



Remember: You can live well with osteoporosis!

How Drugs are Approved in Canada, pt.2

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Fracture Fact:

If you are at high risk of fracture, you should review the various osteoporosis drug treatment options with your physician, assessing the benefits and risks of each, and choosing the best treatment for you.

Once a drug is approved for use in Canada, what happens next? “Approval” means that a doctor can write a prescription for the drug; however, approval does not mean that the cost of the drug is covered under any provincial drug plan. Part 2 discusses the pricing process and how medications do, or don’t, get approved for coverage under your provincial drug plan.

Canadian provinces (except Québec) 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 1: available only by prescription and provided only by a pharmacist

Schedule 2: available without a prescription but provided only by a pharmacist and maintained in an area with no public access (often called “behind the counter” drugs)

Schedule 3: available without a prescription via open access in a pharmacy (known as “over-the-counter” drugs)

Unscheduled: available without a prescription and can be sold in any type of store without professional supervision. There are a number of agencies that regulate the sale of medications in Canada. These are as follows:

(1) The Patented Medicine Prices Review Board (PMPRB)

This is a government agency that regulates the prices charged by drug manufacturers of all patented medicines sold in Canada - new and existing, by prescription or over the counter. The PMPRB is a review 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 to contribute to Canadian health care by ensuring that prices charged by manufacturers for patented medicines are not excessive.

Reporting: To help policy makers make informed decisions by reporting on pharmaceutical trends and on the R&D (Research and Development) spending by pharmaceutical patentees.

(2) The CADTH Common Drug Review (CDR)

The Canadian Agency for Drugs and Technologies in Health (CADTH) provides decision-makers with the evidence, analysis, advice and recommendations they require to make informed decisions in health care. Funded by Canada's federal, provincial and territorial governments, CADTH is an independent, not-for-profit agency that delivers timely, evidence-based information to healthcare leaders about the effectiveness and efficiency of health technologies. The CADTH Common Drug Review (CDR) is a cross-Canada process for conducting objective, rigorous reviews of the efficacy and cost effectiveness of approved drugs. It also conducts reviews of patient input for drugs and provides formulary listing recommendations to Canada's publicly funded drug plans, not including Québec. Prescription drugs are the fastest growing part of the Canadian healthcare budget, which increases the financial pressure on public drug plans, so it is important that provinces and territories have access to high-level evidence and expert advice regarding each drug's benefits and risks and to obtain these in the most cost-effective manner. 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.

It is important to remember that 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.

(3) Pan-Canadian Pricing Alliance

The Pan-Canadian Pricing Alliance is part of an initiative whereby provinces and territories (with the exception of Québec) have been taking a coordinated approach to set prices for generic pharmaceuticals and joint negotiations for brand name drugs. Costs for commonly used generic drugs are being reduced as provinces and territories work together to establish a price point of 18 per cent of the brand name price. Individually, provinces and territories have been paying from 25 to 40 per cent of brand name prices. To date, 10 commonly used generic drugs have been reduced in price, but none of them for osteoporosis.

In addition to the work on generic drugs, provinces and territories have worked together through the Pan-Canadian Pricing Alliance (PCPA) to complete 32 joint negotiations achieving consistency in drug listings and improved value. As a result of this work, \$80 million in annual savings will be achieved for participating provinces and territories.

Provincial/Territorial Formularies

Canada's 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, such as:

How does it compare with alternatives?

Which patients will it benefit?

Will it deliver value for money?

Provinces and territories each decide what drugs they will reimburse or list on their provincial formulary. As a result, 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, 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.

Each provincial government provides drug coverage under various circumstances, such as:

- For people age 65 and over
- For people receiving social assistance or disability benefits
- After a deductible is applied
- Coverage under the Special Access Program, which permits Canadians under certain circumstances to have access to drugs not yet approved by Health Canada
- Listing drugs in one of two ways: **open**, which means they are available as required with no paperwork or special criteria; or **restricted**, which means that patients must meet certain criteria and in most provinces, the physician must complete a form to accompany the patient prescription. Each province has different wording for these listing categories.

