An FOI Services Teleconference

Health Canada's New Requirements for Drugs

Presented by:

David McCarthy

When:

Thursday, August 20, 2015

Eastern Daylight Time: 1:00pm – 2:30pm (GMT-4)

Central Time: 12:00pm – 1:30 pm

Mountain Time: 11:00am – 12:30pm

Pacific Time: 10:00am – 11:30am

Prepare:

Please provide each listener with access to this handout; it is online at www.foiservices.com/vanessa2167.htm

Black & white photocopies can be used.

Connect:

Call in 5-10 minutes before the start time:

1-866-614-1121 (Toll-from free US & Canada)

Conference ID: 3342167

Your unique PIN is on your invoice & your dial-in email.

Registrants from outside the US/Canada should contact FOI for customized instructions.

Please Note:

Each registration you purchase covers one connection. You are welcome to put the conference on a speakerphone and invite as many listeners as you like for your registration. If you need to dial-in from an additional line, another registration with a different PIN is required; call +1-301-975-9400 for more information.

Do not use a conferencing feature to add remote locations to the one registered location. The quality of the connection will be greatly reduced and several features, such as the ability to ask a question, are disabled.

This is an audio-format presentation. For the best connection, use a corded telephone on a land-line. You will be connected for 90 minutes or more; relying on a battery-powered phone may not be wise.

If you ask a question during the live Q&A session, please try to avoid using a speakerphone.

This presentation is recorded. If you register for the live conference, you can order the audio package of an mp3 file and all of the handouts at a 50% discount; contact FOI for details.

Produced by:

FOI Services, Inc.
23219 Stringtown Road; Suite 240
Clarksburg, MD 20871-9563 • USA
Phone: +1-301-975-9400
Email: teleconferences@foiservices.com
Web: www.foiservices.com

***Important Notice**: The information provided in this presentation by each instructor is personal opinion and does not necessarily represent the opinions of FOI, Inc. Companies relying on the information do so at their own risk and assume responsibility for any subsequent consequences and liability. The information provided does not constitute legal advice.*

VANESSA'S LAW

Health Canada's New Requirements for Drugs: Approval, Compliance…and the Dramatic Changes Now Being Implemented

McCarthy Consultant Services Inc.

Presented by:

David McCarthy, President

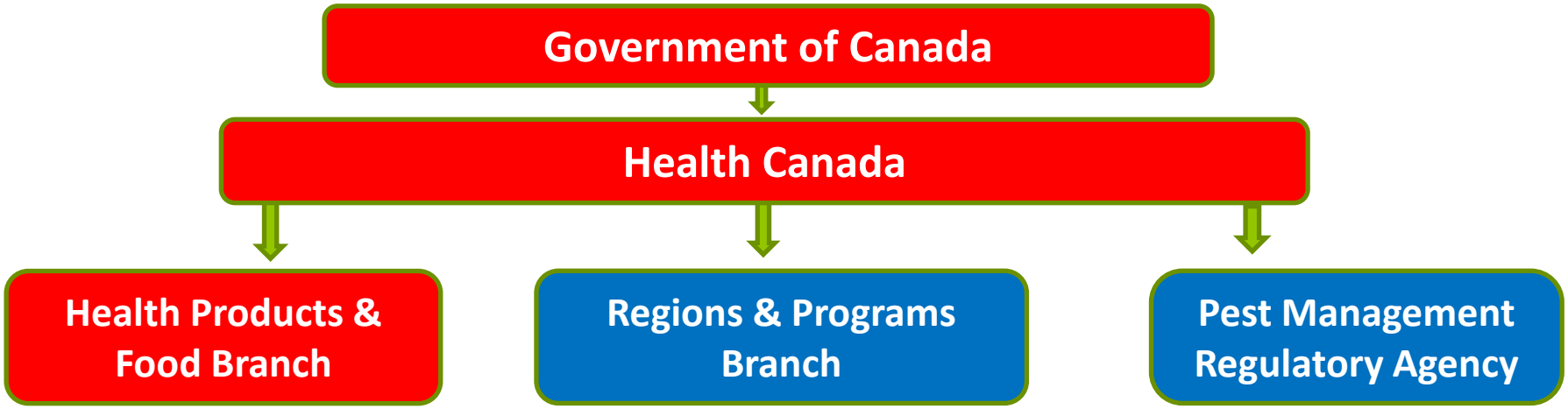
McCarthy Consultant Services, Inc.

www.mccarthyconsultant.com

An FOI Services Teleconference • August 2015

Today's Objectives

- Overview of regulations for drugs
- Overview of regulations for natural health products
- Overview of Provincial Health Care Delivery
- Overview of the changes to the Canadian Food and Drugs Act brought about by Vanessa's Law

