

2009 USP Annual Scientific Meeting

Therapeutics Products Directorate

Andrew Adams
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 (HPFB)
Therapeutic Products Directorate (TPD)**

Andrew Adams

Director, Bureau of Pharmaceutical Sciences

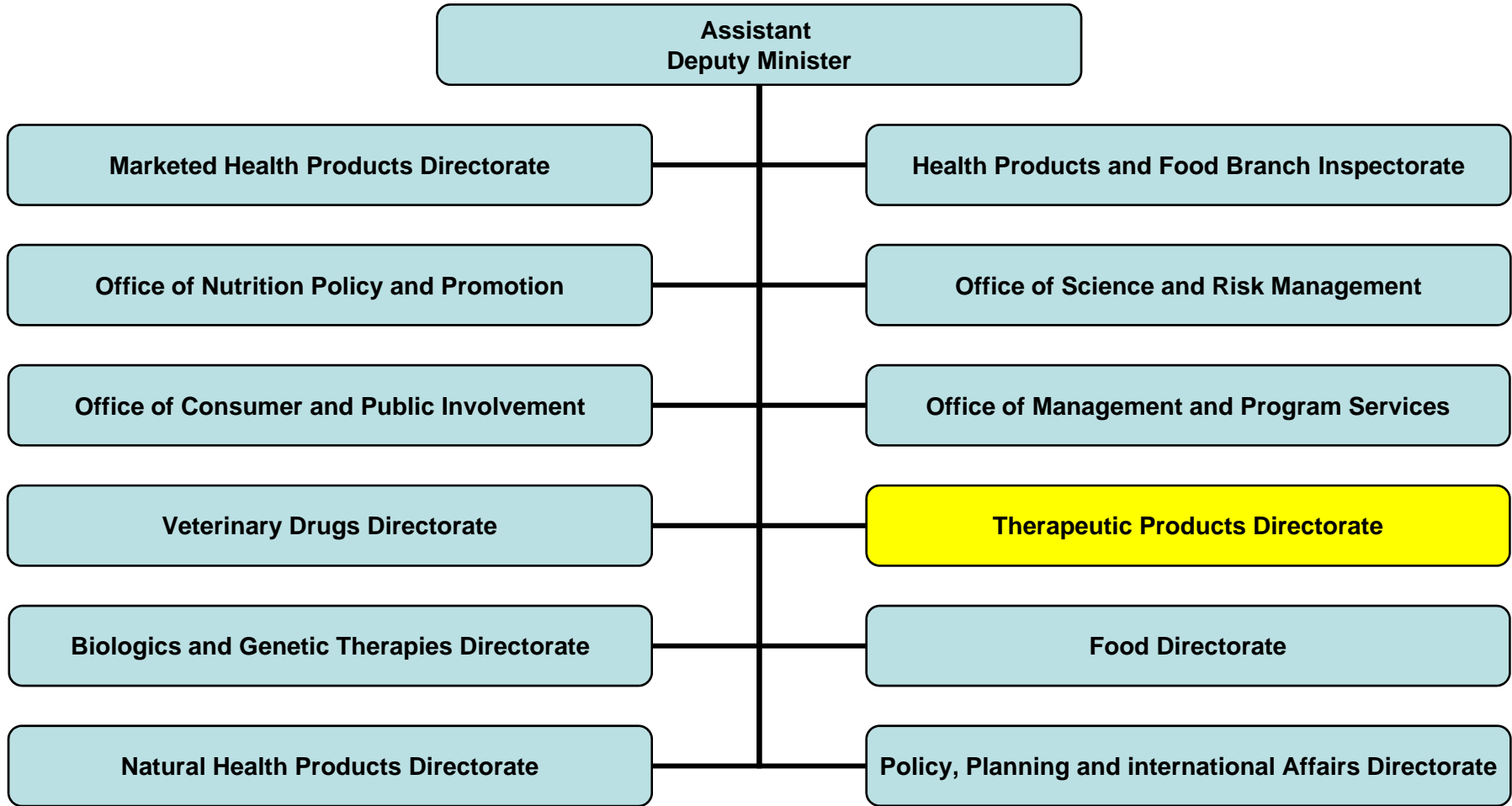


