Osteoporosis Canada
Ostéoporose Canada

COPING
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Remember: You can live well with osteoporosis!

How Drugs are Approved in Canada, pt.1

In this issue

Fracture Fact:
Osteoporosis Canada supports the use of medications that have been proven, in good clinical trials, to significantly reduce a person's risk of fracture.

Have you ever wondered how drugs are made available for use in Canada? What follows is an overview of how drugs are approved in our country. This is a reprint of part 1 of a two-part article published on March 11 and March 25, 2015.

Drug development is a lengthy, carefully considered, step-by-step process because eventually we will be using these drugs to help prevent or treat various diseases.

Research and development

This is where it all begins. In this step, research scientists study a disease or condition very closely at the molecular level in order to determine what chemical compounds might play a role in preventing or treating a specific condition. Approximately 1 out of every 10,000 of these compounds ultimately reaches market.

Pre-clinical trials

After a drug is developed in a laboratory, it must first be tested with pre-clinical trials. This is done on tissue samples and, in some cases, small animals, to see if any significant changes occur – both for the desired effect but also looking for possible side effects. This phase of testing can last up to five years. About 10 to 20 compounds of the original 10,000 make it to the pre-clinical trial stage.

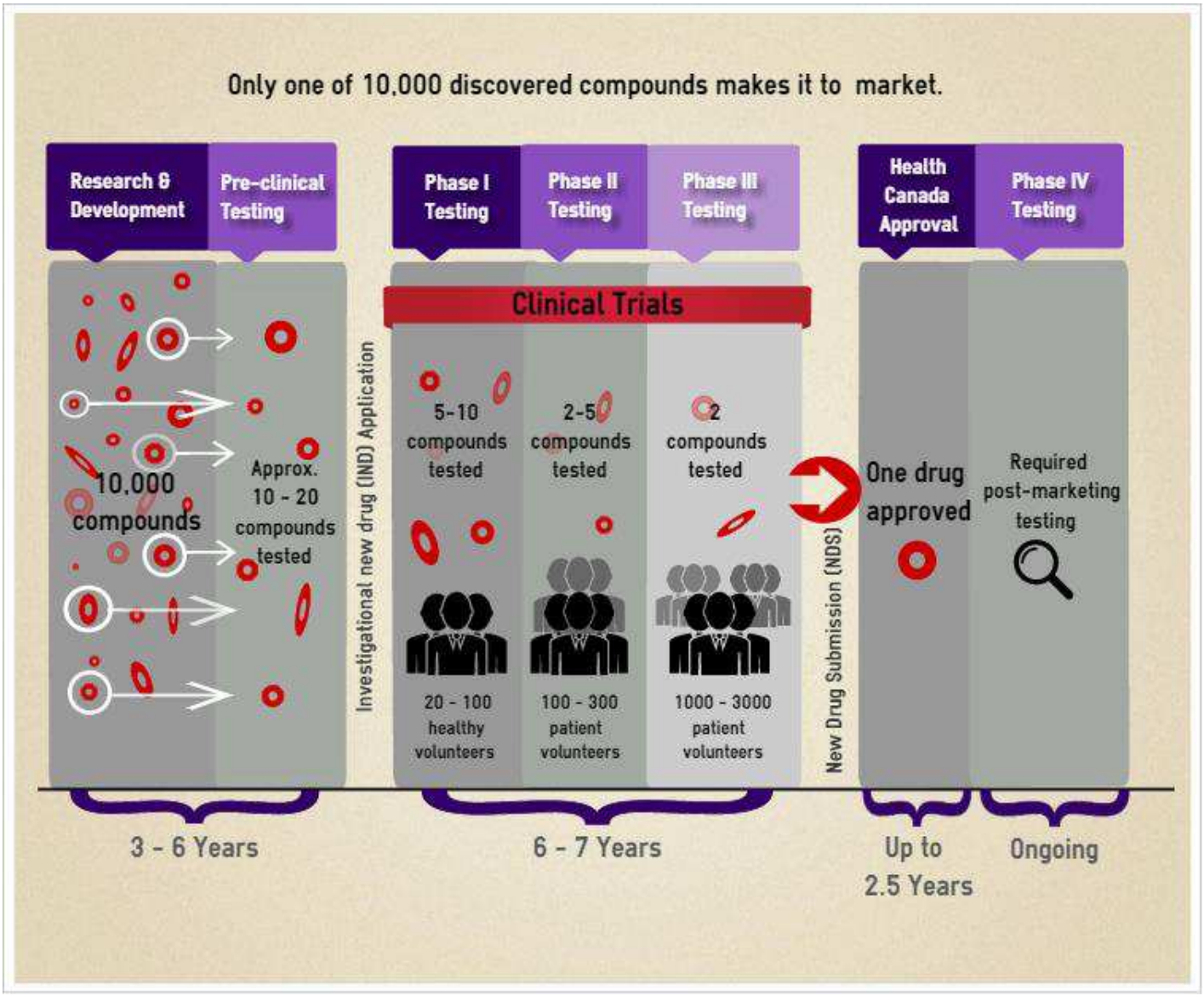
Clinical trials

If the drug is safe for animals, then the manufacturer can apply to proceed with careful studies in people. These are called clinical trials. This process is carefully monitored and the application includes detailed information on the drug's ingredients, its form (pills, liquid, powder, etc.) and proposed methods for testing, along with other information. Clinical trials are used to assess the drug's benefits and risks for humans. These take place in three phases, each with a larger number of test subjects.

