



Santé
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Health
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L'Inspectorat de la Direction générale des produits de santé et des aliments
Health Products and Food Branch Inspectorate



Inspectorate Programme for Medical Devices

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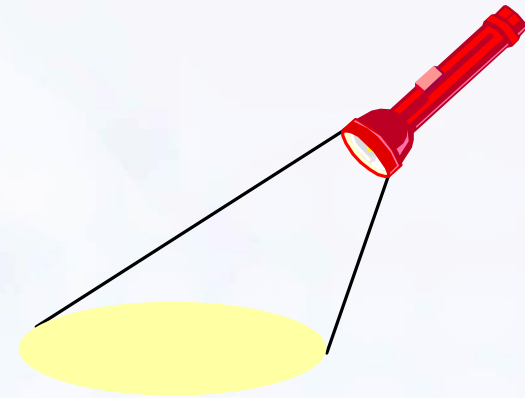
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Presentation Outline



- 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.

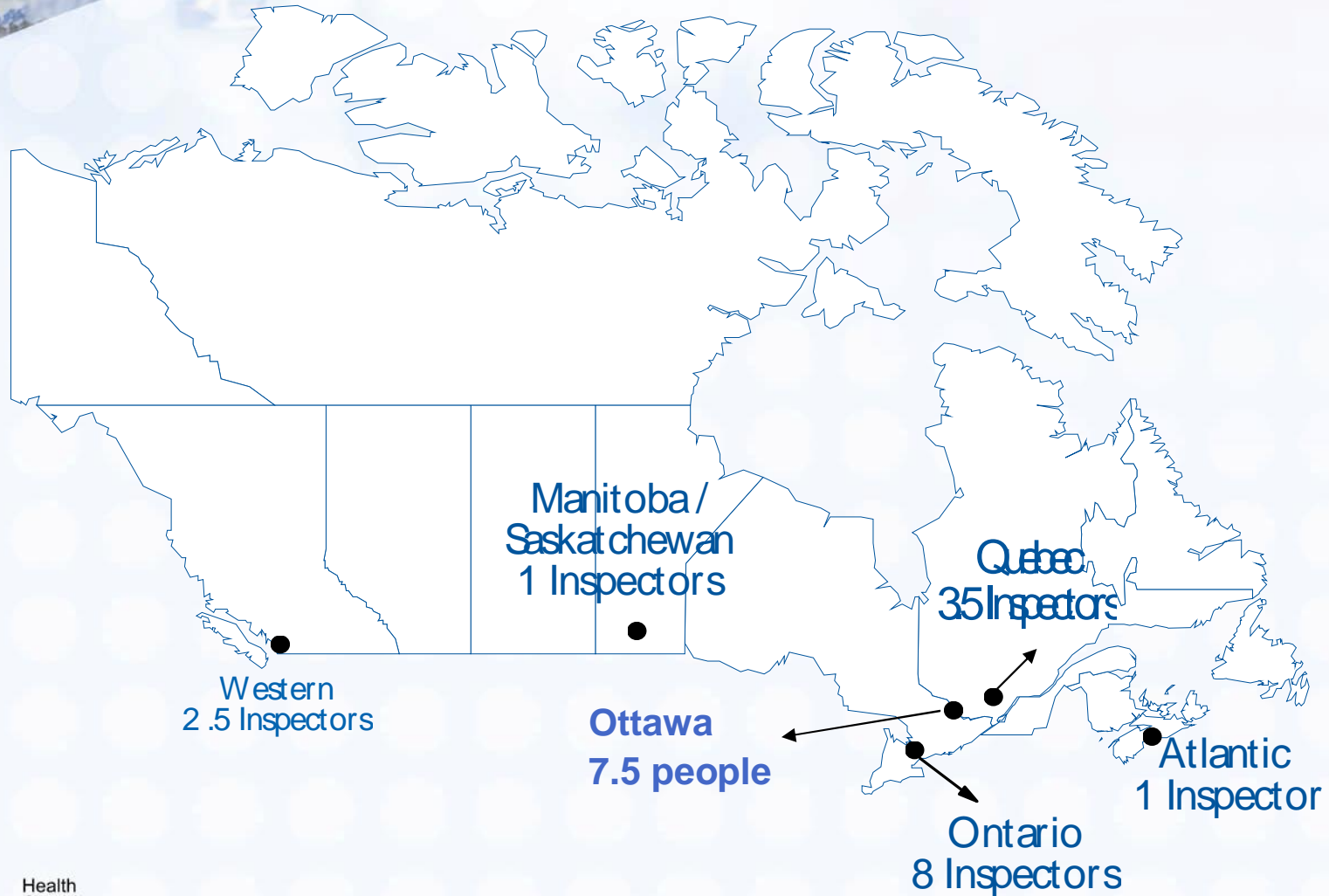


Food and Drugs Act

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



Medical Devices - Inspectorate Resources



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 lead 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 Reporting - Manufacturers and Importers

Key Contributors :

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





Manufacturer's Responsibilities

- Explain the circumstances and cause of the incident
- Provide scientifically valid data
- Propose a course of action and take appropriate corrective action where necessary -
 - Device modification
 - Labeling, instructions for use
 - Recall, etc.

Post Market Surveillance

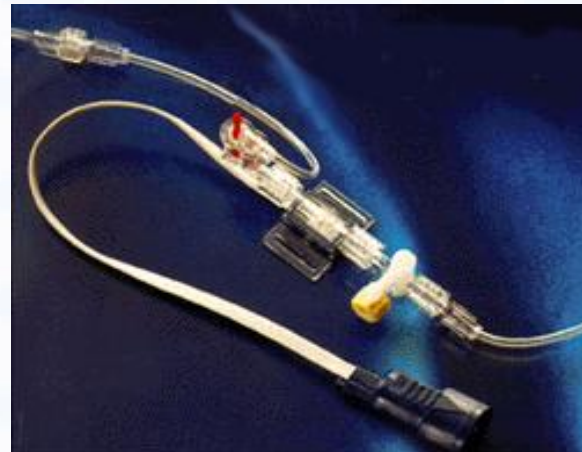


- Laboratory Testing
- Market Surveys
- Audits of Manufacturers
- Technical File Reviews
- Review of Product Claims/ Labelling
- Condition of Approval Studies
- Recalls
- Adverse Event Monitoring



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





Inspectorate Actions

- **Voluntary Reports**
 - Review voluntary reports and complaints received from hospitals, Health Care Professionals - risk managed
- **Mandatory Reports**
 - Review mandatory reports received from manufacturers and assess their actions
 - Follow up with manufacturer where appropriate



INCIDENT INVESTIGATION

- **Review company actions and documentation:**
 - review the manufacturer / importer complaint files or request a summary of related complaints
 - review labelling including directions for use in operator's manual, product inserts, brochures
 - review lot or serial number specific information relating to the problem
 - request and review worldwide records of similar complaints, and compare to volume of sales
 - obtain all pertinent data from manufacturer's assessment, including the testing results
 - ensure that the manufacturer has filed a mandatory report, if necessary
 - discuss compliance with the Act and Regulations
 - review and discuss the acceptability of the actions taken or to be taken by the manufacturer / importer



