What about natural health products?

Question:

What is being done to regulate "natural" treatments?

Question submitted by
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Response:

On January 1, 2004, after an extensive national consultation process, new Canadian regulations governing the manufacture, packaging, labelling, storage, importation, distribution, and sale of natural health products (NHP) came into effect (although a transition period of up to six years will allow enforcement of the regulation to be phased in).

The regulations are composed of several main components: definitions, product licensing, adverse reaction reporting, site licensing and good manufacturing practices, clinical trials, and labelling/packaging.

NHPs are defined as:

a) a plant or plant material, algae, fungus, or non-human animal material;

b) an extract or isolate of (a), the primary molecular structure of which is the same as it had prior to its extraction or isolation;

c) a vitamin, or any of its salts or derivatives;

d) an amino acid or any of its salts;

e) an essential fatty acid;

f) a synthetic duplicate of (b) to (e);

g) a mineral; or

h) a probiotic (a term defined in the regulations as intended to capture such things as acidophilus).

They are manufactured, sold, or represented for use in:

- the diagnosis, treatment, mitigation or prevention of a disease, disorder, or abnormal physical state or its symptoms;
- restoring or correcting organic functions in humans; or
- maintaining/promoting health or otherwise modifying organic functions in humans.

It is important to note, in addition to the medicinal substances identified in the list above, NHPs derived synthetically, homeopathic preparations, and traditional medicines are specifically defined as NHPs.

An exclusion list also specifically identifies substances which are not NHPs.

A full range of health claims will be allowed for NHPs, provided that acceptable evidence exists to support the claim.

All NHPs will require pre-market approval by the Natural Health Products Directorate (NHPD), a significant difference from the regulation of dietary supplements in the U.S. CME

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