

Explanation of Legislative Amendments

(prepared by the government)

Definition of NHPs

Canadians have clearly expressed the desire to recognize NHPs as a unique category of products under the *Food and Drugs Act*. Currently, NHPs are considered to be a subset of "drug" within the definition of the *Food and Drugs Act*. In order to clearly recognize that NHPs are distinct from foods and drugs in legislation, the Government proposes that a definition of "natural health product" be introduced into the Bill. NHPs would be recognized separately from drugs under the definition of "therapeutic product". These proposed changes would allow for continued access to NHPs and support Canadians in making informed decisions about their health care.

"therapeutic product" means

- (a) a drug,
- (b) a natural health product,**
- (c) a device,**
- (d) cells, tissues or organs that are distributed or represented for use in**
 - (i) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,**
 - or**
 - (ii) restoring, correcting or modifying the body structure of human beings or animals or the functioning of parts of the bodies of human beings or animals, or**
- (e) a combination of two or more of the things referred to in paragraphs (a) to (d);**

Consistent with the years of consultation on the NHP definition, it is proposed that the existing NHP definition in the *NHP Regulations* be maintained, with slight modifications necessary so that it may be included at the level of the Act. The proposed definition would include a list of products currently listed on Schedule 1 of the *NHP Regulations*, which lists products considered to be NHPs. Schedule 2 of the *NHP Regulations* outlines products that are not considered to be NHPs. This will be enabled through a regulation-making power to identify products not to be considered a NHP, taking into account the product's risk of injury to health and its intended use. This will continue to support the exclusion of products currently listed in Schedule 2, such as biologics (e.g. insulin), radiopharmaceuticals, substances regulated under the *Tobacco Act*, substances set out in Schedules I to V of the *Controlled Drugs and Substances Act*, substances administered by puncturing the dermis, as well as certain antibiotics. The intention is for the definition of NHPs to operate in the same way as the definition in the current *NHP Regulations*.

"natural health product" means, subject to regulations made under paragraph 30(1)(c.1), any of the following that is manufactured, sold or represented for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or for use I

restoring, correcting or modifying organic functions in human beings:

- (a) a homeopathic medicine,
- (b) a plant, any plant material, an alga, a bacterium, a fungus or any non-human animal material,
- (c) any substance that is extracted or isolated from a thing referred to in paragraph (b) if the primary molecular structure of the substance is identical to the primary molecular structure of the substance before being extracted or isolated from the thing,
- (d) a vitamin,
- (e) an amino acid,
- (f) an essential fatty acid,
- (g) a synthetic duplicate of any thing referred to in any of paragraphs (c) to (f),
- (h) a mineral,
- (i) a probiotic, and
- (j) any product whose medicinal ingredients consist entirely of things referred to in any of paragraphs (b) to (i);

30(1) The Governor in Council may make regulations for carrying the purposes and provisions of this Act into effect, including regulations

(c.1) subject to subsection (1.01), specifying any thing or class of things as not being a natural health product;

30 (1.01) In specifying any thing or class of things as not being a natural health product in regulations made under paragraph (1)(c.1), the Governor in Council must take into account the risk of injury to health and the intended use of the thing or of things of that class.

These proposals will continue to support the regulation of NHPs under their own regulatory framework, and will clarify that the regulatory provisions governing drugs do not apply to NHPs. Furthermore, it is expected that including NHPs within the umbrella term “therapeutic product” will protect against the application of CODEX Alimentarius standards to NHPs.

Standards of Evidence

Concerns regarding standards of evidence for NHPs were also identified as an issue requiring clarification, especially around the type and amount of information required to obtain an authorization for NHPs. Under the existing *NHP Regulations*, traditional knowledge and history of use can form the basis of evidence for obtaining an authorization for an NHP. These are considerations that are only relevant for NHPs.

Under the section governing market authorizations (section 18.7), it will be explicitly stated that the type and amount of information required in the assessment of benefits and risks depends upon the nature of the product including its intended use. This statement will also be introduced in the preamble of the Bill. Bill C-51 provides oversight over a

wide range of therapeutic products and this proposed change will help to clarify that the type and amount of information needed for the issuance of a market authorization varies depending on the type of therapeutic product for which the authorization is sought. At the same time, for drugs that can be very high risk products, this would accommodate the type of clinical trial evidence that is required.

18.7 (1.1) For greater certainty, the type and amount of information required to establish that the benefits associated with a therapeutic product outweigh the risks depends on the nature of the therapeutic product and its intended use.

Preamble

Whereas the Parliament of Canada recognizes that the type and amount of information required to establish that the benefits associated with a therapeutic product outweigh the risks depend on the nature of the therapeutic product and its intended use;

A related amendment would indicate that regulations would specify that traditional knowledge and history of use could be relevant for the purpose of seeking a market authorization for a natural health product. This statement would also be introduced in the preamble of the Bill. These proposed amendments would further distinguish evidence requirements for NHPs and drugs in the Act itself.

30 (1.3) In making regulations under paragraph (1)(y) relating to the information that is required in an application for a market authorization for natural health products, the Governor in Council shall specify that the information to be provided may include information based on
(a) traditional knowledge relating to the product; or
(b) the history of use of the product or any of its ingredients.

