IMDRF International Medical Device Regulators Forum

Regulatory and Policy Updates

Therapeutic Products Directorate
Health Canada

Cindy Evans

Director, Medical Devices Bureau

Bill C-17

On December 6, 2013 the Government of Canada introduced Bill C-17:

Protecting Canadians from Unsafe Drugs Act

(Vanessa's Law)

New legislation to update the laws that apply to drugs and medical devices to increase patient safety in key areas of concern and is currently being review in parliament.

Protecting Canadians from Unsafe Drugs Act (Vanessa's Law) (Bill C-17)

The proposed amendments to the *Food and Drugs Act* include:

- Power to compel information, tests/studies and reassessment
- Power to compel a label change
- Power to recall unsafe therapeutic products
- Tougher measures for those that do not comply
- Ability to incorporate by reference
- Mandatory reporting by healthcare institutions

Status Update - Bill C-17

- The Bill passed in the Canadian House of Commons on June 16, 2014.
- It was then referred to the Senate.
- Following Royal Assent, regulatory changes will be required in order to implement some of the new authorities.

Lancing Devices and Blood Glucose Monitoring Systems

- Health Canada will release a notice to stakeholders outlining labelling and application requirements for these devices.

- This will make more transparent requirements currently being applied

- The objective is to reduce or eliminate the spread of infection.

Health Canada Recognized Standards

- The list was recently updated to:
  - add 15
  - remove 10
  - modify 10

- List posted to website June 16th

http://www.hc-sc.gc.ca/dhp-mps/consultation/md-im/index-eng.php