ENFORCEMENT ACTION

If company 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

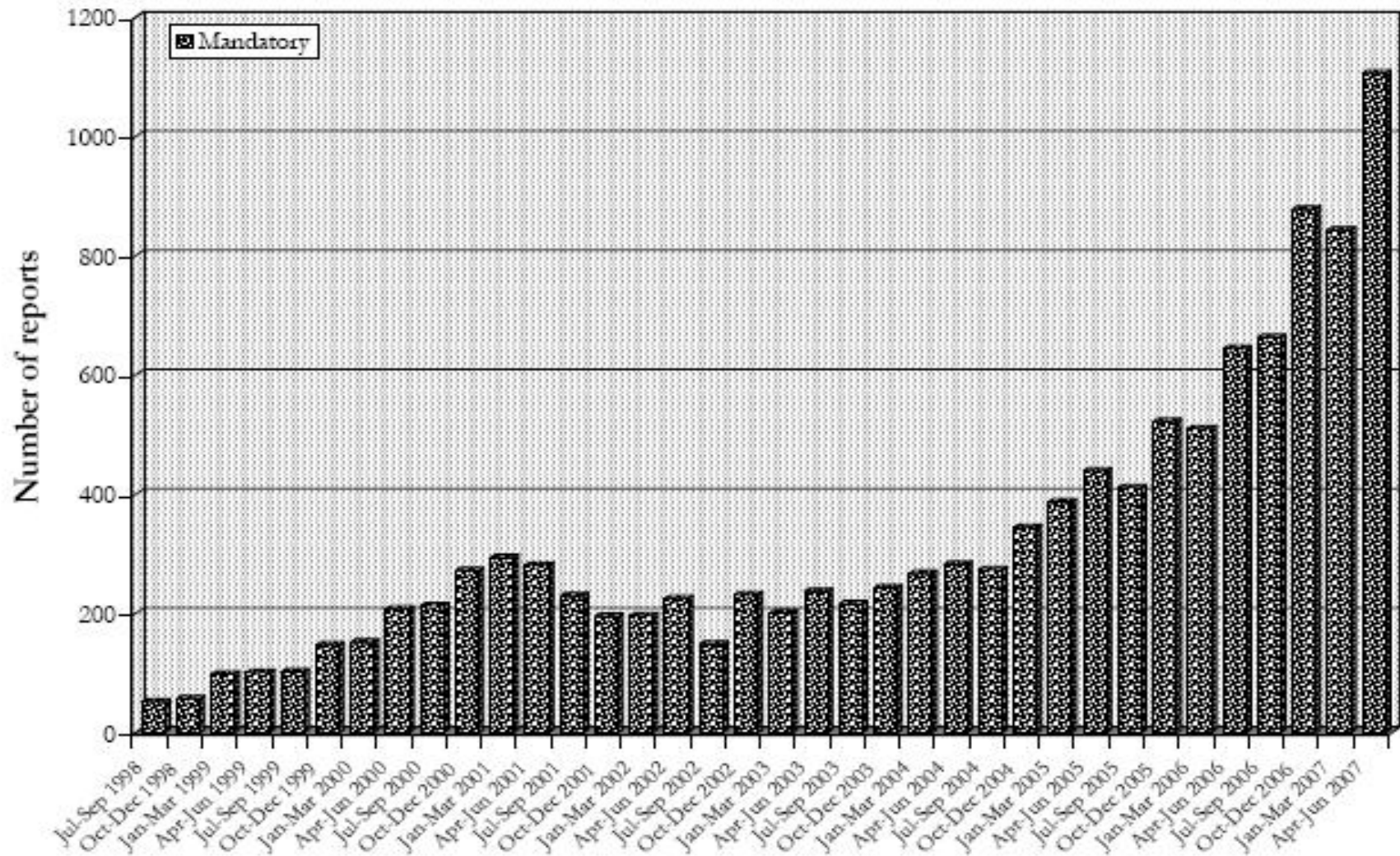


Customs Surveillance

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

