

2009 USP Annual Scientific Meeting

Health Products and Foods Inspectorate

Diana Dowthwaite
September 23, 2009



USP Annual Scientific Meeting

Canadian Food And Drug Regulation Session

September 23, 2009 – Toronto

Standards without Borders: Protecting the Public Health in the Modern World

Health Products and Food Branch Inspectorate (HPFBI)

Diana Dowthwaite

Director General

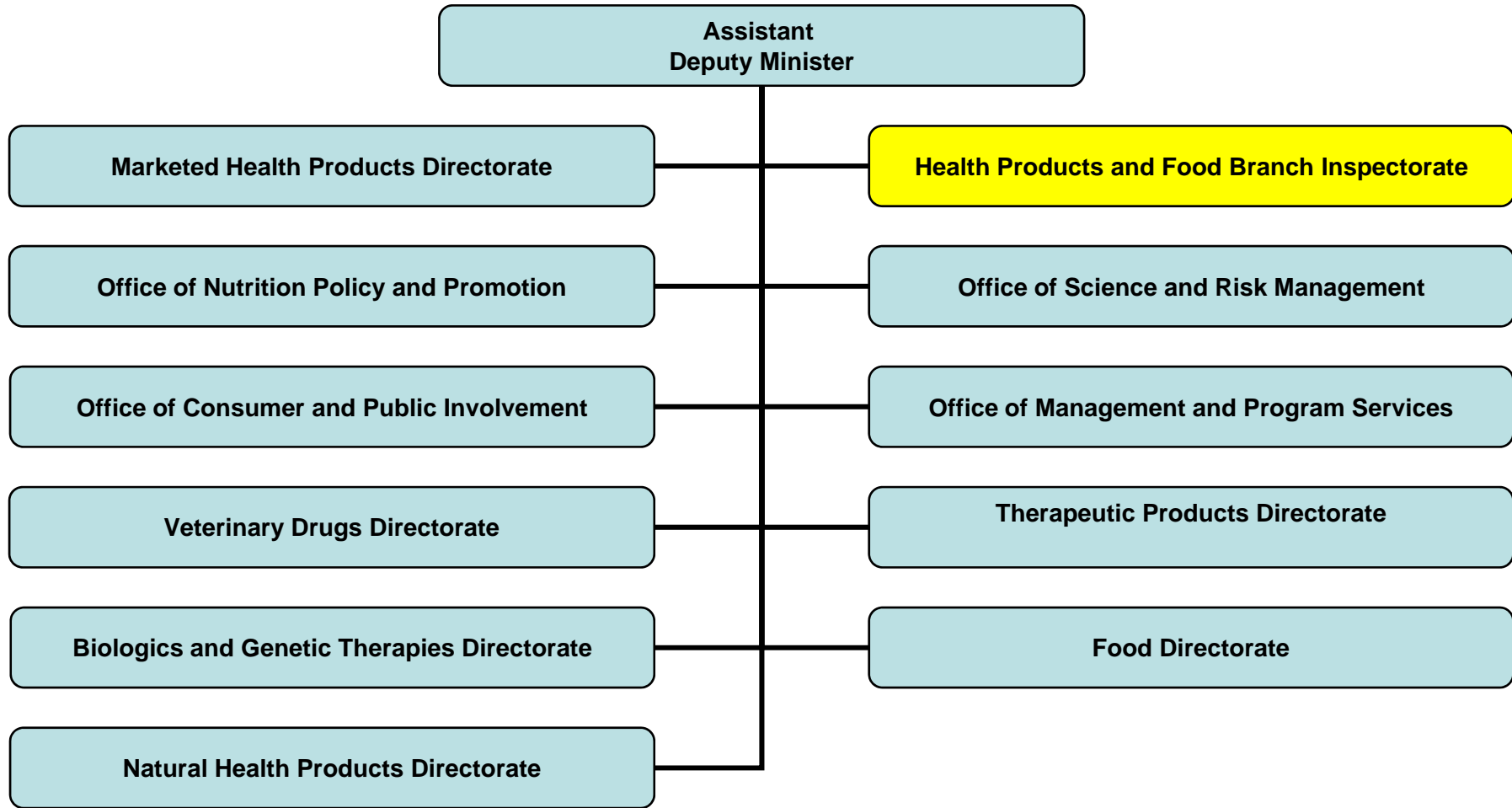


Presentation Overview

- Our organization
- Our responsibilities
- Our challenges
- Initiatives Linked to Product Quality



