

Health Products and Food Branch

Your Health and Safety - Our Priority



Regulatory Framework for Health and Food Products in Canada

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 Health
Canada

Santé
Canada

Canada

Health Products and Foods Responsibilities

Federal

- Regulate the safety, efficacy and quality of **health products and foods**
- Ensure patents are address before market authorization to “**new**” **drugs**
- Control the price of patented medicines
(Patented Medicines Prices Review Board)
- Coordinate and provide leadership on FPT

Provincial

- Delivery of healthcare
- Practice of Medicine/Pharmacy via Colleges
- Drug Formularies / Reimbursement issues
- 70 + P/T statutes administered by P/T agriculture, health, fisheries and/or environment departments, that apply to food manufactured, traded and sold within their borders including **food production, food manufacturers, food service and food retail sectors**

Health Products and Food Branch

The Federal Regulatory Authority

Therapeutic Products Directorate (TPD)

- pharmaceutical drugs (prescription, non-prescription, brands and generics, disinfectants)
- medical devices

Biologics and Genetic Therapies Directorate (BGTD)

- biological and radiopharmaceutical drugs
- blood and blood products
- viral and bacterial vaccines
- genetic therapeutic products
- tissues, organs and xenografts

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The Federal Regulatory Authority - cont'd

Natural Health Products Directorate (NHPD)

- Ensures access to natural health products that are safe, effective, and high quality while respecting freedom of choice and philosophical and cultural diversity
- Includes homeopathics, traditional medicines
- **NHP Regulations effective January 1, 2004** ~~New~~

Veterinary Drugs Directorate (VDD)

- Health Canada evaluates and monitors the safety, quality and effectiveness of veterinary drugs; sets standards and promotes the prudent use of veterinary drugs administered to food-producing and companion animals.

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The Federal Regulatory Authority – cont'd

HPFB Inspectorate – Compliance & Enforcement

- Responsible for establishment licensing, GMP and blood establishment inspections, product investigations and related laboratory analysis functions
- Does NOT cover Foods

Marketed Health Products Directorate (MHPD)

- Responsible for post-market assessment and surveillance of pharmaceutical and biological drugs, medical devices, natural health products, radiopharmaceuticals.
- Does NOT cover Foods

Health Products and Food Branch

The Federal Regulatory Authority - final

Food Directorate (FD)

- Responsible for the establishment of appropriate policies, regulations, standards, and guidelines related to the **safety and nutritional quality of food**
- Identify, advise on, and manage risks and benefits associated with the **food supply**
- **Assess the effectiveness of the activities** of the Canadian Food Inspection Agency (CFIA) related to food safety

CFIA Responsibilities

- Develops standards related to the **packaging, labelling and advertising** of foods
- Inspection and enforcement duties
- Regulation of seeds, veterinary biologics, fertilizers and livestock feeds
 - e.g., *Seeds Act, Feeds Act, Plant Protection Act*

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Federal Regulatory Framework

Minister of Health Responsibilities

- Stem from the *Department of Health Act*
 - 4. (1) ...all matters over which Parliament has jurisdiction relating to the **promotion and preservation of the health of the people of Canada** not by law assigned to any other department, board or agency of the Government of Canada.
 - 5. Minister may designate inspectors

Federal Legislation and Guidance

- *Food and Drugs Act* and its Regulations
 - governs the safety, effectiveness and quality of *drugs, natural health products, foods* and *medical devices* available to Canadians.
- *Controlled Drugs and Substances Act*
 - governs narcotic & controlled drugs
- Patented Medicines (NOC) Regulations
- 13 federal statutes addressing all stages of food continuum
- *Financial Administration Act*
 - fees for review-cost recovery
- *Access to Information and Privacy Act*
- Policies and Guidelines (incl. International Guidelines - ICH) in support of the *Act* and Regulations

Food and Drugs Act

- Purpose
 - Health Fraud and Consumer deception
 - Consumer and purchaser safety
- **Prohibits the sale** and advertising of foods, drugs, cosmetics or devices.... unless ...
 - therefore applies to all foods and drugs SOLD in Canada regardless of where they are made
- Defines a food, drug, cosmetic and device
- Regulation making authority

Unless....

- **“No person shall sell...”**
 - Allows for the regulations to set conditions under which a product may be sold
 - Allows for the pre-market assessment of products;
 - Novel foods and food additives
 - Agricultural chemical in food
 - Drugs (human and veterinary)
 - Natural health products
 - Medical devices – class III and IV

Definition of Food

- Food includes any article manufactured, sold or represented for use as food or drink for human beings, chewing gum, and any ingredient that may be mixed with food for any purpose whatever.

Definition of a Drug

”..... includes any substance or mixture of substances manufactured, sold or represented for use in:

- the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or the symptoms thereof, in man or animal,
- restoring, correcting or modifying organic functions in man or animal, or
- **disinfection** in premises in which food is manufactured, prepared or kept."

Definition of Cosmetic

- Cosmetic includes any substance or mixture of substances manufactured, sold or represented for use in **cleansing, improving or altering** the complexion, skin, hair or teeth, and includes **deodorants** and perfumes
 - Oversight by Consumer Products Safety Bureau (HECSB)
- “**Cosmetics**” with **health claims** are regulated as **drugs**, e.g., anti-persperents, sunscreens with SPF, fluoride toothpaste

Definition of a Medical Device

“... any article, instrument, apparatus or contrivance, ... for use in

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
- (b) restoring, correcting or modifying a body function or the body structure of human beings or animals,
- (c) the diagnosis of pregnancy in human beings or animals, or
- (d) the care of human beings or animals during pregnancy and at and after birth of the offspring, including care of the offspring,

and includes a contraceptive device but does not include a drug”

Food and Drug Regulations

- Part A - Administration
- Part B - Foods
- Part C - Drugs
- Part D - Vitamins Minerals and Amino Acids
- Part E - Cyclamate and Saccharin Sweeteners
- Part G - Controlled Drugs
- Part J - Restricted Drugs
- Cosmetic Regulations
- Medical Device Regulations
- Natural Health Products Regulations **New**

Part A - Administration

- Applies to both foods and drugs
- Definitions
 - general labelling requirements
 - language requirements
 - analysts and inspectors
 - importation
 - sampling by inspectors
 - pressurized containers
 - security packaging

Part B - Foods

- Applies to foods
- Made up of 28 divisions, each dealing with a specific type of food or beverage e.g.,
 - Division 2 – Alcoholic Beverages
 - Division 6 – Food Colours
 - Division 15 – Adulteration of Food
 - Division 16 – Food Additives
 - Division 28 – Novel Foods

Division 16 - Food Additives

- Defined as “any substance the use of which results, or may reasonably be expected to result in it or its by-products becoming a part of or affecting the characteristics of a food.”
- Division 16 tables contain permissible additives
- Petitioners offer submissions to the *Food Directorate* for approval of new food additives or to extend the areas of use or increase the levels of use of an approved one

Division 28 - Novel Foods

- No history of safe use as a food
- Is manufactured using a process not previously applied to that food; or
- A food derived from a genetically-modified organism
- B.28.002 prohibits the sale of novel food unless
 - the manufacturer has notified of an intent to sell
 - HC has “authorized that sale”

Part C - Drugs

- Division 1 - General Section
- Division 1A - Establishment Licensing ***
- Division 2- Good Manufacturing Practices ***
- Division 3 - Radiopharmaceuticals (Schedule C)
- Division 4 - Biologicals (Schedule D)
- **Division 5 - Clinical Trial Regulations**
- Division 6 - Canadian Standard Drugs
- Division 7 - *Canada's Access to Medicines Regime* **New**
- **Division 8 - New Drugs (human and veterinary)**
- Division 9 - Analgesics

