



July 6, 2012

Notice

Our file number: 12-111813-22

Re: Canadian Module 1 Schema Version 2.2

Health Canada is pleased to announce the finalization of the *Canadian Module 1 Schema Version 2.2*. Amendments were made to the *Canadian Module 1 Schema Version 2.1* as a result of comments received from stake holders during the 30-day consultation period ending April 30th, 2012.

The Health Products and Food Branch (HPFB) is committed to implementing an electronic environment which will contribute to the increased efficiencies that must be achieved to deliver appropriate performance standards in the pre-market assessment of new products. Furthermore, it will contribute to effective and efficient records management. This initiative will also address the implementation of the electronic Common Technical Document (eCTD) as part of Health Canada's commitment to the International Conference on Harmonization (ICH).


In order to take full advantage of the functionality of the eCTD specifications and design, practical and efficient solutions to the transmission, receipt and processing of electronic information, the finalised version of the Extensible Markup Language (XML) schema for the Canadian Module 1 is being posted. This is required in order to complete an eCTD drug regulatory activity for submitting to Health Canada.

The finalized *Canadian Module 1 Schema Version 2.2* replaces the 2004 *Canadian DTD Version 1.0*. Health Canada implementation is as per the following schedule:

- As of September 30th, 2012, Health Canada will be accepting regulatory activities built using the revised *Canadian Module 1 Schema Version 2.2*.
- As of March 31st, 2013, Health Canada will no longer be accepting regulatory activities built using the old *Canadian Module 1 DTD Version 1.0*.

The *Canadian Module 1 Schema Version 2.2* is meant to accompany the *Guidance for Industry: Creation of the Canadian Module 1 Backbone* for the implementation of electronic regulatory activities that are compliant with the ICH M2 eCTD specifications.

.../2

Schema Files	File	Checksum
	ca-regional-2-2.xsd	ff564d6e69adebd9a9b4f274e65cf5f1
	xlink.xsd	52d1a3b8596e4fb61d3ec1cde24be16a
	xml.xsd	382b0a4f7529d2c5f7b0af0aa713b0a5

Questions and comments relating to this document should be submitted, preferably in electronic format to:

Submission and Information Policy Division (SIPD)
Therapeutic Products Directorate
Health Canada
Finance Building 2,
Address Locator 0201A1
101 Tunney's Pasture Driveway
Ottawa, Ontario
K1A 0K9

Telephone: 613-957-3123
Fax: 613-941-0825
Email: eReview@hc-sc.gc.ca