Interim NHP Compounding and Raw Materials Policies of January 30, 2006

The Directors of the Canadian Society of Homeopaths and the West Coast Homeopathic Society thank you for this opportunity to provide stakeholder input on these interim policies, on behalf of our 300+ members from across Canada.

We especially appreciate this opportunity because the NHP regulations pertaining to homeopathy were developed with little input from the broad homeopathic profession. As a result, the NHP regulations in their present form will have a severely negative impact on the ability of our members to practice their profession on par with their counterparts in other countries. There are a number of outstanding issues unrelated to these raw materials and compounding documents about which we would welcome further discussion.

Comments Regarding NHPD Interim Policy on Raw Materials

1. Definition of Raw Materials

Before there can be compounding, there must be a product and so we will start with the interim policy on raw materials. Although it is stated that: "The Interim NHP Raw Material Policy clarifies at which point a material becomes an NHP, and therefore when product and site licensing requirements are triggered", most of this Raw Materials policy pertains to NHPs and their manufacture. The inference is that a substance qualifies as a raw material if it fails to meet the NHP requirements for substance and function. However, we suggest that this Raw Materials Policy focus on what raw materials are, not what they are not. The policy requires a clear definition of what constitutes a raw material and how its end use is affected by NHP regulations.

Recommendations: 1. Prepare a definition of raw materials. 2. Include a clarification that raw materials for compounding by a natural health practitioner are not NHPs and do not require either Site or Product licence.

From a homeopathic standpoint, there is no reference to the raw materials used in compounding homeopathic medicines.

Recommendation: Specify that homeopathic medicating potencies (approximately 90% alcohol) used for compounding purposes by natural health practitioners are raw materials and do not require either Site or Product licence.

2. Examples of the Regulations of Various Materials

Most of the scenarios listed in this table do not pertain to situations that affect professional homeopaths and therefore we have no comment. We do support the last example: Importation or sale of material with only an NHP use for compounding by practitioner. For compounding (practice of medicine).

3. Rationale for the Raw Materials Policy

We support the NHPD intent to protect public safety through Site and Product licence requirements and, in particular, the statement that "the safety and quality of those materials that are used by practitioners to compound product for their patient is ensured by the practitioner".

4. Definition of Natural Health Products

We can support the general intent of the definition of NHP as it pertains to homeopathy:
"Natural health product" means a … homeopathic medicine … that is … represented for use in:
(*a*) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
(*b*) restoring or correcting organic functions in humans; or
(*c*) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

However, we do encourage a revising of this definition to more accurately and sensitively reflect the natural and holistic nature of all CAM modalities.

We also want to emphasize that the frequent references to "substance" within the definition have no bearing on the great majority of homeopathic medicines used in Canada today. Statistically speaking, in dilutions of 12c (24x) and above there is no trace of the original substance in homeopathic medicines, not even a molecule. In fact, for most compounds, bio-chemical activity is nil beyond a concentration of $10^{(-8)}$, which represents homeopathic potencies of 4c or 8x. Therefore, whether or not the original source is covered in Schedules 1 or 2, most homeopathic medicines contain no chemical trace of that "substance" and therefore fall outside the definitions relating to "substance(s) set out in Schedule 1 (and 2)". This is a serious flaw in the NHP regulations and needs to be addressed as soon as possible.
Recommendation: Develop new definitions within the NHP definition that relate specifically to and reflect the reality of homeopathic medicines.

Comments Regarding NHPD Interim Policy on Compounding

1. Purpose

We are pleased to see that a policy is being developed to distinguish between manufacturing NHP (covered under the NHP regulations) and compounding NHPs (not covered under the NHP regulations).

2. Definition of Compounding

The key aspect of this definition is recognition that compounding is a process performed by health care practitioners. Thus compounding is an activity within the practice of medicine that falls under provincial or territorial jurisdiction, which is further reinforced in an exclusionary way in your subsequent definition of manufacturer.

However we believe that a more straight-forward definition of compounding would avoid confusion among all parties involved (public, alternative healthcare professionals, regulating officers, etc.).

Recommendation: Prepare a definition of compounding that clearly states:

- **that it is a process performed by health care practitioners, which fall under provincial or territorial jurisdiction**
- **that it involves the preparation of health products (natural, medicinal, etc.) based on an exact specification tailored to a patient's needs and provided by means of a desired vehicle**
- **that it is not available for distribution and sale (which fall under the Manufacturing definition)**
- **that it falls outside the NHP regulations**
- **that it does not require a site licence to perform; and**
- **that the product of compounding does not require a product licence.**

We question why the use of "generally understood" rather than simply "understood" in this definition? "Generally" suggests that there is the possibility under certain circumstances for the understanding to not exist.

Recommendation: Delete "generally".

The examples of "vehicles" used in compounding ("cream, lotion, gel, drops, capsules, etc.") includes no reference to the unmedicated sugar or lactose pillules used in homeopathic compounding.

Recommendation: Add "unmedicated homeopathic sugar or lactose pillules".

Summary of the 2 Recommendations above:

Compounding is <**DELETE generally**> understood as a process whereby a health care practitioner mixes or prepares health products (natural, medicinal, etc.) to an exact specification tailored to a patient's needs, and in a vehicle desired (cream, lotion, gel, drops, capsules, **unmedicated homeopathic sugar or lactose pillules**, etc.). Compounding is generally used to:

1. Provide products unavailable or not readily available;
2. Provide products free of preservatives, dyes and chemical allergens;
3. Vary strengths depending on the individual patient's needs; and
4. Prepare palatable flavoured dosage forms.

3. Other Definitions

Re: *Importer* - means a person who imports a natural health product into Canada for the purpose of sale.

Query: If an "importer" imports for the purpose of selling, what is the definition of a person who imports for the purpose of compounding?

Re: *Natural health product* - "natural health product" means a substance set out in Schedule 1 (see Appendix I) 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

(a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
(b) restoring or correcting organic functions in humans; or
(c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

However, a natural health product does not include a substance set out in Schedule 2 (see Appendix I), 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.

Comment: Our concerns with the above definition have been outlined in our Raw materials comments. This is a serious oversight that requires prompt attention.

Section V: Policy Statement

1. Definition

Compounding is a practice of medicine and is regulated by the provinces, therefore no site licence is required for this activity.

Comment: We agree that compounding is a practice of medicine that falls under provincial or territorial jurisdiction. However, in many cases (such as homeopathy) the practice of CAM is not regulated by any province.

Recommendation: Change "is regulated by the provinces" to "falls under provincial or territorial jurisdiction".

2. Table

Before commenting on the following scenarios individually, we would like to point out that all are based on the act of compounding, which by definition, is a practice of medicine requiring neither Site licence (SL) nor Product licence (PL). Therefore we question the relevance of any of the 17 scenarios listed.

1. Practitioner imports NHP with NPN or DIN into Canada and uses that NHP to compound product (DIN permitted on product to which the transitional provisions still apply). Note: Site license required for importing only.

Recommendation: Delete the site licence requirement for homeopaths who import NHPs, whether for "compounding" or prescribing to patients.

2. Practitioner uses an NHP with NPN or DIN to compound product (DIN permitted on product to which the transitional provisions still apply). No SL required.

Comment: Since the DIN-HM designation will replace the DIN on all homeopathic products after 2009, should we assume that homeopathic medicines will not be included in this scenario after that date?

Recommendation: Clarify this scenario.

3 Unlikely, based on an unrealistic scenario.
4. Exactly. Covered elsewhere.
5. No comment.

6. Practitioner uses an NHP withdrawn from the market for safety reasons to compound product. Not applicable.
Comment: Why bother with situations based on an unrealistic scenario?

