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Registration

SOR/2004-119 11 May, 2004

FOOD AND DRUGS ACT

Regulations Amending the Natural Health Products Regulations (Special Access)

P.C. 2004-618 11 May, 2004

Her Excellency the Governor General in Council, on the recommendation of the Minister of Health, pursuant to subsection 30(1) ([see footnote a](#)) of the *Food and Drugs Act*, hereby makes the annexed *Regulations Amending the Natural Health Products Regulations (Special Access)*.

REGULATIONS AMENDING THE NATURAL HEALTH PRODUCTS REGULATIONS (SPECIAL ACCESS)

AMENDMENT

1. The *Natural Health Products Regulations* ([see footnote 1](#)) are amended by adding the following after section 103:

Sale of Natural Health Product for Emergency Treatment

103.1 Sections C.08.010 and C.08.011 of the *Food and Drug Regulations* apply in respect of natural health products except that

(a) a reference in those sections to "new drug" shall be read as a reference to "natural health product"; and

(b) the reference in subsection C.08.011(1) of the *Food and Drug Regulations* to "section C.08.002" shall be read as a reference to "subsection 4(1) of the *Natural Health Products Regulations*".

COMING INTO FORCE



2. These Regulations come into force on the day on which they are registered.

REGULATORY IMPACT ANALYSIS STATEMENT

(This statement is not part of the Regulations.)

Description

The purpose of this amendment is to place natural health products (NHPs) requested under the conditions of the Special Access Programme (SAP) back under the purview of sections C.08.010 and C.08.011 of the *Food and Drug Regulations* (FRD).

The SAP allows practitioners to access drugs that are unavailable for sale by authorizing a manufacturer to sell a drug that cannot otherwise be sold or distributed in Canada. This access is limited to patients with serious or life-threatening conditions on a compassionate or emergency basis when conventional therapies have failed, are unsuitable, or are unavailable. Requests under the SAP are required to be made by a practitioner for a specific drug in a specific dosage form for a specific patient to treat a serious illness.

Sections C.08.010 and C.08.011 of the FRD establish the authority for the Director to authorize the sale of a new drug to a practitioner for emergency treatment. However, these sections do not apply to NHPs because section 3 of the *Natural Health Products Regulations* exempts NHPs from the application of the FRD.

Since January 1, 2004, over 250 requests for NHPs have been made through the SAP, but the authorization for the sale of these products is not clear. Physicians have notified the Natural Health Products Directorate (NHPD) that some patients have exhausted their supply of drugs and others are running out. Moreover, physicians are continuing to make requests under the SAP for NHPs. To date, the majority of all requests for NHPs made through the SAP are for melatonin. Melatonin is most often requested to treat serious sleep disorders among children who are blind, have autism spectrum conditions, cerebral palsy, or foetal alcohol syndrome. Other requests are for biotin to treat biotinidase deficiency, a genetic metabolic disorder, pharmaceutical strength beta-carotene for treatment of erythropoietic protoporphyria and chenodeoxycholic acid for treatment of cerebrotendinous xanthomatosis.

Because requests made under the SAP are made by practitioners treating patients with serious or life-threatening illnesses, it is critical for the well-being of these patients that access to these products continues uninterrupted. In the interim, a risk-based approach has been put in place to provide access to products on a case-by-case basis. Nevertheless, it is crucial that an expeditious amendment to the *Natural Health Products Regulations* be made to allow NHPs to be released under C.08.010 and C.08.011 of the FRD in order to ensure that affected patients continue to have timely access to the most appropriate and

potentially lifesaving products.

Alternatives

One alternative approach for addressing NHPs requested under the conditions of the SAP is to not amend the *Natural Health Products Regulations*. Under this alternative, release of NHPs requested under the SAP would present exposure to a degree of legal risks because neither the FRD nor the *Natural Health Products Regulations* are authorized to release these products for sale under the conditions required of the SAP. This alternative is not desirable in that it would result in denying access to NHPs that are requested on an emergency and/or compassionate basis.

Benefits and Costs

The NHPD has determined that there are no additional costs, including economic costs, to the amendment. The benefits are explained below and are primarily based on the fact that continuity in service will be maintained, as the SAP will continue to operate in the same manner as in the past.

