Index

ABBREVIATED NEW DRUG CANADIAN INTELLECTUAL SUBMISSION (ANDS) PROPERTY OFFICE (CIPO) Generally, 6:1 et seq. Informational requirements, 1:3 Trademarks and, 10:1 Supplemental, 1:7 **CANADIAN INTERNET** ACCESS TO INFORMATION ACT REGISTRATION AUTHORITY New drug approval process, 1:4 (CIRA) ADVERTISING LIFE SCIENCES Domain names and, 10:2 **PRODUCTS** CANADIAN MEDICAL ASSOCIATION Generally, 3:1 et seq. Marketing to healthcare professionals, 3:5 Advertising Standards Canada (ASC), 3:3 Provincial medical associations, 3:5 Consumer advertising generally, 3:4 **CANNABIS** Cannabis Act, 2:1 et seq. natural health products, 3:4 non-prescription drugs, 3:4 Drugs containing cannabis, 2:3 advertising and promotion, 2:3 prescription drugs, 3:4 Definitions and classifications, 3:2 Importation and exportation of, 2:5 Medical cannabis False, misleading, deceptive advertising, 3:2 generally, 2:2 access to, 2:2 Health Canada, 3:3 advertising and promotion, 2:2 Introduction, 3:1 Labelling requirements, (prescription, licence for sale of cannabis, 2:2 non-prescription, NHPs), 3:4 packaging and labelling, 2:2 Medical devices, 3:4 personal possession limits, 2:2 Regulatory control, 3:3 Overview of access to cannabis, 2:1 Vaccines, 3:4 Regulation of products, 2:1 et seq. Test kits, 2:4 ADVERTISING STANDARDS CANADA **CLINICAL TRIAL APPLICATION** (ASC) (CTA) Generally, 3:3 Amendments, of, 1:9 BIOLOGIC AND GENERIC Regulation of products, 1:9 THERAPIES DIRECTORATE **CLINICAL TRIALS** (BGTD) Generally, 1:9 Generally, 1:5 Human subjects Regulatory control, 3:3 generally, 1:12 Submissions and review, 1:8 authorization, 1:12 **BIOLOGICS** sponsor obligations, 1:12 Regulation of products and, 1:5 suspension or cancellation, 1:12 Natural health products, 1:12 CANADIAN ASSOCIATION OF MEDICAL PUBLISHERS (CAMP) **COMPETITION ACT**

Marketing to healthcare professionals, 3:5

Advertising and labelling, 3:1, 3:4

CONTROLLED DRUGS AND SUBSTANCES ACT	DRUGS—Cont'd Natural health products (NHP)—Cont'd
Regulation of products, 1:1	product licences—Cont'd
CONVENTION ON BIOLOGICAL DIVERSITY (CBD)	amending product licence, 1:12 application for, 1:12 cancellation or suspension, 1:12
Canada's international obligations, 5:5	reporting obligations on licensees,
DATA PROTECTION	1:12
Generally, 9:1 et seq. Canada, in, 9:4 Canada's international obligations, 9:2 Other countries, in, 9:3	scope of NHP legislation, 1:12 site licences, 1:12 New drug approval process, 1:4 Non-prescription drugs
DISPUTE SETTLEMENT UNDERSTANDING (DSU) Mechanisms under TRIPS and NAFTA, 5:6 DRUG IDENTIFICATION NUMBER	advertising and promotion, 3:4 labelling requirements, 3:4 Post-market surveillance, 1:6 Prescription drugs labelling requirements, 3:4
(DIN)	Radiopharmaceuticals, 1:5
Marketing approval, 1:3	Regulation of products, 1:1 et seq. Sale of, 1:2
- 11	Submission and review process, 1:8
DRUGS	Supplemental abbreviated new submis-
Biologics, 1:5	sions, 1:7, 5:7
Changes to new drugs once approved, 1:7	,
Clinical trials, 1:9	FOOD AND DRUG REGULATIONS
Drug-medical device combination products, 1:11	Clinical trials
Drugs containing cannabis, 2:3	amendment to application, 1:9
advertising and promotion, 2:3	application, 1:9
Genetic therapies, 1:5	Data protection and, 9:4
Marketing approval	Notice of Compliance (NOC) Regulations
generally, 1:3	generally, 8:3
drug identification number (DIN), 1:3	framework, 8:3
notice of compliance, 1:3	policy concerns, 8:2
standards for establishments	Patent listing submission, nature of, 8:5
generally, 1:3	FOOD AND DRUGS ACT
establishment licences, 1:3	
good manufacturing practices,	See also DRUGS
application of, 1:3	Biologics, 1:5
Natural health products (NHP)	Clinical trials, 1:9
generally, 1:12	Genetic therapies, 1:5
clinic trials involving human subjects	Medical devices, 1:10
generally, 1:12	Radiopharmaceuticals, 1:5
authorization, 1:12	Regulation of products, 1:1 et seq.
sponsor obligations, 1:12	Regulations under
suspension or cancellation, 1:12	clinical trials
good manufacturing practices, 1:12	amendment to application, 1:9
history of NHP legislation, 1:12	application, 1:9
labelling and packaging, 1:12, 3:4	data protection and, 9:4
product licences	framework, 8:3
generally, 1:12	policy concerns, 8:2