HPFBI in the Health Products and Food Branch



The Inspectorate's Primary Role

- To deliver a national compliance monitoring and enforcement program for all products under the mandate of the Health Products and Food Branch (except food) while supporting:
 - the risk management approach to decision-making; and
 - the vision of a comprehensive regulatory strategy across all product classes.



HPFBI's Regulations

Powers and authority

Food and Drugs Act

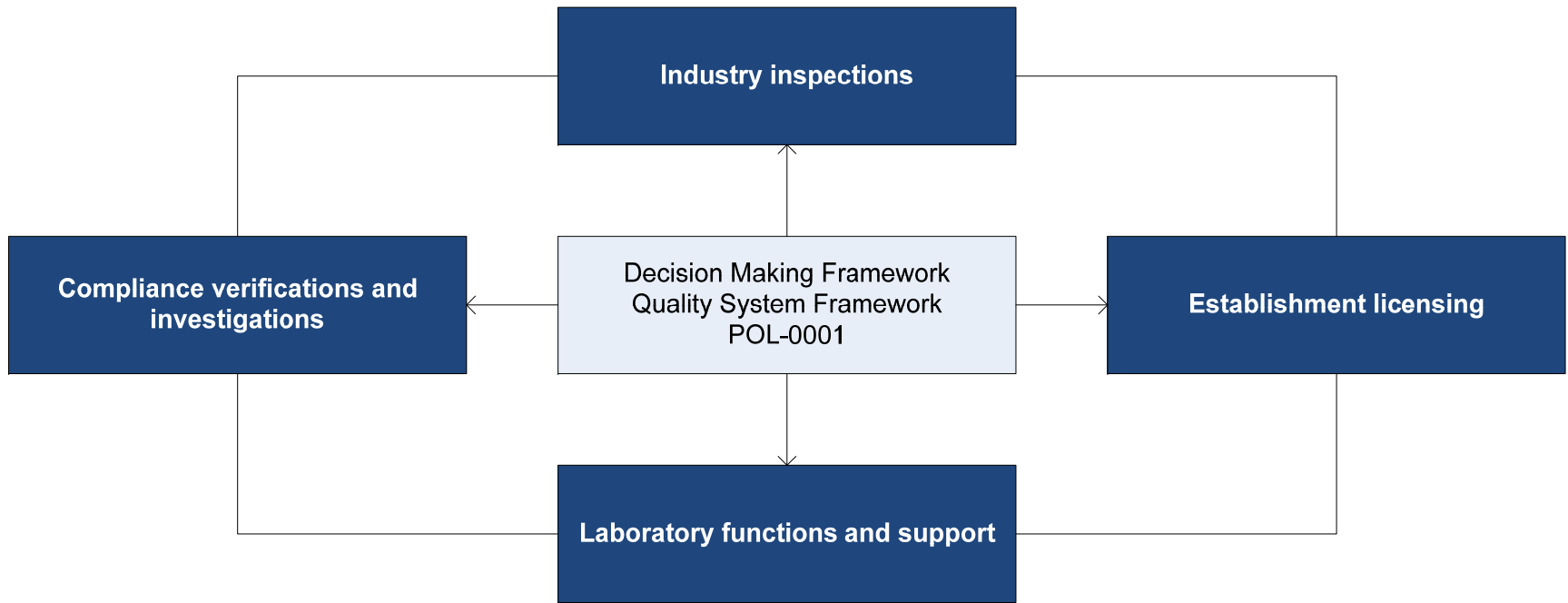
- Definition and powers of an “inspector”

Commonly referenced regulations:

- Food and Drugs Regulations, Part C (Drugs)
- Processing and Distribution of Semen for Assisted Conception Regulations
- Medical Devices Regulations
- Natural Health Products Regulations
- Safety of Human Cells, Tissues and Organs for Transplantation Regulations



Core functions



Industry inspections

- Good Manufacturing Practices (GMPs)
 - Human drugs
 - Veterinary drugs
 - Blood establishments
- Clinical trial sites (GCPs)
- Security inspections for controlled drugs
- Medical devices
- Semen establishments
- Cells, tissues and organs establishments



Compliance verifications and investigations

- Recall monitoring
- Customs surveillance
- Complaints – trade and consumer
- Retail monitoring surveys
- Advertising
- Prosecutions and other enforcement actions



Establishment licensing

- Human and Veterinary Drugs
 - To: fabricate, package/label, test, import, distribute, and, wholesale
- Medical Devices
 - To: import, or distribute (all classes)
- CTO registration
 - For cells, tissues and organs
- Certificates of a Pharmaceutical Product (CPP)
 - As per the WHO scheme for pharmaceuticals moving in international commerce



Laboratory functions and support

- **Laboratories accredited to ISO 17025**
- Chemistry, microbiology/sterility testing including method development and validation
- Support inspection and investigation functions
- Analysis of potential counterfeit products



HPFBI's Cooperation with USP

Past:

- Membership on Expert Committees and participation in collaborative studies
- Providing input to monographs and general chapters

Present:

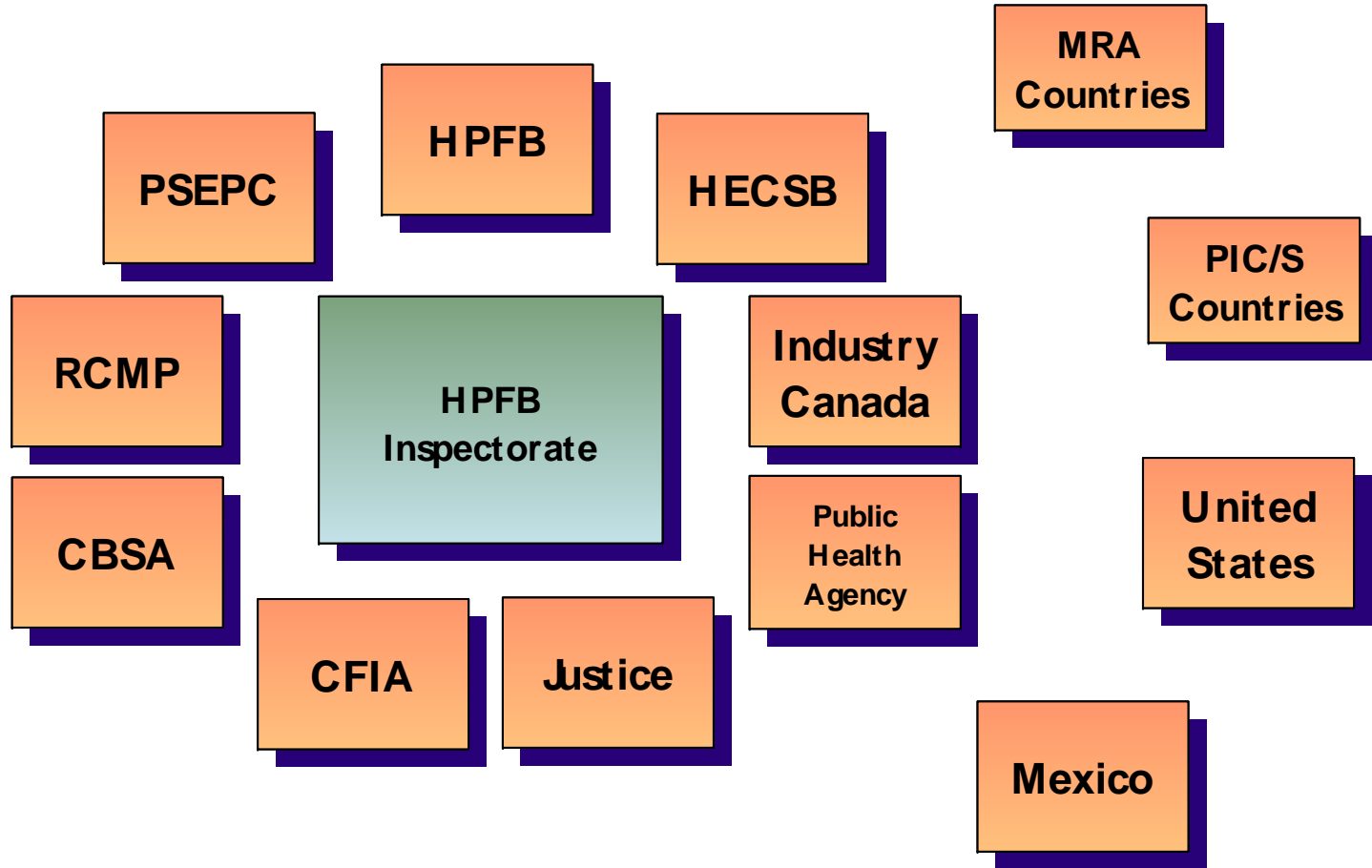
- Collaboration on Evaluation of Reference Standard Candidates
 - An agreement in place since 2004 in which both Inspectorate labs participate
- **USP Reference Standard Expert Committee**
 - **Pauline Lacroix has been a member since 2000**

