Evidence for homeopathic medicines

Natural and Non-prescription Health Products Directorate guidance document

This guidance document was updated on July 6, 2022 to provide details on the updated evidence requirements for homeopathic products making higher-risk claims. Please see Sections 1.2, 3.2 and Appendix 4 for more information.

About this guidance document

The *Natural Health Products Regulations* (the NHPR) require all homeopathic medicines to have a licence before being sold in Canada. Licence holders are issued a product number, which must appear on the label of their product. The product number for homeopathic medicines is preceded by a DIN-HM. To obtain a DIN-HM, a Product Licence Application (PLA) form must be completed by applicants. These applications are assessed by the Natural and Non-prescription Health Products Directorate (NNHPD), which is responsible for issuing product licences for all natural health products (NHPs). The NNHPD uses evidence submitted by applicants to critically assess the safety, efficacy and quality of NHPs prior to approving them for sale in Canada.

The legal requirements for NHPs in Canada are found in the NHPR. This guide is based on the NHPR and is intended to be used as a tool when applying for a product number (DIN-HM) for a homeopathic medicine. The NNHPD reserves the right to request information, material or changes related to a PLA that may not be indicated in this guide.

To complete a PLA form, you may wish to consult the Natural Health Product Licence Application Form User Guide, as well as the instructions embedded in the PLA form. Applicants may also need to consult the document entitled Pathway for Licensing Natural Health Products Making Modern Health Claims and the Guidance Document: Labelling of Natural Health Products. For more information on how applications are managed, refer to the Natural Health Products Management of Applications Policy.

This guide should be read in parallel with the NHPR, which came into effect on January 1, 2004 and were updated on July 6, 2022. This guide refers to other NNHPD documents found on the Internet. Definitions of terms used in the guide are provided in the **Glossary**.

Table of contents

- 1.0 General information
  - 1.1 Definition of a homeopathic medicine
  - 1.2 Evidence to support the use of homeopathic medicines
- 2.0 Homeopathic medicine representation on the product license application form
  - 2.1 Part 4, Product information
  - 2.2 Part 4, Section A - Medicinal ingredients
  - 2.3 Part 4, Section D - Recommended conditions of use
- 3.0 Evidence requirements for homeopathic medicines
  - 3.1 Types of evidence
  - 3.2 Evidence to support a specific recommended use or purpose
  - 3.3 How to include evidence with the product licence application
- 4.0 Quality

- 5.0 Labelling
  - 5.1 Submission of label text
  - 5.2 Labelling requirements specific to homeopathic medicines
  - 5.3 Front-of-package statement
  - 5.4 Labels for very small and small packages
- 6.0 Glossary of terms
- Appendix 1: Substances eligible for a DIN-HM under the NHPR
- Appendix 2: Substances not regulated under the NHPR
- Appendix 3: Examples of references for homeopathic medicines with a specific recommended use or purpose
- Appendix 4: Examples of higher-risk claims for homeopathic medicines with specific recommended conditions of use
- Appendix 5: Specific quality requirements for medicinal ingredients used in homeopathic medicines

1.0 General information

1.1 Definition of a homeopathic medicine

To be considered a homeopathic medicine, a product must meet two criteria. It must be:

1. Manufactured from, or contain as medicinal ingredients, only substances referenced in a homeopathic monograph in one of the following homeopathic pharmacopoeias, as they are amended from time to time:
   - *Homeopathic Pharmacopeia of the United States* (HPUS)
   - *Homöopathisches ArzneiBuch* (HAB) or *German Homeopathic Pharmacopoeia* (GHP)
   - *Pharmacopée française* or *French Pharmacopoeia* (PhF)
   - *European Pharmacopoeia* (Ph.Eur.)
   - *Encyclopedia of Homeopathic Pharmacopoeia* (EHP)
2. Prepared in accordance with the methods outlined in one of the homeopathic pharmacopoeias listed above, as they are amended from time to time.

1.1.1 Homeopathic medicines eligible for a DIN-HM

Provided the medicinal ingredients are found in one of the aforementioned pharmacopoeias and are not prohibited in the NHPR, homeopathic medicines manufactured from the following are eligible for a licence:

- Substances listed on Schedule D of the *Food and Drugs Act* (Biologics, see **Appendix 1**).
- Substances exempted from the *Tobacco Act* because they are subject to the *Food and Drugs Act*, such as homeopathic *tabacum* and *nicotinum* (see **Appendix 1**).
- Substances listed on Prescription drug list (Prescription Drugs, see **Appendix 1**).
- Any substance derived from an animal material. If animal material is contained in the product or was used in the manufacturing of the product, the application must include a completed Animal Tissue Form for each animal material.
- Substances used to manufacture nosodes, isodes, sarcodes, and allersodes. Additional labelling requirements for nosodes can be found in Annex A of the Labelling of Natural Health Products Guidance Document.

1.1.2 Homeopathic medicines eligible for a DIN-HM above a specific homeopathic potency

Due to the potential toxicity of certain medicinal ingredients, some homeopathic medicines will only be authorized for sale if they meet a minimum homeopathic potency established by the NNHPD. Such minimum potencies are based on emerging science, quality observations and adverse reactions and will therefore be higher than the minimum potencies indicated by homeopathic pharmacopoeia. In such cases, the minimum potency established by the NNHPD supersedes any lower potencies indicated by the homeopathic pharmacopoeia, which can be found in the Natural Health Products Ingredient Database (NHPID). The NHPID indicates the minimum acceptable potency for all homeopathic ingredients, if applicable, and should therefore be consulted before filing a PLA form for a homeopathic product.

Additionally, homeopathic medicines listed in the HPUS with "N/A" as the OTC limit and homeopathic medicines with no minimum homeopathic potency in any accepted homeopathic pharmacopoeia must be 12 CH (or equivalent dilution) or higher.

1.1.3 Homeopathic medicines not eligible for a DIN-HM

The NHPR do not apply to homeopathic medicines manufactured from substances on the following lists:

- Schedules I to V of the *Controlled Drugs and Substances Act*
- Schedule C of the *Food and Drugs Act* (Radiopharmaceuticals)

These substances are listed in **Appendix 2**.

Homeopathic medicines intended for injectable use are also excluded from the NHPR.

Products containing medicinal ingredients not found in any of the five accepted pharmacopoeia are not eligible for a DIN-HM. Applicants may apply for a Natural Product Number (NPN) for these products, in which case the evidence requirements outlined in the Pathway for Licensing Natural Health Products Making Modern Health Claims guidance document must be met.

1.1.4 Combination homeopathic medicines

A combination (multiple-ingredient) homeopathic medicine is defined as a homeopathic medicine manufactured from two or more medicinal ingredients. While homeopathic medicines with a single medicinal ingredient are not permitted to make any claim other than "Homeopathic Medicine," "Homeopathic Remedy" or "Homeopathic Preparation", combination homeopathic medicines may make specific claims if supported by homeopathic references.

