Overview of the Health Product Vigilance Transformation Initiative

Workshop on New Directions in Postmarket Surveillance of Pharmaceuticals & other Health Products: Improving Patient & Product Safety

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Canada

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Background on the Initiative

➔ Why did Health Canada give rise to this Initiative?

Many factors point to the need for strengthening & modernizing post-market surveillance and vigilance practices in Canada:

- The limited information available to monitor, assess and identify safety issues adequately with marketed products;
- Market Authorization Holders (MAHs) are required to report adverse reactions in accordance with the *Food and Drugs Regulations*, but are not obligated to report on evolving global knowledge and experience with marketed health products;
- Canada is behind in the use of complementary information sources and the incorporation of international best practices; and
- Canada lacks the regulatory authority to request additional post-market studies/data.

Background on the Initiative

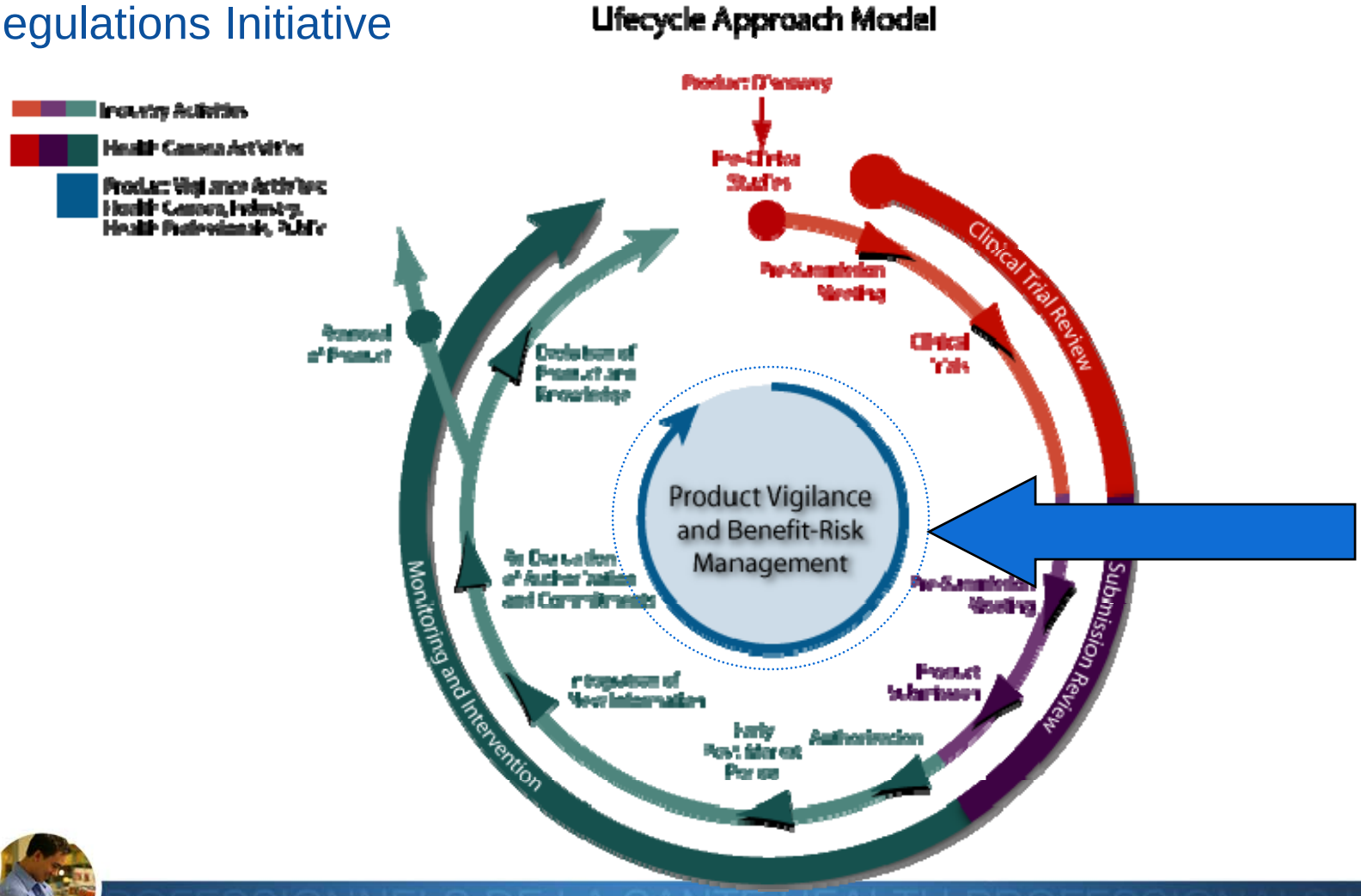
➔ Alignment with other Federal Initiatives

The Health **P**roduct **V**igilance **T**ransformation (PVT) Initiative aligns with:

- Blueprint for Renewal (Part II: 2007)
- Food and Consumer Safety Action Plan (Report: January 2008)
- Federal Post-Market Surveillance Strategy (2007)

Background on the Initiative

➔ Alignment with the Modernization of Legislation and Regulations Initiative



Some Definitions

➔ Pharmacovigilance/product vigilance

World Health Organization's definition[(1)]:

> "the sciences and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems"

Widened to include:

Pharmaceuticals, Biologics*, Medical Devices, Natural Health Products and Veterinary Drugs.

