

POSITION STATEMENT

Sale of Non-Approved Marketed Health Products

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Position Statement

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

Background

All marketed health products for sale in Canada require a market authorization or product licence 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 (NHPs) and homeopathic products per the regulatory requirements of the *Natural Health Products Regulations* (NHPR) promulgated by the federal government six years ago.

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.

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 that does not bear a number issued by Health Canada, it leaves the pharmacist and their patient with no confirmation that the product was properly assessed for its safety, efficacy and quality nor granted approval for sale. In these situations, a pharmacist may consult Health Canada's website (Drug Product Database or the Licensed Natural Health Product Database) to obtain the list of approved products or inquire about a specific product's status. Verifying the information on the website is not always practical however it may be a useful tool for NHPs in view of the NHP licensing backlog experienced by Health Canada. The department set a revised internal target date of March 31, 2010 to address the remaining NHP product licence applications.

Even though an argument can be made that an NHP or homeopathic product without a product license is not necessarily unsafe, the reverse is also true. There is no guarantee that the required criteria for product safety were met. Pharmacists should not be placed in situations where they may be in a position to sell products that have not received approval for sale in Canada.

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 or a product license 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.