Presentation Overview

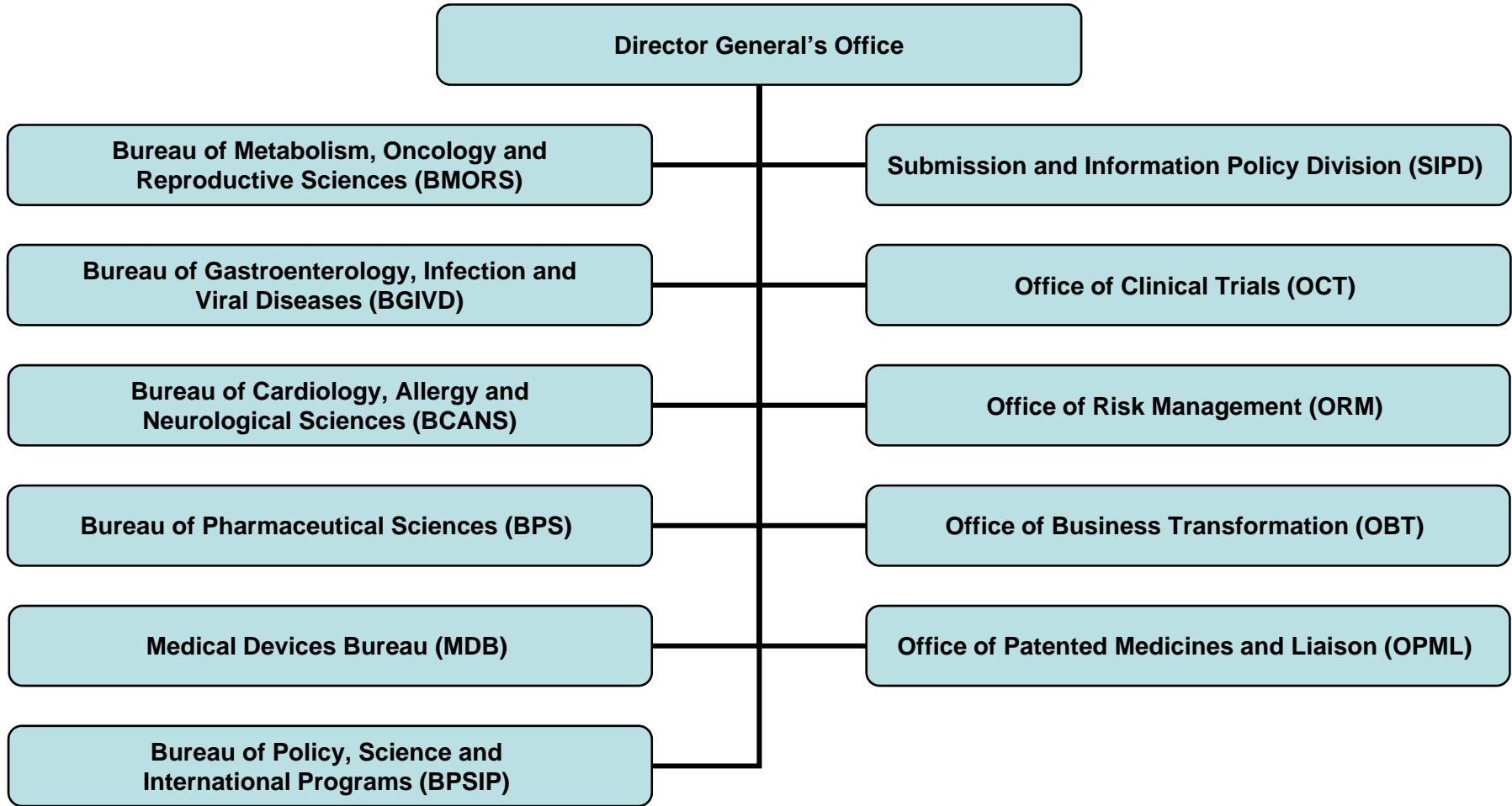
- **Organisation**
- **Responsibilities \ Core Functions**
- **Legislation \ Regulations**
- **Partnerships \ International Activities**
- **Challenges \ Opportunities**
- **Initiatives**



