



Comprehending the Canadian Regulatory Market for Natural Health Products

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10/16/2007

A Natural Health Product (NHP), as defined by Health Canada, is “any plant or plant material, a bacterium, fungus, alga, non-human plant material, or an extract or isolate of these materials.” This includes vitamins and minerals, herbal remedies, homeopathic medicines, traditional medicines such as Traditional Chinese Medicine (TCM), probiotics and other ingredients such as amino acids and essential fatty acids. It is essentially equivalent to the U.S. “dietary supplement” regulatory definition.

The NHP regulations were implemented in January 2004 by Health Canada through its newly formed Natural Health Products Directorate (NHPD). As an addition to the scheme of the Canadian Food and Drug Act and Regulations, NHPs are considered a subset of drugs, in which health claims such as disease treatment or prevention, as well as structure/function claims, are allowed. The regulations include product licenses, labeling requirements, evidence summary reporting, safety summary reporting, quality summary reporting, clinical trial guidance and procedures, GMP and site licenses.

The regulations require pre-market approval from NHPD for all NHPs that are new to the Canadian market, as well as re-approval of all existing NHPs in a six-year transition period. In addition, site licenses are required for Canadian companies that manufacture, package, label or import NHPs.

Market Update

Seventy-one percent of Canadians have used NHPs and 27 percent of Canadians regularly take NHPs on a daily basis, according to a 2005 survey by Ipsos Reid. Information on the NHP market size in Canada is somewhat limited and relatively inconsistent. According to the Canadian Health Food Association (CHFA), NHP retail sales hit approximately \$2.5 billion in 2005 and are expected to grow to \$2.75 billion by 2010. However, Euromonitor International placed retail sales of vitamins and dietary supplements in Canada at \$764 million in 2005, with projected growth to \$889 million by 2010. It is speculated that the market size discrepancy may due to different interpretations and inclusion of functional foods and nutraceuticals in addition to NHPs.

Multivitamins, herbal remedies, algae and fungal products are the most commonly used NHPs, according to the Euromonitor report. Demand for multivitamins is strong compared to that for herbal products, as half of Canadians who report using NHPs take multivitamins. Retail sales of multivitamins, vitamin C, vitamin E, calcium and glucosamine have showed good growth. Fish oil sales, although having positive growth for their omega-3 fatty acid benefits, are still relatively low, possibly because of consumer concern over fish heavy metal contamination and/or the use of alternative omega-3 ingredients such as flaxseed.

The use of herbal supplements reportedly dropped by 10 percent between 2001 and 2004, because of consumer disappointment at exaggerated health benefits associated with botanicals. Concerns over herb and conventional drug interactions, along with recalls by Health Canada of a number of herbal products on account of safety issues have also contributed to the decline of herbal sales. There have been withdrawals of some brands and manufacturers from the market because of inability to meet the new NHP regulations.

Vitamins and dietary supplements saw a 13-percent value growth from 2000 to 2005. Bone, joint and heart condition-specific products are the top three categories, occupying a retail value of 31 percent, 15 percent and 7 percent, respectively, among all dietary supplements in 2005, according to the July 2007 NHPD Status of Submissions Report.

It is projected that multivitamins, including those reputed to possess antioxidant benefits, such as vitamin E and vitamin C, will remain as the best sellers by 2010. Other NHPs such as calcium, minerals, glucosamine and eye health products, addressing age-related problems, are expected to have elevated sales growth because of the rise in the number of aging Canadians. Many herbal NHPs have reached maturity and are expected to continue to face challenges and further sales value decline over the next few years. Nevertheless, demand might strengthen for those herbal NHPs with approved efficacy claims, safety and quality from NHPD under the new regulations. NHPs with secured product licenses and proven efficacy and safety, especially for the elderly, will perform well. NHPs targeting chronic diseases that conventional drugs have not been able to fully address and properly manage, e.g. osteoporosis and arthritis, will have strong demand. A significantly reduced number of NHPs in the Canadian marketplace where overall demand will remain strong is expected.

Regulatory Update

The processing of product and site license applications has been a daunting task for NHPD. The agency developed compendial monographs for primarily medicinal ingredients with well established evidence of efficacy and safety. Since the implementation of the NHP regulations, a total of 21,428 product license applications had been submitted to NHPD by July 06, 2007, covering 18,344 non-compendial products and 3,084 compendial products. Only 6,037 (33 percent) of the non-compendial products have been completed, in which 4,889 (81 percent) were withdrawn or rejected, and 1,148 (19 percent) were approved. Reportedly 2,785 (90 percent) of the submitted compendial applications have been completed, of which 290 (10 percent) were withdrawn or rejected, and 2,495 (90 percent) approved, according to the July 2007 NHPD "Status of Submissions Report."

