To the Editor:
This is an article form a series of monthly columns by Environmental Law Specialist Dianne Saxe, one of the top 25 environmental lawyers in the world, and Ms. Jackie Campbell. These articles are available for publishing at no charge, provided Dr. Saxe and Ms. Campbell are cited as the authors. Dr. Saxe can be contacted at (416) 962-5882 or admin@envirolaw.com. For more information, visit http://envirolaw.com

Are Natural Health Products sufficiently regulated?

Drugs are highly regulated under Canada's *Food & Drugs Act* (FDA), but natural health products (NHPs) fell between the regulatory cracks until Health Canada began regulating these agents in 2004. As a practicing pharmacist, I am concerned that Health Canada does not apply the same stringent factors in licensing NHPs as it does for drugs.

NHP's include homeopathic or traditional medicines, plant materials or extracts, vitamins, amino acids, essential fatty acids, minerals (including iron), and probiotics. They may be manufactured, sold or represented for use in diagnosis, treatment, mitigation or prevention of a disease or disorder (or its symptoms), or restoring or modifying organic functions in humans. The FDA lists several diseases (called Schedule A diseases) for which prevention, treatment or cure claims were historically prohibited in labelling and advertising to the general public. These include cancer, appendicitis, high blood pressure, obesity and heart disease. However, since June 1, 2008, NHPs and certain non-prescription drugs may be advertised as preventive agents for Schedule A diseases. The rationale behind this change is that prevention of such diseases does not require intervention by a practitioner, whereas treatment or cure would.

NHP health claims not rigorous

In one sense, the NHP regime imposes stringent controls on manufacturers. For example, they must report serious adverse reactions to these agents, good manufacturing practices must be followed, and detailed records, including a list of all ingredients and records of lot testing, are required. As well, any NHP recall must be reported within 3 days (a little slow compared with drug recalls, which must be reported "forthwith").

However, the only evidence required to support efficacy claims for NHPs may be information from generally accepted and traditional references or professional consensus. Unfortunately, many of these "other" types of evidence do not meet the rigorous evidence-based standards that drugs must meet. For example, **traditional medicine** is based on knowledge and practices that are indigenous to different cultures and "traditional use" claims require that a product have at least a 50-year history of such use, within a cultural belief system. Evidence to support these claims may be from a traditional reference (e.g.,

the Ayurvedic Pharmacopoeia of India) or through other evidence, including oral history provided by recognized experts. The most commonly available evidence available for **homeopathic medicines** is from references like the homeopathic *materia medica* or homeopathic provings. Provings are non-toxic dilutions that cause symptoms in healthy individuals; these are tested and systematically observed and recorded. Of note, the European Committee for Homeopathy has expressed concern that provings lack consistency in methodology and quality.

Buying NHPs – look at the label!

It is prohibited to sell a NHP unless a product licence has been issued for that product, with one exception. As of March 2010, Health Canada had received over 47,000 product licence applications, and processed over 37,000 of these. However, over 10,000 NHPs were being sold in Canada without a licence, but for which a product licence application had been filed. In August, the government enacted a regulation that will be in force for 30 months, to permit these NHPs to continue to be sold. These products are assigned exemption numbers (EN), which will remain in force until the application is withdrawn, processed and a licence issued (or not), or the regulation is repealed. Of note, Health Canada only assigns EN to products once it has completed its initial assessment, and where information that supports safety, quality and efficacy of the products is available, and specific safety criteria met. Health Canada indicates that this regulation will "preserve" at least $245 million in product sales during the first year. Would such an exemption ever apply to drugs in the midst of the review process? Not a chance.

The exemption regulation is somewhat risky, considering the number of product licence applications that Health Canada refuses. In its recent report, Health Canada states that it received 4366 product licence applications in the first quarter of 2010-11. Of these, it had completed 3661: 2671 products received licenses, 760 were refused and 230 applications were withdrawn. This means that 21% of applications were refused (during another period, the fourth quarter of 2009/10, over 35% of applications were refused). Reasons for refusal are not provided in the report, although past refusals have included failure to meet application requirements, or where quality, safety and/or efficacy issues were identified.

Even pharmacists are confused as to which NHPs they may or may not sell. The National Association of Pharmacy Regulatory Authorities issued a position statement advising pharmacists not to sell a marketed health product that did not have a Drug Identification Number (DIN; these are assigned to all licensed drug products in Canada), a NPN, DIN for Homeopathic Medicine (DIN-HM), or an EN. My College, the Ontario College of Pharmacists, adopted this statement. A NHP must be clearly labelled not only with names of ingredients, but also with recommended use, dose and risk information, as well as the assigned product number, preceded by the NPN, DIN-HM or EM designation. Consumers beware: if a product label does not include this designation, *it hasn't undergone any type of regulatory review* -- don't buy it!

Read Health Canada's on-line advisories for unauthorized health products that may be for sale and be a risk to health. For example, Health Canada published a list of 18 such products being sold in fitness stores on Vancouver Island; these contain stimulants and sex hormones, among other things.

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References available on request from jackie@envirolaw.com