TPD in the Health Products and Food Branch



TPD Organisation



TPD's Mission \ Core Functions

- **Mission:** Contribute to the health of Canadians and to the effectiveness of the health care system by regulating pharmaceuticals and medical devices and by providing Canadians with access to information to make informed choices.
- TPD is the Canadian federal authority that regulates pharmaceutical drugs and medical devices for human use. Prior to being given market authorization, a manufacturer must present substantive scientific evidence of a product's safety, efficacy and quality, as required by the Food and Drugs Act and Regulations.



TPD's Mission \ Core Function

- In addition to pre-market review activities TPD's responsibilities include:
 - Special Access Programme
 - Review of Clinical Trial Applications for pharmaceuticals and Investigational Testing for medical devices
 - Health Hazard Evaluations
 - Providing Canadians with the science-based information they need to make informed choices
 - Making recommendations regarding the scheduling of drugs under the *Controlled Drugs and Substances Act (CDSA)*.



Legislation and Regulations

Food and Drugs Act

Food and Drug Regulations

Medical Devices Regulations

Controlled Drugs and Substances Act

Patent Act

Patented Medicines (Notice of Compliance) Regulations

Food and Drugs Act: <http://laws.justice.gc.ca/en/ShowTdm/cs/f-27///en>

Food and Drug Regulations: <http://laws.justice.gc.ca/en/showtdm/cr/C.R.C.-c.870>

Medical Devices Regulations: <http://laws.justice.gc.ca/en/showtdm/cr/SOR-98-282>

Controlled Drugs and Substances Act: <http://laws.justice.gc.ca/en/showtdm/cs/C-38.8>

Patented Medicines (Notice of Compliance) Regulations: <http://laws.justice.gc.ca/en/showtdm/cr/SOR-93-133>



TPD's Key Partners and International Initiatives

- International Conference on Harmonization (ICH)
- Foreign regulatory authorities
 - US FDA
 - EMA
 - TGA
- Global Harmonization Task Force - GHTF (Medical Devices)
- World Health Organisation (WHO)



TPD's Challenges & Opportunities

- Review workload
- Globalisation of research and products
 - Clinical research in emerging economies
 - Increased sourcing of API's and products from emerging economies (eg. India, China)
- International cooperation and information sharing
- Scientific developments and the changes in the development of pharmaceuticals (eg. Quality by Design)



TPD Goals for 2009-2010

- **Review performance:** Continuing to meet performance targets for new drugs and extending performance targets to other submission / application types.
- **Supporting the modernization of Legislation and Regulations:** Developing a new legislative and regulatory framework for the regulation of health products.
- **Supporting the Cost Recovery Initiative:** Developing a sustainable funding platform for the regulation of health products.



TPD Initiatives

- **Special Access Program:** Modernizing the regulatory framework to permit compassionate access to new therapies.
- **Electronic Review:** Establishing an electronic review environment consistent with international standards.
- **Non-Medicinal Ingredient (NMI) Labelling:** Amending the regulations to require NMI listing on the outer label of non-prescription drugs.
- **Review Improvement Projects:** Submission Planning, Good Review Practices, Summary Basis of Decision, Review Activity Prioritization (Core Review)



Contact Information/Resources & Tools

- TPD's main mailing address :

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- The Drugs and Health Products Website can be found at:

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

