Contact
Regulatory Affairs

This document is also available in PDF format [project_projet_1431_e.pdf]
Pages: 4, Size: 19 K, Date: 2006-05-30

Graham Spry Building
250 Lanark Avenue
A.L. 2005D
Ottawa ON K1A 0K9

06-101780-751

Provincial and Territorial Deputy Ministers of Health
Provincial and Territorial Drug Program Managers
Deans of Pharmacy
Registrars of Provincial Medical and Pharmacy Associations
Industry and Consumer Associations
Canadian Food Inspections Agency, Industry Canada, Standards Council of Canada
Regulatory and Health Professional Associations
Other Interested Parties

Dear Sir/Madam:

Re: *Food and Drug Regulations* - Project # 1431 - Schedule F

This letter is to provide an opportunity for comment on the proposed addition of one medicinal ingredient to Part I of Schedule F to the Food and Drug Regulations.

- Public Involvement & Consultations
- Regulatory Requirements for Advertising
- Special Access to Drugs & Health Products
- Substances: Problematic Use
- Veterinary Drugs
- Legislation & Guidelines
- Reports & Publications

Emergencies & Disasters

Environmental & Workplace Health

First Nations & Inuit Health

Food & Nutrition

Health Care System

Healthy Living

Science & Research

Government Health Partners

Need Larger Text?

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.

The Drug Schedule Status Committee determines the necessity for prescription status for medicinal ingredients on the basis of established and publicly available criteria. These criteria include, but are not limited to, concerns related to toxicity, pharmacological properties and therapeutic uses of the ingredients.

Description of the medicinal ingredient:

Quinine and its salts and derivatives: Quinine is a medicinal ingredient that was originally made from the bark of several species of the cinchona tree and was used for centuries as the primary treatment for malaria. The use of quinine as a malaria treatment declined over the years as new synthetic derivatives of the drug such as chloroquine and mefloquine were developed and used. However, with increasingly drug-resistant strains of malaria appearing, there has been renewed interest in the use of quinine to treat malaria. Quinine is now being prescribed for oral use in combination with other drugs such as the antibiotics doxycycline and clindamycin to treat non-severe malaria infections caused by specific organisms that are resistant to other anti-malarial drugs.

The use of quinine to treat malaria requires individualized instructions and/or direct practitioner supervision. There is a narrow margin of safety between the therapeutic and toxic doses of quinine, especially in populations such as seniors, children, pregnant women or nursing mothers. There are potential or known undesirable or severe side effects at normal therapeutic dosage levels that would need to be managed by a practitioner.

Although it is not currently listed on Schedule F, a prescription has been required for quinine for a number of years because of its Schedule I status on provincial and territorial drug schedules. The

conditions of sale for drugs are determined by provincial and territorial pharmacy regulatory authorities.

The degree of regulatory control afforded by Schedule F (prescription drug) status coincides with the risk factors associated with this medicinal ingredient. Oversight by a practitioner is necessary to ensure that appropriate risk/benefit information is considered before the drug containing the medicinal ingredient is administered and that the drug therapy is properly monitored.

Alternatives

The alternative considered was the status quo i.e., to not add quinine, its salts and derivatives to Schedule F. This was not considered to be an acceptable alternative.

A review of the toxicity, pharmacologic properties, and therapeutic applications of quinine, its salts and derivatives has determined that Schedule F status is the only acceptable alternative for this medicinal ingredient at this time. In addition to the requirement for a prescription, Schedule F drugs must meet other applicable requirements of the *Food and Drug Regulations* such as those regarding labelling, advertising and importation. If not listed on Schedule F, quinine would be considered to be a natural health product as defined by the *Natural Health Products Regulations*. The Natural Health Products Directorate agrees with the proposal to add quinine and its salts and derivatives to Schedule F.

Any alternatives to the degree of regulatory control recommended in this amendment would need to be established through additional scientific information and clinical experience.

Benefits and Costs

The amendment would impact on the following sectors:

- **Public**

The public would have continued prescription access to quinine.

Another benefit is that drug products for human use containing medicinal ingredients listed on Schedule F may be covered by both provincial and private health care plans.

- **Health Insurance Plans**

Drug products for human use containing medicinal ingredients listed on Schedule F may be a cost covered by both provincial and private health care plans.

- **Provincial Health Care Services**

The provinces would continue to incur costs to cover practitioners' fees for services. However, the guidance and care provided by the practitioners will continue to reduce the need for health care services that may result from improper use of drug products for human use that contain medicinal ingredients listed on Schedule F. The overall additional costs for health care services should therefore be minimal.

Compliance and Enforcement

This amendment would not alter existing compliance mechanisms under the provisions of the *Food and Drugs Act* and the *Food and Drug Regulations* enforced by the Health Products and Food Branch Inspectorate.

Consultation

A letter dated October 25, 2004 outlining this regulatory proposal was sent by email to provincial and territorial Ministries of Health, medical and pharmacy licensing bodies, and industry, consumer and professional associations with a 30-day comment period. The letter was also posted on the Therapeutic Products Directorate website. Five responses were received from stakeholders.

- Three respondents expressed support for the amendment without providing further comment.
- Two respondents raised questions regarding the impact of the amendment on the use of quinine as a flavouring in food

products such as tonic water.

Response: Schedule F status applies only to medicinal ingredients in drugs. It does not apply to a substance when used as flavouring in food.

- One respondent objected to the amendment as worded, expressing concern about the ability of naturopathic doctors to treat patients with quinine. This respondent suggested as alternatives maintaining the status quo or excluding homeopathic and botanical forms of quinine from Schedule F or setting a separate schedule of natural substances that are not suitable for over-the-counter use. The respondent suggested that substances listed on a separate schedule would be available only through a licensed health care provider such as a naturopathic doctor.

  Response: The status quo option is discussed in the 'Alternatives' section above. Malaria is a serious, life-threatening disease caused by a parasite that has developed a number of disease-resistant strains. Effective treatment with quinine involves diagnosis of the disease strain causing the infection and generally requires that a prescription antibiotic be given at the same time as quinine. The proposed options would not allow for the use of prescription antibiotics in combination with quinine for effective treatment. In addition, the proposal to create a separate schedule of natural substances is beyond the scope of this amendment since licensing and regulation of practitioners is under provincial/territorial jurisdiction.

The process for this further consultation with stakeholders is described in the Memorandum of Understanding (MOU) to streamline regulatory amendments to Schedule F, which came into effect on February 22, 2005. The MOU is posted on the Health Canada website.

This letter is being sent by email to stakeholders and is also being posted on the Health Canada website and the *Consulting With Canadians* website.

Any comments regarding this proposed amendment should be sent within **75** days following the date of posting of this letter on the Health Canada website. The policy analyst for this project, Karen Ash, may be contacted at:

Project No. 1431
Bureau of Policy, Science and International Programs
Therapeutic Products Directorate
1600 Scott Street, Holland Cross
Tower 'B', 2nd Floor
A.L. 3102C5
Ottawa, Ontario K1A 0K9
facsimile: 613-941-6458 (refer to Project No. 1431)
telephone: 613-948-4623
email: regaff_access@hc-sc.gc.ca

Final Approval

In accordance with the MOU process, it is anticipated that this amendment will proceed directly from this consultation to consideration for final approval by the Governor in Council, approximately 6 to 8 months from the date of posting of this letter on the Health Canada website. If approved by the Governor in Council, publication in the *Canada Gazette*, Part II, would follow. The amendment would come into force on the date of registration.

Yours sincerely,

Original signed by

Neil Yeates
Assistant Deputy Minister