Drugs Sold in Canada

- All drugs must have market authorization from Health Canada before coming to the general market. This includes but is not limited to:
 - drugs imported from other countries;
 - drugs manufactured in Canada.
- Exports generally exempt UNLESS
 - the exporting company needs a Canadian approval in order to enter another country's market
 - Drug is exported under the WTO General Council Decision (Division 7) **New**

Submission Data Requirements

- **New Drugs** typically require preclinical, clinical, chemistry & manufacturing data
- **Generics** typically require bioequivalence and/or pharmaceutical equivalence data, chemistry & manufacturing data
- **Other Drugs** (not “New”) - formulation and labelling regulations require the submission of limited information however sponsors comply with posted DIN Guidelines and labelling standards – known as “DIN only Drugs”

Definition of a New Drug

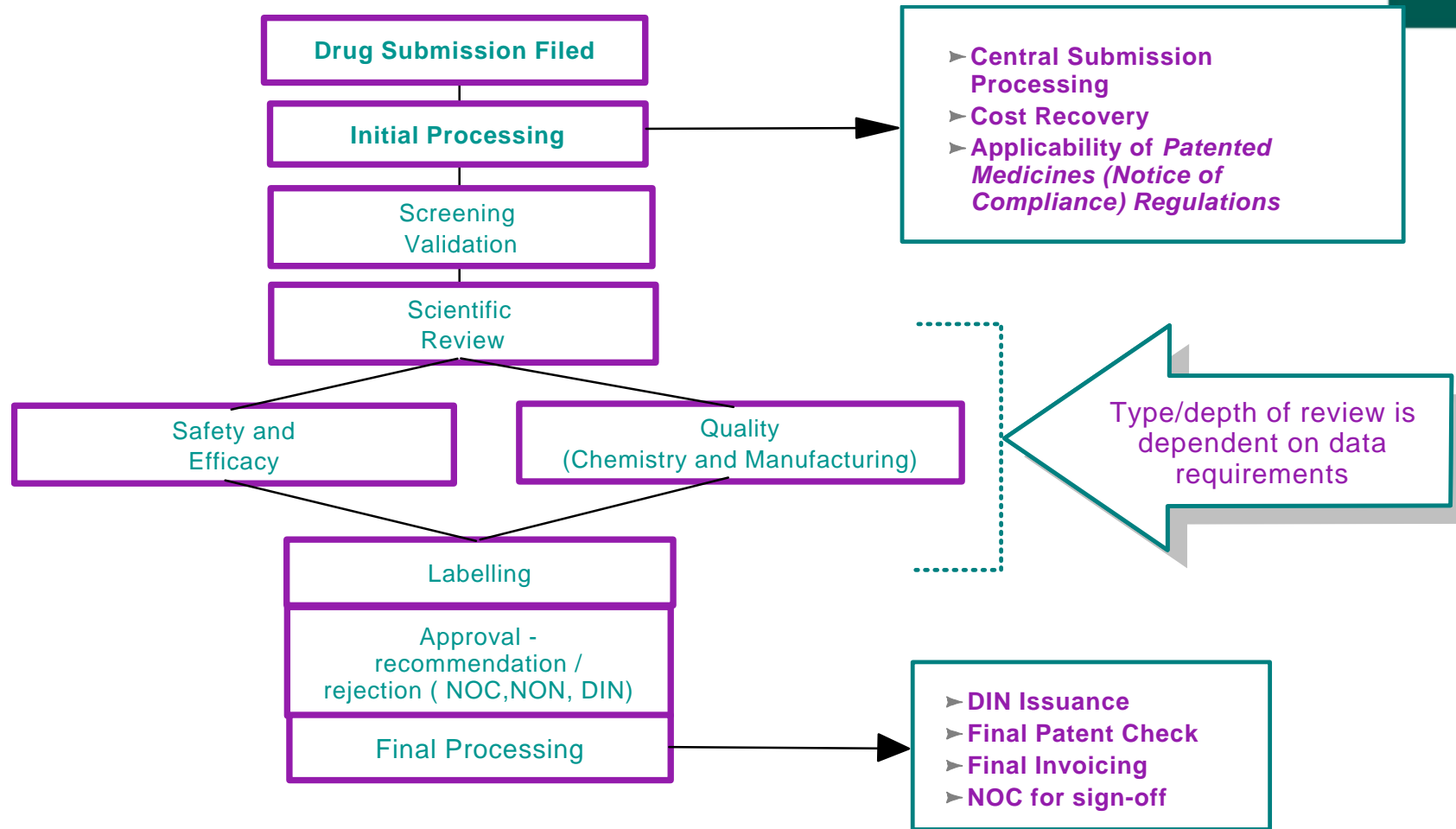
Division 8 (C.08.001)

