



## New federal office will spend millions to regulate herbal remedies, vitamins

Barbara Sibbald

### In brief

The new Office of Natural Health Products promises better regulation of herbal remedies, but its creation raises many questions.

If all goes as planned, physicians will be able to recommend natural health products to patients with confidence within 3 years, but there are questions about how this will happen and at what cost.

The federal government is spending \$7 million over the next 3 years to create a new regulatory organization to oversee herbal remedies and other natural health products. The new Office of Natural Health Products will be responsible for all regulatory functions of these products, such as premarket assessment, labelling, licensing and monitoring.

Presently the products exist in a regulatory void in which they are classified as foods, which precludes any health claims, or as drugs, which makes them subject to costly trials. Labels are vague and consumers rely primarily on friends and family — not physicians — to recommend products. Ottawa says the new regulatory system will provide consumers, physicians and other professionals with accurate, uniform information.

Everyone seems to agree on the need to regulate natural products, but questions are already being raised about how the new office will do this. The Canadian Pharmacists Association (CPhA) worries that the new office will unnecessarily duplicate existing regulatory services at Health Canada's Therapeutic Products Directorate — at taxpayers' expense. Cost is also a primary concern at the Nonprescription Drug Manufacturers Association of Canada. It wonders how the products will be evaluated when the manufacturers can't even agree on the active ingredients in some of them. Others, including Health Minister Allan Rock, say the new office is a giant step forward.

Meanwhile, CMA President Allon Reddoch considers the office "a first step" in recognizing that urgent regulatory action is needed "to maximize the benefits of natural health products while minimizing their risks." He said the CMA believes that the same regulatory standards must apply to both "natural" and pharmaceutical products.

Dr. Frank Chandler, the retired director of Dalhousie University's College of Pharmacy, is enthusiastic about the advantages the office will offer to consumers and professionals. Chandler, who is editing a CMA/CPhA herbal handbook due out this fall, says the present quality of herbs is a "crap shoot. There's about a 30% chance of getting what the label says you are getting. And even if it's present, you still can't be sure of the biological activity."

Dr. William LaValley is also enthusiastic. "I think it's superb for medicine," says LaValley, who runs a complementary medicine practice in Chester, NS. "Right now natural products are stuck in limbo between food and pharmaceuticals, with no quality control."

### A political hot potato

The question of regulation has been a political hot potato for years. Prior to the 1997 federal election, then health minister David Dingwall created a 19-member Advisory Panel on Natural Health Products. Chaired by Chandler, it was to look at ways to license the manufacturers, importers and distributors of natural remedies. Under this plan, most herbs, vitamins

and mineral supplements would have been declared drugs, and subjected to the same kind of licensing and testing as prescription drugs.

This became a volatile election issue, with both consumers and manufacturers demanding a simpler system. In October 1997 the new health minister, Allan Rock, abandoned plans for a licensing crackdown and instead asked the panel to look at alternative ways to regulate the products. He asked a Commons committee to do the same. In May



Dr. William LaValley: we're setting a precedent



1998, the advisory panel presented its recommendations to the House health committee, which subsequently adopted nearly all of them. In March, the federal government accepted all 53 recommendations contained in the House committee's report, *Natural health products: a new vision*.

A 10-member transition team now has 6 months to set up the new Office of Natural Health Products and an expert advisory committee. LaValley, a team member, says it's a crucial step. "If we don't set up the structure properly, nothing will change."

The new office will be responsible for all regulatory functions including, but not limited to:

- pre-market assessment for product licensing;
- licensing of manufacturers;
- postapproval monitoring and compliance; and
- implementation of the standing committee's recommendations.

Many questions about how the new office will work are being left to the transition team. LaValley, who has worked with natural products since 1982, says the new office may use some existing Health Canada test facilities but "its structure will be separate."

This means there will now be 3 regulatory bodies: food, drugs and natural products. As a division of the Health Protection Branch, the new office will be on par with the Therapeutic Products Directorate. Both report to the assistant deputy minister responsible for the Health Protection Branch.

The CPhA has long advocated the need to regulate natural products, but it is concerned this new structure means that services will be duplicated. Executive Director Leroy Fevang says "it's going to cost a lot of money and we feel it's not worth it."

Complaints about the new office's budget are already being voiced by the Nonprescription Drug Manufacturers

Association of Canada. Gerry Harrington, the NDMAC's director of public and professional affairs, says the current budget allocation of about \$2.3-million annually is roughly equivalent to what is now spent on regulating nonprescription drugs.