In combination homeopathic medicines with a specific recommended use or purpose, the homeopathic potency of all medicinal ingredients must generally be between the minimum homeopathic potency indicated in the NHPID and 30 CH or its equivalent. That is, 30 CH or its equivalent is usually the maximum homeopathic potency for homeopathic medicines with a specific recommended use or purpose.

An applicant may submit a PLA for a homeopathic medicine above 30 CH with a specific recommended use or purpose, if evidence is provided to support the safety of the proposed homeopathic potency. The NNHPD will evaluate these on a case-by-case basis.

Products containing a combination of homeopathic and non-homeopathic medicinal ingredients will not be evaluated as homeopathic medicines. Instead, they will be evaluated as NHPs eligible for a NPN or as non-prescription drugs if eligible for a DIN.

1.2 Evidence to support the use of homeopathic medicines

Applicants are responsible for submitting evidence to support the safety, efficacy and quality of a homeopathic medicine, as per Section 5(g) of the NHPR. The evidence submitted must support the proposed Recommended Conditions of Use of the homeopathic medicine.

There are two categories of homeopathic medicines:

- Homeopathic medicines that state a specific recommended use or purpose, and
- Homeopathic medicines that do not state a specific recommended use or purpose (see **chapter 2.2.1** for a definition of each category).

Homeopathic medicines that state a specific recommended use or purpose must be suitable for self-care and not require the supervision of a health care practitioner. Homeopathic medicines that do not state a recommended use or purpose are considered to have a non-specific recommended use or purpose. These medicines are intended for use by the consumer within the context of advice by a health care practitioner. Therefore, they may state a direction of use to the effect of, "To be used as directed by a health care practitioner."

The evidence required will vary depending on which category the homeopathic medicine falls into (specific or non-specific recommended use or purpose) as outlined in **chapter 3**. For homeopathic medicines that fall into the specific recommended use or purpose category, the evidence required will further vary

depending on the level of risk of the health claim, with higher risk claims requiring sufficient modern scientific evidence (e.g. clinical data). Information supporting the recommended conditions of use must be provided by referencing evidence such as clinical trials and/or published homeopathic references. See Appendix 3 for a list of sample references.

Higher-risk homeopathic products are those for non-self resolving or self-limited conditions with potential for harm to health if product efficacy is underperforming. See Section 3.2 and Appendix 4 of this Guidance document for more information on homeopathic products with higher-risk claims.

2.0 Homeopathic medicine representation on the product license application form

2.1 Part 4, Product information

Route of administration

Indicate the route by which the homeopathic medicine is to be delivered.

Routes of administration for homeopathic medicines include, but are not limited to: oral, sublingual, nasal, ophthalmic and topical.

Homeopathic medicines marketed for injectable use (i.e. employing any route of administration requiring puncturing of the dermis) are not covered under the NHPR, and will therefore not be eligible for DIN-HMs. Injectable drug products are regulated under the *Food and Drug Regulations*.

Dosage form

Acceptable dosage forms for homeopathic medicines are those outlined in the accepted homeopathic pharmacopoeia. Dosage forms include, but are not limited to:

- powder;
- granule;
- pellet/globule/pilule;

- tablet;
- solution;
- ointment/cream/lotion/gel;
- syrup; or
- suppositories.

Please note that Appendix 8 of the Product Licensing Guidance Document defines dosage forms.

All dosage forms must meet regulatory requirements, such as those related to quality.

Sterile

Indicate if the homeopathic medicine will be a sterile product. Homeopathic medicines designed for ophthalmic purposes are required to be sterile. Please refer to the Good Manufacturing Practices Guidance Document for the requirements for manufacturing and packaging of sterile products.

2.2 Part 4, Section A - Medicinal ingredients

Standard or grade

A monograph from one of the accepted homeopathic pharmacopoeias must be referenced for each medicinal ingredient. Enter into this box the acronym for the homeopathic pharmacopoeia referenced. Please refer to the acronyms in **chapter 1.1**.

Proper and common names

The NHPID indicates the acceptable proper and common names for each homeopathic ingredient. If a name is not indicated in the NHPID, a Database Issue form should be submitted to NNHPD to request an addition of the proper and/or common name with supporting evidence. Information on the Database Issue form is available on the NNHPD's website.

Quantity per dosage unit (homeopathic potency)

The term "Quantity", as it appears on the PLA form, refers to the amount of medicinal ingredient per dosage unit. A statement of quantity is required for all medicinal ingredients. Enter the homeopathic potency (e.g. 12 CH) in the column entitled "Quantity" on the PLA form. Do not enter the homeopathic potency in the column entitled "Potency".

For homeopathic medicines containing a single medicinal ingredient, one DIN-HM may apply to more than one homeopathic potency. In these cases, only the lowest homeopathic potency need be entered on the PLA form for evaluation. The DIN-HM assigned will apply to all homeopathic potencies higher than the one approved.

If the applicant would also like to indicate an amount (in millilitres, milligrams, etc.) for a medicinal ingredient, in addition to a homeopathic potency, this information should be added to the PLA form under "Potency".

Note that Hahnemanian and Korsakovian dilutions are considered interchangeable for product licensing purposes.

Table 1 - Dilution scales

Scale	Designation equivalence
Decimal (1/10)	X = D = DH
Centesimal (1/100)	CH = C = CK = K
Millesimal (1/1000)	M = MK
50 Millesimal (1/50,000)	LM = Q

Minimum homeopathic potency

The medicinal ingredients in some homeopathic medicines are potentially toxic at material doses. The serial dilutions involved in the manufacture of a homeopathic medicine are a factor which mitigates the risk of toxicity from these medicinal ingredients.

The minimum acceptable potency for a homeopathic ingredient may be higher than that listed in a homeopathic pharmacopoeia, based on emerging evidence, such as adverse reactions for that ingredient. The NHPID must therefore be consulted to verify the acceptable minimum potency for each homeopathic ingredient.

Potency

This field of the PLA form is applicable to homeopathic medicines only if a homeopathic manufacturer would also like to indicate an amount (in millilitres, milligrams, etc.) for a medicinal ingredient, in addition to a homeopathic potency. Please enter the amount (mL, mg, %, etc.) in the sub-column "Amount" and repeat the homeopathic potency in the sub-column "Constituent."

For example:
Potency amount: 25 mg
Potency constituent: of D3 dilution

Please note that the homeopathic potency of each ingredient must still be filled out in the "Quantity" section.

Source information

The NHPID indicates the acceptable source materials for each homeopathic ingredient. If a source material is not indicated in the NHPID, a Database Issue form should be submitted to NNHPD to request an addition of the source material with supporting evidence. Information on the Database Issue form is available on the NNHPD's website.

Table 2: Examples of source material for homeopathic medicines.

