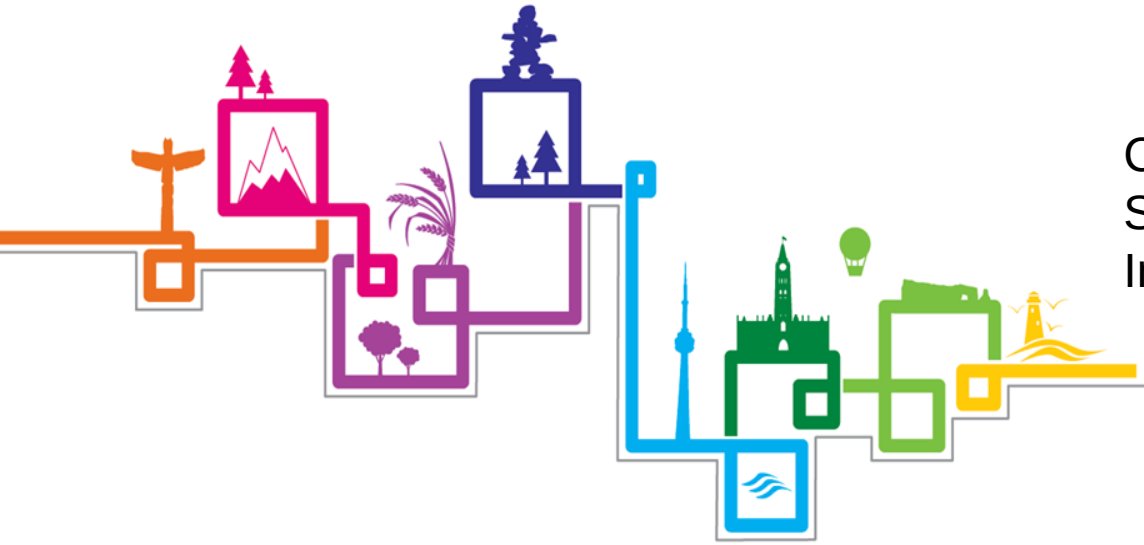
Protecting Canadians from Unsafe Drugs Act
(Vanessa's Law)



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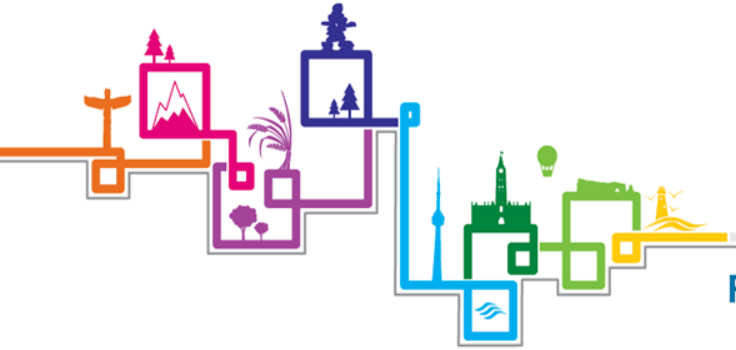
Introduction

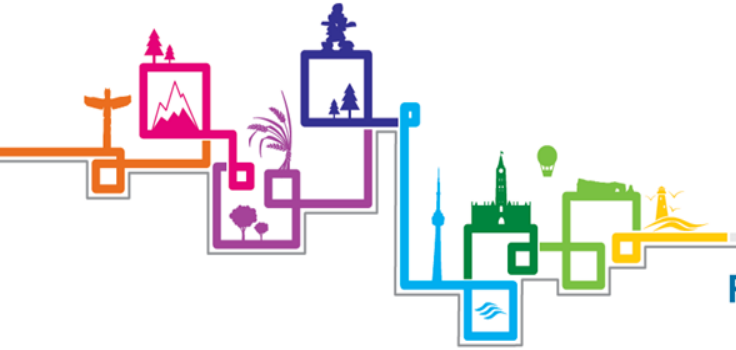
- Canada regulates therapeutic products under *Food and Drugs Act*.
- Regulatory requirements for safety, quality, and efficacy are verified by product and establishment licensing, monitoring and surveillance, and compliance and enforcement.
- Until recently, regulation focused largely on pre-market activities, good manufacturing practices and adverse reaction reports.