Pharmacists also question how staff will be hired. Recommendation 5 in the House committee report states: "The selection of personnel [must] be agreeable to both government and

NHP [natural health products] stakeholders."

Fevang isn't impressed. He says this means that lobby groups will have a say in all hiring done for the new office. "This calls into question the government's arm's-length relationship with these groups."

The CPhA will "watch closely" as the office progresses and try to point out its concerns before final decisions are made, says Fevang.

### How rigorously?

The biggest question for many, though, is how rigorously the products will be evaluated. Harrington points out that while products like Tylenol and Aspirin have but 1 active ingredient, manufacturers can't even agree on the active ingredient in common and widely hyped herbs such as *Ginkgo biloba*, "much less the amount needed."

He says it is enormously difficult to trace pesticides and bacterial contaminants. "Let's not be overly optimistic [about what the new office can do]," he cautions.

But Health Canada is obviously optimistic that these products can be regulated effectively. Its position is that the regulatory process within the Therapeutic Products Directorate is expensive and "unnecessarily stringent, long and convoluted" when natural products are involved. Although some high-risk natural products will still go through the directorate, most will not.

LaValley says 90% of natural health products present little risk. "There's not enough money in the federal budget of Canada or the US to come up with valid efficacy data for all natural health products currently in use," says LaValley. "But we can ascertain safety and we do need to do that."

He says the "most appropriate research for the majority of natural products will be to look at patient results and outcomes through use of these products and their protocols."

He foresees a system in which products are first assessed for posing a potentially high or low risk. They would then be slotted into 1 of 3 "categories of claim": structure/function claims (in cases where the product alters the structure/function of the body), disease claims (in cases where the product would prevent a disease), and disease-treatment claims (for cases in which the product would be used

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Top 10 most popular herbal remedies

Herb	% who use among herbal users	% of users in general population
1. Echinacea	54	19
2. Garlic	52	18
3. Ginseng	42	15
4. Camomile	38	13
5. Ginkgo biloba	20	7
6. Evening primrose	20	7
7. Devil's claw	17	6
8. St. John's wort	17	6
9. Teatree oil	15	5
10. Valerian	13	5

Source: Health Vision '98, a survey of 6849 adults in April 1998 by the Nonprescription Drug Manufacturers Association of Canada and ACNielsen



to treat a disease). The higher the category of claim, says LaValley, the greater the need for clinical evidence. All claims would be vetted through the expert advisory committee and its appropriate subcommittees, which would need proof of safety and efficacy.

LaValley points out that a product with low toxicity can still present a high risk. For example, if the manufacturer of vitamin E, a low-risk product, claims it helps prevent heart disease — a disease claim — it's a low-risk product. But if that same manufacturer claims the product can be used to treat cardiac disease — a disease-treatment claim — then it is deemed to be a high risk. "If the consumer uses this instead of the appropriate conventional treatment, it may lead to his or her demise," warns LaValley. "This office is designed to avoid this mishap." In cases involving high-risk claims, the office will need more evidence.

## Use has tripled

The new regulations are coming at a critical time because an increasing number of Canadians are using natural health products. Surveys of 5500 adults by the Nonprescription Drug Manufacturers Association of Canada indicate that the proportion using herbal remedies has doubled from 15% in 1996 to 30% in 1998. The people using these products are also more likely to be using conventional over-the-counter drugs (90% vs. 81% of the general population) and prescription drugs (78% vs. 72%).

Information about contraindications is vital for all drugs. However, while such information about prescription drugs and OTC products is provided mostly by physicians and pharmacists, the survey found that users of natural products get most of their information from family and friends (30%), health books (18%) and other health professional, print articles and product literature (7%). "This makes it even more important to have proper labelling," says the NDMAC's Harrington.

He thinks the situation is beginning to change. The number of people who cited physicians as a source of information when selecting herbal remedies rose from 3% in 1996 to 11% in 1998.

The new federal measures will at least offer consumers standardized products and provide physicians with the information they need to discuss these products with patients. "A lot of physicians complain about the lack of information and structure," says LaValley. "Now they'll know

that a claim vetted through this office underwent significant scrutiny and that the product is what it says it is."

He says Canada has become a world trendsetter in establishing this separate body to regulate natural health products. "We're setting a precedent that others are watching."

Regulations vary worldwide. If an American manufacturer says a product is a dietary supplement, the onus is on the US Food and Drug Administration to prove harm. "My opinion is that [other countries] will adopt [the Canadian] system," says LaValley. "We've put a lot of thought into this."

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