Category	Medicinal Ingredient Proper Name	Source Material (homeopathic pharmacopoeial definition)
Plant or Plant Material	*Lycopodium clavatum*	(Part of the plant) spores

Category	Medicinal Ingredient Proper Name	Source Material (homeopathic pharmacopoeial definition)
Animal Material (Excluding sarcodes)	*Lachesis mutus*	(Part of the animal) venom
Mineral/Chemical	*Hydrocyanicum acidum* or Hydrogen cyanide	(The name of the mineral or chemical as written on the homeopathic monograph.) Hydrogen cyanide
Nosode	*Medorrhinum*	(Summary of the description as stated in the referenced homeopathic pharmacopoeia) Sterilized extract of purulent urethral secretions from blennorrhagia, containing *Neisseria gonorrhoeae*
Sarcode	*Thyroidinum*	(Animal source plus part) Bovine thyroid

Extract

Not applicable to homeopathic medicines. Please leave this section blank.

Method of preparation

For each medicinal ingredient, indicate the acronym for the homeopathic pharmacopoeia being referenced as well as the method number/class (e.g. HAB Method 4a). See the NHPID, for the acceptable method of preparation for each medicinal ingredient.

An applicant is permitted to reference a method of preparation from one homeopathic pharmacopoeia even if the medicinal ingredient does not appear in that same pharmacopoeia (e.g. HPUS medicinal ingredient that uses a HAB method

of preparation). By stating the method used, the applicant is attesting that the pharmacopoeial method that is followed is appropriate for the medicinal ingredient being used. These applications will be evaluated on a case-by-case basis.

2.3 Part 4, Section D - Recommended conditions of use

Recommended use or purpose

For the purpose of product licensing, homeopathic medicines will be classified into one of two categories based on the homeopathic medicine's recommended use or purpose (claim).

The two categories are:

- Homeopathic medicines with a ***non-specific*** recommended use or purpose; and
- Homeopathic medicines with a ***specific*** recommended use or purpose.

a) Homeopathic medicines with a non-specific recommended use or purpose

No recommended use or purpose (claim) is permitted for these homeopathic medicines. The terms "Homeopathic Medicine", "Homeopathic Preparation" or "Homeopathic Remedy", must appear on the label in place of any claim.

These homeopathic medicines may be single or combination homeopathic medicines.

Any homeopathic potency is acceptable for these homeopathic medicines as long as the homeopathic potency of each medicinal ingredient is equal to or higher than the minimum homeopathic potency indicated in the NHPID.

Table 3 describes the allowable homeopathic potencies for homeopathic medicines with non-specific claims.

b) Homeopathic medicines with a specific recommended use or purpose

An applicant may propose a specific recommended use or purpose if:

- The homeopathic medicine contains two or more medicinal ingredients.
- The claim is supported by homeopathic references.

- The claim identifies a specific symptom or set of symptoms that the homeopathic medicine is intended to treat. The applicant must ensure that the claim does not include any condition listed on Schedule A of the *Food and Drugs Act*.
- The claim is suitable for self-care and does not require the supervision of a health care practitioner.

If the specific recommended use or purpose is for a higher-risk claim, the applicant must submit sufficient modern scientific evidence (e.g. sufficient clinical data) with their PLA. Higher-risk homeopathic products are those for non-self resolving or self-limited conditions with potential harm to health if product efficacy is underperforming. See Sections 1.2, 3.2 and Appendix 4 of this Guidance document for examples of higher-risk claims.

The claim must appear on the label using specific, current and unambiguous terms. The claim may also be followed by wording to the effect of, "...or to be used as directed by a health care practitioner".

The homeopathic potency of all medicinal ingredients in homeopathic medicines with a specific recommended use or purpose must generally be between the minimum homeopathic potency indicated in the NHPID and 30 CH or its equivalent. That is, 30 CH or its equivalent is the maximum homeopathic potency for homeopathic medicines with a specific recommended use or purpose.

An applicant may submit a PLA for a homeopathic medicine above 30 CH with a specific recommended use or purpose, if sufficient evidence is submitted to support the safety of the proposed homeopathic potency. The NNHPD will evaluate these on a case-by-case basis.

Table 3 summarizes the allowable homeopathic potencies for homeopathic medicines with specific claims.

Table 3: Summary of allowable homeopathic potencies by category

Minimum homeopathic potency	*Non-specific* claim (Single or combination medicine)	*Specific* claim (Combination medicine only)
Stated in an accepted pharmacopoeia	Lower limit: as stated in the pharmacopoeia/NHPID [1] Upper limit: no upper limit	Lower limit: as stated in the pharmacopoeia/NHPID [1] Upper limit: 30 CH
NOT stated in an accepted pharmacopoeia	Lower limit: 12 CH Upper limit: no upper limit	Lower limit: 12 CH Upper limit: 30 CH

1 Minimum dilutions indicated in NHPID supersede minimum pharmacopoeial dilutions when different (see Section 1.1.2).

Recommended dose

The information below regarding recommended dose applies to all homeopathic medicines, irrespective of the recommended use or purpose. Table 4 outlines recommended doses for several common dosage forms. The recommended dose for solid dosage forms is the same for adults, seniors and children. The recommended dose for liquid forms differs for adults and children.

a) Sub-population group

Enter the group to which the homeopathic medicine is targeted. Most often, this will be "adults", but may also be "children", "infants", "seniors", "men" or "women". If the homeopathic medicine is targeted to children or infants, the age group(s) must be indicated as well. The following age categories are recommended in most cases: infants 0-11 months; children 1-5 years; children 6-11 years; adults and children 12 and over.

b) Amount to be taken at one time

No. of Dosage Units: Indicate the amount of product to be taken at one time (e.g. 3).
Dosage Unit: Indicate the unit (e.g. pellet)

For non-discrete dosage forms (e.g. powder, liquid, cream), the dosage unit may be expressed as teaspoon, mL, grams, scoop, dropper, etc.

Example - liquid:
No. of Dosage Units: 2
Dosage Unit: teaspoons (5mL)

Example- topical cream:
No. of Dosage Units: apply sparingly
Dosage Unit: cream

c) Frequency

Indicate how often the product should be taken. Example: Three times a day.

Applicants are not permitted to include the term "or as needed" (e.g. four times per day or as needed") as part of the dose frequency (this limitation is not applicable to topical products). A statement to the effect of "four times per day, or as directed by a health care practitioner" would be acceptable.

d) Directions for use

Enter any additional information that may help the consumer receive maximum benefit from the product. For example:

- "Take at least one hour before or after eating."
- The dosing specifications for acute conditions (see Table 4).
- "Dissolve tablet in water before administering."

For children 0-2 years old, the directions for use should include instructions to dissolve the solid dosage form (e.g. granules, globules, tablets) in a small amount of water.

