HEALTH PRODUCTS and FOOD PROGRAM

INSPECTORATE



Canada

Inspectorate Program for Medical Devices

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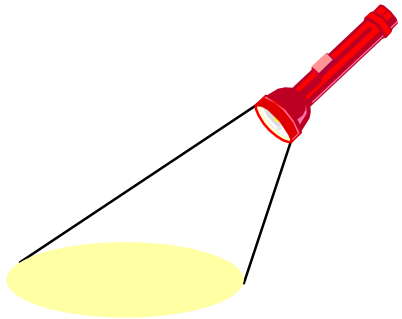
Presentation Outline



- Responsibilities and Resources
- Postmarket Surveillance / Vigilance in Canada and related statistics
- Mandatory and Voluntary Reporting
- Recalls
- International Involvement




Health Responsibilities

- Provincial : Healthcare and healthcare professionals, hospitals
- Federal: Regulation of the sale of Medical Devices, Drugs, etc.




Food and Drugs Act

- Criminal Code of Canada
- Grants inspectors the power to enforce the legislation
- Contains regulations for food, drugs, devices, cosmetics and vitamins




Canadian Medical Device Regulatory System

Groups involved in regulation of medical devices:

Pre-market

- Medical Device Bureau (pre-market review, quality system requirements, health hazard evaluations, clinical trial authorization, special access program)

Post-market

- Marketed Health Products Directorate (risk communication, Canadian Adverse Reaction Newsletter - CARN)
- Medical Device Bureau (laboratory testing)
- Health Products & Food Branch Inspectorate (compliance verification, investigation, customs surveillance, compliance inspection, establishment licensing)




Regulatory Provisions: Essentials

- Health Canada regulates the advertising, manufacture and sale of medical devices in Canada.

- The Food and Drugs Act and Medical Devices Regulations are the tools used to ensure that safe and effective devices are available.

- Manufacturers of devices apply to Health Canada to receive either a Licence or an Authorization to sell their devices.




Canadian Medical Device Regulatory System

- Product licensing
  - Class I device – no licence required
  - Class II, III, IV device – licence required

- Establishment licensing
  - Manufacturers of Class I devices
    - domestic companies
    - foreign companies who sell directly to users
  - Importers of devices
  - Distributors of devices
    - domestic companies
    - foreign companies who sell directly to users




Examples of Classified Devices

- Class I : Reusable surgical instruments, bandages, cell culture media
- Class II: Blood pressure monitors, electrodes, contact lenses, pregnancy test kits, single use surgical instruments, catheters
- Class III: Ventilators, cardiac monitors, hip implants, knee implants, lasers, chlamydia test kits, glucose meters
- Class IV: Defibrillators, pacemakers, coronary stents, HIV test kits, neurosurgical shunts




General Prohibitions

- Advertising, labelling or sale of devices to the general public for specific medical conditions (section 3)
- Sale of devices that are unsafe when used according to directions (section 19)
- Sale, advertising, labelling, packaging, treatment and processing of devices in a false, misleading or deceptive manner (section 20)
- Devices must meet with standards where prescribed (section 21)




Manufacturer / Importer / Distributor

…..no person shall import or sell a Class II, III or IV medical device unless the manufacturer of the device holds a licence in respect of that device or, if the medical device has been subjected to a change described in section 34, an amended medical device licence

Importers / Distributors / Manufacturers of Class I devices not employing a “licensed” importer / distributor require an Establishment Licence




Health Products & Food Branch Inspectorate

1 Coordination Centre

- Ottawa, Ontario (10 people)

5 Operational Centres (inspection & investigation)

- Halifax, Nova Scotia (3 people)
- Montreal, Quebec (8 people)
- Toronto, Ontario (12 people)
- Winnipeg, Manitoba (3 people)
- Vancouver, British Columbia (5 people)




Post-market Surveillance Activities

Compliance Verification & Investigation

- Manufacturer/importer reports (mandatory)
- Recalls (voluntary)
- User reports (voluntary)
- Sale of unlicensed devices
- Sale by unlicensed establishments
- Customs surveillance
  - Unlicensed devices
  - Counterfeit issues
  - Trans-shipment via Canada




Mandatory Problem Reporting

- Mandatory Problem Reports

  (a) is related to a failure or a deterioration in the effectiveness of the device or any inadequacy in its labeling or in the directions for use accompanying it; and

  (b) has led to the death or serious deterioration in the state of health of a patient, user or other person or, where it is reasonable to believe that such an incident, were it to recur, could lead to the death or serious deterioration of the state of health of a patient, user or other person.