Future:

- Possible candidates for other Expert Committees with the call for nominees expected in the fall



HPFBI's Key Partners



HPFBI's International Collaboration

- Mutual Recognition Agreements (MRA)
- Trilateral Cooperation Charter (Mexico, USA, Canada)
- **USP Reference Standard Expert Committee**
- Pharmaceutical Inspection Co-operation Scheme (PICS)
- Official Medicine Control Laboratory Network (OMCL)
- International Conference on Harmonization (ICH)
- Global Harmonization Task Force (GHTF)
- International Laboratory Forum on Counterfeit Medicines (ILFCM)
- WHO Cold Chain Task Force
- Heads of Agencies Work-sharing Consortium



HPFBI's Challenges & Opportunities

- Very high proportion of imported products including APIs
- Increasing complexity of drug supply chains
 - Entrance of smaller, non-traditional, more sophisticated, players into wholesale activities
- *Food and Drugs Act* modernization
- Anti-counterfeit strategy
- Border integrity program
- GMP inspection program review



HPFBI's New Initiatives

Anti-counterfeit strategy

- Key Elements:
 - Part of government-wide strategy to enforce IPR
 - Prevention, detection and deterrents through new compliance and enforcement capacities
 - Appropriate new legislative and regulatory authorities
 - Increase lab capacity
 - Education (industry, associations & general public)
 - Technology
 - Partnership approach
- Set up information sharing networks
- Develop further understanding
 - *A tight supply chain fights diversion.....*



HPFBI's New Initiatives

GMP – Drug Inspection Program review

Review of its GMP inspection program to:

- manage increasing inspection workloads
- increase the effectiveness and efficiency of our GMP Inspection Program while aligning with international changes in regulation.

Goal is to create an inspection model that will integrate:

- effective and efficient, risk based use of resources
- the life cycle approach to drug regulation
- expectations from international regulators and partners
- diversity of regulatory needs within industry



HPFBI's New Initiatives

Border integrity program

- Food and Consumer Safety Action Plan
- Increased resources
- Uniformity and consistency
- Preventing problems in the first place, targeting the highest risk, rapid response
- Counterfeit – Erectile dysfunction drugs
- Unlicensed products, importers



Resources, Tools & Contact Information

For more information on the Inspectorate visit:

<http://www.hc-sc.gc.ca/dhp-mps/compli-conform/index-eng.php>

Recalls:

http://www.hc-sc.gc.ca/dhp-mps/compli-conform/recall-retrait/_list/index-eng.php

Establishment Licence Live List:

<http://webprod.hc-sc.gc.ca/el-le/index-eng.jsp>

Toll free number - 1-800-267-9675



Contact Information

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