Regulation of Homeopathic Medicines in Canada

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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 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.
• 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.
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 textbook 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*