INFORMATION

At a Glance: A Regulatory Framework for Natural Health Products

Natural Health Products Regulations include provisions on: definitions, product licensing, site licensing, good manufacturing practices, clinical trials, labelling and packaging requirements, and adverse reaction reporting. The Regulations will come into force on January 1, 2004 followed by 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).

The **definitions** include the definition of a natural health product (including, for example, vitamins, minerals, herbal remedies and homeopathic medicines) and other terms (recommended conditions of use, adverse reaction, etc.) which are key to the functioning of the proposed Regulations.

A **product licensing system** requires that all licensed products display a product identification number preceded by the prefix NPN, or, in the case of a homeopathic medicine, by the letters DIN-HM on their labels. The number is issued once a product is authorized for sale in Canada by the Natural Health Products Directorate. Product authorization requires either: I) reference to a *natural health product monograph* (published by the NHPD), or ii) submission of other evidence of safety and health claim. The NHPD is finalizing a standards of evidence framework intended to indicate the type of information that will be necessary to support various health claims, where an NHPD monograph is not available. The Regulations include circumstances for refusing, suspending or cancelling a natural health product licence. This system assists Health Canada in ensuring that quality natural health products are sold to the public, and that quick and effective product recalls can be undertaken when necessary.

A system of **site licensing** has been developed. This system requires that all manufacturers, packagers, labellers, and importers be licensed; sites have procedures in place respecting distribution records and product recalls; where applicable, sites have procedures in place for the handling, storage and delivery of their products, and sites meet good manufacturing practice requirements (commonly known as GMPs, as discussed below). The Regulations also set out circumstances for refusing, suspending or cancelling a site licence.

Good Manufacturing Practices (GMPs) are to be employed to ensure product safety and quality. This requires that appropriate standards and practices regarding product manufacture, storage, handling and distribution respecting natural health products be met. The provisions cover: specifications (product), premises, equipment, personnel, sanitation program, operations, quality assurance, stability, records, sterile products, lot or batch samples, and recall reporting.

.../2

Standard **labelling requirements** are established to ensure consumers can make informed choices. Examples of the required label information include: the product name, the quantity of product in the bottle, recommended conditions of use (including such things as: its recommended use or purpose, dosage form, route of administration, recommended dose, and any cautionary statements, warnings, contra-indications and possible adverse reactions associated with the product), as well as any special storage conditions.

The **adverse reaction reporting** system for natural health products assists Health Canada in issuing advisories, where appropriate, to the public. This type of reporting system is an important part of a product authorization system based on risk assessment and the corresponding management of risks. The Regulations require product licence holders to monitor all adverse reactions associated with their product. Serious adverse reactions are reported to Health Canada.

The framework addresses the treatment of **vitamins and minerals**. Since vitamins and minerals are included in the definition of natural health products, they are treated in the same manner as other natural health products. Certain existing regulatory measures (which restrict the health claims that can be made for vitamins and minerals) are repealed. The repeal of provisions dealing with the minimum and maximum daily dose of vitamins and minerals that are permitted in products used to *supplement* dietary intake and in those vitamins and minerals that are used at *therapeutic* levels is also part of these Regulations.

Finally, the Regulations incorporate by reference a number of provisions from the current *Food and Drug Regulations*. Some of these are imperative to the overall compliance and enforcement of the Regulations (e.g., relating to Health Canada inspectors). Others address matters such as child resistant packaging, security packaging and pressurized containers, as well as the manufacture of certain sterile products.

The transition provisions for the *Natural Health Product Regulations* consider a staged approach over the next six years. Each of the three phases will begin in January 2004, and we envision completing the transition over the following schedule:

1. by the end of two years, all manufacturers, importers, packagers and labelers will employ good manufacturing practices (GMPs) and have site licences;
2. by the end of four years, any new Natural Health Products that are on the market will have obtained a NHP product licence (NPN);
3. by the end of six years, NHPs that currently have a product licence as a Drug Identification Number (DIN), will have transferred to have a NPNor a DIN-HM (homeopathic medicine).