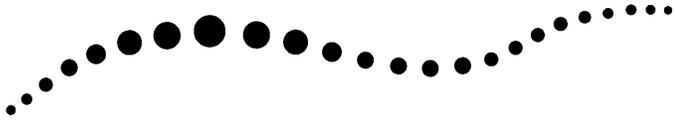


Osteoporosis Society of Canada
La Société de l'Ostéoporose du Canada



COPN – CANADIAN OSTEOPOROSIS PATIENT NETWORK SPRING 2005 NEWSLETTER

1. McGuinty Government Improves Osteoporosis Care

The McGuinty government is launching Ontario's first osteoporosis strategy to help prevent the disease through education and early diagnosis, announced Health and Long-term Care Minister George Smitherman on February 22, 2005. "Our plan is to help prevent osteoporosis and the painful bone fractures it causes by investing in better prevention, better diagnosis and better treatment," said Smitherman.

The osteoporosis strategy will be supported with a \$5 million annual investment. The strategy has five components:

- Helping prevent the onset of osteoporosis by educating seniors and school children about bone health
- Improving early diagnosis by ensuring the appropriate use of bone density testing
- Integrating services to provide enhanced treatment, including creation of a province-wide fracture clinic program to improve diagnosis and prevention of future fractures
- Tools to help practitioners use clinical practice guidelines
- More research to increase knowledge about osteoporosis

Osteoporosis affects approximately 530,000 Ontarians. One in four women and [at least] one in eight men over the age of 50 suffer from the disease. There are more than 57,000 osteoporosis-related bone fractures every year in Ontario, with a resulting cost to the health care system of some \$500 million in hospitalization and long-term care.

"The strategy being launched today will be a strong ally in the fight against osteoporosis," said Karen Ormerod, President and CEO of the Osteoporosis Society of Canada. "Ontarians will benefit greatly from the government's commitment to help prevent osteoporosis and to provide better care for those suffering from it."

The osteoporosis strategy has been developed with work undertaken by the Ontario Women's Health Council, who submitted a report entitled "A Framework and Strategy for the Prevention and Management of Osteoporosis." In 2001, the ministry established a committee including the Osteoporosis Society of Canada and other stakeholders to develop an action plan with specific, feasible recommendations to advance osteoporosis prevention and care. The osteoporosis strategy is based on that action plan.

2. COPN Survey re Osteoporosis Services in Your Area (in Canada)

This is a brief survey to determine the services that are currently being provided for people in your community and catchment area that may be at risk for osteoporosis or have osteoporosis and related fractures. COPN intends to post the services on our web pages once the information has been compiled. These services might be osteoporosis clinics conducted by specialists, self-referral clinics, fracture prevention clinics, and anything else you think pertinent to this survey.

This information will be very beneficial, so please take a few moments to

- 1) Name the service and give a brief description of its program;
- 2) State the location;
- 3) Provide the frequency and duration of the program; and
- 4) Provide contact information: name of contact person, phone number, email address.

Please email your responses to joyce.mcinerney@sjhc.london.on.ca. Thank you very much for your participation.

3. How Drugs Are Approved in Canada – A Brief Summary

Donna Spafford, Clinical Consultant, Osteoporosis Society of Canada

Clinical Trial – A Definition

Any systemic evaluation of medicinal products or devices in human subjects whether in patients or non-patient volunteers to discover or verify the effects of and/or identify any adverse reactions to investigational products, and/or to study their absorption, distribution, metabolism and excretion in order to ascertain the efficacy and safety of products.

Therapeutics Products Directorate (TPD)

Health Canada's Therapeutic Products Directorate is the Canadian federal authority that regulates pharmaceutical drugs and medical devices for human use. Prior to being given market authorization, a manufacturer must present substantive scientific evidence of a product's safety, efficacy and quality as required by the *Food and Drugs Act and Regulations*.

Drugs are reviewed to assess their safety, efficacy and quality before being authorized for sale in Canada. Drugs include prescription and non-prescription pharmaceuticals, disinfectants and sanitizers with disinfectant claims.

Drug Discovery and Development – Stages

- Discovery
- Pre-clinical testing
- Investigational New Drug (IND) Application

- **Clinical Trials, Phase I**
Small number of healthy volunteers (between 20-100 people)
Evaluates dosages for safety
- **Clinical Trials, Phase II**
Drug is tested in about 100-300 people with the illness
Evaluates efficacy and safety
- **Clinical Trials, Phase III**
Drug evaluated in 1,000-3,000 patients for efficacy, safety, side effects

- **Drug Review and Approval**
New Drug Submission (NDS)
TPD review

Drug Discovery and Development - Timeframe

Discovery to IND	2-10 yrs
Phase 1	1-2 yrs
Phase 2	2-3 yrs
Phase 3	2-4 yrs
Drug Approval	+23.6 months

What happens after a drug is on the market?