Preamble

Whereas the Parliament of Canada recognizes the value of traditional knowledge and of the history of use of natural health products in the assessment of their benefits and risks;

Inspectors Powers

There have been concerns raised about the perceived lack of safeguards regarding the exercise of inspector powers. As such, the Government will propose amendments to section 23 to clarify that inspector powers must be exercised reasonably and for the purpose of verifying compliance or preventing non-compliance with the Act or the regulations.

23. (1) For the purpose of verifying compliance or preventing non-compliance with this Act or the regulations, an inspector may, subject to subsection 23.1(1), at a reasonable time enter a place, including a conveyance, in which

the inspector reasonably believes that an activity that is governed by this Act or the regulations is conducted or a document relating to the administration of this Act is located and may, in that place,

(a) examine or test any article that the inspector reasonably believes is an article to which this Act or the regulations apply and take samples, free of charge, of the article and, if the article is a document, make a copy of it or take an extract from it;

(b) open a receptacle or package that the inspector reasonably believes is an article to which this Act or the regulations apply or that contains such an article;

(c) subject to subsections (2) and (3), seize and detain

(i) an article that the inspector reasonably believes is an article to which this Act or the regulations apply, or

(ii) any receptacle, package or conveyance that the inspector reasonably believes contains an article to which this Act or the regulations apply;

(d) direct the owner or the person having possession, care or control of any conveyance that the inspector reasonably believes is or contains an article to which this Act or the regulations apply to move the conveyance;

(e) use or cause to be used a computer or other device that is at the place to examine a document that the inspector reasonably believes is an article to which this Act or the regulations apply that is contained in or available to a computer system or reproduce it or cause it to be reproduced in the form of a printout or other intelligible output and remove the output for examination or copying;

(f) use or cause to be used copying equipment that is at the place and remove the copies for examination;

(g) take photographs or make recordings or sketches; and

(h) direct the owner or person in charge of the place or a person who conducts an activity that is governed by this Act or the regulations at the place

(i) to establish their identity to the inspector's satisfaction, or

(ii) to stop or start the activity.

(2) An inspector may detain an article, a receptacle, a package or a conveyance under paragraph (1)(c) only if the inspector reasonably believes that the detention is necessary

(a) to prevent a risk of injury to health;

(b) to prevent inaccurate representations of the article, or an article in the receptacle, package or conveyance, as the case may be; or

(c) to determine whether the article, or an article in the receptacle, package or conveyance, as the case may be, poses a risk of injury to health.

(3) An article, receptacle, package or conveyance seized under paragraph (1)(c) may be detained only for so long as it is necessary to prevent a risk of injury to health or to determine whether the article, or an article in the receptacle, package or conveyance, as the case may be, poses a risk of injury to health.

(4) The owner or person in charge of the place and a person found in the place shall give an inspector who is carrying out their functions all reasonable assistance and provide them with the information that they may reasonably require.

(5) An inspector who is carrying out their functions may enter on or pass through or over private property without being liable for doing so and without the owner of the property having the right to object to that use of the property.

Amendments are being proposed to clarify that an inspector can only exercise the power to detain an article to identify or prevent a risk of injury to health or to prevent inaccurate representations. A seized article could only be detained for the time needed to identify or prevent a risk of injury to health. This clarification aims to address the concern that prolonged assessment of seized products could have a significant financial impact, particularly for smaller companies.

An amendment is also being proposed to limit the inspector's ability to dispose or order the disposal under section 23.3(c) of a seized article to where the disposal is required to address the risk of injury to health.

23.3 An inspector who seizes a thing under this Act may

(c) if the inspector reasonably believes that the thing could be injurious to human health and that the thing must be disposed of to prevent injury to health,

- (i) dispose of it on notice to and at the expense of its owner or the person having possession, care or control of it at the time of its seizure, or
- (ii) direct its owner or the person having possession, care or control of it at the time of its seizure to dispose of it at their expense.

A new paragraph for the preamble is also being proposed for the purpose of clarifying that risk of injury to health would be a relevant consideration in choosing the appropriate administrative and enforcement measure.

Whereas the Parliament of Canada recognizes that risk of injury to health is a factor relevant to the taking of administrative and enforcement measures;

Public Input and Interpretation

Canadians have expressed a desire to be involved in how the provisions of the Bill are implemented, should the Bill receive Royal Assent. Bill C-51 provides, in section 20.4, the authority to create committees for the purpose of seeking advice. Language is being proposed that would require the establishment of committees to provide advice on the development of guidelines used in the interpretation of the Act and the regulations. The members of such committees would have experience and expertise relevant to the mandate of the committee. They could include health professionals, patients, caregivers,

consumers, industry stakeholders and individuals with specialized knowledge such as scientists and academics. As a first order of business, the Government is committed to creating a committee that will address these issues with respect to NHPs. This underscores the Government's intention to involve the public in the implementation of the Bill.

20.4 (1) The Minister shall establish one or more committees for the purpose of providing advice to the Minister concerning the development of guidelines that relate to the interpretation of this Act or the regulations and may establish other committees for the purpose of providing advice to the Minister concerning any other matter.

(1.1) The membership of each committee established for the purpose of providing advice to the Minister concerning the development of guidelines that relate to the interpretation of this Act or the regulations must reflect a range of experience or expertise relevant to the committee's mandate including, but not limited to,

- (a) experience or expertise in consumer issues;**
- (b) experience or expertise in patient or caregiver issues;**
- (c) specialized knowledge, such as the knowledge possessed by scientists and academics;**
- (d) practical or clinical experience as a health professional; and**
- (e) experience or expertise in industry issues.**