Who was Vanessa?

"*The introduction of Vanessa's Law into the Canadian Parliament feels something like justice because it will prevent such tragedies from happening in other families.*"

The Honourable Terrence Young, Member of Parliament



Protecting Canadians from Unsafe Drugs Act (Vanessa's Law)

- Received Royal Assent on November 6, 2014.

- Represents the most **profound** and **important** changes to Canada's *Food and Drugs Act* in over 50 years.

Vanessa's Law - Objectives

To improve safety of therapeutic products by introducing measures to:

- Strengthen oversight throughout the lifecycle of therapeutic products
- Promote greater confidence in the oversight of therapeutic products by increasing transparency
- Improve reporting of serious adverse drug reactions and medical device incidents

Outline

A. Scope and Definitions
B. Key Elements and Authorities
C. Regulation Making Authorities
D. Transparency Authorities
E. Coming into Force
F. Consultations

A. Vanessa's Law - Scope

- Definition of 'device' amended (combo, IVDDs)
- Applies to newly defined 'therapeutic products'
  - Includes prescription and over-the-counter drugs, vaccines, gene therapies and medical devices
  - Does not include natural health products
- New term 'Therapeutic Product Authorization'
  - Import, sale, advertisement, manufacture, preparation, preservation, packaging, labelling, storage or testing of a therapeutic product
    - Includes valid or suspended licences

B. Vanessa's Law – Key Elements

Strengthening Oversight:

1. Power to Compel Information, Tests/Studies and Reassessments
2. Power to Compel a Label Change
3. Power to Recall Unsafe Therapeutic Products
4. Tougher Measures for Failure to Comply
5. Ability to Incorporate by Reference

Improving Reporting of Serious ADR & Device Incidents

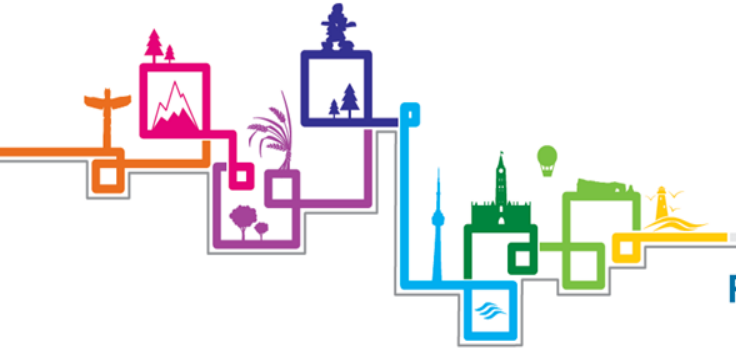
6. Mandatory reporting by Healthcare Institutions

1- Power to Compel Information

Power to Compel Information

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.

- **Can be exercised against anyone the regulator believes has information necessary to determine if a product poses a risk**



1- Power to Compel Information

Power to Require Assessment

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.

Power to Require Tests or studies

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

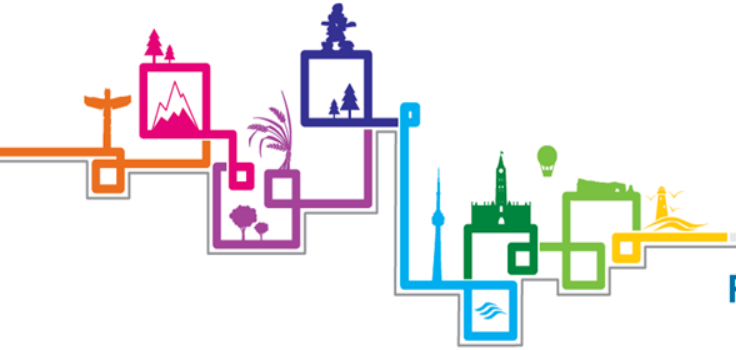
(a) compile information, conduct tests or studies or monitor experience in respect of the therapeutic product; and

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

2- Power to Compel a Label Change

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.**

- **Regulator can order a product or establishment licence holder to make changes to a label or package to prevent injury**