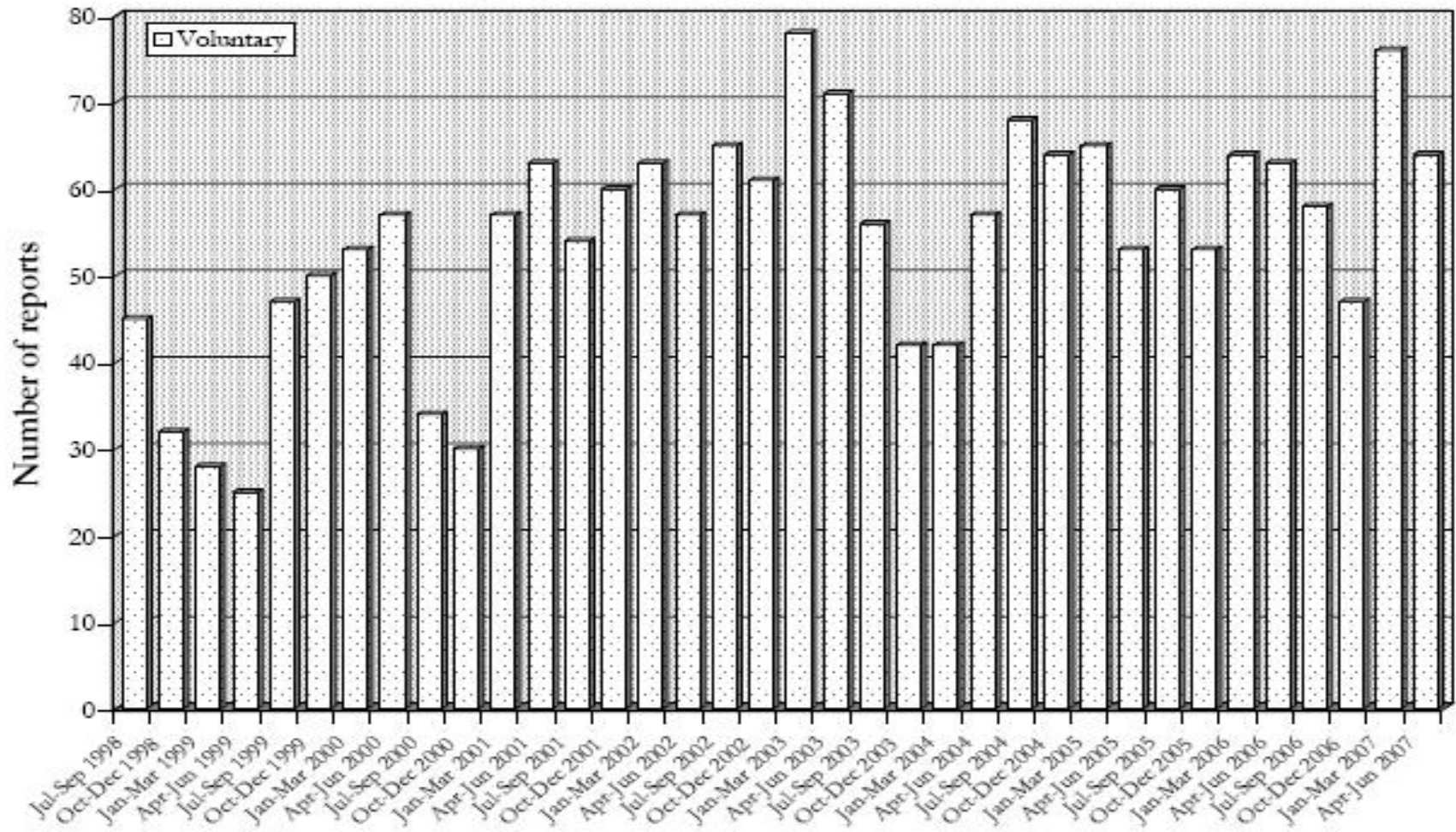
Mandatory Problem Reports July 1998 to June 2007

Mandatories
(July 1, 1998 to June 30, 2007)



Voluntary Problem Reports 1998-2007

Voluntaries
(July 1, 1998 to June 30, 2007)