Table 4: Dosage forms and their suggested recommended dose

Dosage Form	Sub-Population	Amount	Frequency	Acute Dosing
Granules (small pellets, pilules) (Oral)	Adults and children ≥ 12 years	1 whole unit dose (tube or container)	Once daily	10-20 granules 2-3 times daily
	Children 1-11 years [1]			
	Infants 0-11 months [1]			
Globules (regular and large pellets)	Adults and children ≥ 12 years	3-5 globules	2-3 times daily	Every 15-60 min. (up to 12 times/day) or until improvement of symptoms. Then resume general dosing.
	Children 1-11 years [1]			
	Infants 0-11 months [1]			
Tablets	Adults and children ≥ 12 years	1-4 tablets	1-4 times per day	Every 15-60 min. (up to 12 times/day) or until improvement of symptoms. Then resume general dosing.
	Children 6-11 years	1-3 tablets	1-4 times per day	
	Children 1-5 years [1]	½ - 3 tablets	1-3 times per day	
	Infants 0-11 months [1]	½ - 3 tablets	1-2 times per day	

1 Dissolve dose in a small amount of water before administration to infants and children 0-2 years old.

Dosage Form	Sub-Population	Amount	Frequency	Acute Dosing
Oral Drops	Adults and children ≥ 12 years	10-30 drops	1-3 times per day	Every 15-60 min. (up to 12 times/day) or until improvement of symptoms. Then resume general dosing.
	Children 6-11 years	5-15 drops		
	Children 1-5 years	5-10 drops		
	Infants 0-11 months	1-5 drops		
Liquid (Oral drinkable vials)	Adults and children ≥ 12 years	1 ampoule	1-3 times per day	Up to three times per day
	Children 6-11 years	2/3 ampoule		
	Children 1-5 years	½ ampoule		
	Infants 0-11 months	1/3 ampoule		

1 Dissolve dose in a small amount of water before administration to infants and children 0-2 years old.

Dosage Form	Sub-Population	Amount	Frequency	Acute Dosing
Oral solution (Unit dose)	Adults and children ≥ 12 years	Unit oral dose	1-3 times per day	Give one unit dose upon onset of symptoms. Repeat two more times at 15-minute intervals. Repeat process up to 9 times per day if symptoms reappear.
	Children 1-11 years			
	Infants 0-11 months			
Oral Syrup	Adults and children ≥ 12 years	1-2 tsp	Every 4 to 6 hours	Not applicable
	Children 1-11 years	½ -1 tsp	1-3 times per day	
	Infants 0-11 months	½ tsp	1-3 times per day	
Cream/Ointment	Adults and children	Cover affected area	Use as needed	Not applicable

1 Dissolve dose in a small amount of water before administration to infants and children 0-2 years old.

Dosage Form	Sub-Population	Amount	Frequency	Acute Dosing
Nasal spray	Adults and children ≥ 12 years	1-2 sprays/nostril	3-5 times per day	Not applicable
	Children 1-11 years	1 spray/nostril	4 times per day	
	Infants 0-11 months	1 spray/nostril	4 times per day	
Eye Drops	Adults and children ≥ 12 years	2-3 drops	3 times per day	1 drop in the affected eye every 15 minutes for a maximum of 3 hours.
	Children 1-11 years	1-2 drops	3 times per day	
	Infants 0-11 months	1 drop	2 times per day	
Ear Drops	Adults and children ≥ 12 years	1 complete vial	3 times per day	Every 15-60 minutes (up to 12 times per day) or until improvement of symptoms. Then resume general dosage.
	Children 1-11 years	3-4 drops		
	Infants 0-11 months	2-3 drops		

1 Dissolve dose in a small amount of water before administration to infants and children 0-2 years old.

Dosage Form	Sub-Population	Amount	Frequency	Acute Dosing
Suppositories	Adults and children ≥ 12 years	1 suppository	1-4 times per day	Maximum 5 per day
	Children 6-11 years		1-3 times per day	Maximum 4 per day
	Children 1-5 years		1-2 times per day	Maximum 3 per day
	Infants 0-11 months		1-2 times per day	Maximum 2 per day

[1] Dissolve dose in a small amount of water before administration to infants and children 0-2 years old.

Product licence applicants may recommend a dose amount and frequency not outlined above providing the recommendation is accompanied by an adequate rationale.

Duration of use

This refers to a time frame during which it is safe to consume the product without causing health concerns.

a) Non-specific recommended use or purpose

A duration of use statement indicating a specific time frame is optional.

b) Specific recommended use or purpose

A duration of use statement, indicating a specific time frame, is required.

Applicants are advised to establish a duration of use that is appropriate to the condition and/or symptoms stated as the recommended use or purpose. The duration of use should take into consideration the following:

- For some conditions, it is expected that symptoms improve more slowly than for other conditions (homeopathic medicines may be taken for prolonged periods).
- The persistence and/or worsening of symptoms associated with some conditions will warrant consultation with a health care practitioner.
- The development of new symptoms may warrant consultation with a health care practitioner.

Therefore, statements such as "If symptoms persist or worsen, consult a health care practitioner" or "If symptoms do not improve within 7 days, consult a health care practitioner" would be acceptable for the Duration of Use.

Risk information

Cautions and warnings, contraindications and known adverse reactions

Risk information regarding cautions, warnings and contraindications is mandatory where safety concerns have been noted. You must declare any known risk information associated with the use of the product, including all of the risk statements in your terms of market authorization.

Additionally, unless evidence is provided which specifically supports the safety of the medicinal ingredients in pregnant and breastfeeding women, the statement "If you are pregnant or breastfeeding, consult a health care practitioner prior to use" is required.

Homeopathic medicines with a non-specific recommended use or purpose must include a risk statement to the effect of: "If symptoms persist or worsen, consult a health care practitioner," The wording "Or to be used as directed by a health care practitioner" as a direction for use is not adequate to meet the above requirement and, in this case, applicants will be required to also add the statement "If symptoms persist or worsen, consult a health care practitioner."

Homeopathic medicines with a specific recommended use or purpose must either provide risk information appropriate to the proposed claim *or* a statement to the effect of "If symptoms persist or worsen, consult a health care practitioner."

3.0 Evidence requirements for homeopathic medicines

3.1 Types of evidence

The NNHPD recognizes different levels of evidence, ranging from traditional use to randomized, placebo-controlled, double-blind clinical trials as outlined in the Pathway for Licensing Natural Health Products Making Modern Health Claims guidance document.

Homeopathic medicines must be supported by homeopathic provings or references such as the homeopathic *Materia medica*. In addition, sufficient modern scientific evidence (e.g. sufficient clinical data) may be used to support novel conditions of use which are not supported by homeopathic provings or references such as the homeopathic *Materia medica*.

3.2 Evidence to support a specific recommended use or purpose

Sufficient evidence must be provided to demonstrate a clear rationale for the inclusion of each medicinal ingredient in the homeopathic medicine. For a homeopathic medicine with a specific recommended use or purpose (claim), evidence must link each medicinal ingredient to the symptom(s) of the claim it is intended to address. It is not necessary to link each medicinal ingredient to every symptom included in the claim. For example, if the claim is "For the dyspepsia, nausea and bloating associated with indigestion", evidence might demonstrate that ingredient A helps relieve bloating and nausea, ingredient B also helps reduce nausea and ingredient C relieves dyspepsia.

See **Appendix 3** for a list of sample references for homeopathic medicines.

