Progressive Licensing – Amendments to the *Food and Drugs Act*

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Natalie Bellefeuille, Senior Legal Analyst
Progressive Licensing Project
Health Canada



Canada

Health Canada's mandate is to protect and promote the health and safety of Canadians

What is the approach currently taken to satisfy this mandate?

(1) Authorizations to conduct clinical trials

(2) Authorizations to sell and advertise products

(3) Licensing of establishments

***Food and Drugs Act*, R.S.C 1985, c. F-27**

(1) Definitions (s. 2)
(2) Prohibitions (s. 3 – 21)
(3) Compliance and enforcement (s. 22 – 29)
(4) Regulation-making authorities (s. 30 – 30.1)
(5) Fines and Penalties (s. 31 – 36)
(6) Exports (s. 37)
(7) Schedules

The *Food and Drugs Act* does not:

- Prohibit the conduct of certain activities without an authorization or licence
- Authorize the Minister of Health to issue, amend, suspend or revoke authorizations or licences
- Authorize the Minister to impose terms and conditions on authorizations or licences
- Authorize the Minister to require holders of authorizations or licences to conduct post-market activities

Relevant provisions are contained in regulations

- *Food and Drug Regulations,* C.R.C., c. 870
- *Medical Devices Regulations,* SOR/98-282
- *Natural Health Products Regulations,* SOR/2003-196
- *Safety of Cells, Tissues and Organs for Transplantation Regulations, SOR/2007*

Enabling authorities in the *Food and Drugs Act*:

(1) Clinical trials authorizations:

- s. 30(1)(b) + (o) – sale or conditions of sale of any drug

(2) Market approval of products:

- s. 30(1)(b) + (o) – sale or conditions of sale of any drug

(3) Establishment licensing:

- s. 30(1)(b) + (e) + (o) – manufacture, preparation, preserving, packing, labelling, storing and testing of any drug

Why?

- *Food and Drugs Act* has not been comprehensively revised since the 1950's
- At that time, the assessment of risks and benefits of products was poorly understood
  - Existing prohibitions are therefore aimed at preventing fraud on label and the making of adulterated products or in unsanitary conditions
- When this became better understood, changes were made to the regulations to introduce requirements surrounding the pre-market review of products – the *Food and Drugs Act* was not amended accordingly

Why? (continued)

- It has become increasingly clear that post-market surveillance should play as important a role in the assessment of the benefits and risks of products
  - Limited ability to appreciate the benefits and risks of products through clinical trials
- Other jurisdictions have modernized their applicable legislation and rules to support a life-cycle approach to the regulation of products

As a result:

- Different rules applicable to drugs, devices, foods and cosmetics – what about combination products?
  - Definition of “device”
- Greater need to oversee the importation of products
  - More products are being manufactured in other jurisdictions
- Compliance and enforcement measures are not sufficiently flexible
- Fines and penalties do not act as a deterrent
- Outdated terminology/language

Approach to the Modernization of the *Food and Drugs Act*

- The Progressive Licensing Framework was developed as a strategy for the modernization of the existing framework for the regulation of drugs (pharmaceuticals and biologics), the bulk of which is set out in the *Food and Drug Regulations*

- It was decided that the *Food and Drugs Act* would be modernized before the *Food and Drug Regulations*, with an understanding that the great majority of the Framework would be implemented through the *Food and Drug Regulations* and measures within the Department

Approach to the Modernization of the *Food and Drugs Act*

- Changes needed to the *Food and Drug Regulations* to introduce a Progressive Licensing Framework will be ascertained through consultations with key stakeholder groups

- Intent is for Canadian regulatory requirements to be in line with international requirements

- Emphasis will be placed on internal and external training to ensure that expectations are clear

Approach to the Modernization of the *Food and Drugs Act*

- All sections of *Food and Drugs Act* were examined to determine the scope of changes needed to introduce into the *Act* a structure to support a Progressive Licensing Framework.