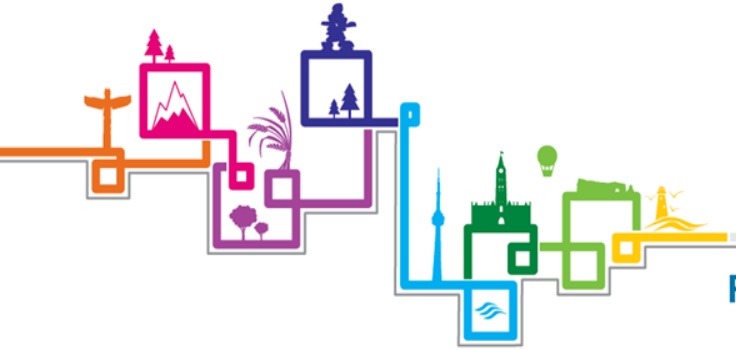


3- Power to Recall Unsafe Therapeutic Products

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.

- **New authority- with several unique aspects**
- **Corrective actions by user or owner may also be acceptable**
- **Authorization of sale with or without conditions is also possible**



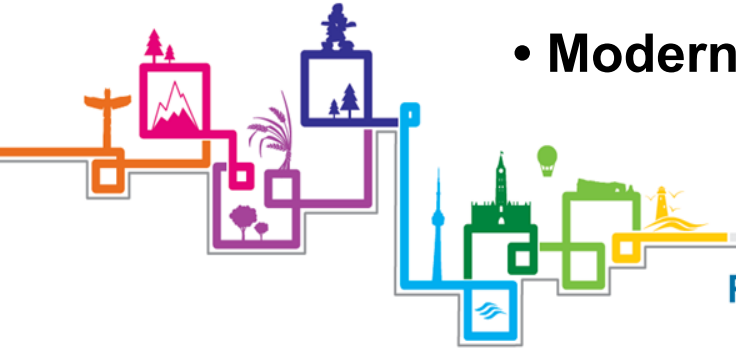
4- Tougher Measures for Failure to Comply

Penalties & Fines- contravention

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.



- **Modernization of penalties**

4- Tougher Measures for Failure to Comply

Penalties & Fines- contravention

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.

- **creates a new *mens rea* offence with substantially higher penalties for knowingly or recklessly causing a serious risk of injury to health in contravening the Act, the regulations, or an Order**

4- Tougher Measures for Failure to Comply

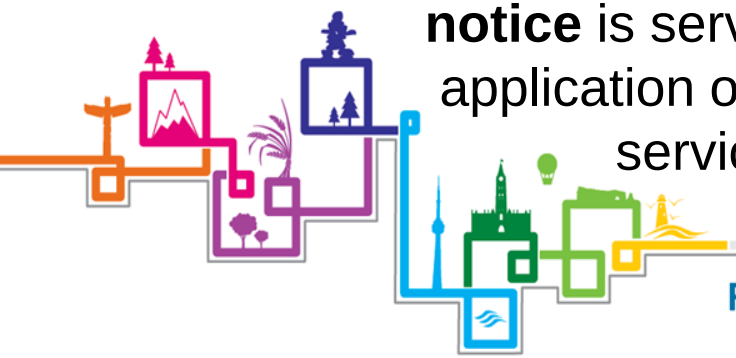
Injunctions

21.5 (1) If, on the application of the Minister, it appears to a court of competent jurisdiction that a person **has done, is about to do or is likely to do anything** that constitutes or is directed toward **the commission of an offence** under this Act in respect of a therapeutic product, the court may issue an injunction ordering the person, who is to be named in the application, to

(a) refrain from doing anything that it appears to the court may constitute or be directed toward the commission of the offence; or

(b) do anything that it appears to the court may prevent the commission of the offence.

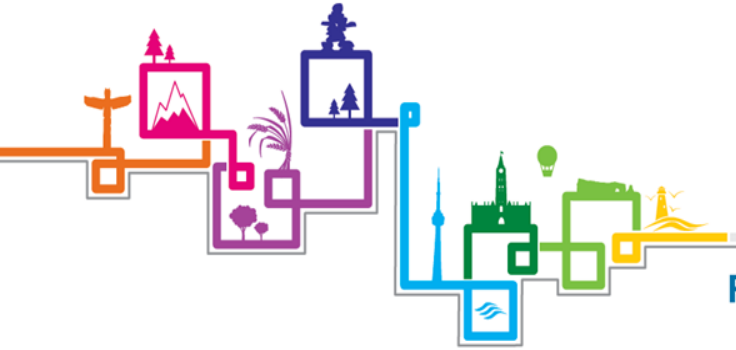
(2) No injunction is to be issued under subsection (1) unless **48 hours' notice** is served on the party or parties who are named in the application or unless the urgency of the situation is such that service of notice would not be in the public interest.



5- Ability to Incorporate by Reference

30.5 (1) A regulation made under this Act with respect to a food or therapeutic product and a marketing authorization may **incorporate by reference** any document, regardless of its source, either as it exists on a particular date or as it is amended from time to time.

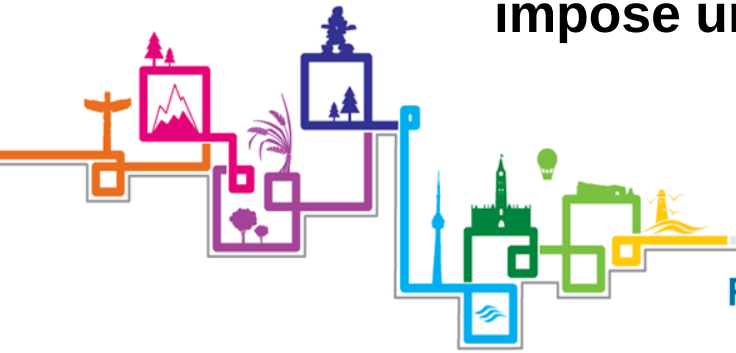
- **Permits technical and non-technical documents to be incorporated into the Food and Drug Regulations by**
- **Simpler and less time-consuming process that does not require regulatory amendment.**



6- Mandatory Reporting by Healthcare Institutions

21.8 A prescribed health care institution shall provide the Minister, within the prescribed time and in the prescribed manner, with prescribed information that is in its control about a **serious adverse drug reaction** that involves a therapeutic product or a **medical device incident** that involves a therapeutic product

- **Regulations required for implementation**
  - **Defining 'serious ADR' and 'medical device incident'**
  - **Prescribing anything that is to be prescribed in 28.1**
- **Before recommending Regs, Minister shall take into account existing information management systems so as to not impose unnecessary burdens**



C. Regulation Making Authorities

Paragraph 30. (1.2)

(a) amendments, suspensions and revocations of therapeutic product authorizations

(b) authorizing Minister to impose terms and conditions on licences, including amendments

(c) safety information obtained through clinical trials *(slide 22)*

(d) authorization holders to provide Minister with information about risk, or relevant to safety of the product

  i. risks communicated outside of Canada

  ii. changes to labelling outside of Canada

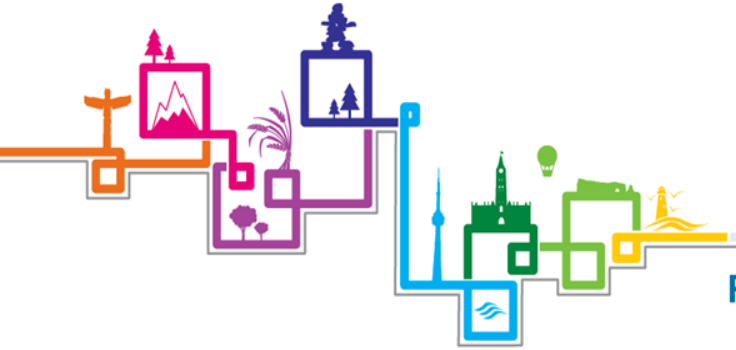
  iii. recalls, reassessments and suspensions or revocations of authorizations or licences outside of Canada

C. Regulation Making Authorities

(d.1) specifying business information under the Act that is not CBI, or circumstances it ceases to become CBI
(d.2) authorizing Minister to disclose, without notifying the person whose business or affairs it relates, or obtaining their consent, business information that

i. is not CBI
ii. has ceased to be CBI

(e) respecting modification of labels and packages in 21.2
(f) recall of therapeutic products or sale of product subject to recall
(g) anything prescribed under 21.71 *(slide 21)*