7. Practitioner uses any substance listed on Schedule 2 to the *Natural Health Products Regulations* to compound product. Not applicable.
8. Practitioner uses any substance that does not meet the NHP definition to compound product (e.g., prescription drugs, biologics, Schedule F ingredients, etc.). Not applicable.
Comments: These restrictions totally disregard the unique nature of homeopathic medicines and the variety of sources that they come from. As noted elsewhere, we want to emphasize that the frequent references to "substance" within the definition have no bearing on the great majority of homeopathic medicines used in Canada today. Statistically speaking, in dilutions of 12c (24x) and above there is no trace of the original substance in homeopathic medicines, not even a molecule. In fact, for most compounds, bio-chemical activity is nil beyond a concentration of $10^{(-8)}$, which represents homeopathic potencies of 4c or 8x. Therefore, whether or not the original source is covered in Schedules 1 or 2, most homeopathic medicines contain no chemical trace of that "substance" and therefore fall outside the definitions relating to "substance(s) set out in Schedule 1 (and 2)". This is a serious flaw in the NHP regulations and needs to be addressed as soon as possible.

9. Practitioner uses any substance (with the exception of a homeopathic medicine) that is required to be sold pursuant to a prescription to compound product. Not applicable.
Comment: Since homeopathic medicines are excluded from this scenario, we have no comment.

10. No comment
11. We understand that this has recently been amended to compounding with no SL requirement. We agree.

12. Practitioner compounds product for another practitioner to provide to his/her patients. SL required – manufacturing.
13. Practitioner provides a stock bottle (e.g., a tincture) to another practitioner to be used by that practitioner to compound product. SL required – manufacturing.
14. Practitioner uses a stock bottle (e.g., a tincture) provided by another practitioner to compound product. SL not required.
15. Practitioner compounds product for anyone other than his/her own patient following a practitioner-patient consultation. SL required – manufacturing.

Comment: In the Raw Products policy, the manufacturing definition includes the following: "practitioners who compound product for a patient are excluded from the manufacturer definition". It does not specify that the patient must be the practitioner's (compounder's), nor should it. For homeopaths, this is an infringement on our ability to prescribe the required remedy in the required potency and at the required time. The result is to deny patients the best possible and timely treatment. Since there is a vast selection of homeopathic medicines – each remedy has many variations of the major x, c, and LM potencies – there is no single source for all variations. Therefore homeopaths must be free to co-operate with colleagues when necessary to readily obtain the desired remedy and potency in order to effectively treat their patients.
Recommendation: Change 12, 13, and 15 so that SL are not required in all 4 cases.

16. We agree, this falls under manufacturing for distribution and sale.
17. Absolutely!

However, we wish to reiterate that since all of the scenarios listed above pertain to compounding, the definition of compounding should take precedence.

Thank you for providing this opportunity for our Societies to submit feedback on these interim policies. We look forward to consulting further with NHPD about other concerns regarding the effect of NHP regulations on the ability of Canadian homeopaths to practice their profession.

The Board of Directors
Canadian Society of Homeopaths
and
The Board of Directors
West Coast Homeopathic Society

Interim NHP Raw Material Policy

Issue:
The *Natural Health Products Regulations* (NHP Regulations) do not specify whether raw materials *are* or *are not* included in the definition of a natural health product (NHP). The NHP definition[i] mentions neither raw material (e.g., ginger root that has just been harvested) nor finished product (e.g., encapsulated ginger that is packaged and labelled for the consumer). The Interim NHP Raw Material Policy clarifies at which point a material becomes an NHP, and therefore when product and site licensing requirements are triggered[ii].

Policy Statement:

- A substance becomes an NHP, and therefore product and site licensing requirements are triggered when the material meets the substance component of the NHP Regulations[iii], and it is manufactured, sold, or represented for use as an NHP (i.e., it meets the function component of the NHP definition[iv]).
- It is important to note that this is a case-specific approach: circumstances or features about a material that may lead Health Canada to conclude that a material is manufactured, sold or represented for use as an NHP include the following:
  - Nature of the substance and whether it is inherently therapeutic
  - Packaging
  - Labelling (including claims)
  - Accompanying information/advertising
  - Form (e.g., in dosage form)
  - Sender
  - Recipient (e.g., retail outlet)
  - Manner in which it is being sold (i.e., to consumers versus as part of the chain of manufacturing)

