Health Canada Santé Canada

-Fact Sheet-
Drug Identification Number (DIN) to Natural Health Product Number (NPN) Transition

December 2009

What are "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 products, traditional medicines (such as Traditional Chinese Medicines and Ayurvedic [Indian] Medicines), homeopathic medicines, fatty acids (such as omega 3, 6 and 9), probiotics and some personal care products such as antiperspirants, shampoos and mouthwashes.

NHPs are regulated under the *Natural Health Products Regulations* (NHPR). NHPs are included in the definition of a "drug" under the *Food and Drugs Act* (FDA) and are regulated as a subset of "drugs" with a separate regulatory framework (the NHPR). The *Food and Drug Regulations* (FDR) and the NHPR provide a comparable level of regulatory oversight. Both regulatory frameworks have premarket review of products for safety, quality, and efficacy. Both regulatory frameworks require that good manufacturing practices (GMP) be met before site/establishment licences are issued.

Background

The NHPR came into force on January 1, 2004. At that time, products which had already received market authorization in the form of a drug identification number (DIN) under the FDR and which now met the natural health product (NHP) definition were given 6 years to come into compliance with the NHPR. These products, referred to as "transitional DINs", were given until December 31, 2009 to obtain a product licence under the NHPR. Licensed natural health products can be identified by the 8-digit natural product number (NPN, or DIN-HM for homeopathic medicines) on the product label. When a DIN is transitioned to an NPN the 8-digit number remains the same, - the change occurs to the prefix before the 8-digit number (e.g. DIN 12345678 is transitioned to NPN 12345678).

All NHPs for sale in Canada require a product licence from Health Canada. The NHPR includes the requirement for pre-market review of a product's safety, quality and efficacy before a product licence is issued. Health Canada reviews all product licence applications and issues licences only when the information provided by applicants supports the high quality of the product, the safe use of the product under the recommended conditions of use and the health claim being made for that product.

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 an NPN or DIN-HM. After an 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 6-12 months.

Licensed Natural Health Products Database (LNHPD)

The Licensed Natural Health Products Database (LNHPD) contains product specific information on those natural health products that have been issued a product licence by Health Canada.

The LNHPD is managed by Health Canada and includes information on licensed natural health products, such as vitamin and mineral supplements, herb and plant-based remedies, traditional medicines (such as Traditional Chinese Medicines or Ayurvedic [Indian] Medicines), omega 3 and

essential fatty acids, probiotics and homeopathic medicines as well as many everyday consumer products, such as certain toothpastes, antiperspirants, shampoos, facial products and mouthwashes.

The LNHPD can be found at the following address:
http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-prod/lnhpd-bdpsnh-eng.php

Drug Product Database

The Drug Product Database (DPD) contains product specific information on drugs approved for use in Canada. The database is managed by Health Canada and includes human pharmaceutical and biological drugs, veterinary drugs and disinfectant products. It contains approximately 23,000 products which companies have notified Health Canada as being marketed.

The DPD, much like the LNHPD, allows consumers to search for information on products that have a DIN. When a DIN is transitioned to an NPN or a DIN-HM the DPD will indicate that the product has been transitioned to an NHP.

The DPD can be found at the following address:
http://www.hc-sc.gc.ca/dhp-mps/prodpharma/databasdon/index-eng.php

Comparison Between Drug and NHP Regulatory Frameworks

It is important to point out that the FDR and the NHPR provide a comparable level of regulatory oversight. Both regulatory frameworks have premarket review of products for safety, quality, and efficacy. Both regulatory frameworks require that good manufacturing practices (GMP) be met before site/establishment licences are issued (GMP requirements for NHPs are set out in Part 3 of the NHPR, while GMP requirements for drugs are set out in Division 2 of the FDR). Currently the issuance of a site licence does not require on-site verification of regulatory compliance to GMPs prior to site licence issuance; instead, a paper-based quality assurance report is submitted to Health Canada. The issuance of an establishment licence does require on-site verification of regulatory compliance to drug GMPs prior to establishment licence issuance.

Impact of DIN to NPN Transition on Insurance Coverage

Under the *Canada Health Act*, insured health services, which must be covered by provincial and territorial health insurance plans, are medically necessary physician and hospital services. Insured hospital services include drugs, biologicals and related preparations when administered in the hospital. In addition to the provision of medically necessary hospital and physician services, provincial and territorial governments may also offer "additional benefits" at their own discretion, such as prescription drug coverage. Since Canada's current health care system is based on the practice of western medicine, for the most part, alternative health care services are not covered by provincial and territorial health insurance plans.

Most Canadians have access to insurance coverage for prescription medicines through public and/or private insurance plans. The federal, provincial and territorial governments offer varying levels of coverage, with different eligibility requirements, premiums and deductibles. The publicly-funded drug programs generally provide insurance coverage for those most in need, based on age, income, and medical condition.

In general, neither non-prescription drugs (with DINs) nor natural health products (with NPNs or DIN-HMs) are covered by public plans. For further information regarding coverage through public insurance plans, please contact your provincial or territorial government. For further information regarding coverage through private insurance plans, please contact your employer or insurance provider.

Compliance Policy

Health Canada's current compliance approach to NHPs which have not received market authorization by way of an NPN or DIN-HM is described in the Compliance Policy for Natural Health Products (http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/pol/complian-conform_pol-eng.php). Under this policy, a product which has received a submission number, i.e., has applied for a product licence, is considered as presenting a lower risk, and generally, such products are not targeted for compliance action unless a risk has been identified. However, compliance action will be taken when products present an unacceptable risk to health, or have not been the subject of a product licence application to Health Canada. As is current practice, Health Canada looks into all consumer and trade complaints concerning natural health products. Any resulting compliance and enforcement action taken will be based on the risk the product poses to the health of Canadians. Compliance and enforcement activities are conducted in accordance with the Health Products and Food Branch Compliance and Enforcement Policy (POL-0001 version 2) (http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/pol/pol_1_tc-tm-eng.php).

The Compliance Policy for Natural Health Products was adopted to provide a reasonable transition period to allow manufacturers and distributors of NHPs to apply for product licences and bring their products into compliance with the requirements of the NHPR. The Policy does not include a precise end-date. As the NHPD continues to address its product licensing backlog and issue product licences, and now that more licensed products are available on store shelves, discussions have begun to determine the approach that should be taken to compliance and enforcement at some time in 2010.

The NHPD is working with the Health Products and Food Branch Inspectorate and in consultation with stakeholders to develop an updated risk-based compliance and enforcement plan. The plan will be phased in beginning the fall of 2010 with an initial phase involving extensive outreach, communication and education activities.

For further questions regarding natural health products please send your inquiries to the following address:

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