- In conducting this scoping exercise, it came to our attention that additional changes to the *Act* were required for the purposes of:
  - Eliminating provisions that have become outdated or that are not actively used by Health Canada
  - Providing explicit authority for the way in which certain products are currently regulated and for certain activities that Health Canada currently carries out

Bill C-51

- Tabled with the House of Commons on April 8, 2008
- Currently at the Second Reading stage
- Steps that will follow Second Reading:
  - Bill will be referred to the Health Committee - Committee will scrutinize each provision and may propose amendments
  - Committee Report
  - Third Reading
- Once all these steps are completed in the House of Commons, an equivalent process has to take place in the Senate

Bill C-51 – Proposed changes to the *Food and Drugs Act*

Key proposals:

- Introduction of the concept of therapeutic product
- Introduction of authorization and licensing structures, supported by new prohibitions
- Introduction of authorities to impose terms and conditions on authorizations and licences
- Introduction of authorities surrounding post-market surveillance
- Introduction of more flexible compliance and enforcement measures
- Increase in maximum fines and penalties

Bill C-51 – Proposed changes to the *Food and Drugs Act*

Overview:

- Preamble
- Definitions
- Purpose
- Prohibitions
- Authorizations and Licences
- Powers of the Minister
- Information
- Compliance and Enforcement
- Regulations
- Fines and Penalties
- Exports

Preamble

The purpose of the preamble is to:

- Provide an understanding of the objectives of the Bill
- Indicate the key objectives, responsibilities and factors that have guided the revisions and inclusions to the *Food and Drugs Act*
  - ongoing assessment of information about therapeutic products over their life-cycle
  - assessment of benefits and risks to be based on scientific and objective evidence

If Bill C-51 becomes law, the preamble will not appear in the consolidated version of the Act

Definitions (s. 2)

Key additions/changes to the definitions include:

- **Therapeutic product**
- Designated therapeutic product
- Prescription therapeutic product
- Practitioner
- Controlled activity
- **Device**
- **Sell**
- Clinical trial
- Confidential business information

Definitions (s. 2)

Therapeutic product:

- The term “therapeutic product” will be defined to encompass drugs, devices, cells, tissues and organs and combinations thereof
- This definition will support the implementation of the authorization and licensing structures being proposed in this Bill and will allow for the regulation of all of the products described above, including their combinations

Definitions (s. 2)

Device:

- Words “but does not include a drug” would be removed
- Would allow for drug-device combination products to be regulated mainly as devices under the *Medical Devices Regulations* or mainly as drugs under the *Food and Drug Regulations*

Definitions (s. 2)

Sell:

- Would be amended to cover leasing activities in relation to medical devices
- Would ensure that provisions in the Act and regulations applicable to the sale of therapeutic products also extend to their lease

Purpose (s. 2.3)

- This provision clarifies the underlying intent of and reason for the *Food and Drugs Act*
- The purpose of the Act is to protect and promote the health and safety of the public
- This is achieved by regulating and prohibiting certain activities in relation to foods, therapeutic products and cosmetics

Prohibitions: General (s. 3 – 3.2)

Certain prohibitions are applicable to foods, therapeutic products and cosmetics

- False or misleading information (s. 3)
- Tampering (s. 3.1)
- Hoaxes (s. 3.2)

Prohibitions: Therapeutic Products (s. 8 – 15.2)

- Adulterated products (s. 8)
- Unsanitary conditions (s. 9)
- No clinical trial without authorization (s. 10)
- No clinical trial contrary to regulations (s. 11)
- Selling, advertising and importing (s. 12)
- Conducting controlled activity (s. 13)
- Deception, etc. (s. 14)
- Counterfeiting (s. 15)
- Prescription therapeutic products (s. 15.1)
- Samples – drugs (s. 15.2)

Prohibitions: Sections 8-9

Existing prohibitions would be broadened to cover:

- The importation for sale of adulterated products
- The collection, processing and conveying for sale of therapeutic products under unsanitary conditions, as well as the importation for sale of such products

Prohibitions: Sections 10-11

Two new prohibitions surrounding the conduct of clinical trials:

(1) Cannot conduct a clinical trial unless authorized to do so by a clinical trial authorization

(2) Cannot conduct a clinical trial unless in accordance with the regulations

Clinical trial would be defined as an investigational study of a therapeutic product that is conducted in humans or in animals (for products that may affect humans through the food supply or via the transmission of disease from animals to humans)

These provisions capture existing regulatory prohibitions

Prohibitions: Section 12

New prohibition on the selling, advertising or importing for sale of a therapeutic product without a market authorization

This captures existing regulatory prohibitions

Exception: Designated therapeutic products

- Products designated as such by regulation – by their nature, these products do not require a benefit-risk assessment (s. 30(1.1))
- Intended to cover cells, tissues and organs
- Establishment licence may be required

