Natural health products: New labels, new credibility?

Bolstered consumer confidence and increased "credibility" for natural health products are among anticipated outcomes of a new Canadian regime to oversee the manufacture and sale of herbal, homeopathic and traditional remedies, probiotics, amino acids and fatty acids.

But critics say the regime is little more than "quackery" that will inevitably lead to medical disaster.

Regulations that came into effect Jan. 1 govern the sale of an estimated 50 000 natural health products and will "ensure that Canadians can choose and use natural health products with safety and confidence," says Phil Waddington, director-general of Health Canada's Natural Health Products Directorate.

"The regulations will give us a lot more credibility," adds Canadian Health Food Association president Donna Herringer. "Consumers know that they've been reviewed and approved before those health claims can be made."

Armed with an $8.6-million budget and a staff of 80, Waddington's directorate is overseeing a regime that will require manufacturers to obtain product licences for all their remedies (within 5 years for existing products, and immediately for new ones). Manufacturers must also obtain site licences for their production facilities, report adverse reactions, abide by good manufacturing practices and meet labelling requirements.

The directorate will also produce a compendium of monographs to facilitate licensing of existing and new products. Monographs have already been developed for 40 products, including black horehound (variously used for stomach, sleep and nervous disorders) and "Heal-All" (used for 28 conditions, including fever, diarrhea, "hemorrhagic affections," boils, acne, backaches and to "strengthen the womb").

As many as 500 monographs will ultimately be developed, allowing industry to license most new products by simple reference to the compendium. Only complex new products that make broad therapeutic claims or resurrected products once pulled from the market will be subject to human clinical trials requirements.

The monographs are being developed by directorate staff and vetted by an expert advisory committee chaired by retired Dalhousie pharmacy professor Dr. Frank Chandler, using standards of evidence that include "traditional use" and inclusion in "traditional references."

Critics say Health Canada hasn't raised the scientific bar anywhere near the height it should be to ensure the efficacy and safety of these products.

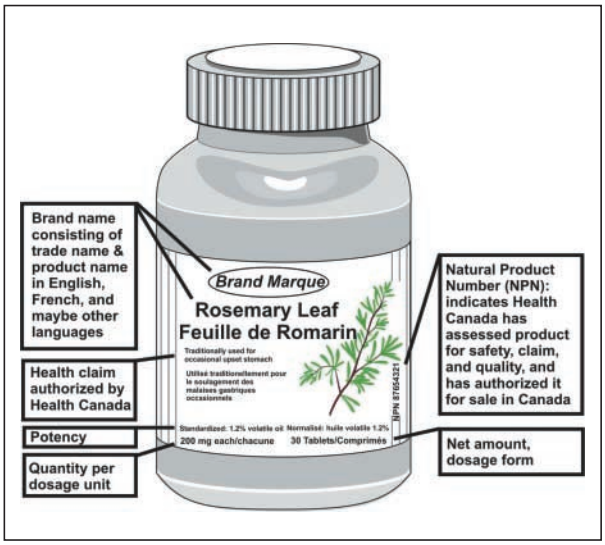
"It's quackery," says Dr. Meera Thadani, assistant professor of pharmacy at the University of Manitoba and a member of the Natural Health Products Advisory Committee struck by Health Canada in 1997 to examine the need for regulation in the area. "It's not scientific. Traditional use can mean that my grandmother used it. But so what? Granny never kept track of things. Thousands of years of use? Well, who was keeping track thousands of years ago? The people who died using the product, that weren't saved by it, don't have a voice in any of this."

Thadani fought against the inclusion of "traditional use" as valid justification for therapeutic health claims, arguing that natural health products should be subject to Food and Drug Act regulations, and that it isn't valid to exempt industry from safety and efficacy proofs because of expense. "So it's costly. Public safety is costly. You expect this of any product that makes a therapeutic health claim."

But Herringer says such proofs would have been inappropriate. "The people in the drugs directorate haven't got the sensitivity or the knowledge of how applied natural health products are used and in what context they are used as therapeutic drugs."

Moreover, she says traditional use is a valid measure of therapeutic benefit. "The evidence is in the length of the use, that it did not cause any harm."

Canadians for Rational Health Policy president Dr. Lloyd Oppel says it's specious to argue that extended use necessarily yields efficacy or safety. He contends that the new regime was created without proper scrutiny by the scientific and medical community in the interests of making it easier for industry "to make what essentially are health claims on the label, in order to induce the public to buy them."



Natural Health Products Directorate

New labels: more information, new promises.

But Waddington, a naturopathic doctor, says the labelling requirements under the new regime make it clear to consumers whether a "scientific" or "traditional" therapeutic health claim is being made. For example, garlic might be labelled 'traditionally used for treating colds and flu,' so that the consumer knows that this is based on traditional evidence and not on new studies that have been brought forward."— *Wayne Kondro*, Ottawa

DOI:10.1053/cmaj.1040326