Homeopathic medicines with specific recommended uses or purposes classified as higher-risk must be supported by sufficient modern scientific evidence (e.g. clinical data). Higher-risk homeopathic products are those for non-self resolving or self-limited conditions with potential harm to health if product efficacy is underperforming (see Appendix 4 for examples).

3.3 How to include evidence with the product licence application

The PLA must include copies of the references for **each** medicinal ingredient. These copies must include:

- The text that makes reference to the recommended use or purpose. It is the responsibility of the product licence applicant to indicate the exact information being referenced in order to ensure clarity; Applications containing evidence without this indication may take longer to assess than those where relevant sections have been clearly marked;
- The authorship;
- The edition;
- The year and the place of publication; and
- The title page.

For homeopathic products making higher risk claims, the PLA will be required to include sufficient modern scientific evidence (e.g. clinical data) to support the claims. Higher-risk homeopathic products are those for non-self resolving or self-limited conditions with potential harm to health if product efficacy is underperforming. See Appendix 4 for a list of examples.

4.0 Quality

Finished homeopathic medicines must meet the quality requirements outlined in the accepted homeopathic pharmacopoeias, as they are amended from time to time, as well as the general quality requirements specified by the NNHPD in the *Quality of Natural Health Products Guide*. For additional information on specific

quality requirements for homeopathic medicines, please refer to **Appendix 5**. Additionally, all finished products must be manufactured under conditions that comply with Section 3 of the NHPR that relate to good manufacturing practices.

5.0 Labelling

For general labelling requirements for all NHPs, please see the Guidance Document: Labelling of Natural Health Products.

5.1 Submission of label text

The NHPR requires that a printed version of the proposed label text for the homeopathic medicine be submitted with the PLA. Advertising information and graphics are not required.

5.2 Labelling requirements specific to homeopathic medicines

The following chart outlines statements that must appear on homeopathic medicines.

Table 5: Labelling requirements for homeopathic medicines.

	Homeopathic Medicines with a Non-Specific Claim	Homeopathic Medicines with a Specific Claim
Identification of Medicine Type	One of the following must appear on the label: "homeopathic medicine", "homeopathic remedy", "homeopathic preparation".	

	Homeopathic Medicines with a Non-Specific Claim	Homeopathic Medicines with a Specific Claim
Statement of Recommendation for Use or Purpose	No recommended use or purpose, whether explicit or implicit, is permitted on the label. If required to use a Product Facts Table, the "Uses" section should state "homeopathic medicine", "homeopathic remedy", or "homeopathic preparation".	Label must state at least one of the recommended use(s) or purpose(s) on the label in specific, current, unambiguous terms, or, when applicable, in accordance with the monograph.

	Homeopathic Medicines with a Non-Specific Claim	Homeopathic Medicines with a Specific Claim
Statement of Risk Information See Section 2.3 of this document for additional information on risk statements requirements.	Label must make statements to the effect of: "homeopathic medicine", "homeopathic remedy", "homeopathic preparation".	Risk information must be appropriate to proposed claim. In the absence of other risk statements, the label must include statements to the effect of: "Consult a health care practitioner/ health care provider/ health care professional/ doctor/ physician if symptoms persist or worsen" AND "Consult a health care practitioner/ health care provider/ health care professional/ doctor/ physician prior to use if you are pregnant or breastfeeding" (unless evidence is provided which specifically supports the safety of the medicinal ingredients in these subpopulations)

5.3 Front-of-package statement

All homeopathic products sold in Canada that do not submit sufficient modern scientific evidence (e.g. clinical data) to support their health claims as part of their PLA are required to include one of the following statements on the front of the package (principal display panel):

1. For any homeopathic product: "This/ These claim(s) is/are based on traditional homeopathic references and not modern scientific evidence."; or

2. For homeopathic products with a non-specific claim: "This product is based on traditional homeopathic references and not modern scientific evidence."

Please see Annex A of the Guidance Document: Labelling of Natural Health Products for more information on format requirements and flexibilities for this statement.

5.4 Labels for very small and small packages

The NNHPD recognizes that small packages, such as those used by some homeopathic medicine manufacturers, may not have an area large enough for the labelling requirements. Flexibilities, exemptions, and specific small package labelling requirements have been introduced to accommodate these products. Please see the Guidance Document: Labelling of Natural Health Products for more information.

6.0 Glossary of terms

Allersode:

Homeopathic preparations of antigens, (substances which, under suitable conditions, can induce the formation of antibodies). Antigens include toxins, ferments, precipitinogens, agglutinogens, opsonogens, lysogens, venins, agglutinins, complements, opsonins, amboceptors, precipitins and most native proteins.

CFU:

Colony forming units (Absent refers to < 10 CFU per g or per mL)

Chemical name:

Any unambiguous chemical name provided by an authoritative reference such as the *Merck Index*, the *United States Pharmacopeia Dictionary*, etc., or a name determined using the *International Union of Pure and Applied Chemistry* (IUPAC) nomenclature system.

Combination (multiple-ingredient) homeopathic medicine:

A homeopathic medicine manufactured from two or more medicinal ingredients.

Dilution level:

See Homeopathic Potency.

Drug identification number (DIN):

The identification number located on the label of prescription and over-the-counter drug products that have been evaluated by the Therapeutic Products Directorate (TPD) and approved for sale in Canada.

DIN-HM:

Stands for DIN-Homeopathic Medicine and is the product licence number located on the label of homeopathic medicines that have been evaluated by the NNHPD and approved for sale in Canada.

Efficacy:

The extent to which a specific intervention, procedure, regimen or service produces a beneficial result under ideal conditions. In other words, it is the ability for a NHP to produce the desired health outcome, when it is used according to the Recommended Conditions of Use, under ideal conditions.

Expiry date:

The earlier of:

- the date, expressed at minimum as a year and month, up to and including which a NHP maintains its purity and physical characteristics and its medicinal ingredients maintain their quantity per dosage unit and their potency; and
- the date, expressed at minimum as a year and month, after which the manufacturer recommends that the NHP should not be used.

Higher-risk homeopathic medicine/ product:

Higher-risk homeopathic products are those for non-self resolving or self-limited conditions with potential harm to health if product efficacy is underperforming (see Appendix 4 for examples).

Homeopathic medicine:

Medicines that are manufactured only from those substances or sources referenced as monographs in the *Homeopathic Pharmacopeia of the United States* (HPUS), the *Homöopathisches ArzneiBuch* (HAB), the *Pharmacopée française* (PhF), the *European Pharmacopoeia* (Ph.Eur.) or the *Encyclopedia of Homeopathic Pharmacopoeia* (EHP), as they are amended from time to time, and that are prepared in accordance with these pharmacopoeias.

Homeopathic potency:

The strength or quantity of a homeopathic medicine. Also called homeopathic attenuation, the potency refers to the number of times the original substance has been diluted and succussed according to a method described in one of the accepted homeopathic pharmacopoeia. Homeopathic potency is written as a number associated with one of the following letters or combinations of letters: X, D, C, CH, K, CK, M, MK, LM or Q. Examples: *Arnica montana* 6X, *Chamomilla* 30 CH.

