Sale of Non-Approved Marketed Health Products

In meeting the ongoing mandate to serve and protect the public; the College reminds members that only products that have received a market authorization or a product license from Health Canada are approved for sale in Canada. As communicated by and outlined on the National Association of Pharmacy Regulatory Authorities' (NAPRA) website - http://napra.ca/pages/Schedules/Schedules_Products.aspx

SALE OF NON-APPROVED MARKETED HEALTH PRODUCTS

Once a marketed health product is approved for sale, approval follows a review by Health Canada for the product's safety, efficacy and quality, and a number is provided to identify the product.

Only products that have received a market authorization or product licence from Health Canada are approved for sale in Canada. Authorized products will bear a Drug Identification Number (DIN) or a Natural Product Number (NPN) or a Drug Identification Number for Homeopathic Medicine (DIN-HM). These numbers serve as a means for the public and healthcare professionals to know that the product is authorized to be sold on the Canadian market.

The Natural Health Products (Unprocessed Product Licence Applications) Regulations promulgated by Health Canada in August 2010 have now been repealed, eliminating the temporary category of authorized products known as Exempted, having an Exemption Number (EN). More information regarding the repeal of the NHP-UPLAR can be found on the Health Canada website.

To assist in confirming if a particular product is licensed by Health Canada members may wish to:

1) Search Health Canada's Drug Product Database (DPD) or the Licensed Natural Health Products Database.
   a. Drug Product Database - http://webprod5.hc-sc.gc.ca/dpd-bdpp/index-eng.jsp.
   b. Licensed Natural Health Products Database - http://webprod5.hc-sc.gc.ca/lnhpd-bdpsnh/index-eng.jsp

2) Visually inspect the product package. All authorized products will bear a Drug Identification Number (DIN) or a Natural Product Number (NPN) or a Drug Identification Number for Homeopathic Medicine (DIN-HM).[1] These numbers serve as a means for the public and health care professionals to know that the product is authorized to be sold on the Canadian market.

3) Contact Health Canada at 1-800-622-6232 to obtain clarification.

Foreign health products are subject to the same Canadian market authorization process, as well as requirements related to the importation of health products as defined by the *Food and Drugs Act* and its Regulations.[2] Products with Canadian market authorization or a product license have been assessed by Health Canada and found to be safe, effective and of high quality under their recommended conditions of use. Unapproved health products of foreign and domestic source offer no guarantee of product integrity, efficacy, or safety.

In the event that a non-approved health product is discovered for sale by any Canadian retailer, members of the College and public alike are encouraged to report the retailer and product to Health Canada using the Health Product Complaint Form (FRM-0317) available on the Health Canada website - http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/frm-0317-eng.php.

Reflecting back to the Code of Ethics[3] - *In holding the patient's well-being at the center of one's professional and/or business practices*; members are advised to neither sell, recommend, nor dispense any unauthorized or unlicensed health product. Additionally, members, as retailers, should remain cognizant of any further legislation governing the sale of products from their place of business.

1. Health Canada POL-0044. Retrieved at: http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/prodnatur/lett-complian-conform-pol-eng.php#a2
2. Health Canada POL 0060. Retrieved at: http://www.hc-sc.gc.ca/dhp-mps/compli-conform/import-export/pol-0060_biu-uif-eng.php#a51
3. OCP Code of Ethics. Retrieved at: http://www.ocpinfo.com/regulations-standards/code-ethics/

DEFINITIONS

"Health product" includes products regulated under the *Food and Drugs Regulations* ("drugs") and the *Natural Health Products Regulations* ("natural health products").

"Drug" as defined in the *Food and Drugs Act* includes any substance or mixture of substances manufactured, sold or represented for use in:

a. the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals;
b. restoring, correcting or modifying organic functions in human beings or animals; or
c. disinfection in premises in which food is manufactured, prepared or kept.

"Natural health product" as defined in the *Natural Health Products Regulations* is a substance set out in Schedule 1 of the *Natural Health Products Regulations* or a combination of substances in which all the medicinal ingredients are substances set out in Schedule 1 of the *Natural Health Products Regulations*, a homeopathic medicine or a traditional medicine, that is manufactured, sold or represented for use in:

a. the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
b. restoring or correcting organic functions in humans; or
c. modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.