Proposed Approach to Homeopathic Products:

Improved Evidence Requirements

Objective

The Department is aiming to align the evidence standards for homeopathic products making higher-risk claims with those for other natural health products (NHPs) making similar claims.

Background

Current evidence requirements allow homeopathic products to make claims for higher-risk, non-self resolving conditions as long as that specific claim can be found in homeopathic references, causing potential risk to health if the product is inefficacious.

This approach is out of alignment with:

- Recommendations of the Standing Committee on Health, that formed the basis of the *Natural Health Products Regulations* (NHPR) with regards to evidence requirements: "The evidence required vary depending on the type of claim being made".
- Requirements for other NHPs, particularly traditional products (e.g. Ayurveda, traditional Chinese medicine).
    - products with claims for higher-risk, non-self-resolving conditions are required to submit modern scientific evidence (as per the Pathway for NHPs Making Modern Health Claims guidance document) equivalent to the approach laid out in the Pathway for Licensing Natural Health Products Making Traditional Claims.

As part of the Self-Care Framework (SCF), Health Canada committed to align the evidence standards by requiring that similar health claims be supported by comparable evidence. Health Canada is proposing to update the evidence standards for homeopathic products to align with changes to NHP labelling requirements. While this change is expected to affect a small number of products, it will ensure that label updates are made at the same time as opposed to sequentially, thereby reducing burden.

Proposal

It is proposed that evidence requirements for homeopathic products be aligned with those for other natural health products including traditional products making similar higher-risk claims.

This means that products with claims for higher-risk, non-self resolving conditions (referred to also as Category III products) would be required to go through the Pathway for Licensing Natural Health Products Making Modern Health Claims, as such requiring modern scientific evidence to support product claims. For these products, the use of the proposed disclaimer for homeopathic products, as described in Annex A of the Guidance Document: Labelling of Natural Health Products would not be appropriate.

Licence holders for higher-risk homeopathic products would have a transition period to provide modern scientific evidence to support any higher-risk claim (i.e., in line with the transition period for marketed products transitioning to the new labelling requirements).

Methodology

Consistent with proposed risk-based categorization system under the SCF, which Health Canada has been consulting on since 2016, the following categorization is proposed (as shown in the chart below).

<table>
<tr><th>CATEGORY 1
(Lowest Risk)</th><th>CATEGORY 2
(Lower Risk)</th><th>CATEGORY 3
(Higher Risk)</th></tr>
<tr><td>• Not sterile
• Topical or buccal
○ Used on the skin
• Locality
○ Effect not conferred through absorption in the blood (local)</td><td>• Those that confer effect through any route of administration
○ Systemic or local effect</td><td>• Narrow safety margin
○ Higher toxicity or frequent misuse
○ Frequent and serious side effects
• Risk of inefficacy
○ Does not self-resolve or self-limit and escalates to a major or serious risk
○ Treat a serious condition or disease (non-symptomatic)
• New product category without a history of safety
○ Switch products
○ New ingredients
○ Listed on a negative schedule requiring higher oversight</td></tr>
<tr><td colspan="2">• No serious impact if inefficacious
○ For minor skin or mouth disease or condition (or symptoms)
○ Disease or condition is self-resolving or self-limited (won't progress)
• Has a broad margin of safety
○ Low risk ingredients (e.g., low toxicity, infrequent misuse)
○ No frequent and serious side effects</td><td></td></tr>
</table>

This definition of use was applied in attempting to determine, for consultation purposes, what is a higher-risk product that would require scientific evidence. Since, with respect to the formulation of such products, most homeopathic products are low-risk (as long as they are diluted properly), the main area of focus for this exercise was with respect to the health claim. In particular, the potential serious impact if the product were to be inefficacious.

With respect to determining what is a higher-risk health claim, Health Canada looked at several key sources where risk is defined by the health claim (or more importantly, if the product were not to confer efficacy). This included:

- analysing the health claims for existing homeopathic products to identify those linked to non-self resolving/limiting conditions (which would move them out of Category I or II under the Self-Care Framework)

- cross-referencing this list with a departmental list of Schedule A.1 proxy claims for NHPs (those that cannot be referenced with respect to treat, mitigate, diagnose or cure)
- ensuring alignment with the list of higher-risk claims under the Pathway for Licensing Natural Health Products used as Traditional Medicines (which was found to be consistent with the understanding of risk within the Self-Care Framework), and
- taking into consideration the risk-based criteria for departmental inspection triaging.

Next Steps

Health Canada is continuing to work on the categorization of natural health products under the SCF, including natural health products, and homeopathic products.

For the period of time from July- August 2021, we are seeking feedback on a proposed list of higher-risk claims that is attached in Annex A. Of note, this won't be the last opportunity for providing feedback on the list. There will be further opportunities for feedback on this as a part of the larger consultation on the SCF this Fall. We are seeking your feedback now to refine the list for a consultation in the Fall 2021.

Annex A: Proposed list of higher risk claims for homeopathic products that would require modern scientific evidence

Treatment, mitigation, diagnosis or cure of (excluding symptoms unless noted otherwise):

- Abscesses
- Anal fissures
- Anemia
- Anxiety
- Treatment of arthritis (e.g. gout, osteoarthritis, rheumatic pain/rheumatoid arthritis, spondylitis, tophi)
- Cataracts
- Chicken pox and shingles
- Childbirth and lactation
- Chronic constipation
- Conjunctivitis
- Cystitis
- Dermatitis (e.g. eczema)
- Dislocated joints
- Earache
- Gastroesophageal reflux disease and acid reflux
- Periodontitis and associated symptoms (e.g. bleeding gums, tooth loss)
- Intestinal parasites/worms
- Kidney stones
- Liver dysfunction
- Menstrual irregularities
- Osteoporosis
- Other infections that left untreated will lead to serious risks, including ear infections, bacterial infections and urinary tract infections
- Prostate health
- Psoriasis
- Respiratory conditions with potential for serious complications(e.g. laryngitis, pharyngitis, sinusitis, tonsillitis)
- Ulcers
- Venous circulation disorders
- Yeast infection (Candida)
- Products with an ocular/ophthalmic route of administration