

COPING

'A newsletter from COPN'

December 12th, 2008

Remember: You can live well with osteoporosis!

Thought for today: A candle loses nothing of its light when lighting another candle –
Kahlil Gibran

“The Pill Process” - Drug Approval

Have you ever wondered how drugs are made available for use in Canada? What follows is Part 1 of 2 of an overview of how drugs are developed for use in our country.

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

Research and development 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. An estimated 1 out of every 10,000 of these compounds reaches market.

Drugs must first be tested, starting with pre-clinical trials. In a purified form, the new drug is tested 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 pre-clinical trials.

If the drug is safe for animals, then the manufacturer can make an application to proceed to 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 I: 20 to 100 healthy volunteers. (5 to 10 compounds reach phase I)

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

Phase III: 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. (2 reach clinical phase III) In a phase III clinical trial for an osteoporosis drug, typically the drug's ability to reduce the number of fractures 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 twenty 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 is 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. (1 of the original 10,000)

Once the trials are completed, all drugs sold in Canada – whether manufactured here or imported from abroad – must be authorized by Health Canada. Within the Health Products and Food Branch (HPFB), the Therapeutic Products Directorate (TPD) reviews and authorizes new drugs and medical devices. The average approval time is around 18 months.

Watch for part II of this article in a few weeks. It will cover how drugs approved for use in Canada become available through the provincial formulary (i.e. the cost is covered by the provincial drug plans).

Funny Bone: Label on package at post office "Fragile. Please throw underhand."

*May your home be aglow
with the warmth and love of the holiday season.*

COPING will return on Jan 9th.

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.

COPN WEEKLY 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.

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