- a) that has not been sold in Canada for **sufficient time and in sufficient quantity** to establish in Canada the safety & efficacy of that substance as a drug
- b) ...new **combination of two or more drugs**
- c) ... new claim or a **condition of use as a drug**, including dosage, route of administration, or duration of action

Clinical Trial Framework

- Division 5 of the *Food and Drug Regulations*
- Came into force in September 1, 2001
- Sponsors must submit applications to conduct trials in Canada
- applications includes preclinical data, drug safety information, chemistry and manufacturing information, and information respecting REB that approved protocol etc.
- application is subject to a 30 day default provision
- 7 day administrative target for the review of bioequivalence trials and Phase I trials in adult healthy volunteers
- regulations include provisions for suspension and cancellation

New Drug Review Process



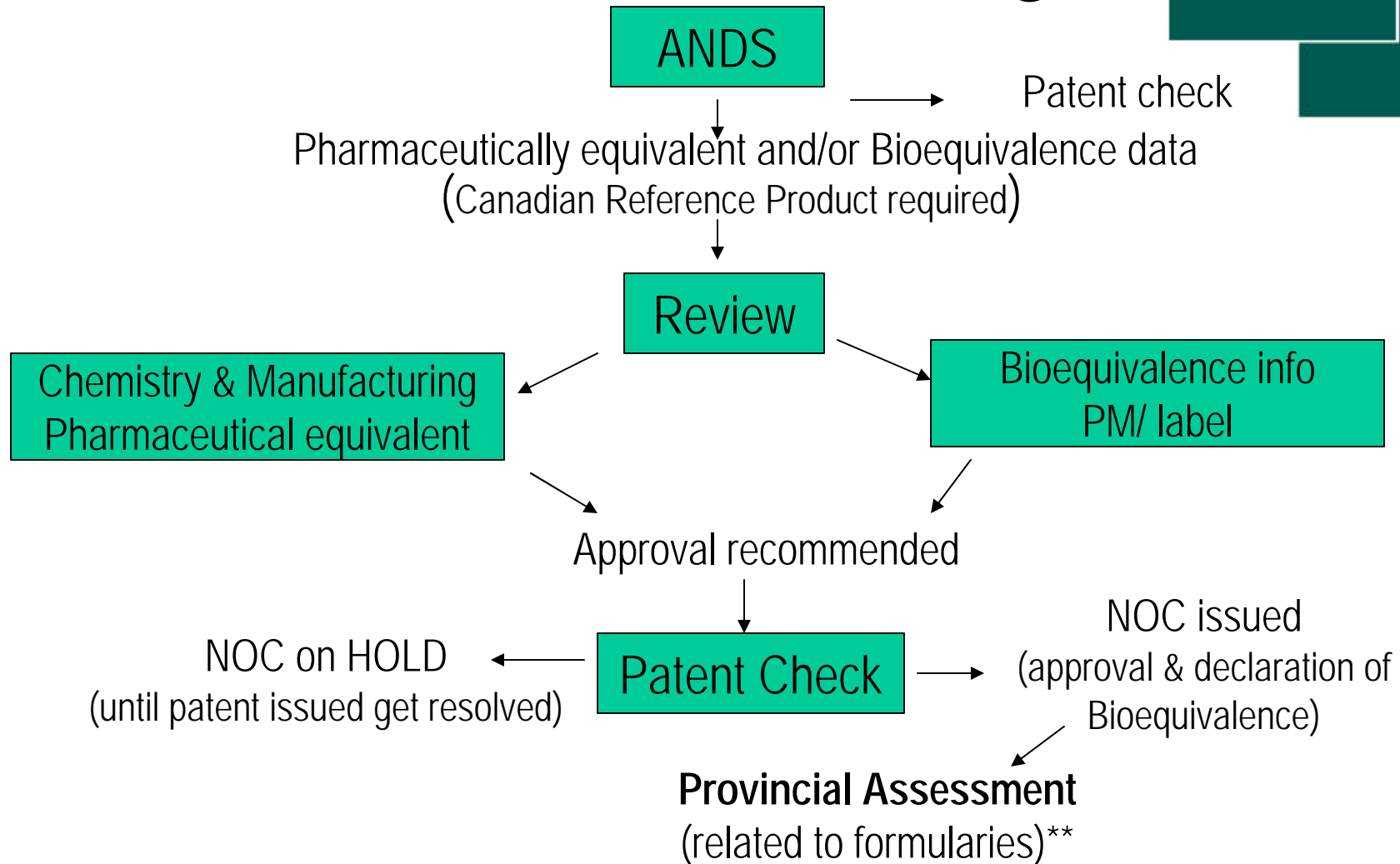


Review of Generic New Drugs

Food & Drugs Act and Regulations amended 1995

- Allow for a generic manufacturer to file an ANDS
- Allows for establishment of bioequivalence by requiring a Canadian Reference Product (CRP)
- Same route of administration as CRP
- Same conditions of use as the CRP
- Ensured safety, efficacy and high quality

Review of Generic New Drugs



Regulatory Decisions

Notice of Compliance (NOC) + DIN Issuance

- Issued under the New Drug Regulations
- Substantial evidence to support the safety, efficacy and quality claims in accordance with the *Food and Drugs Act and Regulations*

DIN Only

- Drugs that are not “new drugs” are issued a DIN only

Note:

- DINS are issued to all drugs authorized for marketing in Canada (8 digit number); must appear on the label
- Manufacturer must notify of first sale
- NPNs are issued to Natural Health Products

Regulatory Decisions – cont'd

Notice of Deficiency (NOD)