Prohibitions: Section 13

New prohibition on the conduct of a controlled activity without an establishment licence

The definition of the term “controlled activity” would cover a list of activities:

- For therapeutic products: manufacturing, collecting, processing, pre- serving, labelling, packaging, importing for sale, distributing, wholesaling or testing
- For designated therapeutic products: manufacturing, collecting, processing, preserving, labelling, packaging, importing, distributing or testing

These are activities for which establishment licences are currently required under the various regulations or in respect of which good manufacturing practice requirements are applicable

Prohibitions: Section 14

This prohibition will combine the former prohibitions on deceptive labelling, packaging, treating, processing, selling, or advertising of drugs and devices into a single prohibition applicable to all therapeutic products

Will be combined with an ability to define in regulations what is considered to be a manner that is false, misleading, deceptive, or likely to create an erroneous impression

Prohibition will have more current terminology: benefits, risks, conditions of use, authorization status or origin

Prohibitions: Section 15

New prohibition on the manufacture, labelling, packaging, sale, import for sale and advertising of counterfeit therapeutic products

Will facilitate cooperation between Health Canada and law enforcement agencies in dealing with counterfeit cases

Prohibitions: Section 15.1

New prohibitions on the sale, advertising and importation for sale of prescription therapeutic products

The term “prescription therapeutic product” would be defined as a therapeutic product designated as such by order

Products would be designated as prescription therapeutic products on the basis of the criteria that currently guide the listing of products on Schedule F of the *Food and Drug Regulations*

Proposed prohibitions capture conduct that is currently prohibited under Division 1 of Part C of the *Food and Drug Regulations*.

Prohibitions: Section 15.2

The existing prohibition on the distribution of drug samples is maintained but revised to refer to a practitioner instead of to a list of health care professionals

The term “practitioner” will be defined to include persons who are legally authorized by a province or territory to prescribe or dispense prescription therapeutic products

- Depending on the province or territory, this could include physicians, dentists, veterinarians, pharmacists, nurses and optometrists

Advertising

Under the current *Food and Drugs Act*:

- prohibition on the advertising of products intended to treat specific diseases/conditions (Section 3 / Schedule A) – aimed at preventing the misbranding of drugs
- Prohibitions on the false, misleading or deceptive advertising of drugs and devices (sections 9 and 20)

Under the current *Food and Drug Regulations*:

- Prohibition on the advertising of drugs listed on Schedule F to the Food and Drug Regulations (section C.01.043) – exception for name, price and quantity

Under Bill C-51:

- Modernized prohibition on the false, misleading or deceptive advertising of therapeutic products (section 14)
- New prohibition on the advertising of prescription therapeutic products (section 15.1(2))
- Exception for name, price and quantity would be maintained in the regulations

Authorizations and Licences

Purpose:

- Provide a mechanism through which Health Canada can regulate a range of therapeutic products with the ability to tailor the appropriate amount of continued regulatory oversight to the nature and risk of the product

- Authorizations and licences is the primary vehicle for achieving and maintaining the integration and flexibility which underlies the Progressive Licensing Framework

Clinical Trial Authorizations: Sections 18.2 – 18.6

- A clinical trial authorization would be required for the investigational use of therapeutic products that have not been marketed in Canada
- Clinical trial authorizations could be amended, suspended or revoked for therapeutic products
- Terms and conditions could be imposed on such authorizations
- Holders or former holders of clinical trial authorizations would be required to continue to report information about a therapeutic product to Health Canada following the discontinuance or cancellation of a clinical trial

Market Authorizations: Sections 18.7 – 19.1

- A market authorization would be required to sell, advertise or import for a therapeutic product
  - Exception for designated therapeutic products
- Market authorizations would be issued on the basis of a favourable benefit-risk profile, and could be subject to specific terms and conditions
  - Benefit-risk assessments will be continue to be based on evidence of safety, efficacy and quality
- Market authorizations could be amended, suspended or revoked
- Market authorization holders could be required to
  - conduct a reassessment of the therapeutic product to which the authorization relates
  - compile information, conduct studies and monitor experience in relation to therapeutic products and to report information, the results of tests or studies, and monitoring to Health Canada

Establishment Licences: Sections 19.2 – 19.7

- An establishment licence would be required for the conduct of controlled activities
- Establishment licences could be amended, suspended or revoked
- Terms and conditions could be imposed on such licences
- Establishment licence holders could be required to:
  - compile information, conduct studies and monitor experience in relation to therapeutic products and to report information, the results of tests or studies, and monitoring to Health Canada