HPLC:

High-performance liquid chromatography

Indication for use:

A specific symptom or set of symptoms that the medicine is intended to treat. This term is replaced by the expression "recommended use or purpose", as stated in the Regulations and other guidance documents.

Isode:

Homeopathic preparations of botanical, zoological or chemical substances, including drugs, excipients or binders, which have been ingested or otherwise absorbed by the body and are believed to have produced a disease or disorder which interferes with homeostasis. They are sometimes referred to as Detoxodes.

Label:

Includes any legend, word or mark attached to, included in, belonging to or accompanying any food, drug, cosmetic, device or package.

Lot:

A quantity of any NHP in dosage form, a raw material or a packaging material, homogeneous within specified limits, constituting all or part of a single batch and identified by a distinctive lot number which appears on the label of the finished product.

Lot number:

Any combination of letters, figures, or both, by which a NHP can be traced in manufacture and identified in distribution.

Monograph (homeopathic):

A monograph is a written description in a pharmacopoeia of an individual homeopathic medicinal ingredient. The description includes, but is not limited to, information about the ingredient name, name synonym, description of the substance, preparation and homeopathic potency for various purposes.

Natural health product (NHP):

A substance set out in Schedule 1 of the Regulations or a combination of substances in which all the medicinal ingredients are substances set out in Schedule 1, a homeopathic medicine or a traditional medicine that is manufactured, sold or represented for use in:

- diagnosing, treating, mitigating or preventing a disease, disorder or abnormal physical state or its symptoms in humans;
- restoring or correcting organic functions in humans; or
- modifying organic functions in humans.

However, a NHP does not include a substance set out in Schedule 2, any combination of substances that includes a substance set out in Schedule 2 or a homeopathic medicine or a traditional medicine that is or includes a substance set out in Schedule 2.

Schedule 1 - Included natural health product substances

1. A plant or a plant material, an alga, a bacterium, a fungus or a non-human animal material
2. An extract or isolate of a substance described in item 1, the primary molecular structure of which is identical to that which it had prior to its extraction or isolation
3. Any of the following vitamins: biotin, folate, niacin, pantothenic acid, riboflavin, thiamine, vitamin A, vitamin B6, vitamin B12, vitamin C, vitamin D, vitamin E
4. An amino acid
5. An essential fatty acid
6. A synthetic duplicate of a substance described in any of items 2 to 5
7. A mineral
8. A probiotic

Schedule 2 - Excluded natural health product substances

1. A substance set out in Schedule C to the *Food and Drugs Act*.
2. A substance set out in Schedule D to the *Food and Drugs Act*, except for the following:
3. a drug that is prepared from any of the following micro-organisms, namely, an alga, a bacterium or a fungus; and
4. any substance set out on Schedule D when it is prepared in accordance with the practices of homeopathic pharmacy

5. A substance regulated under the *Tobacco Act*
6. A substance set out in any of Schedules I to V of the *Controlled Drugs and Substances Act*
7. A substance that is administered by puncturing the dermis.
8. An antibiotic prepared from an alga, a bacterium or a fungus or a synthetic duplicate of that antibiotic.

Natural product number (NPN):

Precedes the product licence number on the label of most NHPs that have been evaluated by the NNHPD and approved for sale in Canada. See also DIN-HM.

Nosode:

Homeopathic preparations of: pathological organs or tissues; causative agents such as bacteria, fungi, ova, parasites, virus particles and yeast; disease products; excretions or secretions.

Potency:

The amount per dosage unit of the standardized components that further characterizes the quantity of the ingredient. For example:

- quantity: 500mg *Echinacea purpurea* extract
- potency: 0.4% echinosides

For homeopathic medicines, please see definition above for Homeopathic Potency.

Product number:

An eight (8)-digit numerical code assigned to each NHP approved under the Regulations, (e.g. DIN-HM 80000001, NPN 80000002)

Quantity:

Refers to the amount of medicinal ingredient(s) per dosage unit. A statement of quantity is required for all products as it represents the amount of medicinal ingredient in the product. For homeopathic medicines, quantity is the homeopathic potency (see definition above).

Recommended conditions of use:

Refers to information about a NHP that enables consumers to make an informed choice regarding its use. It includes the following elements:

- recommended use or purpose;
- dosage form;

- recommended route of administration;
- recommended dose;
- recommended duration of use, if any; and
- risk information, including any cautions, warnings, contraindications or known adverse reactions associated with its use.

Safety:

The ability of a NHP to produce a beneficial health outcome, outweighing the risk associated with using it, in humans, according to the recommended conditions of use.

Sarcode:

Homeopathic preparations of wholesome organs, tissues, or metabolic factors obtained from healthy specimens.

Self-care:

Activities individuals undertake for the prevention, treatment and symptomatic relief of diseases, injuries or chronic conditions that individuals can recognize and manage on their own behalf, either independently or with participation from a health care practitioner.

Single-ingredient homeopathic medicine:

A homeopathic medicine with only one medicinal ingredient.

Source material:

For homeopathic medicines, source material is the starting substance of medicinal value used to manufacture a homeopathic medicine.

Appendix 1: Substances eligible for a DIN-HM under the NHPR

The substances listed below are found in accepted homeopathic pharmacopoeia and are covered by the NHPR. Therefore, they qualify for a DIN-HM.

Homeopathic medicines derived from substances on Schedule D of the *Food and Drugs Act* (Biologics)

Anthracinum

Elaps corallinus

Psorinum

Bacillinum pulmo

Hippozaeninum

Pyrogenium

BCG

Influenzinum

Sinusitisinum

Candida albicans

Lachesis mutus

Staphylococcinum

Candida parapsilosis

Lyssin

Streptococcinum

Cenchris contortrix

Medorrhinum

Syphilinum

Colibacillinum cum natrum muriaticum

Morbillinum

Tuberculinum

Crotalus cascavella

Naja tripudians

Vaccinotoxinum

Crotalus horridus

Pertussinum

Vipera berus

Diphtherinum

Proteus

Homeopathic medicines derived from substances regulated under the *Tobacco and Vaping Products Act*

Nicotinum

Tabacum

Homeopathic medicines derived from substances listed on Prescription drug list (Prescription substances)

Adrenocorticotrophin

Cortisone aceticum

Podophyllinum

Ammonium bromatum

Digitalinum

Podophyllum peltatum

Atropinum

Digitalis purpurea

Rauwolfia serpentina

Atropinum sulphuricum

Digitoxinum

Secale cornutum

Aurum bromatum

Hydrocotyle asiatica

Strontium bromatum

Aurum iodatum

Kali bromatum

Sulphanilamidum

Aurum metallicum

Lithium bromatum

Thyroidinum

Aurum muriaticum

Lithium carbonicum

Veratrinum

Aurum muriaticum kalinatum

Lithium muriaticum

Veratrum album

Aurum muriaticum natronatum

Natrum bromatum

Veratrum nigrum

Aurum sulphuratum

Nicotinum

Veratrum viride

Chloralum

Phenacetinum

Yohimbinum

Appendix 2: Substances not subject to the NHPR

These substances are found in accepted pharmacopoeia but are not subject to the NHPR and therefore do not qualify for a DIN-HM:

Homepathic medicines derived from substances in Schedules I to V of the *Controlled Drugs and Substances Act* (Narcotic ingredients)

Erythroxylon coca

Narceinum

Synthetic cannabinoid receptor type 1 agonists

Morphinum

Narcotinum

Cocainum

Morphinum aceticum

Opium

Cocainum muriaticum

Morphinum muriaticum

Phenobarbital

Codeinum

Morphinum sulphuricum

Homeopathic medicines derived from substances in Schedule C of the *Food and Drugs Act* (Radiopharmaceuticals)

Iridium metallicum

Strontium bromatum

Strontium nitricum

Radium bromatum

Strontium carbonium

Uranium nitricum

Appendix 3: Examples of references for homeopathic medicines with a specific recommended use or purpose

The following list of reference texts is intended as a guide only and is not intended to be all inclusive. The NNHPD does not specifically endorse any of the references listed. While references outside of this collection may also provide valuable

information, the use of references intended for use by the general public is not encouraged.

Allen, H.C. *The Materia Medica of the Nosodes*. India: Boericke et Tafel; 1910.

Allen, T.F. *The Encyclopedia of Pure Materia Medica*. A record of the positive effects of drugs upon the healthy human organism. New Delhi (India): Jain Publishers; 1877.

Allen T.F. *Encyclopedia of Pure Materia Medica*. (10 vol). Edit. New York, (NY): Boericke et Tafel; 1879-1974.

Boericke, W. Materia Medica with Repertory. New Delhi (India): Pratap Medical Publishers PVT Ltd; 1996.

Boericke, W. *Pocket Manual of Homeopathic Materia Medica with Repertory* (9th Ed.): New Delhi (India): Jain Publishers Pvt. Ltd. 1984, 1985 (Indian Reprint).

Bradford, L.Th. *Index to Homeopathic Provings*. India: Boericke et Tafel; 1901.

Charrette, G. *La Matière Médicale Homéopathique expliquée*. Paris (France): Le François; 1952 - 2ème édition, Le François; 1976.

Charrette, G. *La Matière Médicale Pratique*. France: Le François; 2ème édition, 1932, 3ème édition, 1949.

Chiron. *Eléments de Matière Médicale Homéopathique*. France: Peyronnet; 1935; 3ème édition; 1955.

Clarke, J.H. *A Dictionary of Practical Materia Medica*. (3 vol.). London (U.K.): The Homeopathic Publishing Co.; 1902.

Clarke, J.H. *Dictionary of Practical Materia Medica*. New Delhi (India): The Homeopathic Publishing Company; 1925.

Coulamy A., Jousset C. *Basses dilutions et drainage en homéopathie*. Paris (France): Similia; 2000.

Demarque D., Jouanny J., Poitevin B., Saint-Jean Y. *Pharmacologie et matière médicale homéopathique*. France: CEDH, 1993.

Duprat H. *Traité de matière médicale homéopathique*. France:
Tome I : Imprimerie de Trévoux; 1948.
Tome II : Baillière et fils; 1948.
Tome III : Georg & Cie; 1948.

Ecalle H., Delpech L., Peuvrier A. *Pharmacopée Homoeopathique française*. Paris (France): Librairie J.B. Baillière et Fils; 1898.

Espanet, A. *Traité méthodique et pratique de matière médicale & de thérapeutique.*. Paris (France): Baillière; 1861.

Fare, Ch. *Éléments de matière médicale homéopathique vétérinaire*. France: CEDH; 1993.

Farrington, E.A. *A Clinical Materia Medica*. Philadelphia (PA): Sherman & Co.; 1887.

German Commission D. Keller K., Greiner S., Stockebrand P. *Homöopathische Arzneimittel - Materialien zur Bewertung* (Commission D). Francfort (Allemagne): Govi Verlag, Band I, II, III;1995.

Ghose, S.C. *Drugs of Hindoosthan*. Calcutta (India): Hahnemann Publishing Co. Private Ltd.; 1970.

Guermonprez, Michel et al. *Matière médicale homéopathique*. (1 vol.). Paris (France): Doin Editeurs; 1985.

Guermonprez M., Pinkas M., Torck M. *Matière médicale homéopathique*. France: Boiron; 1995.

Hahnemann C.F.S., Jourdan A.J.L. [Trad. de]. *Traité de matière médicale ou de l'action pure des médicaments homéopathiques*. Paris (France): Baillière; 1834.

Hahnemann S., Jourdan A.J.L. [Trad. de]. *Doctrine et traitement des maladies chroniques*. Paris (France): Baillière; 1846.

Hahnemann S., Simon V. et L. [Trad. de]. Traité de matière médicale homéopathique comprenant les pathogénésies du traité de matière médicale pure et du traité des maladies chroniques. Paris (France): Baillière; 1891.

Hering C. *The Guiding Symptoms of our Materia Medica*. (10 vol.), Philadelphia (PA): Boericke et Tafel; 1890.

Hering, C. *The Guiding Symptoms of our Materia Medica*. New Delhi (India): Jain Publishers; 1974.

Homoepathic Pharmacopoeia of India. India: Government of India, Ministry of Health; 1971.

Homöopathisches Arzneibuch 2000 (German Homeopathic Pharmacopoeia). Stuttgart (Germany): medpharm GmbH Scientific Publishers; 2003.

Horvilleur A. *Matière médicale homéopathique*. Lyon (France): Camugli; 1979.

Jahr, G.H.G., Catellan Frères. *Nouvelle Pharmacopée Homoeopathique*. Paris (France): J.B. Baillière et Fils; 1862.

Jouanny, J. *The Essentials of Homeopathic Materia Medica*. France: Boiron; 1984.

Jouanny J. *Notions essentielles de matière médicale homéopathique*. Lyon (France): Boiron; 1975.

Julian O.A. *Matière médicale d'homéopathie*. Paris (France): Peyronnet; 1971.

Julian, O.A. *Biothérapiques et Nosodes*. Paris (France): Librairie Maloine S.A.; 1962

Julian, O.A. *Dictionnaire de Matière médicale homéopathique - Les 130 nouveaux homéothérapiques*. Paris (France): Masson; 1981.

Kent, J.T. *Matière médicale homéopathique*. France: Annales Homéopathiques Françaises; 1976.

Kent, J.T. *Repertory of Homeopathic Materia Medica*. Delhi (India): B. Jain Publishers (P) Ltd.; 1996.

Kollitsch, P. *Homéopathie. Matière Médicale. Thérapeutique*. Paris (France): Maloine; 1965.

Lathoud, J.A. *Études de Matière Médicale Homéopathique*. France: Martin & Ternet; 1982.

Murphy, R. *Homeopathic Remedy Guide* (2nd edition). Blacksburg (Virginia): H.A.N.A. Press; 2000.