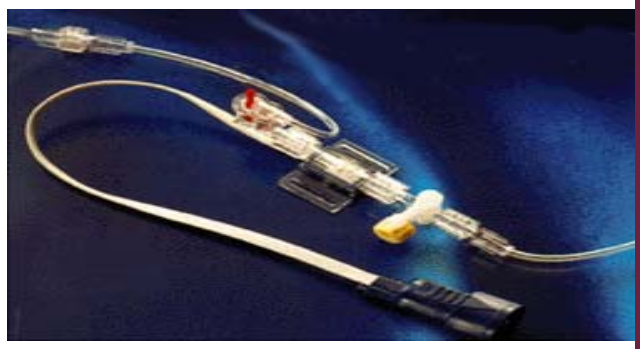

Mandatory Problem Reporting

- Manufacturers and importers are required to report incidents regarding a medical device
  - Within 10 days: if incident led to death or serious deterioration of health
  - Within 30 days: if incident were to reoccur, could lead to death or serious deterioration of health




Mandatory Reports Address

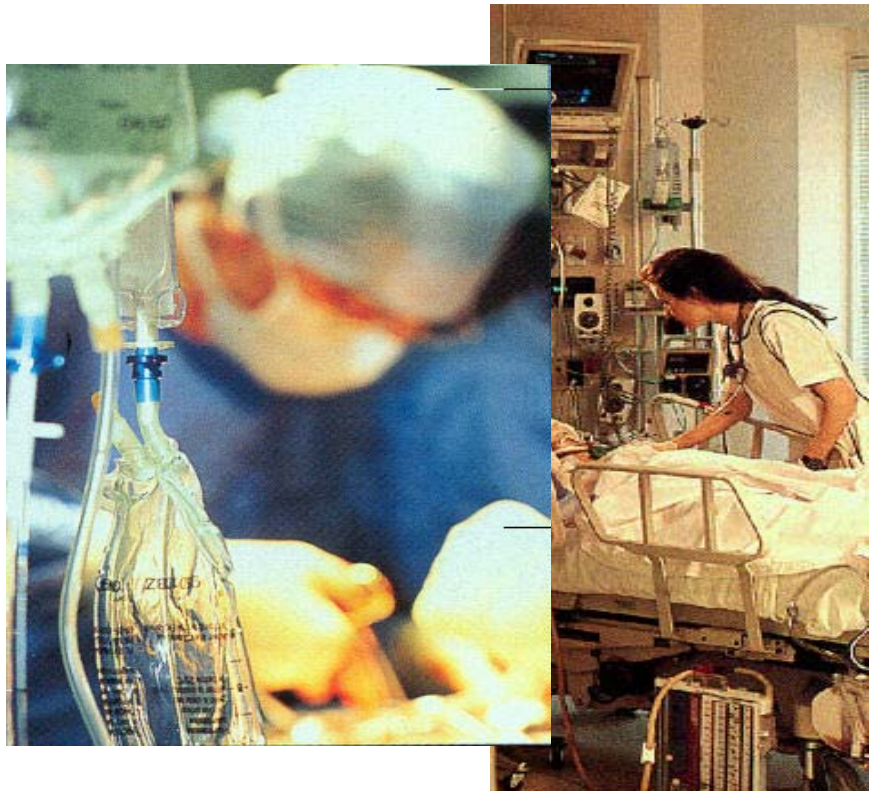
- Device:
  - Failure, or ;
  - Deterioration in effectiveness, or ;
  - Inadequacy in labeling or directions for use
- Incidents anywhere in the world where there is corrective action



Mandatory Reporting
- Manufacturers and Importers

Key Contributors :

- Distributors
- Doctors and Hospitals
- Clinics and other
- Health Care Facilities
- Canadian Public