FOOD AND DRUGS ACT—Cont'd Regulations under—Cont'd	INTERNATIONAL TRADE OBLIGATIONS—Cont'd
Notice of Compliance (NOC) Regula-	Dispute settlement mechanisms
tions, 8:3	generally, 5:6
patent listing submission, nature of, 8:5	NAFTA, 5:6, 9:2
	TRIPS, 5:6, 9:2
GENERAL AGREEMENT ON TARIFFS AND TRADE	Implementation in Canada
	generally, 5:4
Canadian international obligations, 5:2 , 9:2	Bill C-22, 5:4
	Bill C-91, 5:4
HEALTH CANADA	legislation, 5:4
Biologic and Genetic Therapeutics Directorate (BGTD), 3:3	Life sciences products, relevant provisions re
Biologics, 1:5	basic obligations, 5:5
Genetic therapies, 1:5	data protection, 5:5
Health Products and Food Branch, 3:3	enforcement, 5:5
Licensing service division, 1:8	exceptions, limited, 5:5
Marketed Health Products Directorate,	licensing, compulsory, 5:5
3:3	non-discrimination, 5:5
Radiopharmaceuticals, 1:5	patentability, 5:5
Regulatory control, advertising life sci-	patent protection, term of, 5:5
ence products, 3:3 Therapeutic Products Directorate, 1:8 ,	patent rights, 5:5
1:11	Negotiations
2722	NAFTA, 5:3
HEALTH CARE PROFESSIONALS	TRIPS, 5:3
Marketing, to	Trans-Pacific Partnership (TPP), 5:8
generally, 3:5	LICENCES
Innovative Medicines Canada (IMC), 3:5	Establishment
	drugs, 1:3
pharmaceutical advertising advisory board (PAAB), 3:5	medical devices, 1:10
provincial medical associations, 3:5	Product
•	generally, 1:12
INCOME TAX ACT	amending product licence, 1:12
Generally, 13:1 et seq.	application for, 1:12
INNOVATIVE MEDICINES CANADA	cancellation or suspension, 1:12
(IMC)	reporting obligations on licensees, 1:12
Generally, 3:5	Site licences, 1:12
INTERNATIONAL TRADE	·
OBLIGATIONS	MARKETED HEALTH PRODUCTS
Generally, 5:1	DIRECTORATE
Canada's previous obligations	Marketing, advertising and labelling, 3:3
Berne Convention for the Protection of	MARKETING
Literary and Artistic Works, 5:2	See also ADVERTISING AND PROMO-
Canada-US Free Trade Agreement, 5:2	TION OF LIFE SCIENCES
General Agreement on Tariffs and	PRODUCTS
Trade, 5:2	Healthcare professionals, to
Paris Convention for the Protection of	generally, 3:5
Industrial Property, 5:2	Innovative Medicines Canada (IMC),
CETA, 5:7	3:5