Consumers

With this amendment patients will continue to have timely access to products as recommended by practitioners for serious or life-threatening situations.

The SAP provides patients with timely access to products that are not approved for sale in Canada. Most of these drugs treat patients with life threatening diseases or serious conditions such as intractable depression, epilepsy, transplant rejection, hemophilia and other blood disorders, terminal cancer, and AIDS. The SAP can also respond to specific health crises, such as an outbreak of a communicable disease, by providing access to otherwise unapproved drugs.

Health Care Practitioners

Practitioners would have continued, uninterrupted access to NHPs that are otherwise unavailable for sale in Canada.

Natural Health Products Industry

The SAP is an authorization for the manufacturer to sell an unapproved NHP at the request of a physician to treat patients with serious or life-threatening illnesses. This amendment will provide the legal means to allow manufacturers to continue to sell these products under the approved conditions.

Consultation

The Health Products and Food Branch has communicated with physicians who have been unable to obtain certain NHPs through the SAP. Given the pressing public health concerns, the costs of a broader consultation were determined to far outweigh the benefits.

While not fully achieved in the *Natural Health Products Regulations*, the policy intent of the *Natural Health Products Regulations* has always been to regulate substances that are safe for over-the-counter use and appropriate for self-care, leaving those substances that require the oversight of a practitioner to be regulated under the FDR.

The proposed *Natural Health Products Regulations* pre-published in the *Canada Gazette*, Part I, on December 22, 2001, included a margin of safety criterion to allow the proposed Regulations to apply to those substances that can safely be used for self-care, i.e., products that can be selected and used by consumers without requiring practitioner intervention. Subsection 2(2) of the proposed *Natural Health Products Regulations*, as pre-published in the *Canada Gazette*, Part I, read:

"For the purposes of these Regulations, a substance or combination of substances, a homeopathic preparation or a traditional medicine is not considered to be a natural health product if there is a narrow margin of safety between its recommended dose and its toxic dose, as determined by observing the following factors on the basis of the information referred to in subsection (3) that is available:

- (a) the lowest dose at which it produces toxicity in humans; and
- (b) the highest dose at which it does not produce toxicity in humans."

Comments were received that the "margin of safety" criterion was not clear and would be difficult to apply. As well, some concerns were raised that including the margin of safety criterion may in fact mean that many products would not be considered an NHP simply because of the lack of specific, documented data on their use.

The margin of safety criterion is only one factor of the Schedule F factors that are considered to determine whether a substance should be placed on Schedule F (a substance can be placed on this Schedule if it meets other factors or the totality of the factors). Schedule F factors are an administrative list of factors currently used to determine whether a substance/drug should be placed on Schedule F (see http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/listschf_e.html).

The NHPD's intention in including the margin of safety criterion in the proposed Regulations in the *Canada Gazette*, Part I, was to allow the Regulations to apply to those substances that can be safely used for self-care, i.e., products that can be selected and used by consumers without requiring practitioner intervention. In the Regulatory Impact Analysis Statement published along with the *Natural Health Products Regulations* in the *Canada Gazette*, Part II, on June 18, 2003, clarification was given that while this criterion will continue to be applied as part of the standards of evidence framework, the *Natural Health Products Regulations* now state in subsection 2(2):

"For the purposes of these Regulations, a substance or combination of substances or a traditional medicine is not considered to be a natural health product if its sale, under the *Food and Drug Regulations*, is required to be pursuant to a prescription when it is sold other than in accordance with section C.01.043 of those Regulations."

Compliance and Enforcement

This amendment allows for NHPs previously requested through the SAP to continue to be requested through the same process. There would therefore be no change to existing compliance mechanisms under the provisions of the *Food and Drugs Act* and the *Natural Health Products Regulations* enforced by the Health Products and Food Branch Inspectorate.

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[Footnote a](#)

S.C. 1999, c. 33, s. 347

[Footnote 1](#)

SOR/2003-196

NOTICE:

The format of the electronic version of this issue of the Canada Gazette was modified in order to be compatible with hypertext language (HTML). Its content is very similar except for the footnotes, the symbols and the tables.



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