

2009 USP Annual Scientific Meeting

Health Products and Foods Branch

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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)

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Presentation Overview

- HPFB overview
- Role and recognition of pharmacopeia in the Canadian regulatory system
- HPFB and USP cooperation
- Key challenges and opportunities



HPFB's Core Function

Mandate

To take an integrated approach to managing the health-related risks and benefits of health products and food by:

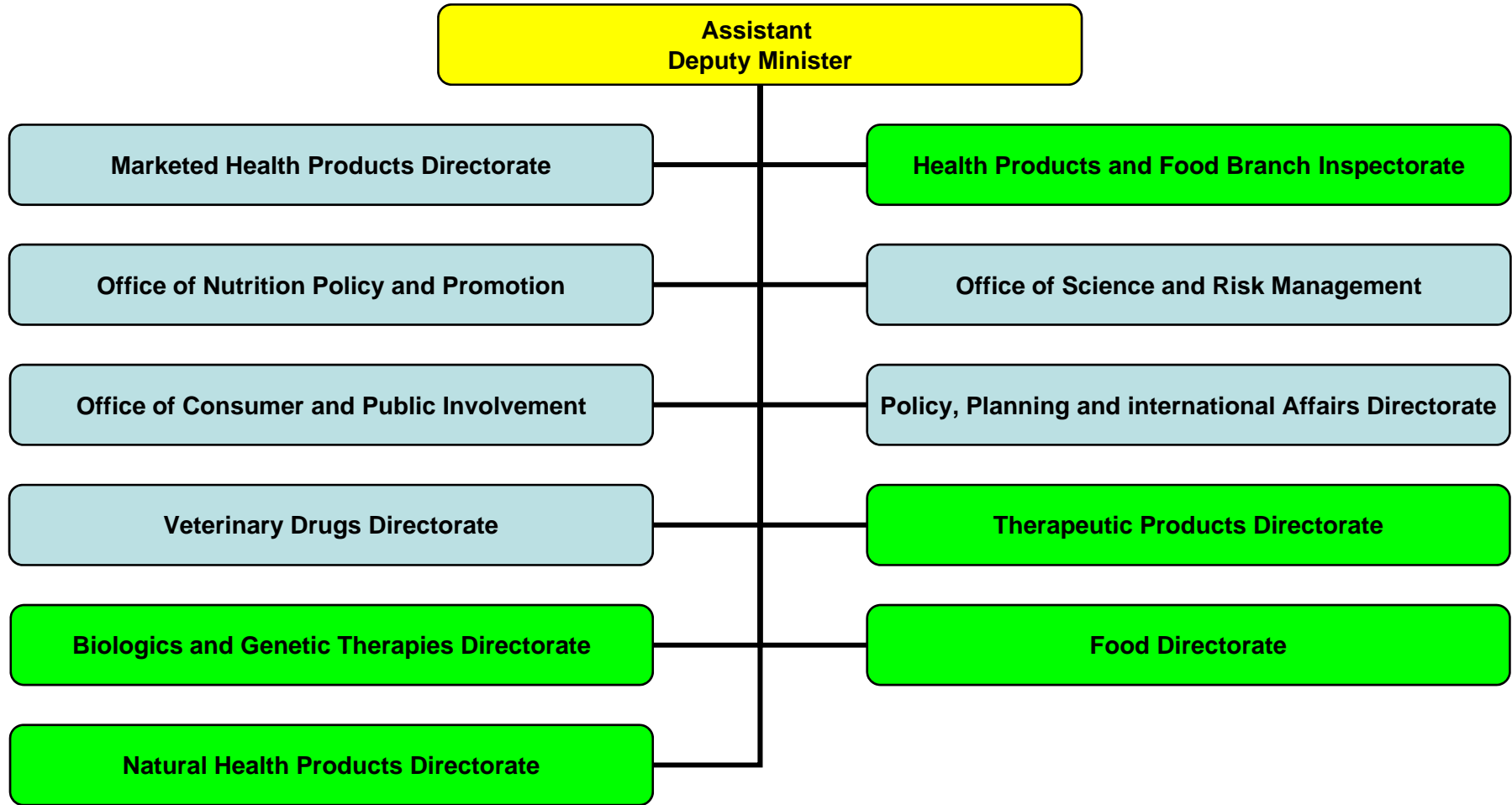
- minimizing health risk factors to Canadians while maximizing the safety provided by the regulatory system for health products and food; and,
- promoting conditions that enable Canadians to make healthy choices and providing information so that they can make informed decisions about their health

The *Food and Drugs Act*

- Food and Drug Regulations
- Natural Health Products Regulations (NHPR)



HPFB's Core Function



Pharmacopeia – Key Partners in Promoting Public Health

Pharmacopeia play a vital role in promoting public health through:

- The development of public monographs, test methods and reference standards for establishing product quality
- Education, training and outreach programs
- The advancement of scientific discussion, and
- More recently, the verification that ingredients from specific sources conform to pharmacopeial monographs



