

Committee on Technical Barriers to Trade

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6.

1.	Member to Agreement notifying: <u>CANADA</u> If applicable, name of local government involved (Articles 3.2 and 7.2):
2.	Agency responsible: Department of Health Agency or authority designated to handle comments regarding the notification shall be indicated if different from above: National Enquiry Point
3.	Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], other:
4.	Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Drugs for use in human clinical trials
5.	Title, number of pages and language(s) of the notified document: Proposed Amendment to the Food and Drug Regulations (1024 – Clinical Trials) (pages 227-260; English and French)
6.	<p>Description of content: The purpose of this proposed amendment is to introduce proposed regulatory requirements for the sale and importation of drugs for use in human clinical trials. The new requirements would be located in Division 5 of the <i>Food and Drug Regulations</i> and would apply to clinical trials in humans using both new and old drugs. Consequential amendments would be required to Division 8 of the Regulations to maintain the status quo for clinical trials in animals using new veterinary drugs. Although the Foods Directorate (the unit in Health Canada responsible for the regulations of veterinary drugs) has indicated that a broader framework would also be desirable for veterinary drugs, this will be dealt with at a later date.</p> <p>The proposed framework incorporates the following features:</p> <ul style="list-style-type: none">- all human drug clinical trials conducted in Canada (Phase I to IV) would be subject to an assessment by the Therapeutic Products Programme (TPP) of Health Canada under either the registration or the 30-day default system;- clear and transparent requirements for application, information, amendments, notification, labelling, record keeping and adverse drug reaction reporting;- the introduction of an inspection system against the proposed regulatory requirements including good clinical practice principles and good manufacturing practices; and- a clear authority to refuse a submission, suspend the sale of drugs and cancel the conduct of clinical trials in Canada which do not meet the updated regulatory requirements.

7.	Objective and rationale, including the nature of urgent problems where applicable: Protection of human health
8.	Relevant documents: Canada Gazette, Part I, 22 January 2000
9.	Proposed date of adoption: Not stated Proposed date of entry into force: 1 September 2000
10.	Final date for comments: 21 February 2000
11.	Texts available from: National enquiry point [X] or address, e-mail and telefax number of the other body: