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Regulation of Homeopathic Medicines in Canada

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Purpose

The presentation will:

- provide an overview of how homeopathic medicines are regulated in Canada; and
- highlight some of the current challenges and the path forward.

Health Canada's Regulatory Role

- Health Canada's Natural and Non-prescription Health Products Directorate is the regulating authority for natural health products (NHPs) and non-prescription and disinfectant drugs for sale in Canada.

- Health Canada's role is to ensure that Canadians have access to NHPs (which includes homeopathic medicines) and non-prescription and disinfectant drugs that are safe, effective and of high quality.

Natural Health Products

- In Canada, “natural health product” refers to a range of health products including:
  - Vitamin and mineral supplements
  - Homeopathic medicines
  - Plant and herbal remedies
  - Traditional medicines
  - Amino acids and essential fatty acids
  - Probiotics
  - Certain personal care products

- Authorized NHPs bear either a natural product number (NPN) or homeopathic medicine number (DIN-HM) on their labels.

- There are currently over 80,000 NHPs authorized for sale in Canada.

Regulation of NHPs and Homeopathic Medicines

- NHPs are regulated under the *Natural Health Products Regulations,* implemented in 2004

- The *Natural Health Products Regulations* which cover product licensing, site licensing, post-market reporting requirements (e.g. adverse reaction reporting)
  - Require companies to submit information about the safety and efficacy of the product or to meet monographed standards
  - Do not prescribe evidence standards; these are outlined in guidance documents

- In Canada, homeopathic medicines (HMs) fall under the definition of an NHP and are specifically referenced within the *Natural Health Products Regulations* as being included within their scope.

Regulation of HMs: Historical Context

- Prior to 2004, HMs fell under the *Food and Drug Regulations* and were regulated as non-prescription drugs.

- In the 1990s, HM industry requested that Health Canada allow the use of condition-specific product claims (instead of “homeopathic remedy”)

- In 1997, Health Canada updated its HM policy to allow specific health claims appropriate for self-care
  - This policy decision remains in effect to date.

Licensing and Evidence Requirements for HMs

- There are currently two ways to licence HMs:
  - For non-specific claims (e.g. Homeopathic remedy)
  - For specific claims (e.g. Homeopathic remedy for the relief of X symptom)

- HMs have their own licensing pathway; it is one of three for NHPs, each with differing evidentiary standards for safety and efficacy:
  - **HM** – evidence must come from an accepted homeopathic reference (evidence for HM products may also come from clinical trial data)
  - **Modern NHP** – evidence is stratified by risk and ranges from clinical trials, to positive decisions from other regulatory agencies, to text book references
  - **Traditional NHP** – evidence must point to long history of use and come from pharmacopoeia or other reference texts deemed acceptable by Health Canada

- Evidence specific for HMs is used to support conditions of use, claims, dose, and route of administration, and comes from:
  - Provings (homeopathic testing)
  - References to Homeopathic pharmacopoeia or *Materia Medica*