Osteoporosis Canada
Ostéoporose Canada
COPING
March 11, 2015

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 an updated version of a two-part article that was originally published in December 2008 and March 2009.

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.

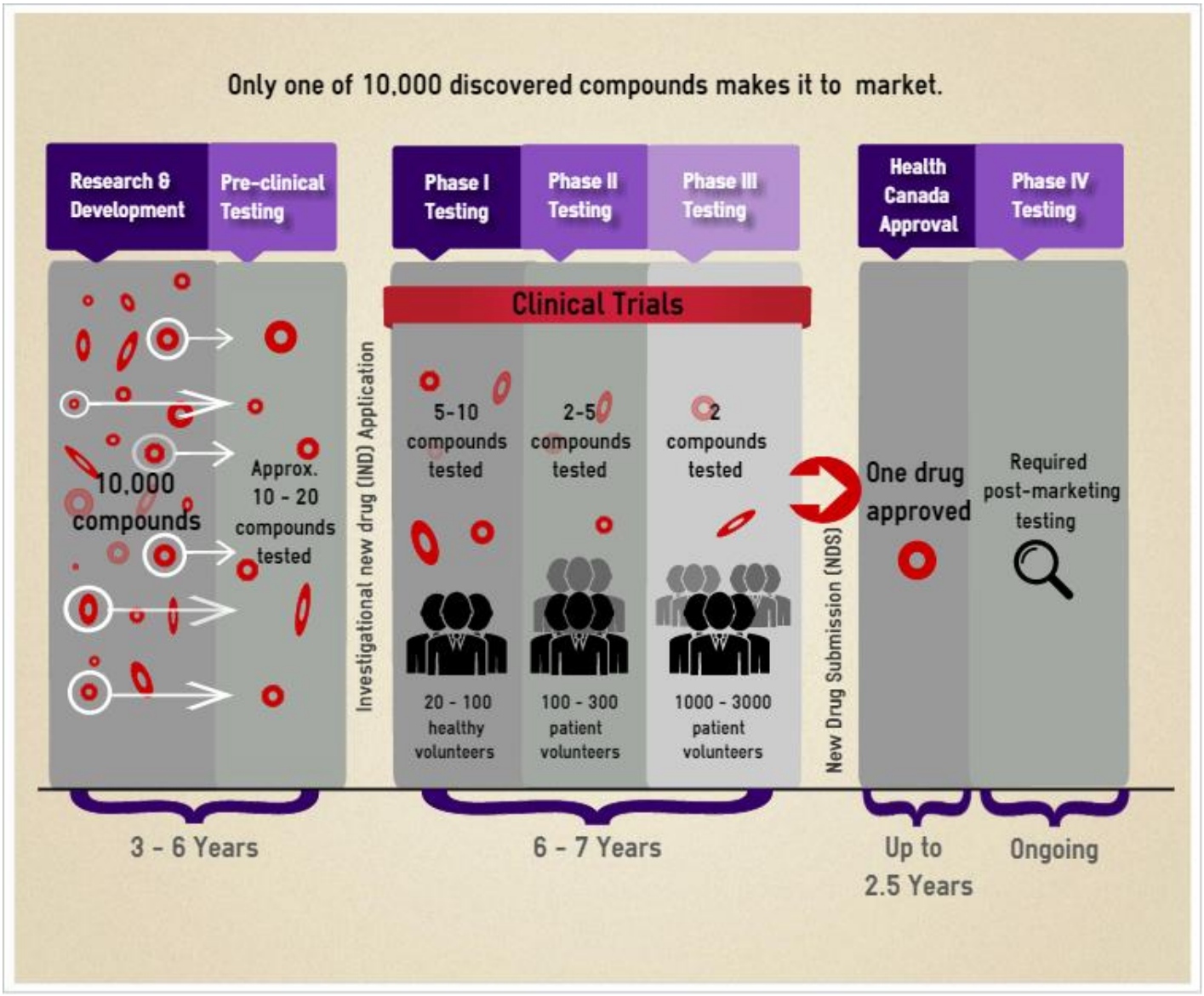
Clinical trials

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.

FUNNY BONE:

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

BONE MATTERS

Take charge of your bone health

Travelling with Osteoporosis

DATE **Thursday, April 9, 2015**
TIME **2:00 – 3:00 pm EDT**

PRESENTERS **Maureen C. Ashe PhD PT**
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

Chia Pudding with Pistachio Pesto

Course: *Desserts & Sweets*
Preparation Time: *20 mins*
Cooking Time*: 5 mins*
Refrigeration Time: *3 hrs*
Yields: 6 to 8 *servings*

1/2 milk product serving(s) per person

Calcium: 21% DV/ 226 mg

You'll love how easy it is to make this pudding, which is remarkably similar to tapioca. Its soft, creamy texture is the perfect foil for the subtle crunch of the fabulous maple-pistachio pesto garnish.

Ingredients

Pesto:
1/2 cup (125 mL) raw pistachios, unsalted, shelled
15 mint leaves
2 tsp (10 mL) freshly squeezed lemon juice
3 tbsp (45 mL) maple syrup

Pudding:
4 cups (1 L) **Milk**
2 eggs, beaten
1/3 cup (80 mL) brown sugar
6 tbsp (90 mL) chia seeds
1/8 tsp (0.50 mL) maple extract
1 cup (250 mL) fresh raspberries

Tips
Wonderfully healthy chia seeds can be found in all large supermarkets and even some pharmacies. The seeds may be black or white; sometimes they are packaged separately, sometimes together. The choice is yours!

Preparation

In a small food processor, pulse the pistachios, mint and lemon juice 2 or 3 times. With the machine running, add the maple syrup in a thin stream until the mixture is the consistency of pesto. Refrigerate.

Fill a large bowl with ice cubes and little cold water and set aside.

In a large saucepan, combine milk, eggs and brown sugar.

Cook over medium-high heat, stirring constantly until the mixture comes to a boil.

Immediately place the saucepan in the bowl of ice water and whisk the mixture for 5 min to cool it.

Transfer the mixture to a bowl, add chia seeds and maple extract and stir to combine. Cover and refrigerate for 3 hours.

Serve the pudding with raspberries and a heaping tablespoon of pistachio pesto.

For more information about this recipe:
http://www.dairygoodness.ca/getenough/recipes/chia-pudding-with-pistachio-pesto

This issue of COPING is sponsored by Dairy Farmers of Canada

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getenough.ca