



## Adverse drug reactions in Canada

### *Hematologic reactions to sterol and sterolin-containing products*

**A**lthough not approved by Health Canada, sterol and sterolin-containing products (eg, Moducare Sterinol) are used primarily for their presumed immune-enhancing properties. A search of the Health Canada adverse reaction database revealed four reports in which sterol and sterolin-containing products were suspected of being associated with hematologic adverse reactions, such as hemolytic anemia. Health professionals are reminded to ask their patients to list the natural health products they are taking and to be vigilant for potential interactions. Patients should be advised not to medicate themselves with products that claim to treat serious medical conditions. Health Canada continues to monitor the safety profile of natural health products.

### **Adverse reaction reporting in 2003**

Health Canada received 9209 new domestic reports of suspected adverse reactions in 2003. There has been a steady increase in reporting adverse reactions in Canada over the past 5 years; in 2003, 7.5% more reports were received than in 2002. Among reactions reported in 2003, 70% were judged to be “serious.” Pharmacists reported 26%, physicians

reported 24%, and health professionals (type not specified) reported 22% of reactions. The rest were reported by patients, nurses, and “others.”

### **Case presentation**

Health Canada has received two case reports in which clopidogrel (Plavix) is suspected of being associated with hepatitis. In one, an 84-year-old woman, who was also taking acetylsalicylic acid, developed hepatitis at 8 weeks. In the other, a 76-year-old woman developed hepatitis after 11 months of clopidogrel therapy.

### **Public opinion survey on key issues pertaining to postmarket surveillance of marketed health products in Canada**

Survey results are available at [www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index\\_adverse\\_adr\\_reports\\_e.html](http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index_adverse_adr_reports_e.html).

### **Summary of advisories**

A summary of health professional and consumer advisories posted between November 18, 2003, and February 9, 2004, is available in this issue of the *Canadian Adverse Reaction Newsletter*. To consult the full listing, see [http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index\\_advisories\\_e.html](http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index_advisories_e.html).

**Source:** Health Canada. *Canadian Adverse Reaction Newsletter* 2004;14(2):1-4. For the complete text of any of these reports, check the website [www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index\\_adverse\\_newsletter\\_e.html](http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index_adverse_newsletter_e.html)