- Importation or sale of material for further processing by manufacturers ("further processing" is distinct from "directions for use") does not trigger product licensing (PL) and site licensing (SL) requirements; rather, these materials are treated as NHP active medicinal ingredients (AMIs)[1]. Note: Processing by manufacturers requires a site licence for the activity of manufacturing.
- Importation or sale of material not manufactured, sold or represented for use as an NHP for compounding by practitioners does not trigger PL and SL requirements; instead, these materials fall into the "practice of medicine".
- Under this policy, those products that are manufactured, sold or represented for use as NHPs are regulated as NHPs, and for example, those products that are sold or represented for use as foods are regulated as foods[v], while those products that are clearly neither foods nor finished NHPs are treated as AMIs, such as bulk powdered melatonin that is being shipped to a manufacturer for encapsulation and packaging.

Examples of the Regulation of Various Materials

[1] Note: "treated as AMIs" means that no PL is required to sell the material and no SL is needed to import the material; however, any processing of the material requires an SL for manufacturing.

Material	Regulated as NHP (SL required to import and PL required to sell)	Regulated as Food	Treated as Active Medicinal Ingredient (AMI)	For compounding (practice of medicine)
Importation or sale of mint manufactured, sold or represented as *tasty beverage.*		x		
Importation or sale of herb, tincture, or freeze-dried extract (e.g., of chamomile) manufactured, sold or represented as *treatment for stomach upset*.	x			
Importation or sale of herb, tincture, or freeze-dried extract (e.g., of chamomile) manufactured, sold or represented as *treatment for stomach upset* for **further processing by manufacturer**.	x			
Importation or sale of herb, tincture, or freeze-dried extract (e.g., of chamomile) for **further processing by manufacturer** (i.e., not manufactured, sold or represented for NHP use).			x	
Importation or sale of herb, tincture, or freeze-dried extract (e.g., of chamomile) manufactured, sold or represented as *treatment for stomach upset* for **use by practitioner**.	x			
Importation or sale of herb, tincture, or freeze-dried extract (e.g., of chamomile) for **use by practitioner** (i.e., not manufactured, sold or represented for NHP use).				x
Importation of encapsulated garlic for packaging and/or labelling prior to its sale.	x			
Importation or sale of material with only an NHP use for retail sale.	x			
Importation or sale of material with only an NHP use for further processing by manufacturer.			x	
Importation or sale of material with only an NHP use for compounding by practitioner.				x

Rationale for policy:

- The safety and quality of those materials that go directly to consumers must be assured through product and site licensing requirements.
- The safety and quality of those materials that truly are ingredients in the manufacture of NHPs is ensured through the manufacturing process, since a site licence (and therefore adherence to good manufacturing practices (GMPs)) is a requirement for manufacturing NHPs, and a product licence will be obtained for the final product.
- The safety and quality of those materials that are used by practitioners to compound product for their patient is ensured by the practitioner.

[i] "Natural health product" means a substance set out in Schedule 1 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

(*a*) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;

(*b*) restoring or correcting organic functions in humans; or

(*c*) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

However, a natural health product 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.

[ii] Under the NHP Regulations, product and site licensing requirements are as follows:

- As per Section 27, a site licence is required to manufacture, package, label or import an NHP for sale (practitioners who compound product for a patient are excluded from the manufacturer definition); and
- As per section 4, a product licence is required to sell an NHP.

[iii] The substance component refers to the medicinal ingredient in an NHP. Schedule 1 of the NHP definition outlines the medicinal ingredients that NHPs may contain. Schedule 2 of the NHP definition specifies those substances that are not permitted in an NHP.