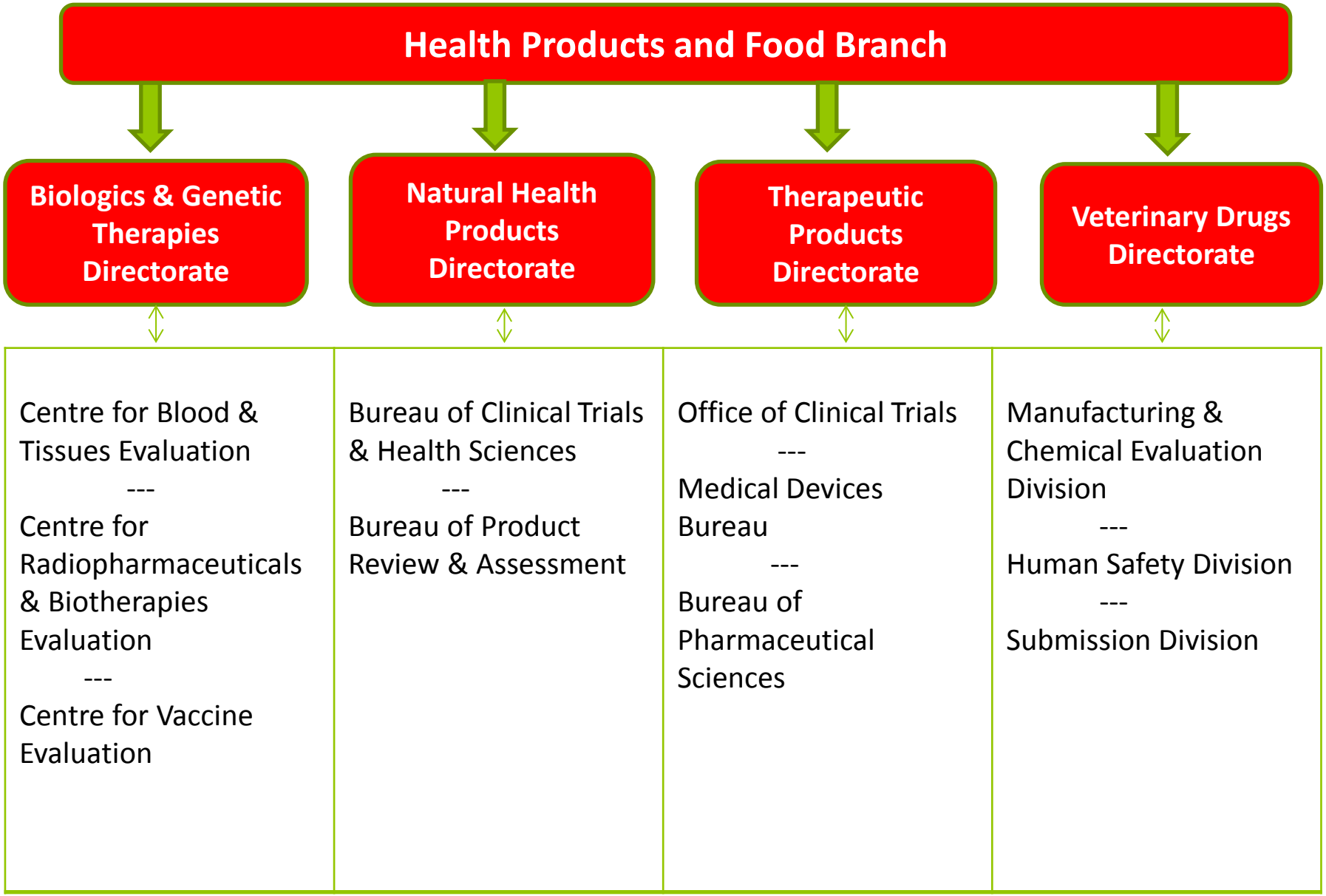


- Biologics & Genetic Therapies Directorate
- Marketed Health Products Directorate
- HPFB Inspectorate
- Natural Health Products
- Therapeutic Products Directorate
- Veterinary Drugs Directorate
- Food Directorate

- Alberta Region
- Atlantic Region
- British Columbia Region
- Manitoba Region
- Ontario Region
- Quebec Region
- Saskatchewan Region

- Registration Directorate
- Compliance, Lab Services & Regional Operations Directorate
- Environmental Assessment Directorate

- Regions & Programs: www.hc-sc.gc.ca/contact/ahc-asc/index-eng.php#rpb
- Pest Management: www.hc-sc.gc.ca/cps-spc/pest/index-eng.php


Health Products and Food Branch
Biologics & Genetic Therapies Directorate
Natural Health Products Directorate
Therapeutic Products Directorate
Veterinary Drugs Directorate
Centre for Blood & Tissues Evaluation

Centre for Radiopharmaceuticals & Biotherapies Evaluation

Centre for Vaccine Evaluation
Bureau of Clinical Trials & Health Sciences

Bureau of Product Review & Assessment
Office of Clinical Trials

Medical Devices Bureau

Bureau of Pharmaceutical Sciences
Manufacturing & Chemical Evaluation Division

Human Safety Division

Submission Division

Key Organizational Areas

Therapeutic Products Directorate (TPD)
www.hc-sc.gc.ca/dhp-mps/index_e.html

Biologics and Genetic Therapeutics Directorate (BGTD)
www.hc-sc.gc.ca/dhp-mps/brgtherap/index_e.html