Nash, E.B. *Principe de Thérapeuthique Homéopathique*. France: Doin; 1950.

Sarembaud A., Poitevin B. *Médicaments à usage homéopathique : dictionnaire pratique*. Paris (France): Masson; 1996.

Schroyens, F. *Synthesis - Repertorium Homeopathicum Syntheticum* (edition 8.1). London (United Kingdom): Homeopathic Book Publishers; 2001.

Schwabe W. *Pharmacopoea homeopathica Polyglotta*. Leipzig (Germany): Edition française Willmar Schwabe; 1933.

Sieffert G. *Formulaire de thérapeutique positive (Homoepathie).* Leipzig (Germany): Dr. Willmar Schwabe; 1899.

Tetau M. *Matière médicale homéopathique clinique et associations biothérapiques.* Paris (France): Maloine; 1978.

The Homeopathic Pharmacopeia of United States (HPUS). United States: published by the Pharmacopeia Convention of the American Institute of Homeopathy: Boston (U.S.A); 2004.

The Pakistan Homoeopathic Pharmacopoeia. Pakistan: published by National Council for Homoeopathy Pakistan (2nd ed.); 1997.

Vannier L., Poirier J. *Précis de Matière Médicale Homéopathique*. Paris (France): Doin; 1972.

Varma P.N., Indu Vaid. *Encyclopaedia of Homoeopathic Pharmacopoeia*. New Delhi (India): Jain Publishers (P) Ltd.; 1995.

Vermeulen, F. *Concordance Materia medica*. Haarlem (The Netherlands): Ary Bakker; 1994.

Villechauvaix, J. *Pour comprendre et utiliser l'homéopathie*. France: G. Doin & Cie; 1934.

Voisin, H. *Homéopathie Clinique. Matière Médicale*. Annecy (France): Imprimerie Moderne; 1949.

Voisin, H. *Matière Médicale du Praticien Homéopathe*. Paris (France): Maloine SA éditeur - LHF; 1978 (2ème édition, 2ème tirage).

Weber, G.P.F. *Codex des médicaments homéopathiques*. Paris (France): J.B. Baillière et Fils; 1854.

Wyrth Post Baker. *Compendium of Homeotherapeutics*. Leesburg Pike, Falls Church (VA): American Academy of Homeotherapeutics; 1974.

Zandvoort, R.V. *The complete repertory mind including Boger's Boenninghausen repertory additions* (3rd revised edition). IRHIS; 1998.

Zissu, R. & Guillaume, M. *Fiches de Matière Médicale Homéopathique* - 3 volumes. France: Doin; 1973-1977.

Appendix 4: Examples of homeopathic medicines with higher-risk recommended conditions of use

The list below contains examples of specific higher-risk homeopathic product claims, which relate to a disease or condition that is non-self resolving or self-limited and has potential for harm if the product is underperforming.

This list serves as a guide only, and is not intended to be all inclusive.

Abscesses

Anal fissures

Anemia

Arthritis (Treatment of) (e.g. gout, osteoarthritis, rheumatic pain/rheumatoid arthritis, spondylitis, tophi)

Cataracts

Childbirth and lactation

Chronic constipation

Conjunctivitis (pink eye)

Cystitis

Dislocated joints

Fever

Gastroesophageal reflux disease and acid reflux

Gastrointestinal conditions of a serious nature (e.g. infectious diarrhea)

Periodontitis and associated symptoms (e.g. bleeding gums, tooth loss)

Intestinal parasites/worms

Kidney stones

Liver dysfunction

Osteoporosis

Other eye conditions (e.g. glaucoma/high ocular pressure)

Other infections that left untreated will lead to serious risks (e.g. urinary tract infections, ear infections, bacterial infections)

Prostate health

Respiratory conditions with potential for serious complications (e.g. laryngitis, pharyngitis, sinusitis, tonsillitis)

Skin conditions of a serious nature (e.g. eczema, psoriasis)

Ulcers (with exception of oral canker sores)

Venous circulation disorders

Weight loss

Yeast infection (Candida)

Appendix 5: Specific quality requirements for medicinal ingredients used in homeopathic medicines

Specific Quality Test Requirements per Category of Homeopathic Medicines.

The following chart outlines the specific quality tests required for different categories of homeopathic medicines. General quality requirements specified by the NNHPD in the *Quality of Natural Health Products Guide* also apply.

Category of Homeopathic Medicine	Identity Testing (raw material stage)	Microbial contaminants (finished product stage)	Chemical Contaminants (raw material stage) Not required for homeopathic potencies 1 CH (2X) or higher
Mineral/Chemical	Required (as per homeopathic pharmacopoeia)	Required	Heavy metal testing (required for minerals only)
Zoological (including sarcodes)	Required (as per homeopathic pharmacopoeia)	Required	Heavy metal and pesticide testing (required for all)
Botanical	Required (as per homeopathic pharmacopoeia)	Required	Heavy metal and pesticide testing (required for all). Aflatoxin testing (required for ginseng/tree nuts only)
Nosode	Required (as per homeopathic pharmacopoeia)	Required N.B. Sterilization technique must be stated (e.g. as per USP)	Since the minimum homeopathic potency for all nosodes is higher than 1 CH (2X), chemical contaminant testing is not required.

Examples of accepted techniques for identity testing include: HPLC fingerprinting, macroscopic and microscopic identification, and certificates of botanical origin. Other techniques can be found in the *Quality of Natural Health Products Guide*.

Raw Material Testing

Test Parameters	Test	Method(s)	Tolerances
Identity (raw material)	Chemical fingerprinting	TLC, HPTLC or HPLC or GC, and/or spectroscopic methods	Characteristic for the ingredient
	Appearance and Odour	Observation and Smell	Clear, colourless, etc.
Purity - Chemical contaminants (raw material)	Heavy metals [arsenic, cadmium, lead, total mercury, cadmium (if applicable)]	Pharmacopoeial or WHO	Refer to Quality of NHP Guide
	Pesticides	Pharmacopoeial or WHO	Refer to Quality of NHP Guide
	Mycotoxins	AOAC-International	Refer to Quality of NHP Guide

Finished Product Testing

Test Parameters	Test	Method(s)	Tolerances

Test Parameters	Test	Method(s)	Tolerances
Purity - Microbiological contaminants (finished product)	Contaminating fungus (yeast and mould)	Pharmacopoeial or WHO	Pharmacopoeial or WHO
	Total Aerobic Count	Pharmacopoeial or WHO	Pharmacopoeial or WHO
	Escherichia coli	Pharmacopoeial or WHO	Pharmacopoeial or WHO
	Salmonella spp.	Pharmacopoeial or WHO	Pharmacopoeial or WHO
	Staphylococcus aureus	Pharmacopoeial or WHO	Pharmacopoeial or WHO
	Pseudomonas aeruginosa (for products in liquid form with an ethanol content < 50%)	Pharmacopoeial or WHO	Pharmacopoeial or WHO

Date modified:
2022-07-06