- gross deficiencies that **impede the review** from being completed
- clock stops and drug company must submit a response before clock starts at beginning again (review time accumulates)

Notice of Non-Compliance (NON)

- gross deficiencies with the information provided; evidence of **failure to comply** with requirements of *Food and Drugs Act* and Regulations
- clock stops and drug company must submit a response before clock starts at beginning again (reduced review time)

Withdrawals - NON-W or NOD-W

- Information submitted in response to a NON or NOD does not resolve the deficiencies.
- Withdrawals are considered **final decisions**
- Only final decisions can be “appealed” under the new *Reconsideration Policy*

Post Market Roles and Activities

Marketed Health Products Directorate

- Legislated responsibilities; ‘Duty of Care’ regarding drug safety

Activities

- Monitor and collect adverse drug reaction and medication incident data, and communicate these to health professionals and public (e.g. Advisories for therapeutic products, Canadian Adverse Drug Reaction Newsletter, Dear Health Care Provider Letters)
- Review and analyze safety data
- Conduct risk/benefit assessments of **marketed** products
- Regulatory oversight of advertising activities

Risk Management Authorities

- Adverse drug reaction reporting
- Establishment of records and to furnish to the Minister upon request
- Request for safety evidence and a stop sale
C.01.013
- Cancellation of a DIN – C.01.014.6
- Suspension of an NOC, CT C.08.006
- Little authority to compel labelling changes, post-market commitments etc.

For more information

- Visit the Health Canada website:
 - <http://www.hc-sc.gc.ca>
 - access Guidelines, Policies, Forms, Templates, etc.
 - New Notice of Compliance Database **New**
 - Drug Product Database
 - Summary Basis of Decision **New**

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Questions?