* Biologics include: blood and blood products, cells, tissues, organs, gene therapies, radiopharmaceuticals, biotechnology-derived therapeutic products and therapeutic/diagnostic vaccines.

(1) http://apps.who.int/medicinedocs/en/d/Js4893e/3.html#Js4893e.3

Goal of the Health Product Vigilance Transformation (PVT) Initiative

Since the purpose of performing product vigilance is to gather knowledge to contribute to the assessment of a product's overall benefit-risk profile, the goal of the PVT initiative is:

> To deliver a systematic, comprehensive, coordinated approach to regulated health product vigilance (PV) through the development and implementation of an overarching PV framework integrating the various PV tools adopted by the Health Products and Food Branch (HPFB).

Objectives of the Health Product Vigilance Transformation (PVT) Initiative

The initiative includes the following activities:

- –Development of a Product Vigilance framework providing a consistent approach across product lines for PV transformation within the Branch;
- –Design/revision and implementation of individual PV tools (such as DSEN, RMPs, PSURs, MI reports, CMDSNet, AR's, etc.);
- –Development of the required policies, regulations and processes to support implementation;
- –Consultations (internal and external) to inform the development and design activities.

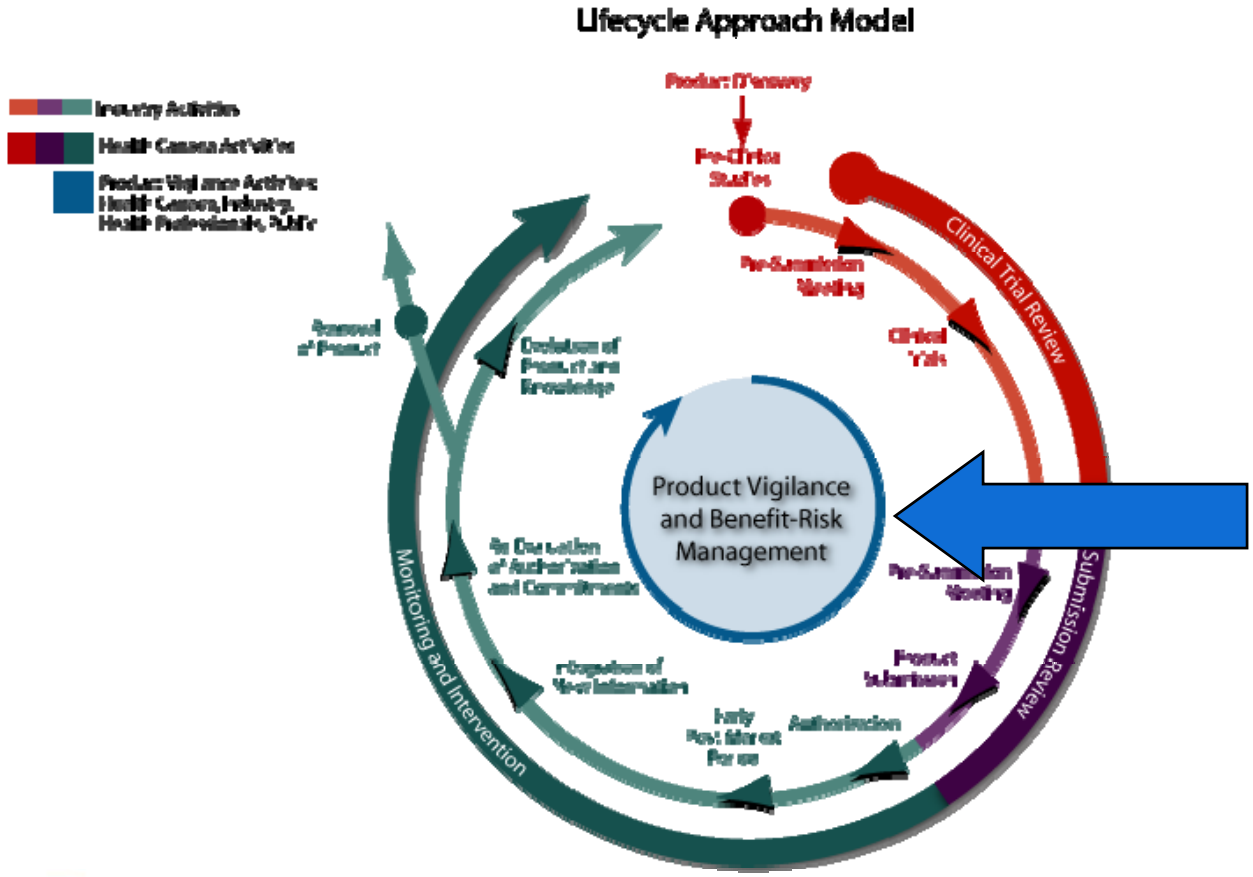
Objectives of the Health Product Vigilance Transformation (PVT) Initiative