Drug Safety Monitoring

Health Canada's **Marketed Health Products Directorate (MHPD)** is responsible for monitoring the safety and effectiveness of drugs and natural health products after they are made available to the public. It monitors adverse reactions and investigates complaints and problem reports. These products include prescription and non-prescription medications, vaccines, natural health products and medical devices.

Advertising

Unlike the United States that has much more direct-to-consumer advertising, Canada permits only very limited advertising for drugs. It is possible that many Canadians see or read advertising that originates from the US. 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.

We hope that you enjoyed reading about how drugs are approved for use in Canada. As you can see, many complex steps and many highly skilled individuals are involved in making sure that only drugs that meet government standards for safety and effectiveness get to your drug store and ultimately into your medicine cabinet.

If you have questions about this article or any other aspect of osteoporosis, please call **toll-free 1-800-463-6842** (416-696-2663 in the Greater Toronto Area) to speak to an information counsellor.

FUNNY BONE:

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BONE ***MATTERS***

Take charge of your bone health

Travelling with Osteoporosis

DATE Thursday, April 9, 2015

PRESENTERS Maureen C. Ashe PhD PT

TIME 2:00 – 3:00 pm EDT

Dolores Langford MSc. BScPT

Join us to learn how to keep your bones healthy while travelling with osteoporosis. Watch the online webcast for safety tips, how to keep up with your exercise routine and fall prevention strategies while travelling on foot, by plane, or by car.

Register now to watch the webcast, live or archived, with the interactive Ask a Question feature!

REGISTER [HERE](#) or go to **www.osteoporosis.ca**

Moved? Changed phone number or e-mail address?

Let us know by calling 1-800-463-6842 or emailing copn@osteoporosis.ca and we'll update your information. This will ensure we keep you up to date!

A Recipe from our Sponsor

Cream of Roasted Red Pepper and Bocconcini Soup

Course: *Soups & Creams*

Preparation Time: *20 mins*

Cooking Time: *1hr, 20 mins*

Yields: *4 to 6 servings*

3/4 milk product serving(s) per person

Calcium: 14% DV/ 151 mg

This soup's rich, roasted flavour is perfectly complemented by the soft creaminess of Canadian Bocconcini and a sweet, balsamic tang.

Ingredients

1 head of garlic
1 tbsp (15 mL) **butter**, melted, divided
2 onions, thickly sliced
4 red, orange or yellow bell peppers, seeded and cut into quarters
Salt
Freshly ground pepper
2 cups (500 mL) tomato juice, no salt added
1 1/2 cups (375 mL) of **milk**
6 oz (180 g) **Canadian Bocconcini**, 3–4 small balls per serving
1 tbsp (15 mL) balsamic glaze, homemade or store-bought
2 tbsp (30 mL) fresh parsley, finely chopped

Cheese alternative: Canadian Fresh Mozzarella.

For more information about this recipe:

<http://www.dairygoodness.ca/getenough/recipe/s/cream-of-roasted-red-pepper-with-bocconcini>



Preparation

Preheat oven to 450°F (230°C).

Cut top off and place head of garlic on aluminum foil. Drizzle with some butter and close up foil. Cook in the oven for 35–40 minutes or until golden. Let cool and press to squeeze out cloves from their skins.

In an oven-safe dish, mix onions and peppers with the remaining melted butter. Season with salt and pepper.

Cook in the oven for 20 minutes or until vegetables are soft and nicely coloured.

Transfer to a skillet. Add roasted garlic, tomato juice and milk. Bring to a boil, cover and simmer 15 minutes at medium-low heat.

Using a food processor, blend until smooth. If needed, gently reheat for 5 minutes in a skillet.

Divide soup among bowls, garnish with Bocconcini, balsamic glaze and parsley.

Tip

This recipe can be easily multiplied and frozen in separate portions if desired.

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