MARKETING—Cont'd	NOTICE OF COMPLIANCE
Healthcare professionals, to—Cont'd	See also PATENTED MEDICINES (NOC
pharmaceutical advertising advisory	REGULATIONS)
board, 3:5	Notice of compliance regulations
provincial medical associations, 3:5	generally, 8:1
Labelling requirements	framework of, 8:3
natural health products, 1:12	policy concerns addressed by, 8:2
non-prescription drugs, 3:4	PATENTABILITY REQUIREMENTS
prescription drugs, 3:4	See also PATENT LAW
MEDICAL CANNABIS	Double patenting, 6:3
See also CANNABIS	Life forms, patentability of
Access to, 2:2	generally, 6:5
Advertising and promotion, 2:2, 3:4	Abitibi case, 6:5
Licence for sale of cannabis, 2:2	deposit of biological materials, 6:5
Packaging and labelling, 2:2	Harvard Mouse case, 6:5
Personal possession limits, 2:2	Monsanto case, 6:5
MEDICAL DEVICES	Novelty and inventiveness, 6:3
Generally, 1:10	Overlapping subject matter, 6:3
Advertising and promotion, 3:4	Sufficiency of specification, 6:3
Approval to sell in Canada, 1:10	Utility, 6:3
Establishment licences, 1:10	PATENTED MEDICINES (NOC
Investigational testing, 1:10	REGULATIONS)
Reporting obligations, 1:10	Addressing listed patents
Special access, 1:10	generally, 8:7
	confidentiality, 8:7
NATURAL HEALTH PRODUCTS	invalidity allegations, 8:7
(NHP)	non-infringement allegations, 8:7
Generally, 1:12	notice of allegation
Clinic trials involving human subjects	generally, 8:7
generally, 1:12	other challenges, 8:7
authorization, 1:12	sufficiency of, 8:7
sponsor obligations, 1:12	Certificates of supplementary protection
suspension or cancellation, 1:12	generally, 8:6
Good manufacturing practices, 1:12	CSP term, 8:6
History of NHP legislation, 1:12	eligibility for, 8:6
Labelling and packaging, 1:12	Initiating proceedings
Product licences	generally, 8:8
generally, 1:12	abuse of process, 8:8
amending product licence, 1:12	appealing a ruling, 8:9
application for, 1:12	burden of proof, 8:8
cancellation or suspension, 1:12	indirect infringement, 8:8
reporting obligations on licensees, 1:12	on or after September 21, 2017, 8:8
Scope of NHP legislation, 1:12	prior to September 21, 2017, 8:8
Site licences, 1:12	Section 8 damages, 8:10
	summary dismissal, 8:8
NEW DRUG SUBMISSIONS	time period, 8:8
Abbreviated, 5:7	Notice of compliance regulations
Access to Information Act, 1:4	generally, 8:1
Patent listing and, 8:5	framework of, 8:3

PATENTED MEDICINES (NOC	PATENT ENFORCEMENT—Cont'd
REGULATIONS)—Cont'd	Patent infringer, proceedings against
Notice of compliance regulations	generally, 7:3
—Cont'd	litigation, 7:3
policy concerns addressed by, 8:2	litigation
Patent listing	checklist before commencing, 7:5
generally, 8:5	pre-litigation
challenging, 8:5	generally, 7:3
maintenance of patent register, 8:5 nature of submission, 8:5	alternative dispute resolution, 7:3
,	cease and desist letter, 7:3
timing requirements, 8:5	PATENT INFRINGEMENT
PATENT ENFORCEMENT	See also PATENT ENFORCEMENT
Generally, 7:1	Generally, 7:4
Defences to infringement	Checklist before commencing infringe-
generally, 7:6	ment suit
non-inducement to infringe, 7:6	generally, 7:5
non-infringement	additional circumstances, 7:5
generally, 7:6	assessment, 7:5
invalidity, 7:6	basic information, 7:5
licence, 7:6	relief sought, 7:5
Experimental testing, 7:8	Defences to
Expert witnesses	generally, 7:6
generally, 7:7	non-inducement to infringe, 7:6
definition of, 7:7	non-infringement
qualifications of, 7:7	generally, 7:6
role of, 7:7	invalidity, 7:6
Infringement	licence, 7:6
generally, 7:4	Definition, 7:4
checklist before commencing infringe-	Proof of, 7:4
ment suit	Types, 7:4
generally, 7:5	PATENT LAW
additional circumstances, 7:5	Generally, 6:1 et seq.
assessment, 7:5	DNA, RNA, and antibodies, patentability
basic information, 7:5	of
relief sought, 7:5	generally, 6:6
defences to, 7:6	antibodies, 6:6
definition, 7:4	background, 6:6
proof of, 7:4	disclosure, 6:6
types, 7:4	Fertilized eggs, patentability of, 6:7
Monopoly rights	Infringement
generally, 7:2	see also PATENT
actual rights, 7:2	INFRINGEMENT defences to
duration of rights, 7:2	defences to, 7:6
remedies	invalidity, 7:6
generally, 7:2	licence, 7:6
accounting of profits, 7:2	non-inducement to infringe, 7:6
damages, 7:2	non-infringement, 7:6
delivery up, 7:2	Life forms, patentability of
injunctions, 7:2	generally, 6:5