[iv] The function component refers to the NHP definition capturing those substances that are manufactured, sold or represented for use in: (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans; (b) restoring or correcting organic functions in humans; or (c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

[v] Canadian Food Inspection Agency (CFIA) Status of Substances List could be used to help in mitigating the risk of some higher risk food-like ingredients of NHPs. The Status of Substances List is the tool that CFIA uses to determine whether or not a substance being sold or represented for use as or in a food is indeed suitable for use in a food. This tool will help CFIA to continue to take action as they did before the NHP Regulations on non-compliant foods (e.g. herbs that are not safe for sale in bulk) without the products "defaulting" to be NHPs.

Interim NHP Compounding Policy
Natural Health Products Directorate,
Health Products and Food Branch, Health Canada

TABLE OF CONTENTS

I. PURPOSE

The purpose of the Interim NHP Compounding Policy is to provide stakeholders with the opportunity to comment on the work that NHPD has done to date on the development of an NHP Compounding Policy. The NHP Compounding Policy will be finalised after this consultation.

The NHP Compounding Policy will distinguish between the manufacturing of natural health products, an activity regulated by the *Natural Health Products Regulations*, and the compounding of natural health products, an activity unregulated by the *Natural Health Products Regulations*.

II. BACKGROUND

The Natural Health Products Directorate (NHPD) recognizes the need to clearly define what is meant by compounding and to outline the implications and scope of this concept. The NHP Compounding Policy will clarify the distinction between the manufacturing and compounding of NHPs, including whether or not a site licence is required for a particular activity.

Recognizing the importance of stakeholder input in the development of the policy, the NHPD has developed the Interim NHP Compounding Policy.

Compounding is generally understood as a process whereby a health care practitioner mixes, or prepares health products (natural, medicinal, etc.) to an exact specification tailored to a patient's needs, and in a vehicle desired (cream, lotion, gel, drops, capsules, etc.). Compounding is generally used to:

1. Provide products unavailable or not readily available;
2. Provide products free of preservatives, dyes and chemical allergens;
3. Vary strengths depending on the individual patient's needs; and
4. Prepare palatable flavoured dosage forms.

The practice of compounding is excluded from the scope of NHP Regulations through the manufacturer definition:

The regulation of the practice of medicine, which includes compounding, is of provincial jurisdiction. It was never the intent of the NHP Regulations to regulate the practice of complementary and alternative or traditional practitioners. The Regulatory Impact Analysis Statement (RIAS) published with NHP Regulations in the Canada Gazette, Part II, contains a statement that clarifies this policy intent:

> "Health care practitioners (for example, pharmacists, Traditional Chinese Medicine (TCM) practitioners, herbalists, naturopathic doctors, etc.) who compound products at the request of a patient are not included within the manufacturer definition. NHP Regulations are not aimed at regulating the practice of complementary and alternative health care practitioners or the practice of traditional Aboriginal medicine. The NHPD intends to adopt a guidance document regarding the distinction between manufacture and sale of NHPs and compounding and distribution of compounded products by complementary and alternative health care practitioners and Aboriginal healers."

NHPD will continue to work in partnership with practitioners in developing the NHP Compounding Policy, ensuring that appropriate guidelines are developed to support Canadians in making safe and informed decisions about natural health products.

More information on the *Natural Health Products Regulations* can be found at: http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index_e.html.

Implementation of the *Natural Health Products Regulations* (NHP Regulations)

On January 1, 2004, the *Natural Health Products Regulations* came into force. The NHP Regulations contain requirements for the manufacture, packaging, labelling, storage, importation, distribution and sale of NHPs.

III. SCOPE

The NHP Compounding Policy will distinguish between the manufacturing of natural health products, an activity regulated by the *Natural Health Products Regulations*, and the compounding of natural health products, an activity regulated by the provinces and territories.

IV. DEFINITIONS

Importer - means a person who imports a natural health product into Canada for the purpose of sale.

Manufacturer - means a person who fabricates or processes a natural health product for the purpose of sale, but does not include a pharmacist or other health care practitioner who, at the request of a patient, compounds a natural health product for the purpose of sale to that patient.

