

## UPDATED POSITION STATEMENT

### Sale of Non-Approved Marketed Health Products

August 2010

#### *Position Statement*

Pharmacists should not sell a marketed health product without a Drug Identification Number (DIN), Natural Product Number (NPN), Drug Identification Number for Homeopathic Medicine (DIN-HM) or an Exemption Number (EN).

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#### **Background**

All marketed health products for sale in Canada require a market authorization, product licence or an exemption number for natural health products (NHPs) from Health Canada. This condition applies to drugs per the regulatory requirements outlined in the *Food and Drug Regulations*. This same condition applies to natural health products, homeopathic products as well as exempted products per the regulatory requirements of the *Natural Health Products Regulations* (NHPR) promulgated by the federal government six years ago and the recently promulgated *Natural Health Products (Unprocessed Product Licence Applications) Regulations* (NHP-UPLAR).

Under the federal drug approval process, drugs, natural health products and homeopathic products must complete a review process and obtain a market authorization or a product licence from Health Canada in order to be sold. The approval follows a review by Health Canada for the product's safety, efficacy and quality. Once approved for sale, a number is provided by Health Canada to identify the marketed health product. For instance, drugs are identified by a Drug Identification Number (DIN), natural health products by a Natural Product Number (NPN) and homeopathic products by a Drug Identification Number for Homeopathic Medicine (DIN-HM). These numbers are indicated on the package label by the manufacturers and serve as a means for the public and health care professionals, such as pharmacists, to know that the product completed Health Canada's review and is approved for sale. In place for many years, this approval process is the single most important element of the federal/provincial/territorial safety net system.

New Regulations promulgated on August 4, 2010 allow the legal sale of a category of products for which Health Canada has not yet issued a product licence but has completed an initial assessment to ensure that information supporting the safety, efficacy and quality of the product has been provided and that specific safety criteria have been met. This category of products will receive an Exemption Number (EN) from Health Canada.

Pharmacists are obliged to hold the health and safety of the public or patient as their first and foremost consideration. As such, they must follow very specific standards of practice to fulfill this role. When presented with a product, a pharmacist requires confirmation that the product is authorized for sale by Health Canada whose mandate is to ensure the product's safety, efficacy and quality. Regulations under the *Food and Drugs Act* oblige manufacturers to place the authorization number on the label to facilitate the identification by pharmacists and others. As Health Canada allows for a transition period under the new NHP-UPLAR before the Exemption Number appears on the product label, pharmacists and others may have to consult the Natural Health Products Exempted Database to verify approval status of the exempted products.

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NAPRA and its members, the provincial and territorial pharmacy regulatory authorities, abide by the condition set out in federal regulations whereby marketed health products that have not been issued a market authorization, a product license or an exemption number by Health Canada for their sale, should not be sold by pharmacists. In formulating a specific position on this matter, NAPRA members wish to reinforce this fundamental regulatory requirement in the interest of public safety.