Veterinary Drugs Directorate (VDD)
www.hc-sc.gc.ca/dhp-mps/vet/index_e.html

Natural Health Products Directorate (NHPD)
www.hc-sc.gc.ca/dhp-mps/prodnatur/index_e.html

Regions and Programs Branch
www.hc-sc.gc.ca/contact/ahc-asc/index-eng.php#rpb

Drug

"**Drug**" includes any substance or mixture of substances manufactured, sold or represented for use in:

a. the diagnosis, treatment, mitigation, or prevention of a disease, disorder, abnormal physical state, or its symptoms, in human beings or animals.

b. restoring, correcting or modifying organic functions in human beings or animals, or

c. disinfection on premises where food is manufactured, prepared or kept

General Classification of a Drug

OTC (Over-the-Counter)
Prescription
Biologics/Biotechnology
Radiopharmaceuticals
Blood and blood derived products

Sell

"Sell" includes offer for sale, expose for sale, have in possession for sale and distribution, whether or not the distribution is made for consideration.

Adulteration

A drug for human use is adulterated if it contains:

a. strychnine, or any of its salts

b. extracts or tinctures of
   i. strychnos nux vomica
   ii. strychnos ignatii, or
   iii. a strychnos species containing strychnine, other than those species mentioned in (i) and (ii)

c. methapyrilene or any of its salts

d. echimidine or any of its salts; or

e. any of the following plant species or extracts or tinctures thereof:
   i. symphytum asperum
   ii. symphytum x uplandicum, or
   iii. any other plant species containing echimidine

Some Other Regulatory Prohibitions

The Food and Drug Regulations contain many other specific prohibitions, some of which are:

1. No manufacturer or importer shall sell a drug for human use that contains as an ingredient:
   a. chloroform, or
   b. arsenic or any of its salts or derivatives

2. No manufacture shall use methyl salicylate as a medicinal ingredient in a drug for humans.

3. No manufacturer shall use a colouring agent in a drug other than a colouring agent listed in these regulations.

Submissions Applications

- Clinical Trial Application (CTA) (human drugs)
- Clinical Trial Application Amendment (CTA-A) (human drugs)
- Veterinary Investigational New Drug (VIND) (veterinary drugs)
- Veterinary Investigational New Drug --Amendment (VIND-AM) (veterinary drugs)
- Drug Identification Number (DIN) Application (Division 1)
- Post-Authorization Division 1 Change
- Administrative Change (only applies to manufacturer/sponsor and/or product name change and licensing agreements).

New Drug Submission (NDS)

- Supplement to a New Drug Submission (SNDS)
- Abbreviated New Drug Submission (ANDS)
- Supplement to a Abbreviated New Drug Submission (SANDS)
- Notifiable Change (NC)
- Post-Authorization Division 1 Change

HC-SC 3011

HC-SC 3011 form is on the Therapeutic Products Directorate website

www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/form/hc3011_sc3011_e.html

Guidance Documents - Applications and Submissions - Drug Products

www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/index-eng.php

Clinical Trial Applications (CTAs) - Guidance documents

www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/clini/cta_application-eng.php

Health Canada Review Process

- 60 –180 day for OTC drugs
  - category IV Monographs
  - regular OTC
- 12-24 months for prescription drugs
  - new drugs and generics
- 24++ months for biologics, blood products, radiopharmaceuticals
- Marketing authorization/Notice of Compliance
- Issuance of DIN
- No sale before DIN issued

To obtain a full electronic copy of the TPD Quarterly Drug Submission Performance report for Q1-2014-15 contact publications@hc-sc.gc.ca

Review Fees (in Canadian Dollars)

- New, active substances (NDS) - $322,056
- Abbreviated NDS (Generic) - $163,120
- DIN (Labelling Standard, category IV) - $1,625
- DEL (Drug Establishment License) - $6,836 to $16,397 ++
- Mandatory 2% increase in fees every April 1st.

Advertising

Advertising includes any representation by any means, for the purpose of promoting directly or indirectly the sale or disposal of any food, drug, cosmetic or device.

9(1) No person shall label, package, treat, process, sell or advertise any drug in a manner that is false, misleading, or deceptive or is likely to create an erroneous impression regarding its character, value, quantity composition, merit or safety.

Where Regulated?

- The Food and Drugs Act and Regulations
- The Controlled Drugs and Substances Act and Regulations
- The Broadcasting Act and Regulations

Who Regulates?

- Advertising Standards Canada (A.S.C.) www.adstandards.com
- Pharmaceutical Advertising Advisory Board (PAAB) www.paab.ca
  (These two independent agencies are endorsed by Health Canada)
- Broadcast Clearance Advisory (BCA) www.mijo.ca

What is Regulated?

