



Health Canada Santé Canada

Therapeutic Products Programme  
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March 31, 1999

99-009924

Pharmaceutical Issues Committee  
Deans of Pharmacy  
Registrars of Medicine  
Registrars of Pharmacy  
Provincial Deputy Ministers of Health  
Manufacturers  
Associations and Other Interested Parties

Dear Sir/Madame:

Re: **Amendment to the *Food and Drug Regulations* - Schedule 1108  
(Prohibited substances)**

This is to provide you with an opportunity to comment on the Therapeutic Products Programme's intention to amend provisions in the *Food and Drug Regulations* regarding prohibited substances in order to allow these substances to be used within certain limits in homeopathic preparations and in other drug products, and to add two homeopathic pharmacopoeias to the publications listed in Schedule B to the *Food and Drugs Act*.

Further information concerning this regulatory initiative is included in the attached copy of the Notice of Intent to be published in *Canada Gazette*, Part I. Any comments regarding this proposed amendment should be addressed to the regulatory officer, referenced in the notice.

o/s

Dann M. Michols  
Director General

Attachment

HEALTH CANADA

FOOD AND DRUGS ACT

***Food and Drug Regulations - Amendment***

Prohibited Substances (Schedule 1108)

This notice provides an opportunity to comment on a revised proposal to amend provisions in the *Food and Drug Regulations* regarding prohibited substances. The Therapeutic Products Programme (TPP) of Health Canada is revising its original proposal for an amendment to these *Regulations* to allow acceptable concentrations of "prohibited substances" in drugs. It is now proposed that these substances be permitted in concentrations below certain limits in drug products. These limits will be prescribed in certain homeopathic pharmacopoeias to be added to Schedule B to the *Food and Drugs Act*.

The *Food and Drugs Act* and *Regulations* control the production, importation and sale of drugs in Canada. Under this legislation, only drugs that are considered safe, effective and of high quality may be sold in Canada, based on evidence submitted by a sponsor. Therefore, only approved evidence-based claims are permitted on product labels. When there is no evidence to support a health claim, minimal requirements are mandated. These requirements ensure that there is no deception on the part of the sponsor with respect to a product's character, value, quantity, composition, merit or safety.

Schedule B to the *Food and Drugs Act* is a list of official standards. Drugs must meet or exceed these standards unless a specific standard has been prescribed in the *Food and Drug Regulations*.

The *Food and Drug Regulations* define restrictions for "prohibited substances" in the following way:

1. Section C.01.036 states that no manufacturer or importer shall sell:
  - S a drug that contains phenacetin in combination with any salt or derivative of salicylic acid;
  - S a drug for human use that contains oxyphenisatin, oxyphenisatin acetate or phenisatin;
  - S a drug for human use that contains mercury or its salts or derivatives with certain exceptions in which the substance is present as a preservative and is demonstrated to be the only satisfactory way to maintain sterility/stability of the drug.

2. Section C.01.038 states that a drug for human use is adulterated and therefore prohibited if it contains:
  - strychnine or its salts or derivatives;
  - extracts/tinctures of *Strychnos nux vomica*, *Strychnos ignatii*, or a *Strychnos* species containing strychnine;
  - methapyrilene or its salts;
  - echimidine or its salts;
  - *Symphytum asperum*, *Symphytum x uplandicum* (plant extracts or tinctures) or any other plant species containing echimidine.
3. Section C.01.040 states that no manufacturer or importer shall sell a drug for human use that contains:
  - chloroform;
  - arsenic or its salts or derivatives.
4. Section C.01.040.1 states that no manufacturer shall use methyl salicylate as a medicinal ingredient in a drug for internal use in humans.

Homeopathic products are drugs and are, therefore, regulated under the *Food and Drug Act and Regulations*. These products are subject to the restrictions listed above. However, it has been determined that these provisions may unnecessarily restrict legal access to many homeopathic products that may contain minute amounts of these substances and which are considered to present a minimal risk to users. Indeed, homeopathic products which contain acceptable amounts of "prohibited substance" are commonly used worldwide. Many consumers, manufacturers and distributors of these product therefore argue that Canadians should be provided with equal access to these low risk products.

A letter was distributed to stakeholders on September 25, 1997 to solicit comments on TPP's proposal to amend the current restrictions on "prohibited substances". In addition, the proposal was posted on the Therapeutic Products Programme website at:

**<http://www.hc-sc.gc.ca/hpb-dgps/therapeut/htmleng/consult.html>**.

This regulatory proposal originally presented a recommendation to revoke sections C.01.036, C.01.038, C.01.040 and C.01.040.1. in their entirety. However, it was determined that the *Food and Drugs Act* does not provide sufficient authority for the revocation of these prohibitions. Therefore the original proposal requires revision.

TPP is now proposing to amend the *Food and Drug Regulations* by prescribing standards for the safe use of these "prohibited

substances". The proposal would allow drug products to contain these "prohibited substances" in concentrations which meet the most stringent specifications described in the Pharmacopoeias. This proposal would result in the addition of *Homeopathic Pharmacopoeias* of the United States (HPUS) and *Homöopathische Arzneimittel* (HAB)(German Homeopathic Pharmacopoeia) to Schedule B to the *Food and Drugs Act*.

A new drug submission (NDS) will be required to demonstrate safety where a "prohibited substance" is proposed for use as a medicinal ingredient in a drug.

Interested parties are encourage to provide comments on this revised policy proposal to Lauraine Begin, Policy Division, Bureau of Policy and Coordination, Therapeutic Products Programme, Holland Cross, 1600 Scott Street, Tower B, 2<sup>nd</sup> Floor, Address Locator 3102C5, Ottawa, Ontario, K1A 1B6, or by Internet at [lauraine\\_begin@hc-sc.gc.ca](mailto:lauraine_begin@hc-sc.gc.ca).

Comments must be received within 30 days of publication of this notice. All comments should cite the *Canada Gazette*, Part I, and the date of the publication of this notice.

o/s

DANN M. MICHOLS  
Director General  
Therapeutic Products  
Programme

Date: March 31, 1999