

COPING

'A newsletter from COPN'

March 6th, 2008

Remember: You can live well with osteoporosis!

Thought for today: Friends are angels who lift us to our feet when our wings have trouble remembering how to fly.

“The Pill Process” - Drug Approval (Part Two)

In December you read how drugs are approved for use in Canada. This part talks about the pricing process and how your medications do, or don't, get approved for coverage under your provincial drug plan.

Canadian provinces (except Quebec) use a standard way to categorize drugs (known as a drug-scheduling model) to ensure consistent conditions of sale across the country. Canada has four categories:

Schedule I: available only by prescription and provided by a pharmacist

Schedule II: available only from a pharmacist & maintained in an area with no public access. (often called “behind the counter” drugs)

Schedule III: available via open access in a pharmacy (known as “over-the-counter” drugs)

Unscheduled: can be sold in any store without professional supervision.

There are a number of agencies that regulate the sale of medications in Canada.

The Patented Medicine Prices Review Board (PMPRB)

The Patented Medicines Price Review Board (PMPRB) regulates the prices charged by drug manufacturers of all patented medicines sold in Canada - new and existing, under prescription or over the counter, to ensure they are not excessive.

The PMPRB is an independent quasi-judicial body that carries out its mandate independent of other organizations such as:

- Health Canada, which approves drugs for safety and efficacy
- Public drug plans, which approve the listing of drugs on their respective formularies (The formulary is the list of all the drugs the government will pay for under its publicly funded, drug program.)

The PMPRB has a dual role:

Regulatory: To protect consumers and contribute to Canadian health care by ensuring that prices charged by manufacturers for patented medicines are not excessive.

Reporting: To contribute to informed decisions and policy-making by reporting on pharmaceutical trends and on the R&D (Research and Development) spending by pharmaceutical patentees.

The Common Drug Review (CDR)

Recognizing that prescription drugs are the fastest growing component of the Canadian health care budget and this increases the financial pressure on public drug plans, the CDR was set up to provide access to high level evidence and expert advice regarding each medicine's benefits and risks and to do this in the most cost effective manner. All federal, provincial and territorial drug plans participate in CDR, except Québec. The decisions of the CDR help each public drug plan to determine if they will or will not add a specific medication to their list of "covered" drugs.

In 2007, the CDR reviewed 29 submissions or resubmissions for new drugs.

- 14 drugs were assessed as 'Do not list'
- 12 drugs were labelled as "list with criteria/conditions"
- 2 drugs were labelled as "list in a similar manner to other drugs in class"
- 1 drug received unrestricted listing

It is important to remember that the restrictions can occur if the drug being reviewed is found to be very similar to pre-existing drugs on the Canadian market or if it is felt to be too costly for general use. Only a tiny percentage of drugs are not approved due to safety concerns.

Provincial/Territorial Formularies:

Canada's 19 public drug plans differ in terms of the people they serve and the drugs they cover, but all need answers to critical questions for each new drug.

How does it compare with alternatives?

Which patients will it benefit?

Will it deliver value for money?

Provinces and territories decide what drugs they will reimburse or 'list on its formulary'. Drug accessibility varies greatly from province to province. Each province uses a number of factors to decide whether to cover the cost of drugs, such as cost effectiveness analyses, cost, government priorities and patient advocacy. Sometimes certain drugs receive a restricted listing if special monitoring is required or the cost of the drug is high.

The federal government also has review processes for six different formularies under its control. These include formularies for First Nations and Inuit people, veterans, Canadian Forces, designated migrants, RCMP and Correctional Services).

Drug Safety Monitoring:

Health Canada's Marketed Health Products Directorate (MHPD) is responsible for coordinating the surveillance of drugs and natural health products after they are made available to the public. It monitors adverse reactions and investigates complaints and problem reports.

Advertising:

Canada permits only very limited advertising for drugs, unlike the United States that has much more direct-to-consumer advertising. It is possible that many Canadians see or read advertising that originates from the U.S. Any Canadian-made advertisements are reviewed and pre-cleared by two independent agencies: Advertising Standards Canada (ASC) and the Pharmaceutical Advertising Advisory Board (PAAB) to determine compliance with the Food and Drugs Act and various advertising codes.

As you can see, many steps and many highly skilled individuals are involved in getting a drug to your pharmacist and ultimately into your medicine cabinet.

Funny Bone: Two can live as cheaply as one, for half as long.

Remember: It is important for you to eat a **healthy diet**, get some appropriate **exercise**, take your **calcium and vitamin D** and if your doctor has prescribed a **medication** don't forget to take it as directed.

COPING will come to you every second Friday. We hope you enjoy it and find the information useful. Don't forget to log on to www.osteoporosis.ca for up to date information.

The material contained in this newsletter is provided for general information only. It should not be relied on to suggest a course of treatment for a particular individual or as a substitute for consultation with qualified health professionals who are familiar with your individual medical needs. Should you have any health care related questions or concerns, you should contact your physician. You should never disregard medical advice or delay in seeking it because of something you have read in this or any newsletter.