Phase 1: 20 to 100 healthy volunteers (approximately 5 to 10 out of 10,000 compounds reach phase 1).

Phase 2: 100 to 300 patients with the target disease are used to identify side effects, if any, and ideal dosage amounts (approximately 2 to 5 out of the original 10,000 compounds reach phase 2).

Phase 3: 1,000 to 3,000 patients with the disease are used to confirm the drug's effectiveness. Very often some patients are treated with a placebo (a pill with no medicine in it) to remove any risk of bias. This phase can last from one to five years (approximately 2 of the original 10,000 compounds reach phase 3). For example, in a phase 3 clinical trial for an osteoporosis drug, it is the drug's ability to reduce the number of fractures that is assessed.



At the beginning of this process, if a drug or chemical compound seems to have some promise as a treatment or therapy for a disease, the manufacturer will likely apply for patent protection. In Canada, a patent is good for 20 years from the time of filing and it gives the manufacturer the right to eventually sell the drug without competition until the patent expires. After these 20 years, competing drug companies are permitted to produce and sell generic versions of the drug. On average, it takes 10 to 12 years of research to bring a drug to Health Canada for the approval process. This typically means that there are only 8 to 10 years left on the patent protection of the drug before other companies can sell the drug as a generic.

If a drug is found to be unsafe, it is either dropped or sent back for further development. If the drug shows dramatic benefits, it can be "fast-tracked" for approval and use by the public (approximately 1 of the original 10,000 compounds).

Once the trials are completed, all drugs that are sold in Canada – whether they are manufactured here or imported from abroad – must be authorized by Health Canada. It is the HPFB's (Health Products and Food Branch) mandate within Health Canada to manage health-related risks and benefits of health products and foods. Within the HPFB, the Therapeutic Products Directorate (TPD) reviews and authorizes new drugs and medical devices. TPD is the Canadian federal authority that regulates pharmaceutical drugs and medical devices for human use. Before they can bring a product to market, a manufacturer must file a New Drug Submission and present sound scientific evidence of a product's safety, efficacy and quality as required by the *Food and Drugs Act and Regulations*. The average approval time is around 18 months. If approval is granted, the drug is given a Notice of Compliance (NOC) and a Drug Identification Number (DIN) and can be marketed in Canada.

We Welcome Your Feedback

- Have a question?
- Is there an osteoporosis-related topic that you would like to see featured in the newsletter?
- Looking for a great volunteer opportunity?

Please contact us by calling Osteoporosis Canada's toll-free number **1-800-463-6842** or emailing copn@osteoporosis.ca.

Her Royal Highness The Duchess of Cornwall in Ottawa celebrating Canada's 150th Anniversary

In celebration of Canada's 150th anniversary, Their Royal Highnesses, The Prince of Wales and The Duchess of Cornwall, were in attendance for many festivities in Ottawa on July 1st including the inauguration of The Queen's Entrance at Rideau Hall.

The inauguration's reception was hosted by Their Excellences the Right Honourable David Johnston, Governor General of Canada, and Mrs. Sharon Johnston with Dr. Famida Jiwa, President & CEO of Osteoporosis Canada in attendance.

During the reception, Dr. Jiwa had the honour of meeting and speaking with HRH The Duchess of Cornwall about the work of Osteoporosis Canada.

HRH The Duchess of Cornwall is the President of the National Osteoporosis Society in the U.K. and an active champion of osteoporosis, having lost her mother and grandmother to the disease.

Dr. Famida Jiwa, President & CEO and HRH The Duchess of Cornwall

Dr. Famida Jiwa and His Excellency the Right Honourable David Johnston, Governor General of Canada

FUNNY BONE:

Have you heard about the pill that's half aspirin and half glue? It's for splitting headaches.

A Recipe from our Sponsor

Bocconcini, tomato and strawberry salad

Course: *Salads*
Preparation Time: *15 mins*
Yields: 4 to 6 *servings*

2/3 milk product serving(s) per person

Calcium: 6% DV/ 65 mg

Ingredients

7 oz (200 g) **Canadian Bocconcini**
2 tomatoes, sliced
1 lb (450 g) strawberries, sliced
2–3 tbsp (30–45 mL) fresh basil, chopped
1 tbsp (15 mL) olive oil
1 tbsp (15 mL) balsamic vinegar
Salt and freshly ground pepper

Preparation

Slice Bocconcini with a knife or an egg slicer.

Arrange Bocconcini, tomatoes and strawberries on a serving dish.

Sprinkle with basil, olive oil and balsamic vinegar.

Season with salt and pepper and serve.

Nutrition Tip

For a fresh dessert, combine Bocconcini cheese with melon balls of different varieties (watermelon, honey, cantaloupe etc.)

For more information about this recipe:
https://www.dairygoodness.ca/getenough/recipes/bocconcini-tomato-and-strawberry-salad

This issue of COPING is sponsored by Dairy Farmers of Canada

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These newsletters are not intended to replace individualized medical advice. Readers are advised to discuss their specific circumstances with their healthcare provider.