

Regulations for new natural health products in place by year's end?

New regulations governing herbs and other natural health products are expected to be in place by December. "Most Canadians want some regulation [of] health products, such as proper labelling and assurances of quality," says Phillip Waddington, the naturopath who heads the new Natural Health Products Directorate (NHPD) at Health Canada. "But they also want access to these products."

He bases these views on previous studies showing that 50% of Canadians now use these products, along with the directorate's extensive consultations last year involving nearly 3000 people in 11 cities.

"We know we're headed in the right direction," says Waddington. A second draft of the NHPD's proposed regulations will be posted online for feedback this month (www.hc-sc.gc.ca/hpb/onhp/welcome_e.html) and Waddington hopes to publish the regulations in the *Canada Gazette* by year's end. Manufacturers will then have about 2 years to comply.

The major questions for the scientific and medical communities concern the standard of evidence that will be used to assess the products. Waddington cautions that the proposed standards are still "very tentative" but promises that "safety will not be compromised."

Cellphones and cancer?

A case-control study conducted in Germany has linked cellphones to cancer in humans (*Epidemiology* 2001;12[1]:7-12). Researchers at the University of Essen asked 118 people with uveal melanoma about their use of digital mobile phones. The responses were compared with those from members of a 475-person control group who did not have the disease.

The researchers found that the study participants with cancer had a much higher rate of cellphone use than the controls. Lead scientist Andreas Stang cautioned that the results need to be replicated.

Several previous studies have found no such link. One of them (*Radiat Res* 1999;151[5]:513-31) concluded that the association between radio-frequency radiation and cancer is "weak and inconsistent." — *Barbara Sibbald, CMAJ*

For example, Waddington stresses that products such as Ripped Force (page 613) are not currently approved for sale in Canada and won't be under the NHPD. It and similar products are available in some stores and via the Internet and "we're trying to catch these products so they don't slip through."

The standard of evidence used to regulate these and other products will not be limited to clinical trials, which Waddington says "are not as necessary as you think they would be for proving efficacy." He says the NHPD also may look at anecdotal evidence and population studies.

Based on this evidence, health claims will be set for each product. There are 3 levels of claim: risk reduction, structure and function, and cure. The last cate-

gory will require the same level of evidence — a double-blind, randomized clinical trial — as a prescription drug.

The directorate's Expert Advisory Committee, which includes 2 pharmacists, 3 physicians, 4 scientists and 5 complementary medicine practitioners, is already looking at developing monographs. The level of required testing — it will be done by NHPD employees — is still being debated. Laboratories and other resources will be shared when possible with the Therapeutic Products Program (TPP), which regulates prescription drugs.

Until the new regulatory framework is established, natural health products will continue to be regulated by the TPP. — *Barbara Sibbald, CMAJ*

Rabies death a reminder of need for caution around bats

A 9-year-old boy who died recently of bat rabies is the first reported victim of human rabies in Canada since 1985 (*CCDR* 2000;26[24]:209-11. Available: www.hc-sc.gc.ca/hpb/lcdc/publicat/ccdr). The case is a reminder to physicians that Canadian immunization guidelines recommend postexposure prophylaxis for anyone who has slept unattended in a room where a bat is present, even in the absence of evidence of a bite (National Advisory Committee on Immunization. *Canadian Immunization Guide*. 5th edition. Ottawa: Health Canada; 1998:149-56).

The boy, who was staying with his parents at a cottage in the Laurentian Mountains north of Montreal, slept in a bedroom with his brother. On Aug. 28, 2000, bats were discovered in the bathroom and kitchen. They were removed by the father, who in one case used his bare hands to capture a bat. About 3 days later the boy showed his mother an erythematous lesion on his arm that had a small central laceration. The boy was well until Sept. 22, when he awoke feverish with pain in his arm. Despite supportive care, rabies immune globulin and vaccination, he died Oct. 6.

Viral strains of bat rabies cause most human cases of rabies in North America. People sleeping in a room where a bat is discovered should be vaccinated immediately against rabies unless a bite can be reasonably excluded. Physicians should be aware that many bites do not leave marks (Hoey J, Todkill A. Bat rabies after undetected exposure: implications for prophylaxis. *CMAJ* 1997;157:55).

In this case, prophylaxis was given to 27 health care workers at the first hospital where the patient was treated and to 17 workers at the second hospital. It was given because of possible percutaneous or mucous membrane exposure to the patient's saliva. Twelve close playmates for whom exposure to the boy's saliva could not be ruled out also received prophylactic vaccination. The boy is the 22nd Canadian to die of rabies since 1925. — *CMAJ*