- Advertising of drug products for sale in Canada
- Advertising of OTC drugs to the general public
- Advertising of Prescription drugs to healthcare professionals
- Print, TV, radio, internet
- Exceptions to the Regulations such as press release, scientific journal articles

OTC Drugs

- Advertising must comply with terms of marketing authorization (DIN)
- No mandatory review of print advertising
- Mandatory review of radio, T.V. advertising
- Issuance of continuity number
- Direct to Consumer (DTC) Advertising permitted
- Dispute resolution process in place
- Health Canada does enforcement/compliance action

Guidance Document Labelling of Pharmaceutical Drugs for Human Use

www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/label_guide_ld-eng.php

Prescription Drugs

- Advertising must comply with terms of the marketing authorization Notice of Compliance (N.O.C.)
- DTC advertising not permitted
- All advertising copy must be reviewed by PAAB prior to use (Pharmaceutical Advertising Advisory Board - www.paab.ca/)
- Advertising only to medical professionals
- Dispute resolution processes exist
- Health Canada does enforcement/compliance action

Labelling

- *9(1) No person shall label, package, treat, process, sell or advertise any drug in a manner that is false, misleading or deceptive, or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit, or safety.*
- *9(2) A drug that is not labelled or packaged as required by, or is labelled or packaged contrary to the regulations shall be deemed to be labelled or packaged contrary to section (1).*

- ***Label*** - Includes any legend, word or mark attached to, included in, belonging to or accompanying any food, drug, cosmetic, device or package
- ***Package*** - Includes any thing in which any food, drug, cosmetic or device is wholly or partially contained, placed or packed.
- ***Main Panel*** - The main or principle display area on a label.
- ***Outer Label*** - The label on or affixed to the outside package of a drug.
- ***Inner Label*** - The label on or affixed to an immediate container of a drug.

Labelling

Continued…

- *Common Name* - That name for an ingredient that can be found in scientifically recognized but non-official publications.
- *Proper Name* - That name appearing in the regulations, or in Schedule B publications (USP, BP, NF, etc.).
- *Standard* - The standard to which a drug may be manufactured and represented.
    - Prescribed Standard – usually found in Division 6 of the Regulations on “Canadian Standard Drugs”.
    - Compendial Standard – contained in the publications listed in Schedule B to the Act.
    - Manufacturers Standard – established by the manufacturer and differing in some respects to a compendial standard

Labels Must Contain…

- The proper or common name of the product on the main panel of the inner and outer labels.
- The Drug Identification Number (DIN) on the main panel of the inner and outer labels.
- The applicable standard must be in close proximity to the proper name on the inner and outer label.
- Medicinal ingredients must be declared by proper or common name on the inner and outer label.
- Name and address of manufacturer, or importer of record, and distributor must be on the inner and outer labels.
- Lot number must be on the inner and outer labels.
- Net contents must be on the inner and outer labels.
- Adequate directions for use must be on the inner and outer labels.
- Warnings and cautions must be on the inner and outer labels.
- Expiration date must be on the inner and outer labels.

www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/label_guide_ld-eng.php

Clinical Trial Applications (CTA)

- CTA required before study can commence
- Sponsor representative in Canada
- 30 day default period for review
- GMP for drug manufacturing
- Health Canada inspects trial sponsors and trial sites

www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/clini/cta_contact_information-eng.php

Special Access Program

- For drugs not currently available in Canada
- Physician application to Health Canada
- Not always accepted
- Covers a specific patient
- No time limitation
- Can be cancelled by Health Canada
- May need to file New Drug Submission (NDS)

www.hc-sc.gc.ca/dhp-mps/acces/drugs-drogues/sapfs_pasfd-eng.php

To Import Drugs to Canada from Other Countries

Importer must have:

1. A Drug Establishment License (DEL) – this includes GMP requirements
   www.hc-sc.gc.ca/dhp-mps/compli-conform/licences/drugs-drogues/index-eng.php
2. A quality control department
3. Copy of Health Canada market authorization for the product
4. Master Production Document for the drug
5. Batch documentation and certificates of analysis for each lot or batch imported
6. Copy of the most recent FDA inspection report pertaining to the manufacturer
7. Stability data for the drug including the ongoing stability protocol
8. A set of SOP's to manage the drug importation under the GMP requirements

DRUGS - GMP

(Good Manufacturing Practices)

Required for:

- Fabricator
- Packager/Labeller
- Importer
- Distributor
- Wholesaler
- Tester

www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/index-eng.php

Offences and Penalties…

What happens if you don't comply?

