Health Canada Santé Canada

Canada

Patient Involvement in the Development and Safe Use of Medicines

Regulatory Agency Perspectives in Engaging Patient Partners / Other Stakeholders in the Planning and Conduct of Pain Trials

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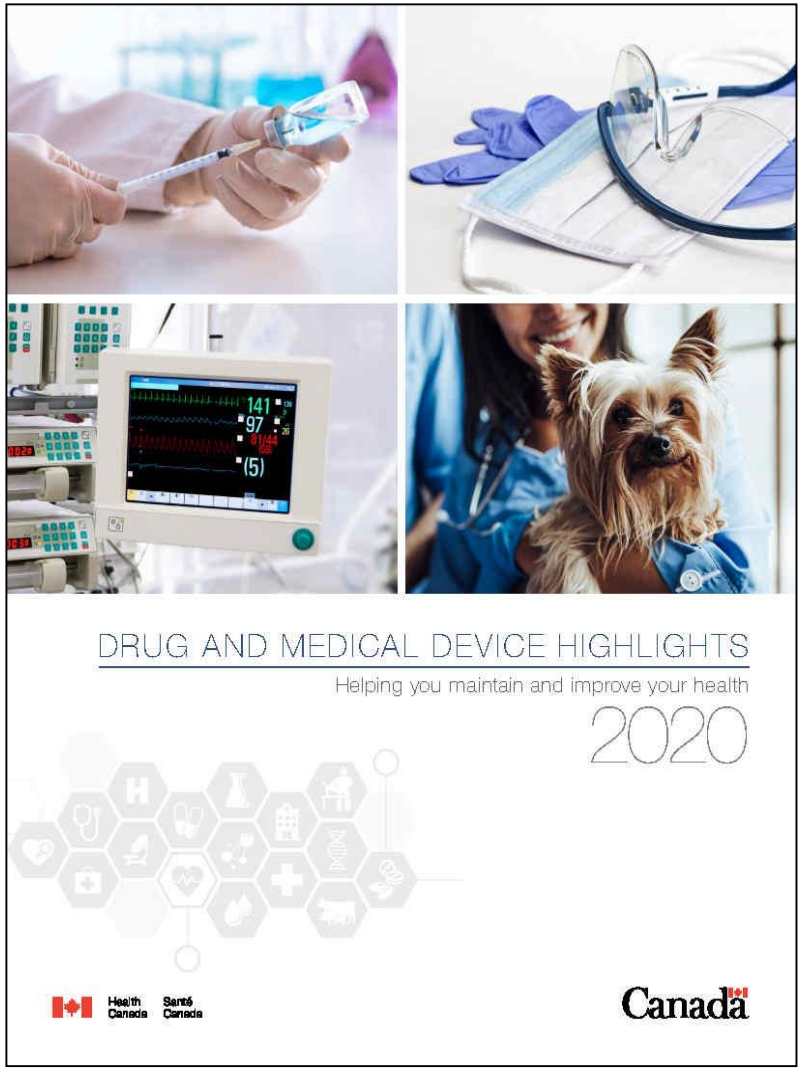
YOUR HEALTH AND SAFETY... OUR PRIORITY.

Who we are…

- Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health

- The Health Products and Food Branch (HPFB) serves as the regulatory authority for the safety, efficacy and quality of therapeutic products (drugs and medical devices) in Canada

- The Office of Pediatrics and Patient Involvement (OPPI) works within HPFB to integrate patient expertise across HPFB's regulatory and policy work, among other files



Patient-Focused Drug (Device) Development (PFDD)

Patient-focused drug development PFDD is a systematic approach to help ensure that patients' experiences, perspectives, needs, and priorities are captured and meaningfully incorporated into drug / device development and evaluation.

Main premise:

Patients have knowledge and expertise regarding their disease that industry / regulators do not have

This is especially true of diseases that are more rare

Drug (device) development and regulation can be enhanced by integrating patient expertise across the lifecycle

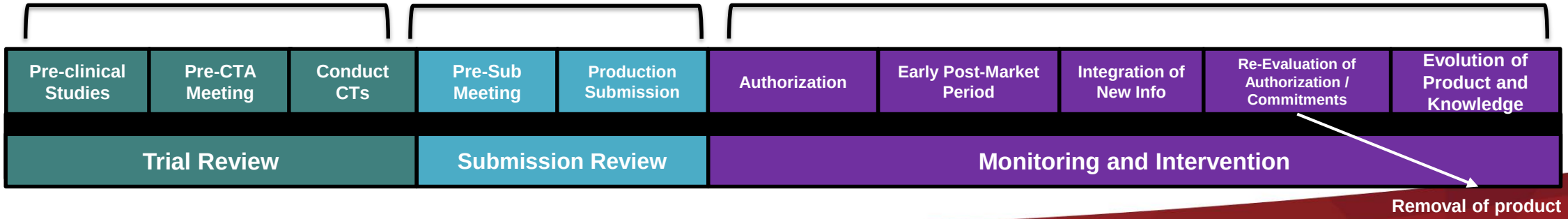
PFDD Spans the Drug (and Medical Device) Lifecycle

Illustrative Examples of how PFDD can Support Regulatory Activities:

- **Inform trial design, resulting in higher quality data and meaningful endpoints**
- **Determine whether the proposed studies meets unmet medical needs**
- **Inform review staff on the nature of the disease, its progression, and risk tolerances within the patient community**
- **Inform policy directions (e.g., modernization efforts, patient reported outcomes, etc.)**

- Inform on risk-benefit profiles, decisions around terms and conditions (e.g., post-market study needs)
- Provide information on disease progression (esp. important for rare diseases)
- Identify whether outcomes are meaningful to patients
- Inform decisions around the product monograph
- Inform policy directions (e.g., modernization efforts, etc.)

- Provide expertise on advisory panels related to risk management plans, post-market studies, terms and conditions, real-world experience with new products
- Provide insight into risk tolerances, particularly if there is a concern that the risk profile has changed in the post-market space
- Inform decisions around post-market communications; leverage networks to disseminate communication material
- Identify if new products meet unmet medical needs or if there are challenges that remain



Health Canada Approach to Patient Involvement

- Aligns with Patient-Focused Drug Development (PFDD)
  - Exploring how to systematically integrate meaningful patient involvement activities across the drug and medical device lifecycles to better inform HPFB's decision-making
  - **Vision:** Health Canada's regulatory and policy decisions are informed by the patients impacted by those decisions via structured and meaningful patient involvement activities
- Take a product-lifecycle approach, rather than focusing on one specific stage of drug development
- Consideration of international initiatives, collaborations and engagement processes

Patient Involvement and Pain

- There are currently no initiatives focusing on patient involvement specific to pain or chronic pain therapies
- Health Canada is open to engaging with both patients and the broader community impacted by chronic pain to identify issues that are meaningful to patients (within our mandate)
- Ultimately, we all work towards a common goal…better outcomes for patients who use the health products that Health Canada regulates

Questions?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