...a Role Recognized in the Canadian *Food and Drugs Act and Regulations*

- “Schedule B” to the Act officially recognizes certain pharmacopeia including the European Pharmacopeia, the National Formulary and the United States Pharmacopeia
- Schedule B standards referenced in a number of important other provisions within the Act and Regulations relating to deception, labelling and testing, for example:
 - Section 10 (2) of the Act: **Where** a standard has not been prescribed [by the Regulations] for a drug, but **a standard for the drug is contained in any publication referred to in Schedule B, no person shall label, package, sell or advertise any substance in such a manner that it is likely to be mistaken for that drug, unless the substance complies with the standard.**
 - Regulations: Part C (Drugs), Division 2 (GMP), Raw Material Testing: Where the specifications referred to...are not prescribed, they shall...be acceptable to the Director who **shall take into account the specifications contained in any publication mentioned in Schedule B to the Act**



Incorporation by Reference

- As a result, standards contained in pharmacopeia listed in Schedule B are legally recognized in Canada unless otherwise specified
- “Incorporation by reference” of Schedule B publications stipulates that the standards represent “the most recent editions, including all errata, supplements, revisions and addenda”
- Canada is rather unique in its recognition of more than one pharmacopeia, a situation that accommodates the concept of “interchangeability” of standards through the ICH Q4B process
- Important to note that the Minister retains the authority to require additional or different requirements if deemed necessary to establishing the quality, safety or efficacy of a substance or product (e.g., functionality tests or impurity tests for a new multi-source drug)



The Canadian Reality

- For all intents and purposes, Canada does not have its own pharmacopeia (Canadian Formulary last published in 1949!)
- On a global scale, Canada represents a relatively small market for many of the products covered by Schedule B standards
- Health Canada's approach recognizes the importance of other international pharmacopeia in establishing and maintaining public standards
- Vast majority of drug products sold in Canada for which a Schedule B standard exists are labelled to the USP or Eur Ph
- These realities explain why the Health Products and Food Branch supports collaboration with leading pharmacopeia, most notably the United States and European pharmacopeias



HPFB's Cooperation with USP

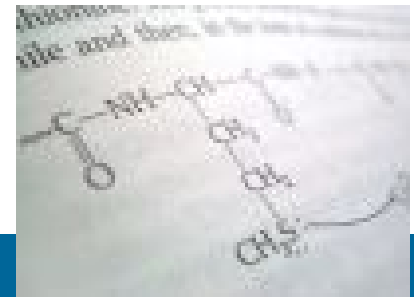
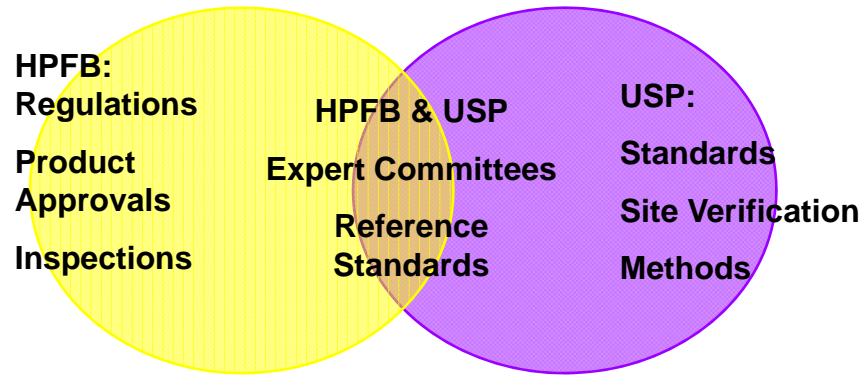
- Health Canada has enjoyed a longstanding and productive relationship with the USP, one that has included:
 - Participation on a wide number of USP Expert Committees, the Council of Experts and USP sponsored workshops and consultations
 - Reference Standards work
 - Development of proposed impurity test methods for multi-source drugs
- Health Canada officials have also served as delegates to the USP Convention
- Number of bilateral meetings held in recent years to explore how two organizations may best cooperate to promote public health



HPFB and USP – Complementary Roles



Share the goal of ensuring quality and safety of health products and food



Time to Engage in More Strategic Discussions

...given common challenges:

- Global dimension of product development and distribution and growing concerns over product quality and supply chain integrity
- Complexity of new technologies and delivery systems
- Introduction of more science and risk-based approaches to regulating product quality
- Gap between available resources, workload and increasing public expectations



Time to Engage in More Strategic Discussions

...and new opportunities:

- *Food and Drugs Act* modernization
- USP's global presence, including in countries that are increasingly important global sources of ingredients and products such as China and India
- USP's verification programs for dietary supplements, drug substances and pharmaceutical ingredients
- USP's responsibilities for the Food Chemical Codex and increasing attention on the importance of monographs for food additives following recent report on the *Listeria* outbreak



Future Possibilities?

- Greater intelligence and sharing of information on ingredients, products and sites
- More coordinated training and technical assistance, particularly in priority non-ICH regions
- Other?



In Summary

- Regulators, pharmacopeia, harmonization initiatives and other international organizations play complementary roles in promoting public health and the availability of quality health products and food
- More effective action calls for a more strategic and coordinated approach that builds upon existing relationships
- The HPFB and USP are well positioned for such discussions



Contact Information/Resources & Tools

For more information on HPFB, visit:

- The HPFB Internet site: <http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/index-eng.php>
- 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>