- The Food and Drugs Act falls under the Criminal Code of Canada and charges for offences can be laid under those provisions…which means you can go to jail!
- Jurisdictional penalties

Food and Drug Act Penalties (Pre-November 2014)

Every person who contravenes any of the provisions of this Act or of the regulations made under this part is guilty of an offence and liable to:

a) on summary conviction for a first offence to a fine not exceeding $500.00 or to imprisonment for a term not exceeding 3 months or to both and for a subsequent offence, to a fine not exceeding $1000.00 or to imprisonment for a term not exceeding 6 months, or both; and

b) on conviction on indictment to a fine not exceeding $5000.00 or to imprisonment for a term not exceeding 3 years or to both

Jurisdictional Penalties

These penalties are applied through activities of Health Canada, usually without recourse to the courts.

- Product recalls
- Suspension of a Drug Establishment License (DEL)
- Product seizure
- Suspension of a Notice of Compliance (NOC) for a New Drug
- Cross border shipment refusals at customs
- Health Canada public notice about product problems

www.hc-sc.gc.ca/home-accueil/rto-tor/index-eng.php

For More Information:

Access to Therapeutic Products - The Regulatory Process in Canada:
www.hc-sc.gc.ca/dhp-mps/index-eng.php

Applications and Submission Related Information:
www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/form/hc3011_sc3011-eng.php

Preparation of DIN Submissions:
www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/pre_din_ind-eng.php

Management of Drug Submissions:
www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/mgmt-gest/mands_gespd-eng.php

Application Review Fees (effective April 1, 2015):
www.hc-sc.gc.ca/dhp-mps/finance/fees-frais/index-eng.php

Post-Drug Identification Number (DIN) Changes Guidance Doc:
www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/change_din-eng.php

For More Information:

Link to Label Standards:

www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/label-etiquet-pharm/index-eng.php

Link to Category IV Monographs:

www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/cat-iv-mono/index-eng.php

Listing of Drugs Currently Regulated as New Drugs

www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/newdrug-drognouv/ndrugs_ndrogue-eng.php

For More Information

HC's policy on Factors for listing drugs in Schedule F:
www.hc-sc.gc.ca/dhp-mps/prodpharma/pdl-ord/pdl_qa_fin_ord-eng.php

Consumer Advertising Guidelines for Marketed Health Products (for Non-prescription Drugs including Natural Health Products):
www.hc-sc.gc.ca/dhp-mps/advert-publicit/pol/guide-ldir_consom_consum-eng.php

Summary

- The Canadian system differs from that of the EU and USA
- Discussions/meetings with Health Canada are favoured
- Regulatory and compliance systems are complex
- FDA/EU approval does not ensure Health Canada approval

Natural Health Products (NHPs)

- Regulations established in 2004

- A subset of the Drug Regulations

www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php

Definition:

A substance set out in Schedule 1 or a combination of substances in which all the medicinal ingredients are substances set out in Schedule 1, a homeopathic medicine or a traditional medicine, that is manufactured, sold or represented for use in:

a. the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;

b. restoring or correcting organic functions in humans; or

c. modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

However, a natural health product does not include a substance set out in Schedule 2, any combination of substances that includes a substance set out in Schedule 2 or a homeopathic medicine or a traditional medicine that is or includes a substance set out in Schedule 2.

Natural Health Products

Schedule 1

1. A plant or a plant material, an alga, a bacterium, a fungus or a non-human animal material
2. An extract or isolate of a substance described in item 1, the primary molecular structure of which is identical to that which it had prior to its extraction or isolation
3. Any of the following vitamins:
   biotin, folate, niacin, pantothenic acid, riboflavin, thiamine, vitamin A, vitamin B6, vitamin B12, vitamin C, vitamin D, vitamin E, vitamin K 1, vitamin K 2
4. An amino acid
5. An essential fatty acid
6. A synthetic duplicate of a substance described in any of items 2 to 5
7. A mineral
8. A probiotic

Natural Health Products

Schedule 2 (Excluded Natural Health Product Substances)

1. A substance set out in Schedule C to the Act

2. A substance set out in Schedule D to the Act, except for the following:
   a drug that is prepared from any of the following micro-organisms, namely, an alga, a bacterium or a fungus; and
   any substance set out on Schedule D when it is prepared in accordance with the practices of homeopathic pharmacy

3. A substance regulated under the Tobacco Act

4. A substance set out in any of Schedules I to V of the Controlled Drugs and Substances Act

5. A substance that is administered by puncturing the dermis

6. An antibiotic prepared from an alga, a bacterium or a fungus or a synthetic duplicate of that antibiotic

Examples of NHPs:

- Vitamins and Minerals
- Herbal Remedies
- Homeopathic Medicines
- Probiotics
- Other products such as amino acids and essential fatty acids

Product Licence

- To be legally sold, must have a product licence.
- Application required (no fee)
- Labelling
- Safety and efficacy evidence

www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-site-exploit/form/index-eng.php

Labelling

Main Panel

- Brand name
- Product name
- Dosage form
- “sterile”, if applicable
- Net amount (weight, measure, number)
- Natural product licence number
- NPN XXXXXXXX

