/IT/OUTSOURCING

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A TRADITION OF EXCELLENCE

Creative. Approachable. Business-focused.

These are the qualities clients tell us they value in a law firm, and they're the qualities the lawyers at Cassels Brock possess in abundance. We've been in business for over 120 years and have more than 200 lawyers committed to providing the very best legal advice to all our clients and an outstanding overall value proposition, whether entrepreneurial start-ups, mid-market enterprises or multinational corporations.

Cassels Brock is a full-service firm, organized into practice areas that meet clients' wide-ranging needs. While clients may initially come into the firm via one practice area, the full range of our expertise is available to them through their primary lawyer.

- Aboriginal
- Advertising & Marketing
- Aerospace
- Automotive
- Business
- Charity & Not-For-Profit
- Class Actions
- Communications
- Competition (Antitrust)
- Construction
- Education
- Employment
- Energy & Utilities
- Entertainment
- Family
- Fashion
- Financial Services
- Franchise
- Government Relations
- Information Technology
- Infrastructure
- Insolvency & Restructuring
- Insurance – Corporate & Regulatory
- Intellectual Property (Copyright, Trade-marks & Patents)
- International Business
- International Trade
- Life Sciences
- Litigation
- Mergers & Acquisitions
- Mining
- Municipal, Planning & Environmental
- Pension, Benefits & Executive Compensation
- Privacy
- Private Equity
- Product Liability
- Real Estate
- Registration and Compliance
- Securities
- Sports
- Tax
- Trusts & Estates

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