Archived Content

Health Canada Santé Canada

-Notice-
Update on the Assessment of Naturally-Sourced Medicinal Ingredients found on Schedule F

December 2009

Summary

On March 2, 2009, a notice to stakeholders announced that Health Canada's Natural Health Products Directorate (NHPD), in collaboration with the Therapeutic Products Directorate (TPD), would be undertaking the scientific assessment of a number of naturally-sourced substances currently listed in Schedule F to the *Food and Drug Regulations*. The purpose of this initiative was to determine which of these substances should remain unchanged, be modified, or removed entirely from the Schedule.

The scientific assessments of the eleven substances are now complete. Recommendations made jointly by the NHPD and TPD to Health Canada's Drug Schedule Status Committee[1] (the Committee) were reviewed and ratified by the Committee. Based on the recommendations of the Committee, the regulatory process to amend Schedule F will commence with the publication of Notices of Intent. These documents will describe the proposed amendments to Schedule F for the 11 substances, the rationale for the change and will invite your comments. Modifications to Schedule F may result in some of these ingredients becoming available in Canada (under certain conditions) in nonprescription drugs and natural health products (NHPs).

Further information on this initiative is available in the background portion of the Notice-Assessment of Naturally Sourced Medicinal Ingredients found on Schedule F (March 2, 2009) at: http://www.hc-sc.gc.ca/dhp-mps/prodnatur/bulletins/schedulef_annexef-2009-eng.php

Background

Naturally-sourced ingredients generally fall under the jurisdiction of the *Natural Health Products Regulations* of the *Food and Drugs Act* except for those listed in Schedule F[2].

Following the coming into force of the *Natural Health Products Regulations* in 2004, the Natural Health Products Directorate (NHPD) identified naturally-sourced substances on Schedule F that require assessment as to whether or not they should continue to be sold pursuant to a prescription under the *Food and Drug Regulations* (i.e., continue to be listed in Schedule F). When a substance is

[1] Health Canada's Drug Schedule Status Committee reviews and ratifies all recommendations regarding prescription status and exemption from prescription status. The Committee's membership includes representation from each of the Health Product and Food Branch's regulatory Directorates.

[2] Schedule F is a list of medicinal ingredients, the sale of which is controlled under sections C.01.041 to C.01.049 of the *Food and Drug Regulations*. Part I of Schedule F lists ingredients that require a prescription for human use and for veterinary use. Part II of Schedule F lists ingredients that require a prescription for human use, but do not require a prescription for veterinary use if so labelled or if in a form unsuitable for human use.

Canada

not listed in Schedule F, a drug that contains that substance may be sold as a nonprescription drug under the *Food and Drug Regulations* or as an NHP under the *Natural Health Products Regulations*. The Schedule F entries for some naturally-sourced substances mean that every health product containing that Schedule F substance must be sold by prescription, regardless of whether or not the Schedule F substance is present as a natural constituent or added as a pure single ingredient, and regardless of the dose and indication (unless exempted from the Schedule).

Because the current Schedule F entries for naturally-sourced substances have resulted in prescription drug status for products that could possibly be made available to the public as nonprescription NHPs, Health Canada has decided to review the naturally-sourced substances listed in Schedule F. This initiative does not include synthetic ingredients, i.e., those which are not naturally-sourced.

Health Canada's review of the naturally-sourced substances listed in Schedule F will determine if there are substances that could be regulated (in whole or in part) as nonprescription products under the *Natural Health Products Regulations*.

The NHPD's external Expert Advisory Committee on Natural Health Products (EAC)[3] had identified a subset of these substances as having the potential to be considered for sale without a prescription. Of these substances, the NHPD had selected 11 for which science assessments would be completed to determine if continued prescription status is appropriate.

The 11 substances which were recently assessed are listed below.

Health Canada is proposing that the following 4 substances be removed from Schedule F:

Apiol, oil of
Apiol (huile d')

Deanol, and its salts and derivatives
Déanol, ses sels et derives

Centella asiatica extract and active principles thereof
Centella asiatica (extrait de) et ses principes actifs

Theobromine and its salts
Théobromine et ses sels

Health Canada is proposing that the Schedule F listings for the following 7 substances be modified such that the substances are permitted for sale without a prescription at certain doses or for certain indications:

Dimethyl sulfoxide
Diméthylsulfoxyde

[3] The Expert Advisory Committee is a committee of external experts that provides to NHPD advice on the safety, use and regulation of NHPs.

Dopamine and its salts
Dopamine et ses sels

Gold and its salts
Or et ses sels

Levocarnitine and its salts and derivatives
Levocarnitine et ses sels et dérivés

Lovastatin
Lovastatine

L-Tryptophan, when sold as a single ingredient
L-Trytophane, s'il est vendu comme seul ingrédient

Uracil and its salts
Uracile et ses sels

Modifying or removing Schedule F entries follows a formal process whereby a recommendation for prescription status, or exemption from prescription status, for a substance is based on a set of publicly available factors for listing drugs in Schedule F. These factors include, but are not limited to, toxicity, pharmacological properties and therapeutic uses of medicinal ingredients.

The scientific assessments of the 11 naturally-sourced substances involved a comprehensive survey of the peer-reviewed scientific literature. This information forms the basis of the assessment of the substance against the factors for listing in Schedule F. Based on the scientific assessments, recommendations can include removing certain Schedule F entries or modifying others by adding appropriate qualifiers (e.g., dose, route of administration or indication) to allow an exemption from prescription status, or making no change to the existing entry.

While some naturally-sourced substances will remain in Schedule F as is, others may not warrant prescription status. By modifying the listings for these substances, products could be submitted to the NHPD for pre-market review which would establish nonprescription conditions of use by assessing the products as per the standards of evidence applicable to natural health products.

Next Steps

Notices of Intent will be published in the *Canada Gazette*, Part I and posted to the Health Canada and the *Consulting with Canadians* websites to provide an opportunity for comment on the regulatory proposal to amend Schedule F to the *Food and Drug Regulations*. The formal consultation will soon be initiated.

The consultation documents will include the proposed change to the entry of the substance on Schedule F i.e., modification to the current entry or removal of the substance, and describe and

provide the scientific rationale for the changes. After the comment period closes, Health Canada will review the comments, make any necessary changes to the proposed amendment and then proceed to the next step in the regulatory process. Upon final approval of the proposed change by the Minister of Health and Treasury Board Ministers, the amendment will be published in the *Canada Gazette*, Part II, at which time the regulatory change would come into effect.