



NATURAL HEALTH PRODUCTS

Fact Sheet

Making sense of complementary and alternative medicines

What are Natural Health Products? Under new regulations in Canada, natural health products (NHPs) are defined as vitamins, minerals, herbal remedies, homeopathic medicines, traditional medicines such as Traditional Chinese Medicines, probiotics, and other products like amino acids and essential fatty acids (e.g., Omega-3). Sometimes these kinds of products are also referred to as "complementary" or "alternative" medicines.

NEW NATURAL HEALTH PRODUCT REGULATIONS IN CANADA

It is estimated that approximately 50 per cent of Canadians use some form of natural health products, or "complementary" or "alternative" medicines. In the interest of consumer safety and product availability, Health Canada has adopted the new Natural Health Products Regulations under the Foods and Drugs Act. Prior to the new regulations, NHPs were covered under the Food and Drug Regulations, but as more Canadians began to use NHPs, it became apparent that neither treatment as a food, nor a drug under the current regulations would be appropriate, and that a new policy which would directly address the unique nature of NHPs was required. Having products go through regulatory approvals will

increase consumer confidence in safety and effectiveness of the NHPs. Product reviews by Health Canada before the product can be sold will assure consumers that what is on the label is what is in the bottle and that health claims are supported by appropriate levels of evidence. (Source: Health Canada web site, June 10, 2004).

Consumers will be able to make informed decisions because the new regulations require more information on the label, such as specific directions for use, recommended use or purpose (health claim), medicinal and non-medicinal ingredients, and any cautions, contraindication (i.e., when it should not be taken), or known adverse reactions associated with the product.

All NHPs in Canada now need a product license before being sold. Health Canada requires detailed information about the medicinal (treatment) ingredients, source, potency (strength), non-medicinal ingredients, and recommended use before they will issue a license. Once a product is assessed, the label will show a license number beginning with the letters "NPN," or in the case of a homeopathic medicine, by the letters "DIN-HM" indicating that the product has been reviewed and approved by Health Canada for safety and usefulness.

Standards of evidence such as history of use or traditional references, observational studies, expert committee reports, and clinical or trial data are relied upon by industry to make health claims. To address the need for ongoing research for NHPs, Health Canada has committed \$5 Million over five years to create the NHP Research Program.

The NHP regulations came into force January 1, 2004, with no transition period for new NHP products. As of January 2006, all products that were manufactured, packaged, labeled, or imported before January 1, 2004, and that do not have a drug identification number (DIN), must comply with "good manufacturing practices and site license requirements of the regulations." By January 1, 2010, NHPs that currently have a DIN will have transferred to have an NPN or a KIN-HM.

Please note that the regulations apply to over-the-counter (OTC) NHPs and not compounds made by hand by private practitioners such as naturopathic doctors or homeopaths. For more information on the NHP Regulations, visit www.hc-sc.gc.ca/hpfb-dgpsa/nhpd-dpsn/index_e.html.

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IS IT OK TO USE NHPs IF I HAVE ALS?

People with ALS can be attracted to complementary or alternative therapies either because drug trials have so far been unsuccessful or because of the misperception that these remedies are "natural" and therefore harmless at worst. Searching for an answer can sometimes leave you open to spending large amounts of money on unproven therapies. On the positive side, use of some alternative and complementary therapies may promote improved quality of life, maintain hope, and enhance feelings of control. Over the years, people with ALS have been known to take NHPs such as Vitamin E and other antioxidants, creatine, Co-enzyme Q10, and others. A clinical trial of creatine on its own did not show positive effects in terms of slowing down muscle weakness. The jury is still out on its effect when combined with other compounds. It is a good idea for doctors to track which kinds of therapies benefit which patient profiles to

develop rationales for more clinical trials research.

If you are thinking about or are already using any NHP, it is important to talk to your doctor about it. Even though they are "natural," they may interfere with other drugs you are taking for ALS symptom management or may worsen some symptoms.

The ALS journey is different for everyone. What has worked for one person may or may not work for you. Whether the perceived benefit is due to the actual product or a placebo effect is hard to say without clinical trials.

Consult with professionals with experience with NHPs such as pharmacists, or homeopathic and naturopathic doctors. The knowledge they provide will help inform you and your doctor.

To ensure discussion about use of complementary and alternative medicines, doctors must have a respectful and compassionate attitude toward

patients' questions and beliefs. Not doing so may cause patients to keep the information to themselves because they think their doctor will tell them it is useless and to stop taking it.

For additional insight into evaluating unproven therapies in ALS, see

Alternative Treatments and Unproven Therapies Fact Sheet

NHP Checklist:

To make decisions about using an NHP, use these questions as guides for you and your doctor:

- What is the health claim being made as a result of product use?
- What is the cost?
- Could the product be harmful in any way?
- Will it interfere with anything else I need to take to manage my ALS symptoms?
- Does the product label bear a DIN, NPN, or DIN-HM?
- Does my ALS doctor know of any other people who have taken it?