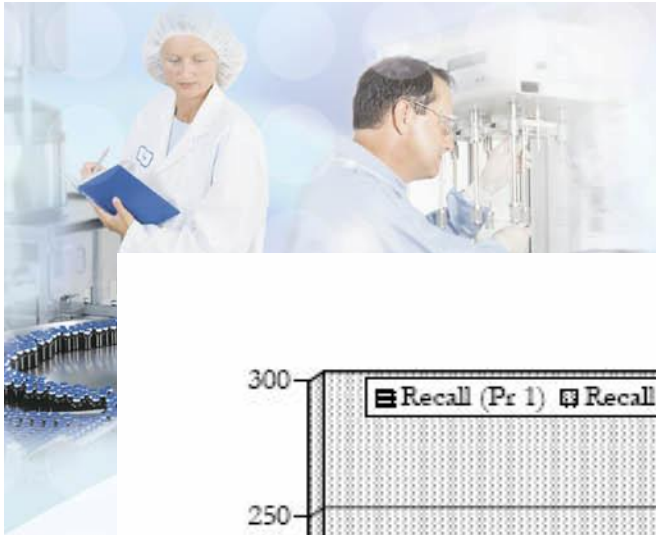
Medical Device Recalls

- All Medical Device Recall Data is posted on Health Canada's website
- Manufacturer and importer must inform Health Canada "on or before undertaking a recall"
- Full list of information requirements in the Medical Device Regulations.
- Some company alerts/notices are posted on Health Canada's website
 - Company is contacted by Health Canada
 - Permission to post is requested