Marketed Health Products Directorate

The Marketed Health Products Directorate is responsible for coordination of consistency of post-approval surveillance and assessment of signals and safety trends concerning all marketed health products. The MHPD works in close collaboration with other Directorates in the Health Products and Food Branch and with other involved branches.

Biologics and Genetics Therapies Directorate

The Biologics and Genetics Therapies Directorate is responsible for the regulation of biological and radiopharmaceutical drugs, including blood and blood products, viral and bacterial vaccines, genetic therapeutic products, tissues, organs and xenografts. This includes evaluating and monitoring their safety, efficacy and quality.

Provincial Formularies

Each provincial government provides drug coverage

- For people age 65 and over
- For people on social assistance and disability.

Provincial Formularies

Province	Alendronate (Fosamax) 10mg/70mg	Calcitonin (Miacalcin) Nasal Spray	Raloxifene (Evista) 60 mg daily	Risedronate (Actonel) 5 mg/35mg
Newfoundland	Listed (SA)	Listed (SA)	Listed (SA)	Listed (SA)
Nova Scotia	Listed (EDS)	Listed (EDS)	Listed (EDS)	Listed (EDS)
Prince Edward Island	Not listed	Not listed	Not listed	Not listed
New Brunswick	Listed (SA)	Listed (SA)	Listed (SA)	Listed (SA) *35 mg not listed
Quebec	Listed (Open)	Listed (Open)	Listed (Open)	Listed (Open)
Ontario	Listed (LU)	Not Listed	Listed (LU)	Listed (LU)
Manitoba	Listed (EDS)	Listed (EDS)	Listed (EDS)	Listed (EDS)
Saskatchewan	Listed (EDS)	Listed (EDS)	Listed (EDS)	Listed (EDS)
Alberta	Listed (SA)	Listed (SA)	Listed (SA)	Listed (SA)
British Columbia	Listed (SA)	Not Listed	Listed (SA)	Listed (SA)
Yukon	Listed (EDS)	Not listed	Not Listed	Not listed
NWT	Listed (EDS)	Not Listed	Not Listed	Not Listed

Drugs are available on provincial drug benefit plans in two different ways:

- As General Benefits (Open) Available as required and appropriate with no paperwork or criteria required (e.g., Didrocal, HRT in all provinces)
- As Restricted Benefits: Individuals must meet certain criteria; a form has to be completed by the physician that accompanies the individual's prescription. Only Manitoba does not require the completion of the form.

Each province has different words to express this:

SA – Special Access: The Special Access Programme (SAP) is a programme to help patients in special circumstances get drugs that aren't approved for sale in Canada.

EDS – Exception Drug Status

LU – Limited Use

No Listing Status: The drug does not appear in the Drug Benefit Book, and it cannot be listed as a medication. For example, in Ontario, the Section 8 process is reserved only as a form of reimbursement for drugs that have no other listing status.

4. Tell us your story of living with osteoporosis, stories that might help others

Here are some topics that you may wish to consider. Email us at

COPN@osteoporosis.ca. Please note that stories you submit may be published in subsequent newsletters or on the COPN web site.

- How you have managed to increase your bone mineral density.
- How you are working (or not) with weight-bearing exercises.
- How you are managing to get enough calcium, especially if you are intolerant to dairy products.

- What are your family's experiences with osteoporosis; how are you managing? How has your family been affected by osteoporosis?
- How are you helping your children to be aware of the osteoporosis in your family?
- Being a caregiver to someone with osteoporosis.
- Your struggle to be diagnosed with osteoporosis.
- Your surprise at the diagnosis of osteoporosis/osteopenia: what was your immediate reaction?
- Did you have problems getting an effective osteoporosis drug? What happened?
- Any other aspect of being a person with osteoporosis – tell us your story.

Newsletter disclaimer: We invite you to contribute to this newsletter. Selection of material is at the discretion of the editor. Opinions expressed in material published in the COPN newsletter do not necessarily reflect the position of the Osteoporosis Society of Canada. Individuals contributing material are solely responsible for the content, accuracy and originality of the material. To contribute to the next edition of the COPN newsletter, contact us at COPN@osteoporosis.ca.