Natural health product - "natural health product" means a substance set out in Schedule 1 (see Appendix I) 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

> (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
>
> (b) restoring or correcting organic functions in humans; or
>
> (c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

However, a natural health product does not include a substance set out in Schedule 2 (see Appendix I), 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.

Sell – includes offer for sale, expose for sale, have in possession for sale and distribute, whether or not the distribution is made for consideration (from the *Food and Drugs Act*).

V. POLICY STATEMENT

The table below includes various scenarios to distinguish between the manufacturing of NHPs (regulated under the NHP Regulations), and the compounding of NHPs (regulated by the provinces and territories). It also indicates when a site licence is required.

- Compounding is a practice of medicine and is regulated by the provinces, therefore no site licence is required for this activity.
- The product resulting from a practice of medicine (in this case, compounding) does not require a product licence.

#	**Scenario\Requirement for Site Licence**	**Site Licence Needed?**		**Note**
		YES	**NO**	
1	Practitioner imports NHP with NPN or DIN into Canada and uses that NHP to compound product (DIN permitted on product to which the transitional provisions still apply).	x		SL needed for importing only.
2	Practitioner uses an NHP with NPN or DIN to compound product (DIN permitted on product to which the transitional provisions still apply).		x	
3	Practitioner uses an NHP with neither an NPN nor a DIN to compound product.		x	
4	Practitioner uses raw material to compound product[v].		x	
5	Practitioner wildcrafts a herbal product (i.e., herbs are harvested in the wild) for use in a compounded product.		x	
6	Practitioner uses an NHP withdrawn from the market for safety reasons to compound product.	Not applicable.		Not permissible.
7	Practitioner uses any substance listed on Schedule 2 to the *Natural Health Products Regulations* to compound product.	Not applicable.		Not an NHP. This is compounding of a product that does not fit the NHP definition.
8	Practitioners uses any substance that does not meet the NHP definition to compound product (e.g., prescription drugs, biologics, Schedule F ingredients, etc.).	Not applicable.		Not an NHP. This is compounding of a product that does not fit the NHP definition.
9	Practitioner uses any substance (with the exception of a homeopathic medicine) that is required to be sold pursuant to a prescription to compound product.	Not applicable.		Not an NHP. This is compounding of a product that does not fit the NHP definition.
10	Practitioner compounds a sterile product.	x		This is manufacturing.
11	Practitioner compounds an NHP to be used in a clinical trial.	x		This is manufacturing.
12	Practitioner compounds product for another practitioner to provide to his/her patients.	x		This is manufacturing.

13	Practitioner provides a stock bottle (e.g., a tincture) to another practitioner to be used by that practitioner to compound product.	x		This is manufacturing.
14	Practitioner uses a stock bottle (e.g., a tincture) provided by another practitioner to compound product.		x	
15	Practitioner compounds product for anyone other than his/her own patient following a practitioner-patient consultation.	x		This is manufacturing.
16	Practitioner compounds product intended for distribution or sale outside the established practitioner-patient relationship.	x		This is manufacturing.
17	Practitioner compounds a product in advance of a practitioner-patient relationship (i.e., bulk compounding) AND product is given to patient in the context of a practitioner-patient relationship.		x	

Appendix I: Schedules 1 and 2 of the Natural Health Product Definition

Schedule 1 (Subsection 1(1))

Included Natural Health Product Substances

Item	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 (Subsection 1(1))

Excluded Natural Health Product Substances

Item	Substances
1.	A substance set out in Schedule C to the Act
2.	A substance set out in Schedule D to the Act**, except for the following**: (a) a drug that is prepared from any of the following micro-organisms, namely, an alga, a bacterium or a fungus; and (b) any substance set out on Schedule D when it is prepared in accordance with the ractices of homeopathic pharmacy
3.	A substance regulated under the Tobacco Act
4.	A substance set out in any of Schedules I to V of the Controlled Drugs and Substances Act
5.	A substance that is administered by puncturing the dermis
6.	An antibiotic prepared from an alga, a bacterium or a fungus or a synthetic duplicate of that antibiotic