

INFORMATION

Natural Health Products in Canada - A History

In Canada, natural health products, also referred to as complementary medicines or traditional remedies, are subject to the *Food and Drugs Act* and *Regulations*.

Internationally, the regulation of these types of products varies. Generally they are regulated as drugs in the European Union countries. Australia has recently classified many of these products as “complementary medicines” and has made legislative and regulatory changes to regulate these products as a subclass of “therapeutic goods.” In the United States many natural health products are regulated as “dietary supplements”, a category that does not require pre-market review or proof of safety by the manufacturer before marketing, and is not permitted to make treatment-cure claims.

Interest in natural health products continues to grow. In the last few years, as the use of natural health products has become more widespread, it became apparent that a review of the current regulatory framework was necessary. Currently, studies indicate that over 50% of Canadians use some form of natural health products.

May 1997

Many Canadians began expressing concerns about the regulation and accessibility of herbal remedies. Health Canada responded by establishing the Advisory Panel on Natural Health Products. The Panel provided the Department with direction and advice.

October 1997

The Minister of Health announced a full public review by the House of Commons Standing Committee on Health (SCOH) of the legal regime governing natural health products. The objective of the review was to ensure a balance between Canadians' freedom of choice with respect to natural health products and the assurance of consumer safety. The review was also to address the issue of an appropriate regulatory framework for natural health products in Canada.

October 1997- April 1998

The House of Commons Standing Committee on Health (SCOH) consulted a wide range of interested parties both at home and abroad. It heard from over 150 individuals, associations and coalitions representing many Canadians, including: health care providers, industry, consumer groups, herbalists, and the Advisory Panel on Natural Health Products. The SCOH prepared recommendations on a distinct regulatory framework for natural health products.

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May 1998

The Final Report of Health Canada's Advisory Panel on Natural Health Products entitled *Regulatory Framework for Natural Health Products* was presented to the House of Commons Standing Committee on Health.

November 4, 1998

The Standing Committee on Health tabled its Report *Natural Health Products: A New Vision* in the House of Commons. At that time, the then Minister of Health, Allan Rock, announced he would move quickly to address their recommendations.

March 26, 1999

The Minister of Health tabled the Government Response to the Standing Committee on Health's Report, *Natural Health Products: A New Vision* in the House of Commons. The Government accepted all 53 of the Standing Committee's recommendations and indicated that these would form the basis of the broad policy framework to be established for natural health products. The Minister of Health also announced the creation of the Office of Natural Health Products, now the Natural Health Products Directorate (NHPD), which would provide Canadian consumers with the assurance of safe products while continuing to ensure access to a full range of health products, one of the Committee's key recommendations.

May 1999

On May 19, 1999 the Minister of Health announced the appointment of a 17 member Transition Team to help establish the new Directorate and its regulatory framework. The establishment of the Transition Team was recommended by the Standing Committee on Health in its report in order that a new regulatory framework be established quickly. The Team included 14 members from the natural health private sector, as well as representatives from Health Canada.

November 1999

Health Canada, in co-operation with Dalhousie University, held a Natural Health Products Research Priority-Setting Conference in Halifax, Nova Scotia, from November 6-8, 1999. Over 60 representatives from the scientific, governmental, academic, industry and community sectors took part in this unique opportunity to determine a direction for research activities in the area of natural health products.

January 2000

The Assistant Deputy Minister, Health Protection Branch announced the appointment of Philip Waddington, Doctor of Naturopathy, as the new Director General of the Natural Health Products Directorate.

June 1999- May 2000

The Transition Team worked diligently throughout the 10 months to determine ways for the Directorate to implement the 53 recommendations made by the SCOH. The team produced six reports that highlight their progress during this period, all of which can be found at the Directorate's website: www.hc-sc.gc.ca/hpfb-dgpsa/nhpd-dpsn/tprogress_reports_e.html

The Transition Team submitted to the Minister of Health its final report entitled *Final Report: A Fresh Start*. The report, a summary of the discussions and recommendations of the Transition Team meetings, outlines broad policy directions toward a regulatory regime for natural health products. An Expert Advisory Committee was also formed to advise the Director General of the Directorate on issues related to the safety, use and regulation of natural health products.

June - September 2000

The Natural Health Products Directorate conducted open consultation meetings with interested Canadians across the country on the proposed regulatory framework for natural health products. Over 2,100 participants in 11 cities (Ottawa, Kingston, Halifax, Fredericton, Montréal, Québec, Vancouver, Calgary, Regina, Winnipeg and Toronto) took part in the consultation meetings. The Natural Health Products Directorate heard from industry representatives and associations, consumer associations, professional associations, academics, consumers, and other government bodies.

March - May 2001

A second version of the proposed regulatory framework was drafted and then released at the end of March 2001. Phase II of the consultation process was held between March and May 2001. Feedback was accepted on the proposal, and targeted stakeholder consultation sessions were held at the request of the stakeholder.

September 2001

On September 28, 2001 a working draft of the proposed regulatory framework was shared with stakeholders through its posting on the Natural Health Product Directorate's website. Updates on outstanding issues were also communicated via the website.

November 2001

An industry working group was formed upon recognition of the need to have a specific vehicle for the Natural Health Products Directorate to continue communicating and consulting with Industry as the Natural Health Products Directorate moved toward the regulation of natural health products. This group, in addition to other stakeholders, provided the Natural Health Products Directorate with timely advice regarding the planning and implementation of the proposed regulatory framework for natural health products.

December 2001 - March 2002

On December 22, 2001 the proposed *Natural Health Products Regulations* were pre-published in the *Canada Gazette*, Part I. A public comment period began on this day and ended on March 22, 2002. The Directorate received over 600 submissions during this comment period and undertook an in-depth analysis of them. The final *Natural Health Product Regulations* will be published in Part II of the *Canada Gazette*.

June - July 2002

The Directorate completed a cross-country consultation on its *Good Manufacturing Practices for Natural Health Product Guidance Document*. Information workshops were held in six cities (Halifax, Montreal, Toronto, Winnipeg, Edmonton, and Vancouver).

November 2002

The Directorate proceeded with cross-country information and town hall consultations on the proposed *Standards of Evidence (SOE)* for the evaluation of safety and claims of natural health products, in Halifax, Saskatoon, Toronto, Vancouver and Montreal.

December 2002- January 2003

In the interest of understanding the impact of the proposed Regulations on the natural health product industry, the Natural Health Products Directorate undertook a Business Impact Test from December 6, 2002 until January 22, 2003. 108 responses were received, a robust sample representing all business activities, sizes, product types and provinces.

June 2003

The Natural Health Products Directorate proceeded with the publication of the Regulations in the *Canada Gazette*, Part II followed by a short period to come into force, namely January, 2004 and a transitional period that will span from 2 to 6 years- 2 years for site licensing and 6 years for products with Drug Identification Numbers (DIN).

Many stakeholders have invested significant time and effort in participating in this consultation process. The Natural Health Products Directorate would like to take this opportunity to thank our stakeholders for their valuable contribution.