Tackling Patient Safety - Vanessa’s Law and Changes to Drug, Pharmacy and Medical Device Regulation

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OVERVIEW – TACKLING PATIENT SAFETY

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   4. Penalties and offences
   5. Risk management strategies and compliance

B. Safeguarding Health Care Integrity Act, 2014
   – Regulation of hospital pharmacies
What is Vanessa’s Law? - Overview

- An Act to Amend the Food and Drugs Act (Bill C-17)
  - Strengthen safety oversight of therapeutic products throughout their life cycle
  - Mandatory reporting by health care institutions of serious adverse drug reactions and medical device incidents involving therapeutic products
  - Promote greater confidence in the oversight of therapeutic products by increasing transparency

- Alternative title: Protecting Canadians from Unsafe Drugs Act (Vanessa’s Law)
What is Vanessa’s Law? - Overview

• Most significant amendment to FDA in over 50 years

• “Life-cycle approach” – pre-market safety and effectiveness assessments → post-market safety and assessment

• Royal Assent on November 6, 2014 – some provisions in force and others pending development of regulations
Vanessa’s Law – Overview

- Regulates a broad range of activities for therapeutic products including:
  
  (i) Disclosure of clinical trial and investigational tests
  
  (ii) Increased powers of Minister – disclosure of confidential business information, packaging/labeling, assessments and testing and product recalls
  
  (iii) Mandatory reporting of serious adverse drug reactions and medical device incidents for health care institutions
  
  (iv) Regulation making authority for therapeutic products
  
  (v) New offences and penalties for non-compliance
Definitions and Scope

• “Therapeutic product” is broadly defined as any **drug** or **device** or combination of the two
  – This includes non-prescription, over-the-counter medicines, vaccines and gene therapies
  – “Therapeutic product” does **not** include a natural health product
Definitions and Scope

- “Therapeutic product authorization”
  - the authorization that permits the import, sale, advertisement, manufacture, preparation, preservation, packaging, labelling, storing and testing of a therapeutic product
Definitions and Scope

• “Confidential business information” (CBI) – means business information that:
  – is not available to the public;
  – for which reasonable measures have been taken to ensure it is not available to the public; and
  – That has actual or potential economic value to the person or their competitors because it is not publically available, and its disclosure would result in a material financial loss / material financial gain to a competitor
Key Provisions – New Ministerial Powers – Confidential Business Information

• Where the Minister believes a therapeutic product may present a **serious risk of injury** to human health:
  – may **order** any person to provide information to Minister where necessary to determine risk
  – may **disclose** CBI with no notice or consent from the affected party

• May also disclose CBI with no notice or consent to certain entities if the purpose of disclosure is the protection or promotion of human health or safety of public
Key Provisions – New Ministerial Powers – Packaging/Labelling

• Where believes necessary to prevent injury to health, Minister may order holder of therapeutic product authorization to modify or replace product label or packaging
Key Provisions – New Ministerial Powers - Recall

- Minister may **order** a therapeutic product to be recalled where they believe it presents a **serious or imminent risk of injury to health**
- If believes corrective action can effectively address risk, the order may provide for corrective action
- May authorize sale with or without conditions
Key Provisions – New Ministerial Powers - Product Information

• Subject to regulations, the Minister has power to order the authorization holder to:
  – Compile information
  – Conduct assessments, further product testing or studies
  – Monitor experience

and supply the information to the Minister
Key Provisions - Public Disclosure

- Authorization holder must make prescribed information relating to clinical trials and investigational tests publicly available.
- Minister must make all orders and regulatory decisions under Vanessa’s Law available to the public.
Key Provisions: Reporting Adverse Drug Reactions and Medical Device Incidents

• Prescribed health care institutions must report serious adverse drug reactions or medical device incidents that involve therapeutic products to Health Canada

• Definitions and specifics of reporting obligations to be set out by regulation

• Must take existing information management systems into account
Key Provisions - Regulations

• The Governor-in-Council may make regulations with respect to therapeutic products

• Broad authority
  – Regulations respecting assessments, tests and studies, monitoring of experience, information compilation, definitions and reporting by health care institutions
  – May incorporate documents by reference
Offences and Penalties

• Maximum monetary penalties for violation
  – increase from $5,000 to $5M per day upon conviction
  – unlimited amount at the discretion of the court where involves false or misleading statements to Health Canada or willful or reckless harm to human health

• Imprisonment of up to 2 years (for conviction by indictment)

• Strict liability for violations, subject to due diligence defence unless willful and reckless
Offences and Penalties

• Corporate officers, directors, agents who direct, authorize, assent to, participate in or otherwise acquiesce in the commission of an offence are individually liable and subject to penalties, whether or not prosecuted for the offence
  – Vicarious liability and personal liability for officers and directors
Offences and Penalties

- If an offence is committed on more than one day, it constitutes a separate offence for each day it is committed
Risk Management and Compliance

• Need to understand and comply with the therapeutic product provisions / mandatory reporting obligations

• Critically important to develop/update compliance programs (i.e. policies and procedures, systems and processes) to be able to rely on statutory due diligence defence
Compliance Considerations

• Comply with all orders of the Minister ASAP
  – It is an offence not to comply with an order of the Minister
  – Each day the violation occurs is treated as a separate offence.

• Ensure you are aware of product recalls
  – It is an offence to sell a recalled product, even if you are not aware of the recall
Compliance Considerations

• Conduct an internal audit of compliance program in relation to the requirements for therapeutic products or interacting with therapeutic products

• Update or implement written compliance policies to ensure that procedures relating to all activities regulated by the Act are in place

• Consider need to update contracts/clinical trial protocols to address new requirements
Compliance Considerations

- Conduct updated employee compliance training
- Appoint a Compliance Officer to manage and monitor corporate compliance
- Retain all information about therapeutic products and efforts to achieve compliance
Safeguarding Health Care Integrity Act, 2014 (Bill 21)

• Received Royal Assent on December 11, 2014

• Amends Drug and Pharmacies Regulation Act (DPRA) to expand oversight authority of Ontario College of Pharmacists (OCP) to hospital and institutional pharmacies

• Licensing requirements and inspection authority (regulations being developed)
Changes to Federal and Ontario drug oversight

• March 2013 - discovery of diluted chemotherapy drugs being provided to hospital patients raises questions about safety and quality of drug supply

• April 2013 – Health Canada provides interim direction for compounding and admixing of medications to address regulatory gaps while examining long-term oversight

• May/Sept. 2013 - Changes to *Pharmacy Act* (inspection of drug preparation premises) and *Public Hospitals Act* (drugs must be purchased from “prescribed supplier”)*
Changes to Federal and Ontario drug oversight

• Aug. 2013 – release of independent report “A Review of the Oncology Under-Dosing Incident” prepared by Dr. Jake Thiessen
• Oct. 2013 – introduction of Bill 117 to implement recommendation that hospital pharmacies be licensed by OCP
• April 2014 – report by Standing Committee on Social Policy released – additional recommendations
• July 2014 – Bill 21 introduced
Overview of Legislative Changes

• Applies to both public and private hospitals

• Definition of “hospital pharmacy” … where drugs are compounded, dispensed or supplied for hospital patients … includes primary location or locations, together with any other locations in the hospital where drugs are stored or supplied from and any other location prescribed in regulations …
Accreditation and Inspection Authority

- Hospital pharmacies must be accredited with the OCP
- OCP will monitor compliance with the DPRA and will have inspection authority over those areas deemed to be a hospital pharmacy
- Only certain provisions of the DPRA apply to a hospital pharmacy and some provisions do not apply in the same way
- OCP having regulation making authority, including with regard to inspections, operations and standards
Next Steps

• Conduct internal review process to determine practical and administrative changes that may be necessary to comply with the DPRA

• OCP engaging in consultation process and developing draft inspection criteria - look for opportunities to engage
Questions?

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