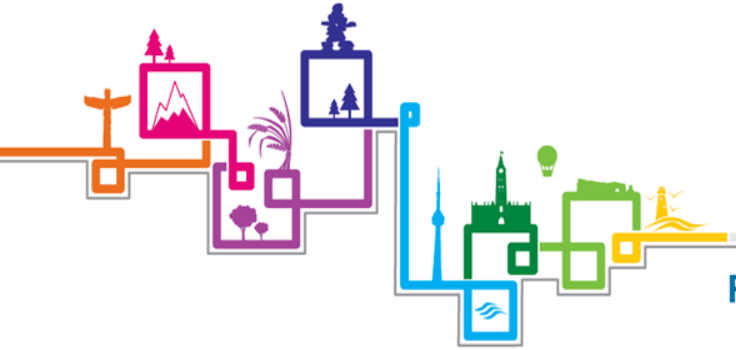
D. Vanessa's Law- New Transparency Authorities

1. Public Disclosure of Health Canada Regulatory Actions

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

- **orders to compel information, label change, recall**
- **orders to conduct assessments, tests and studies**

Also positive and negative decisions and rationales about issuance, reassessment, license suspension/revocation and terms and conditions

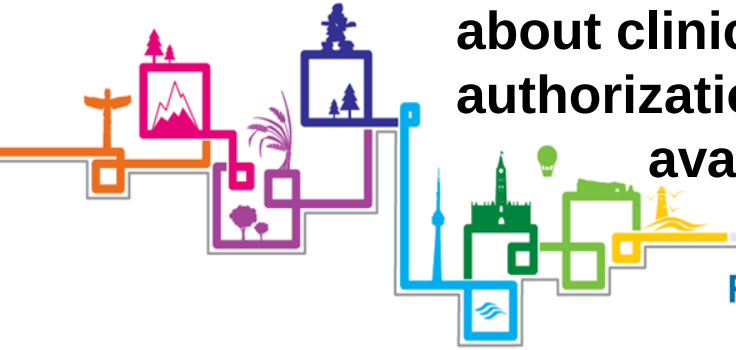


D. Vanessa's Law- New Transparency Authorities

2. Public Disclosure about Clinical Trials and Investigational Testing

21.71 The holder of a therapeutic product authorization referred to in paragraph 30(1.2)(*c*) shall ensure that prescribed information concerning the clinical trial or investigational test is made public within the prescribed time and in the prescribed manner

- **Therapeutic product authorization holders to make publicly available information about clinical trials (for drugs) and investigational testing (for medical devices)**
- **Regulations will specify how, where, when and what information about clinical trials and investigational test an authorization holders will have to make publicly available**



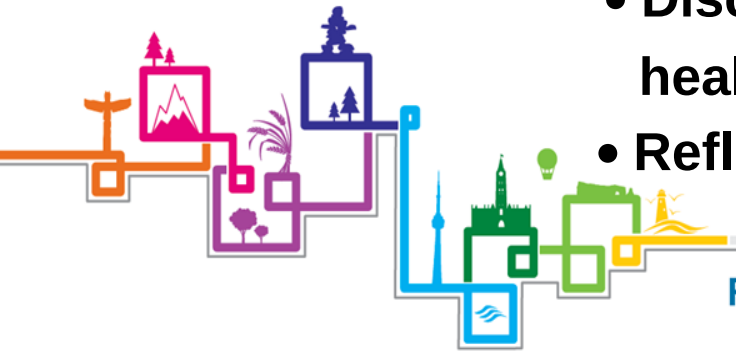
D. Vanessa's Law- New Transparency Authorities

3. Minister can Disclose Confidential Business Information about Therapeutic Products

Disclosure- serious risk

21.1 (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.

- **The risk doesn't have to imminent**
- **Disclosure has to further a public safety or health purpose**
- **Reflects what can be done now in common law**

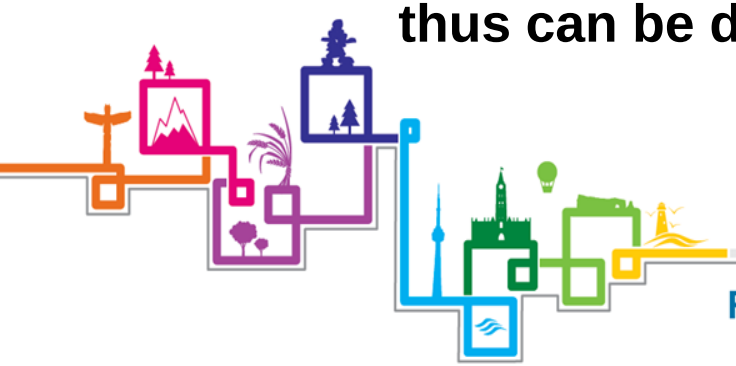


D. Vanessa's Law- New Transparency Authorities

"confidential business information" means- subject to regulations- business information:

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

- **Authority to make Regulations that specify what isn't CBI and thus can be disclosed without consent**



D. Vanessa's Law- New Transparency Authorities

Disclosure- health and safety

21.1 (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

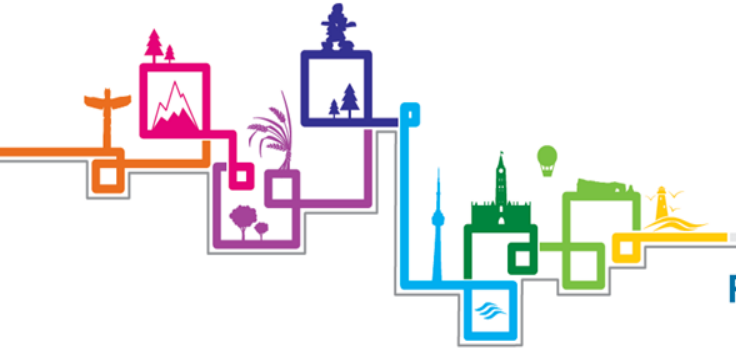
(b) a person from whom the Minister seeks advice; or

(c) a person who carries out functions relating to the protection or promotion of human health or the safety of the public.

- **'Government' is further defined**
- **To someone carrying out functions re: health & safety**
- **Reflect current common law**

E. Coming In To Force- Upon Royal Assent

- ✓ Compel information (s. 21.1)
- ✓ Direct label change/package modification (s. 21.2)
- ✓ Recall unsafe therapeutic products (s. 21.3)
- ✓ Incorporate by reference (s. 30.5)
- ✓ Disclose confidential business information (s. 21(2) - 21(4))
- ✓ Tougher fines and penalties (s. 31 – 31.4)
- ✓ Seek a court order / Injunction (s. 21.5)
- ✓ Make orders publicly available (obligation) (s.21.4(2))



E. Coming In To Force- Requiring Regulations

- Order a reassessment (s. 21.31)
- Require tests and studies (s. 21.32)
- Attach terms and conditions to market authorizations (s. 30(1.2)(b))
- Therapeutic product authorization holders to register clinical trials (s. 21.71) and provide new safety information to Minister (s. 30(1.2)(d))
- Healthcare institutions to report serious adverse drug reactions and medical device incidents (s. 21.8)
- Minister to disclose regulatory decisions and rationales (s. 30(1.2)(b.1))

F. Consultations- Guide to New Authorities

- Consultation on the Amendments to the Food and Drugs Act: March 25th - June 8th, 2015
- Scope
  - The Minister's authority to require and disclose information
  - The Minister's authority to order a label change/package modification, and
  - The Minister's authority to order a recall

http://www.hc-sc.gc.ca/dhp-mps/consultation/drug-medic/consult_unsafedrugsact-guide-lesdroguesdangereuses-eng.php

F. Consultations- Transparency Needs-based Assessment

- March 25th - May 25th 2015
- Scope:
  - to assess information needs about therapeutic products taking into account:
    - Who is the end-user (e.g., patient, physician, government bodies);
    - What information is required (and what is not);
    - When should information be made available;
    - How and from whom do end-users prefer to receive information (method of access).

http://www.hc-sc.gc.ca/dhp-mps/consultation/drug-medic/consult_unsafedrugsact-lesdroguesdangereuses-eng.php

Conclusion

"It is difficult to overstate the impact this bill will have for Canadians who take prescription and over the counter drugs. It represents a quantum leap forward in protecting vulnerable patients and reducing serious adverse drug reactions. It is absolutely necessary to reduce deaths and injuries caused by adverse drug reactions, seventy percent of which are preventable, and will serve Canadians extremely well."

The Honourable Terrence Young, Member of Parliament