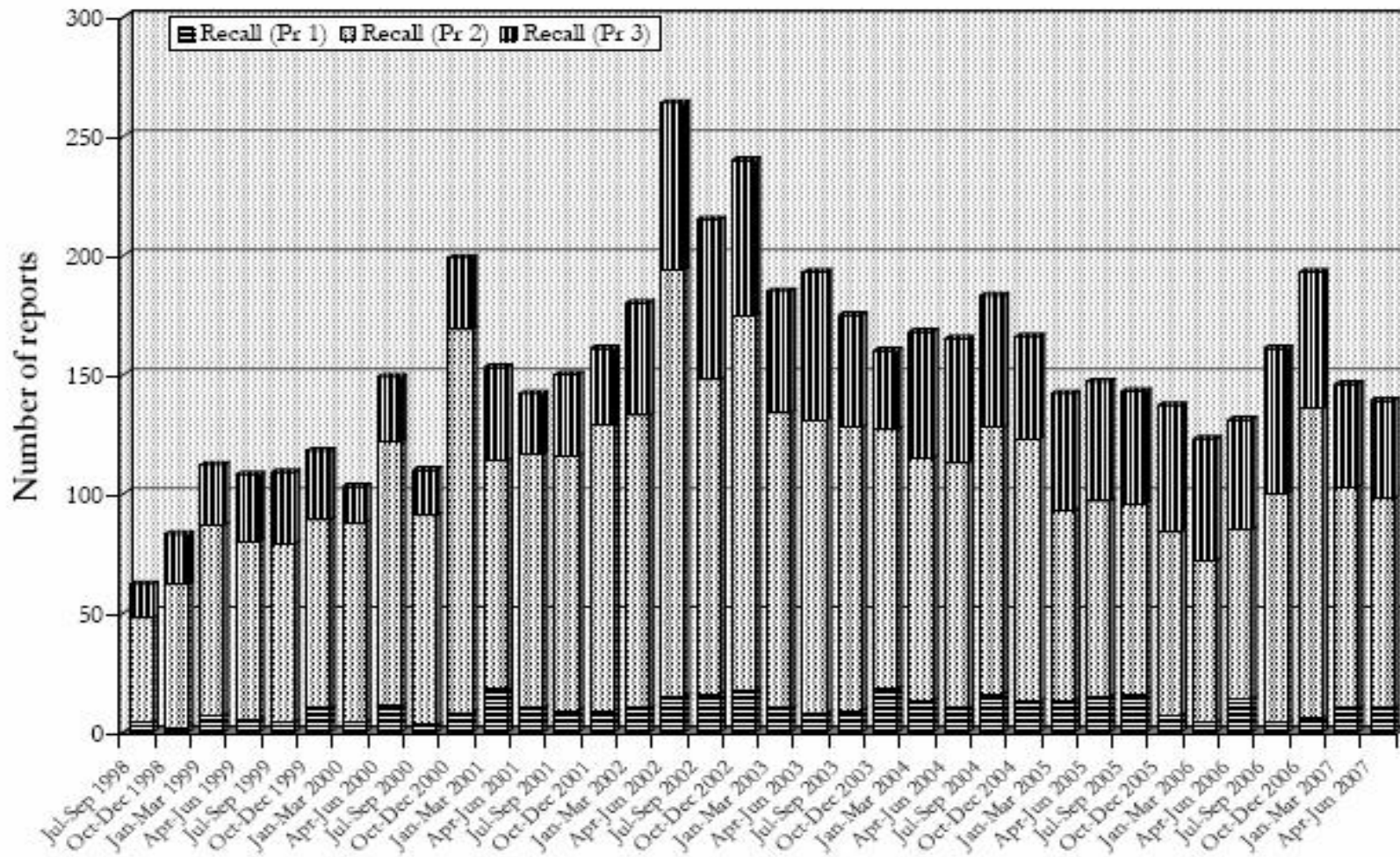
Medical Device Recalls

- Regulatory Requirement
- Recall Reports and Monitoring
- 500 to 700 recalls per year
- Regional Effectiveness checks



Medical Device Recalls from 1998 to 2007

Recalls
(July 1, 1998 to June 30, 2007)





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



NCAR Programme

- National Competent Authority Reports (NCAR)
- US, EU (UK, Germany, France, etc.), Switzerland, Australia, Japan...
- Higher risk issues
- www.ghtf.org

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.

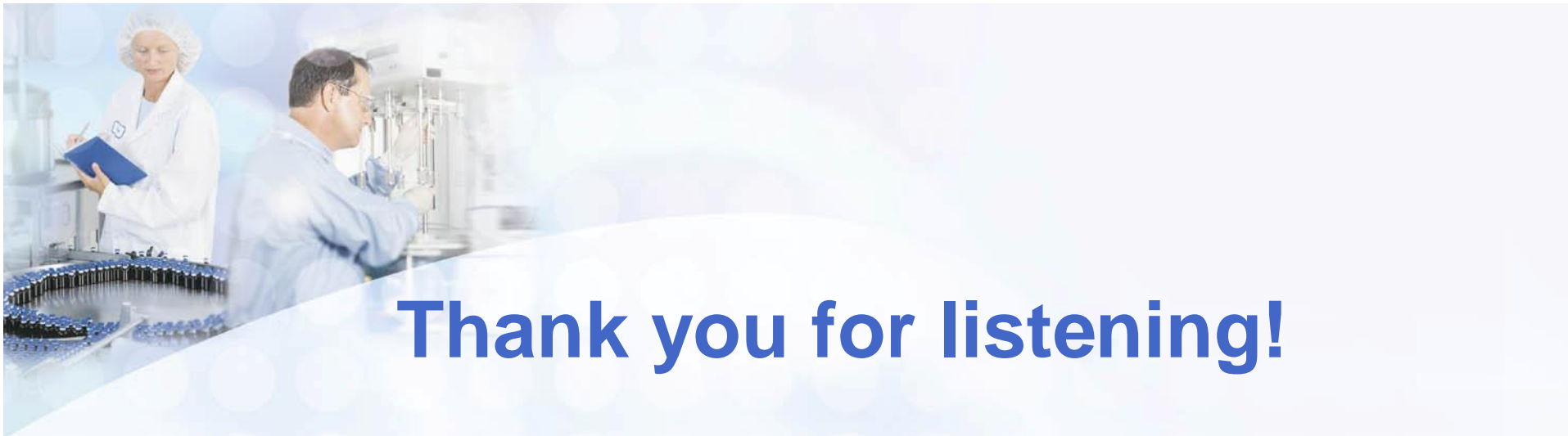
www.ghtf.org



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!

**For further questions:
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