Powers of the Minister: Sections 19.8 – 20.3

- Power to require information (s. 19.8)
- Power to require compiling of information or conduct of tests or studies, etc. (s. 19.9)
- Power to require information after discontinuance or revocation of clinical trials (s. 20)
- Power to require that labels be revised (s. 20.1)
- Power to require reassessment (s. 20.2)
- Power to disclose risk information (s. 20.3)

Information: Sections 20.5 – 20.8

- Power to require persons to provide information in their control to Health Canada – serious risk to human health (s. 20.5)
- Obligation for health care institutions to report serious adverse reactions (s. 20.7)
  - information that must be reported and institutions to which this applies would be specified in regulations
- Obligation for Health Canada to establish and maintain a publicly accessible register that contains information about therapeutic products (s. 20.8)

Information: Sections 20.9 – 21.2

- Authority to disclose personal information to specified persons where necessary to identify or respond to a serious risk to human health (s. 20.9)
- Authority to share confidential business information with specified persons where a signed confidentiality agreement is in place (s. 21.1) and with the public when there is a serious and imminent risk of injury to the health (s. 21.2)
  - A new definition of “confidential business information” would set out the three conditions that must be met for business information to be treated as confidential by Health Canada
  - The definition entrenches common law principles

Compliance and Enforcement: Section 23

Changes proposed to s. 23 are for the purposes of:

- Clarifying authority to enter and inspect a conveyance, and order that it be moved
- Allowing the use of newer technologies in the conduct of inspections
- Allowing inspectors to pass through private property to inspect a place where a controlled activity is being conducted

Compliance and Enforcement: Sections 23.1 - 28

- Telewarrants (s. 23.1(4))
- Restrict movement of articles (s. 23.2)
- Storage and disposal of things seized (s. 23.3)
- Automatic forfeiture (s. 23.5)
- Corrective measures (s. 23.8)
- Removal of imported products (s. 23.9)
- Product recalls (s. 24)
- Documents/records (s. 25 – 28)

Regulations: Sections 30(1) – 30(1.1)

- Definitions (b)
- Designated therapeutic products (d) + 30(1.1)
- False, misleading or deceptive or likely to create an erroneous impression (o)
- Conduct of controlled activities (p)
- Designation of prescription therapeutic products (q)
- Terms and conditions (s)
- Conduct of clinical trials (w)
- Classes of authorizations and licences (x)
- Applications for and issuance, amendment, suspension and revocation of authorizations and licences (y)

Regulations: Sections 30(1) – 30(1.1)

- Pre-filing meetings (z. 1)
- Exercise of ministerial powers surrounding post-market surveillance (z. 2)
- Reassessments (z. 3)
- Reporting by health care institutions (z. 6)
- Personal information and confidential business information (z. 7)
- Product recalls (z. 11)
- Product, person and activity exemptions (z.13 – z.15)

Fines and Penalties: Section 31

- Increase in maximum fines and imprisonment (s. 31(1))
  - Highest fines and penalties are intended for the most severe contraventions
  - Due diligence defence available (s. 31(2))
- New provision applicable to wilful or reckless contraventions (s. 31(3))
- Sentencing criteria (s. 31(4))
- Continuing offence (s. 31(6))

Exports: Section 37

- The existing provision creates an absolute exemption from the application of the Act and regulations for products manufactured in Canada for the purpose of being exported
- The proposed amendment would maintain the general exemption, but would allow for exceptions to be made by regulation
- Such exceptions would be useful in dealing with products destined for countries that lack the vigorous regulatory systems and infrastructure needed to mitigate risks
- The details surrounding the application of section 37 would also be set out in to the regulations

Conclusions

- Bill C-51 contains an initial set of proposals for the implementation of the Progressive Licensing Framework into the *Food and Drugs Act*
- The majority of the Framework will be implemented through changes to the *Food and Drug Regulations*
- Stakeholders will be consulted for the development of the *Food and Drug Regulations*
- Intent is to align with international requirements
- Internal and external training will be essential to ensuring that expectations are clear

Contact Information

Natalie Bellefeuille
Senior Legal Analyst, Progressive Licensing Project
Health Canada

Tel: (613) 946-6425
E-mail: natalie_bellefeuille@hc-sc.gc.ca