Any Panel

- Name and address of product licence holder
- Name and address of importer (if applicable)
- Proper name of each medicinal ingredient
- Quantity of each medicinal ingredient per dosage unit

Safety and Efficacy

- Clinical trial data
- References to published studies, journals, pharmacopeias, traditional resources
- Potency of each medicinal ingredient
- Use or purpose
- Route of administration
- Dosage
- Duration of usage
- Risk information
- Storage conditions
- Lot number/expiry date
- Source material of medicinal ingredients

Site Licence

- Application required (no fee)
- Evidence of GMP compliance
- Product specifications
- Premises
- Equipment
- Personnel
- Sanitation program
- Operations
- Quality assurance
- Stability

GMP Regulations for NHPs
laws-lois.justice.gc.ca/eng/regulations/SOR-2003-196/

Natural Health Products - GMPs

(Good Manufacturing Practices)

Required for:

- Manufacturer
- Packager
- Labeller
- Importer
- Distributor

Interface
Natural Health Product - Food

Examples:

- Energy drinks
- Vitamin supplements in candy format
- Juice or water with added vitamins
- Classified as natural health products in 2004
- Many now moving back to foods – e.g., energy drinks
- Carefully review guidance document

VANESSA'S LAW

"PROTECTING CANADIANS FROM UNSAFE DRUGS ACT"
November 6, 2014

The Protecting Canadians from Unsafe Drugs Act is know as Vanessa's Law in honour of the late daughter of Conservative MP Terence Young. In March 2000, the 15-year-old died of a heart attack while on a prescription drug for bulimia and bloating. The medication, Prepulsid, was later deemed unsafe and pulled from the market.

HISTORY

- Food and Drugs Act revisions under consideration since mid-1990s (Legislative Renewal).

- Concern that insufficient legal authority available to protect the public.

- First attempted changes were abandoned.

- Member of Parliament's daughter (Vanessa) dies from unexpected reactions to a drug.

- Vanessa's Law passed in November 2014.

OVERVIEW

- Post-marketing changes
- Covers drugs and medical devices, but not natural health products
- Better addresses the health and safety risks of drugs and medical devices
- Significantly increases the power and authority of the Food and Drugs Act.

Key Changes to the Food and Drugs Act

1. Definitions
2. Increased Powers for Health Canada
3. Penalties

www.parl.gc.ca/HousePublications/Publication.aspx?Language=E&Mode=1&DocId=6767163&File=27#1

Key Changes to the Food and Drugs Act

(Continued)

1. Definitions

- Drug…Section 2 of the Act
- Confidential Business Information…Section 2(3)
- Therapeutic Product…Section 2(3)
- Therapeutic Product Authorization…Section 2(3)

Key Changes to the Food and Drugs Act

(Continued)

DRUGS

"Drug" includes any substance or mixture of substances manufactured, sold or represented for use in:

a. the diagnosis, treatment, mitigation, or prevention of a disease, disorder, abnormal physical state, or its symptoms, in human beings or animals.
b. restoring, correcting or modifying organic functions in human beings or animals, or
c. disinfection on premises where food is manufactured, prepared or kept

Key Changes to the Food and Drugs Act

(Continued)

CONFIDENTIAL BUSINESS INFORMATION

"Confidential business information" in respect of a person to whose business or affairs the information relates, means — subject to the regulations — business information

a) that is not publicly available,
b) in respect of which the person has taken measures that are reasonable in the circumstances to ensure that it remains not publicly available, and
c) that has actual or potential economic value to the person or their competitors because it is not publicly available and its disclosure would result in a material financial loss to the person or a material financial gain to their competitors;

Key Changes to the Food and Drugs Act

(Continued)

THERAPEUTIC PRODUCT

``therapeutic product" means a drug or device or any combination of drugs and devices, but does not include a natural health product within the meaning of the Natural Health Products Regulations.

Key Changes to the Food and Drugs Act

(Continued)

THERAPEUTIC PRODUCT AUTHORIZATION

“therapeutic product authorization” means an authorization — including a licence and a suspended authorization or licence — that is issued under the regulations and that authorizes, as the case may be, the import, sale, advertisement, manufacture, preparation, preservation, packaging, labelling, storage or testing of a therapeutic product;

Key Changes to the Food and Drugs Act

(Continued)

INCREASED POWERS TO HEALTH CANADA

To disclose confidential business information…Section 21.1(2)(3)

21.1 (1) If the Minister believes that a therapeutic product may present a serious risk of injury to human health, the Minister may order a person to provide the Minister with information that is in the person's control and that the Minister believes is necessary to determine whether the product presents such a risk.

Disclosure — serious risk

(2) The Minister may disclose confidential business information about a therapeutic product without notifying the person to whose business or affairs the information relates or obtaining their consent, if the Minister believes that the product may present a serious risk of injury to human health.