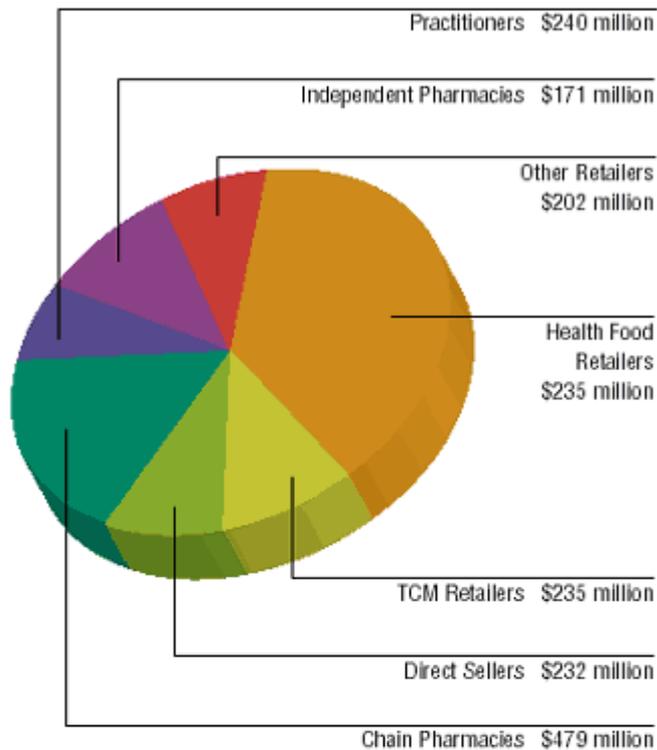
As of July 6, 2007, a total of 905 site license applications had been received, of which 186 applications were withdrawn or refused and 530 site licenses granted by NHPD.

Also, NHPD has recently started to take enforcement action on products without submission numbers beyond their priority deadlines and those which pose high risk to consumers. Technically, any product without a product license (i.e. Natural Product Number, NPN) cannot be sold in the market. However, there is huge backlog of product license applications. NHPD acknowledges it does not have enough resources to process these applications in a timely manner, leaving many applications in the processing pipeline. So far, it appears NHPD's enforcement has primarily focused on products that do not have submission numbers. It is believed that NHPD will step up its enforcement actions after resolving the applications backlog.

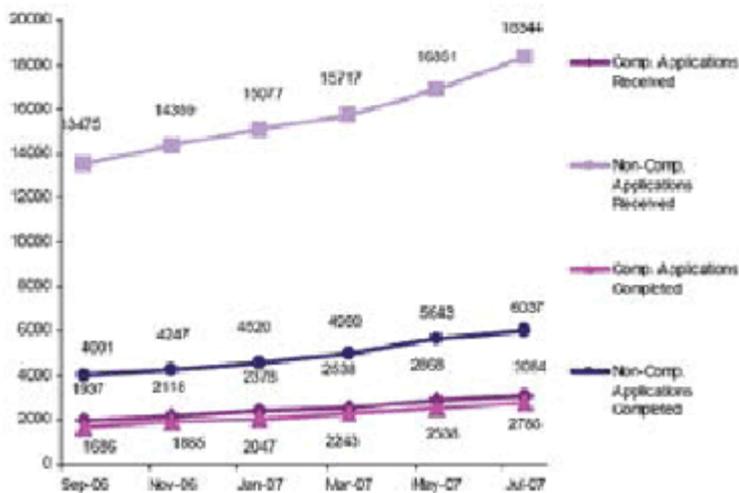
Currently, NHPD does not charge processing fees for product and site license applications. Earlier in 2007, Health Canada released a cost recovery framework consultation, by which various amounts of application fees have been proposed to recoup NHPD's costs and expedite processing time. The proposed application fee on a NHP product and/or site license is in the range of \$1,260 to \$3,610. In addition, maintenance fees such as site license renewal fee and annual product license fee were introduced. The implementation of these proposed new fees is scheduled for April 2008.

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The Canadian Natural Health Product Market at Retail in 2005—\$2.5 Billion



Product License Applications Received & Completed Since Sept. 2006



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