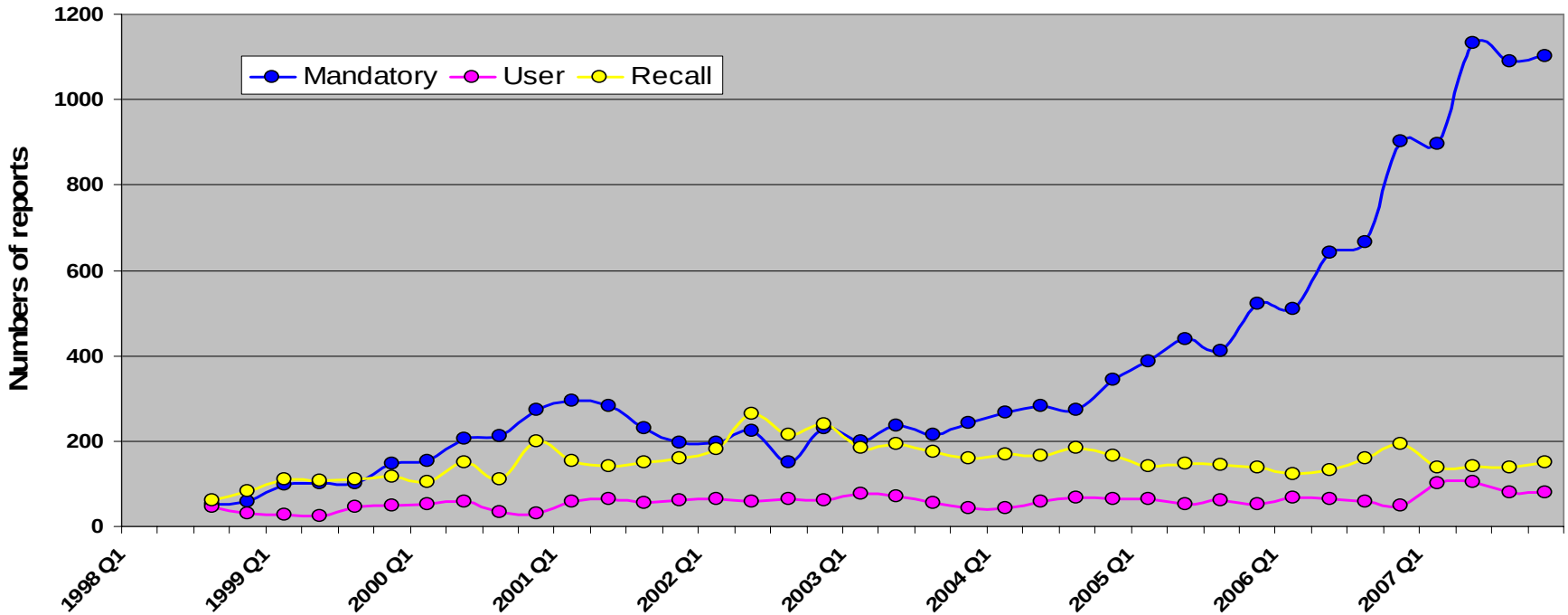

Other Regulatory Provisions

Complaint Handling / Distribution Records

- Special Access - devices for emergency use or if conventional therapies have failed, are unavailable or are unsuitable
- Investigation Testing – clinical trials involving human subjects.




Mandatory, Voluntary Problem Reports and Recalls






Post-market Surveillance Activities

Compliance INSPECTIONS

- Class 1 manufacturers
- Importers
- Distributors
- Retailers (compliance monitoring of market authorizations - CMMA)

Noncompliances are specific situations where there is a nonconformity to a Regulation.

- Establishment Licensing
- Complaint Handling
- Device Licensing
- Labelling




Post-market Surveillance Activities

- Areas of Concern – Patient Safety
  - Increasing numbers of mandatory reports
  - Increasingly finding unlicensed devices
  - Increasingly finding unlicensed establishments

  - Lack of/inadequate procedures
    - Recalls; complaint handling; mandatory reporting; distribution records; storage/handling/delivery/install/service

  - Labelling issues




Customs Surveillance

- Refused entry into Canada via the Canadian Border Services Agency (Customs)
- Currently no systematic means of screening for unlicensed devices (UDI)
- Specific companies or devices can be targeted at Customs




Enforcement Action

If a company's action is inadequate, Health Canada may:

- Request Safety and Effectiveness Information
- Request Recall
- Issue Regulatory Stop Sale
- Refuse Importations
- Issue Letter to Healthcare Facilities / Healthcare Providers
- Issue Public Warning / Public Advisory
- Suspend or Cancel the Medical Device Licence
- Seize and Detain Product
- Prosecute Company




International Exchange of Information

- Global Harmonization Task Force
  - Encourage harmonization and convergence in regulatory practices related to ensuring the safety, effectiveness / performance and quality of medical devices

- Study Group 2 – Vigilance and Post Market Surveillance
  - Define post market medical device reporting and surveillance requirements and guidelines on an international basis




Global Harmonization Task Force

A global exchange of information on serious device problems involving USA, UK, Sweden, Norway, The Netherlands, Japan, Ireland, France, Spain, Germany, Australia, Canada and Switzerland.

www.ghtf.org



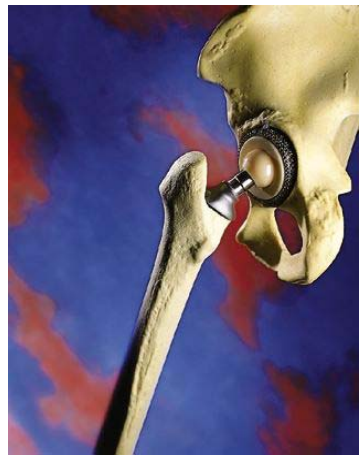

References

Inspectorate Web link:

- www.hc-sc.gc.ca/dhp-mps/compli-conform/index_e.html

Inspectorate Problem Reporting Web link:

- www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/index_e.html






Thank you for listening!

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