Disclosure — health or safety

(3) The Minister may disclose confidential business information about a therapeutic product without notifying the person to whose business or affairs the information relates or obtaining their consent, if the purpose of the disclosure is related to the protection or promotion of human health or the safety of the public and the disclosure is to

(a) a government;
(b) a person from whom the Minister seeks advice; or
(c) a person who carries out functions relating to the protection or promotion of human health or the safety of the public.

Key Changes to the Food and Drugs Act

(Continued)

INCREASED POWERS TO HEALTH CANADA

- **To order a person to provide the information necessary to assess product risk…Section 21.1(1)**

21.1 (1) If the Minister believes that a therapeutic product may present a serious risk of injury to human health, the Minister may order a person to provide the Minister with information that is in the person's control and that the Minister believes is necessary to determine whether the product presents such a risk.

Key Changes to the Food and Drugs Act

(Continued)

INCREASED POWERS TO HEALTH CANADA

- **To order a label modification or to modify or replace its package…Section 21.2**

21.2 The Minister may, if he or she believes that doing so is necessary to prevent injury to health, order the holder of a therapeutic product authorization that authorizes the import or sale of a therapeutic product to modify the product's label or to modify or replace its package.

Key Changes to the Food and Drugs Act

(Continued)

INCREASED POWERS TO HEALTH CANADA

To order a product recall…Section 21.3(1), (2), (3), (4), (5), (6)

21.3 (1) If the Minister believes that a therapeutic product presents a serious or imminent risk of injury to health, he or she may order a person who sells the product to

(a) recall the product; or

(b) send the product, or cause it to be sent, to a place specified in the order.

(2) For greater certainty, if the Minister makes an order under paragraph (1)(a) and believes that corrective action is an effective means of dealing with the risk, the order may require the person who sells the product to, instead of requesting the product's return, request the product's owner or user to allow corrective action to be taken in respect of the product and then take that corrective action, or cause it to be taken, if the request is accepted.

(3) Subject to subsection (5), no person shall sell a therapeutic product that the Minister orders them, or another person, to recall.

(4) The Minister may authorize a person to sell a therapeutic product, with or without conditions, even if the Minister has ordered them, or another person, to recall it.

(5) A person does not contravene subsection (3) if they sell a therapeutic product that they have been authorized under subsection (4) to sell, provided that they sell it in accordance with any conditions that the Minister establishes.

(6) No person shall be convicted of an offence for the contravention of subsection (3) unless it is proved that, at the time of the alleged contravention, the person had been notified of the recall order or reasonable steps had been taken to bring the purport of the recall order to the notice of those persons likely to be affected by it.

Key Changes to the Food and Drugs Act

(Continued)

INCREASED POWERS TO HEALTH CANADA

- **To order a product assessment…Section 21.31**

21.31 Subject to the regulations, the Minister may order the holder of a therapeutic product authorization to conduct an assessment of the therapeutic product to which the authorization relates and provide the Minister with the results of the assessment.

Key Changes to the Food and Drugs Act

(Continued)

INCREASED POWERS TO HEALTH CANADA

- **To order additional tests…Section 21.32**

21.32 Subject to the regulations, the Minister may, for the purpose of obtaining additional information about a therapeutic product's effects on health or safety, order the holder of a therapeutic product authorization to

(a) compile information, conduct tests or studies or monitor experience in respect of the therapeutic product; and

(b) provide the Minister with the information or the results of the tests, studies or monitoring.

Key Changes to the Food and Drugs Act

(Continued)

INCREASED POWERS TO HEALTH CANADA

- **To make publicly available any orders under Sections 21.1 to 21.3…Section 21.4(2)**

21.4 (1) For greater certainty, orders made under any of sections **21.1** to **21.32** are not statutory instruments within the meaning of the Statutory Instruments Act.

21.4 (2) The Minister shall ensure that any order made under any of sections **21.1** to **21.32** is publicly available.

Key Changes to the Food and Drugs Act

(Continued)

PENALTIES

- **Penalties range from $250,000 .– to $5,000,000.00…Section 31.2**

31.2 Subject to section **31.4**, every person who contravenes any provision of this Act or the regulations, as it relates to a therapeutic product, or an order made under any of sections **21.1** to **21.3** is guilty of an offence and liable

(a) on conviction by indictment, to a fine not exceeding $5,000,000 or to imprisonment for a term not exceeding two years or to both; and

(b) on summary conviction, for a first offence, to a fine not exceeding $250,000 or to imprisonment for a term not exceeding six months or to both and, for a subsequent offence, to a fine not exceeding $500,000 or to imprisonment for a term not exceeding 18 months or to both.

Key Changes to the Food and Drugs Act

(Continued)

PENALTIES

- **Due Diligence…Section 31.3**

31.3 Due diligence is a defence in a prosecution for an offence under this Act, other than an offence under section **31.4**.

