Informing You About Natural Health Products

Information Sheet #4 - for Pharmacists - Informing Yourself

Protecting and promoting the health and safety of Canadians, their families and communities is of paramount importance to the Government of Canada. The Government is committed to ensuring that regulation of natural health products balances the protection of consumers' health and safety with the freedom to choose complementary and alternative products.

The *Natural Health Products Regulations* have been in force since January 1, 2004, and were put in place to help assure that Canadians have access to natural health products that are safe, effective and of high quality. They do so by setting out requirements for the manufacture, packaging, labelling and importation of natural health products for sale in Canada.

Natural Health Products

Natural health product (or NHP) is a term used in Canada to refer to a group of health products including: vitamin and mineral supplements, herbal remedies and other plant-based health products, traditional medicines (such as traditional Chinese medicines and Ayurvedic [East Indian] medicines), homeopathic medicines, fatty acids (such as omega 3, 6 and 9), probiotics and some personal care products such as antiperspirants, medicated shampoos and mouthwashes.

Requirements for sale in Canada

The *Natural Health Products Regulations* are administered by the Natural Health Products Directorate (NHPD) within Health Canada and apply to the manufacturing, packaging, labelling and importation of NHPs for sale in Canada. The regulations include specific labelling and packaging requirements as well as good manufacturing practice standards. Evidence supporting health claims is assessed by Health Canada. To be sold in Canada, NHPs must undergo pre-market review and be granted product licenses, and the Canadian facilities that manufacture, package, label and import NHPs must obtain valid site licences.

Compounding of NHPs

The product and site licensing requirements of the *Natural Health Products Regulations* do not apply to health care professionals who compound products on an individual basis for their patients.

This information is stated in the Natural Health Product Compounding Policy available at:
http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/pol/policy_compound-politique_compose-eng.php

This Policy provides a clear distinction between the manufacturing of NHPs which is regulated and the compounding of NHPs which is not.

NPNs and DIN-HMs

NHPs that have been issued a product licence bear an eight-digit Natural Product Number (NPN) or Homeopathic Medicine Number (DIN-HM) on the label. A NPN or DIN-HM on a label means that the product has been assessed by Health Canada and has been found to be safe and effective under the recommended conditions of use. The absence of a NPN or DIN-HM means the product has not yet been assessed by Health Canada, however this does not necessarily mean that the product is unsafe.

DIN Transition

Prior to the adoption of the *Natural Health Products Regulations* in 2004, some products (e.g. vitamins and minerals) were assessed by Health Canada and issued a Drug Identification Number (DIN). As with a NPN or DIN-HM, a DIN is a valid licence to sell a natural health product in Canada. The use of a DIN for NHPs is being phased out beginning January 1, 2010. Therefore, some NHPs may still be found on store shelves with a DIN on the label and not a NPN or DIN-HM. After a NPN is issued for a product that once had a DIN, the older label stock (bearing the DIN) may still be used and found on the labels of NHPs on the market for a period of time.

Standards of Evidence

The safety and efficacy of health claims associated with NHPs must be supported by appropriate evidence. Health Canada recognizes that NHPs are different in composition, use patterns and manufacturing practices than products regulated as drugs. Given this and the diversity of NHPs, Health Canada accepts various types of evidence ranging from traditional uses, references to monographs, standards, published studies, journals, pharmacopoeias, traditional resources and clinical trial data. The type and amount of evidence required is dependant on a number of factors, including the nature of the proposed claim(s), product composition, dose and dosage form and overall risk.

For product applications where a monograph can be referenced as safety and efficacy evidence, the NHPD has developed a **Compendium of Monographs** available at:
www.healthcanada.gc.ca/nhp_monographs

Each published monograph, although not intended to be a comprehensive study of the medicinal(s) ingredient(s), is a thorough review of scientific literature conducted to develop a fully referenced document. These monographs can be used to support the safety and efficacy of a product as part of the pre-market assessment process.

Licensed Natural Health Products Database and MedEffect™ Database

Up-to-date information on licensed NHPs can be found in the **Licensed Natural Health Products Database (LNHPD)**, which is available online at:
www.healthcanada.gc.ca/lnhpd

The **MedEffect**™ Database provides known safety information associated with NHPs. Health care professionals are encouraged to report all adverse reactions to Health Canada as this will help identify rare or serious adverse reactions previously unknown as well as make changes in product safety information; issue public warnings and advisories, and/or remove unsafe products from the Canadian market. Information on how to report an adverse event is also available at the following link.

The **MedEffect**™ Database can be accessed at:
www.healthcanada.gc.ca/medeffect

Scheduling

NHPs are not scheduled on the federal drug schedules (e.g., Schedule F of the *Food and Drug Regulations* or schedules under the *Controlled Drugs and Substances Act*).

Provincial and territorial health authorities determine how drugs will be sold within their respective jurisdictions based on unique drug scheduling systems. Natural health products are examined under these systems as applicable. Pharmacists are encouraged to contact their respective scheduling bodies regarding the scheduling status of NHPs.

Special Access Program

The Special Access Program (SAP), includes provisions set out in the *Natural Health Products Regulations* and the *Food and Drug Regulations* to authorize a manufacturer to sell a drug or NHP that can not otherwise be sold or distributed in Canada. The SAP allows practitioners to request access to drugs or health products, including NHPs that are not licensed for sale in Canada. This access is limited to individual patients with serious or life-threatening conditions on a compassionate or emergency basis when conventional therapies have failed, are unsuitable, or are unavailable.

The practitioner is responsible for initiating a request for SAP approval on behalf of a patient and ensuring that the decision to prescribe the drug or recommend the NHP is supported by credible evidence available in the medical literature or provided by the manufacturer. It is also the practitioner's responsibility to ensure that patients are well informed of the possible risks and benefits of the drug or NHP being requested.

More information on the Special Access Program and how to access it can be found at:
www.hc-sc.gc.ca/dhp-mps/acces/drugs-drogues/index-eng.php

Compliance and Enforcement

To be sold in Canada, NHPs must meet the requirements of the *Natural Health Products Regulations*.

Over 19,000 natural health product licences (representing over 25,000 products) have been issued and other products are currently under review and assessment for a licence. In order to ensure that access to safe NHPs is not limited while the review process is being completed, Health Canada has adopted a risk-based approach to compliance and enforcement related to unlicensed products.

Under this approach, action is taken (e.g. requesting NHPs be removed from store shelves) specifically when an unacceptable risk to health is identified; when the unlicensed product does not currently have a product licence application under assessment at Health Canada; and/or when the unlicensed product is manufactured, packaged, labelled or imported by Canadian sites that do not hold valid site licences.

This approach enables Health Canada to target NHPs that present a risk to health without restricting access to other lower-risk NHPs that are awaiting the assessment of their licence application. This explains why unlicensed NHPs without a NPN or DIN-HM can currently be found on store shelves.

Detailed information on compliance and enforcement is available in the following documents:

-Compliance and Enforcement Policy

-Compliance Policy for Natural Health Products

-Natural Health Products Compliance Guide

-Health Products and Food Branch Inspectorate Recall Policy

These policies are available at:

http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/pol/index-eng.php