PATENT LAW—Cont'd	PHARMACEUTICAL PRICING AND
Life forms, patentability of—Cont'd	MARKET ACCESS—Cont'd
Abitibi case, 6:5	Patented medicine prices review board
deposit of biological materials, 6:5	—Cont'd
Harvard Mouse case, 6:5	provincial pricing issues, 4:8
Monsanto case, 6:5	statutory framework
Organ and tissues, 6:7	generally, 4:2
Patentability requirements	excessive pricing provisions, 4:1 to
generally, 6:3	4:8
double patenting, 6:3	process provisions, 4:1 to 4:8
novelty and inventiveness, 6:3	Reporting requirements, 4:1 to 4:8
overlapping subject matter, 6:3	PRIVACY LAW
sufficiency of specification, 6:3	Generally, 12:1 et seq.
utility, 6:3	Breaches and breach response, 12:6
Patent application	Compliance, 12:7
prosecution, of, 6:2	Fundamental principles, 12:3
Prosecution of patent application	Human subject research, 12:5
generally, 6:2	Legislative framework, 12:2
action, final, 6:2	Organizational privacy vigilance, 12:7
allowance and issuance, 6:2	Personal health information, 12:4
amendment after allowance, 6:2	·
appeals, 6:2	PRODUCT LIABILITY
convention priority, 6:2	Generally, 11:1 et seq.
entity status, 6:2	Causation, 11:3
examination of application, 6:2	Class actions, 11:6
filing prior art, 6:2	Contract and statutory claims, 11:5
maintenance fees, 6:2	Damages, 11:7
national entry, 6:2	Innovator liability, generic drug sales,
official filing date, 6:2	11:4
ownership, 6:2	Limitation periods, 11:8
publication, 6:2	Negligence claims
public disclosure restrictions, 6:2	generally, 11:2
re-examination of patents, 6:2	design defect claim, 11:2
reissue and disclaimer, 6:2	failure to warn claim, 11:2
request for examination, 6:2	manufacturing defect claim, 11:2
Stem cells, patentability of, 6:7	Procedural issues, 11:9
PHARMACEUTICAL ADVERTISING	Québec law principles, 11:10
ADVISORY BOARD (PAAB)	SUPPLEMENTAL ABBREVIATED
Marketing to healthcare professionals, 3:5	NEW DRUG SUBMISSION
	(SANDS)
PHARMACEUTICAL PRICING AND	Generally, 1:7, 5:7
MARKET ACCESS	•
Patented medicine prices review board	TAX ISSUES
generally, 4:1 to 4:8	Generally, 13:1
compendium of guidelines, policies and	Goods and Services Tax (GST), 13:5
procedures, 4:3	Harmonized Sales Tax (HST), 13:5
constitutionality, 4:5	Québec Sales Tax (QST), 13:5
mandate, jurisdiction and process, 4:4	Scientific research and experimental
mandatory reporting requirements, 4:6	development
proposed new regulations, 4:7	generally, 13:2

TAX ISSUES—Cont'd

Scientific research and experimental development—Cont'd advancement, 13:2 content, 13:2 tax credits, 13:2 uncertainty, 13:2
Transfer pricing, 13:3
Withholding tax, 13:4

THERAPEUTIC PRODUCTS DIRECTORATE (TPD)

Generally, 10:1 et seq.

See also HEALTH CANADA Generally, 1:8, 1:11

TRADEMARKS AND DOMAIN NAMES

Domain names
generally, 10:2
dot-ca, 10:2
recourse for aggrieved trademark
owner, 10:2

TRADEMARKS AND DOMAIN NAMES

—Cont'd Trademarks generally, 10:1 licences, 10:1 opposition process, 10:1 pharmaceutical trade dress protection generally, 10:1 application requirements, 10:1 distinctiveness of, 10:1 functionality of, 10:1 registration and renewal, 10:1 registration process (prior to proposed changes) generally, 10:1 application requirements, 10:1 registrability, examination for, 10:1 regulatory issues, intersection of, 10:1

WORLD INTELLECTUAL PROPERTY OFFICE (WIPO)

Patentability of DNA, RNA and antibodies, **6:6**