Key Changes to the Food and Drugs Act

(Continued)

PENALTIES

- **Knowingly or recklessly causes a serious risk of injury to human health…Section 31.4**

31.4 A person who contravenes section **21.6**, or who knowingly or recklessly causes a serious risk of injury to human health in contravening another provision of this Act or the regulations, as it relates to a therapeutic product, or an order made under any of sections **21.1** to **21.3** is guilty of an offence and liable

(a) on conviction on indictment, to a fine the amount of which is at the discretion of the court or to imprisonment for a term not exceeding five years or to both; and

(b) on summary conviction, for a first offence, to a fine not exceeding $500,000 or to imprisonment for a term not exceeding 18 months or to both and, for a subsequent offence, to a fine not exceeding $1,000,000 or to imprisonment for a term not exceeding two years or to both.

Ontario Ministry of Health and Long-Term Care

- $50 B + budget
- Budget growing about 4% to 5% a year
- Unsustainable

Federal and Provincial Drug Programs

- Common Drug Review (Federal)
- Pan-Canadian Oncology Drug Reviews (Federal)
- Provincial Selection

Ontario Drug Benefit Program

- Ontario citizens covered by the Ontario Health Insurance Plan for most medical services
- Province decides on drugs for their Formulary
- Doctors can prescribe from the list
- Patient (or their insurance plan) pays
- 65 + pay only $100 deductible

Special Plans

- New Drug Funding Program – for some cancer drugs administered in hospitals
- Exceptional Access Program – covers some 850 prescription drugs not on the Ontario Drug Benefit Program
- Special Drugs Program – may pay for certain outpatient drugs used to treat a number of serious conditions

- www.cancercare.on.ca/cms/one.aspx?portalId=1377&pageId=11801
- www.health.gov.on.ca/en/pro/programs/drugs/odbf/odbf_except_access.aspx
- www.health.gov.on.ca/en/public/programs/drugs/programs/sdp.aspx

istries of Health

- Alberta: www.health.alberta.ca/
- British Columbia: www.gov.bc.ca/health/
- Manitoba: www.gov.mb.ca/health/
- New Brunswick: www.gnb.ca/0051/0394/
- Newfoundland & Labrador: www.health.gov.nl.ca/health/
- Northwest Territories: www.hlthss.gov.nt.ca/
- Nova Scotia: www.gov.ns.ca/DHW/
- Nunavut: www.hss.gov.nu.ca/en/Home.aspx
- Ontario: www.health.gov.on.ca/
- Prince Edward Island: www.gov.pe.ca/health/
- Quebec: www.msss.gouv.qc.ca/
- Saskatchewan: www.saskatchewan.ca/live/health-and-healthy-living
- Yukon: www.hss.gov.yk.ca/

Thank You! Questions?

To ask a question.
The operator will explain how you can ask a question. For privacy reasons, each question will be announced only by the first name of the person reported at dial-in, but anyone in your group may ask the question(s). Please try to avoid using a speakerphone while asking your question.

If you have a question later or would like to arrange a private discussion, you are invited to email David McCarthy at McCarthy@McCarthyConsultant.com or phone +1-905-836-0033.

Additional information.
These slides, with live links, as well as instructions for ordering the audio recording of this presentation at the 50% attendee discount are available at
www.foiservices.com/vanessa2167.htm

We value your feedback.
Please return the evaluation at the end of this handout to enter a prize drawing for a $100 amazon.com gift card and/or arrange to receive a certificate of attendance verifying your participation in this 1.5 hour educational session.

Training Evaluation Form

TC150820

Health Canada's Requirements for Devices: Approval, Compliance...and the Dramatic Changes Now Being Implemented
David McCarthy, Presenter - August 20, 2015

Win a $100 Amazon.com Gift Certificate from FOI!

Just complete this form and fax it to +1-301-569-7506 by August 27, 2015
and you will be entered in a drawing for an Amazon.com Gift Certificate

Please indicate your primary job responsibility (circle one):

Regulatory Affairs QA/QC Statistics Medical Writing Electronic Submissions General Management
Other (please specify):_____

Please rate various aspects of this course

(1 = Poor; 2=Fair; 3=Good; 4=Very Good; 5=Excellent – please circle your answers)

What is your overall rating of the course?	1	2	3	4	5
How do you rate the content of the course?	1	2	3	4	5
Were course materials clear and understandable?	1	2	3	4	5
Was the length of the course adequate to cover the content?	1	2	3	4	5
Was the instructor knowledgeable about the subject matter?	1	2	3	4	5
How would you rate the instructor overall?	1	2	3	4	5

Other comments:

Please feel free to comment on any aspect of this course, including the instructor, content, and technical arrangements:

_____

_____

_____

_____

_____

_____

_____

☐ **Check here to receive a Certification of Attendance verifying your 1.5 training contact hours for this educational session.** Please provide your legibly printed name with your signature next to it, email address, and fax this form to the number below. Your certificate will be emailed to you.

By providing the information below and faxing this page to +1-301-569-7506 by August 27, 2015 you will be entered in a drawing for a $100 Amazon.com Gift Certificate from FOI.

Your Name: _____

Company Name: _____

Email Address: _____