Post-Market Surveillance/Health Product Vigilance

Passive → **Reactive** → **Pro-active** → **SUSTAINABILITY**

- **Passive**: e.g. spontaneous AR reporting by health professionals and consumers; mandatory reporting by sponsors
- **Reactive**: e.g. action in response to interventions by US FDA, EU-EMEA, etc.)
- **Pro-active**: e.g. electronic health record use, active surveillance, requested post-market trials, risk management planning, automated signal generation, e-coding on AR reports by sponsors, PSUR review, PvP, RMP.

Objectives of the Health Product Vigilance Transformation (PVT) Initiative



We are in the process of developing a model for Health Canada's Product Vigilance & Benefit-Risk Management Cycle.

Guiding Principles

- Adopt a product lifecycle approach
- Align with international best practices and standards
- Facilitate industry compliance with vigilance practices
- Align with Health Canada's Decision-Making Framework
- Continuously improve product vigilance
- Uphold product efficacy and safety standards

Why are we talking about TRANSFORMATION?

The PVT project is about strengthening and modernizing the post-market surveillance core business functions. This is Business Process Re-engineering, as it consists of:

- Engaging new stakeholders (or the same groups of stakeholders) in new ways;
- Opening up new communication channels to gather new sources of information;
- Modifying our processes to integrate new product vigilance (PV) tools;
- Modifying our regulations and policies to reflect current international best practices;
- Restructuring the business information;
- Restructuring the organization by promoting technology (Information Management (IM) and Information Technology (IT)).

Process Steps Towards the Transformation

STEPS (project phases)	DESCRIPTION
Phase 0	**Initiation & Planning:** a working group was formed, a governance model was established, a project charter and a project plan were developed.
Phase 1	**Development of the PV Framework:** creation of the product vigilance model, development of a PV framework document, stakeholders consultations.
Phase 2	**Design and Policy Approach for each PV tool:** provision of direction on how to apply the PV tools in the Branch, and definition of roles and responsibilities.
Phase 3	**Implementation and Integration of the PV tools within Branch business operations:** revision/implementation of business processes, including all tools and associated documents, staff training, evaluation of the implementation, and information to the stakeholders on the results.

Expected Benefits

- Improved planning for product vigilance (better / earlier) prior to marketing a product
- Improved benchmark safety information
- Improved on-going benefit-risk balance assessment / evaluation
- Potential Reduction of risks to patients
- Enhanced development of regulatory policies, procedures and best practices to advance the strategic objectives for the Branch product vigilance
- Improved stakeholder understanding of the proposed product vigilance framework
- Improved efficiencies in the management of vigilance activities within the Branch, obtained through a common set of policies and principles guiding health product vigilance
- Increased confidence of Canadians in the regulatory process

Accomplishments to Date

✓ **A solid foundation for our project was established with the following deliverables being completed**:

•Project Governance	•Project Charter
•Project Overview and Scope	•PVT WG Terms of Reference
•Initial Project Plan	•Internal Communication Plan

Next Steps

- Finalise the **Health Product Vigilance Framework document** that will be used to initiate a discussion with our stakeholders, both internally and externally, and to share Health Canada's vision on Product Vigilance .

- Undertake the **consultation** with our stakeholders.

Next Steps

- Work towards the **cohesive integration of the Product Vigilance tools** supporting Health Product Vigilance and Benefit-Risk Management within the Health Products and Food Branch's business processes.

Conclusion

- The vigilance of health products is a **key element of a life-cycle approach**, and work is currently underway to adopt modern methods of vigilance for health products in Canada.

- The goal is **for tools and requirements to "work together"** in a cohesive fashion and that regulatory approaches are, whenever possible, **aligned with those of comparable international regulatory counterparts**.

  - This will also involve the integration of **International Conference on Harmonisation (ICH) vigilance tools.**

Conclusion

•In recognition of the fact that many of the Product Vigilance tools that will be mentioned in today's workshop are already in international use, there is also a **need to clarify Health Canada's current expectations regarding the use of certain vigilance tools prior to the implementation of the new vigilance framework**.

•In a notice posted in February 2008, Health Canada committed to accomplished this through a **series of notices that will be posted on the Health Canada's Web site**.

QUESTIONS?