Medical Xpress

How to find more information about a drug that your doctor prescribed

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You've just been given a prescription for a new drug from your doctor. Your doctor told you why she was prescribing the medication, gave you its name and some information about common side-effects. Your

pharmacist is also available to help you use the medication properly, but you want more details and general information.

You'd also like to know things such as how quickly the drug was approved by Health Canada, whether there have been any recent safety warnings about the drug, how the drug compares to other medications for the same condition and what information Health Canada took into consideration when it approved the drug.

You're aware that a general internet search may yield unreliable information, so you decide to look at what's on the various Health Canada websites.

General information: The product monograph

Every drug that's approved by Health Canada comes with what's known as a product monograph (PM). According to Health Canada a PM "is a factual, scientific document on the drug product that, devoid of promotional material, describes the properties, claims, indications, and conditions of use for the drug, and that contains any other information that may be required for optimal, safe, and effective use of the drug."

PMs can be downloaded from the Drug Product Database after you type in either the brand or generic name of the drug. Most of the document is written in language that would be hard for the average consumer to understand, but at the end there is typically a seven- or eight-page section of consumer information that offers more detailed information about issues such as safety, what the drug is used for and when you should avoid using it.

While the PM has to be approved by Health Canada, it is actually written by the company marketing the drug, and the actual contents are often subject to negotiation. It's also not clear how often a PM is revised. All

Health Canada says is that revisions take place when there is new safety information or when there are new uses of the drug, but there is no timeline given for how quickly those revisions need to be done.

Safety information

The PM will give you aggregate safety information, but it doesn't tell you how many times doctors, consumers and manufacturers have reported safety concerns or if Health Canada has issued a safety warning.

For the reported safety concerns, you need to go to the Canada Vigilance Adverse Reaction Online Database.

For Health Canada's health warnings, you'll need to go to the Recalls and Safety Alerts website. However, when you get there, there are no instructions about how to do a search so it's trial and error and hopefully you'll find what you need.

Information about clinical trials

Clinical trials are the studies that companies have to do before a drug can be marketed. But these studies usually only include a small subset of people who have the condition that the drug's designed to treat. They often leave out groups such as the elderly, children, women who might become pregnant and people taking multiple other drugs.

If you want to know if the drug you have been prescribed has been tested on people similar to you, you can read section 7.1 of the Summary Basis of Decision which gives details about the clinical trials. Information about the age and sex of patients in the trials is there, but unfortunately Health Canada only discloses that information in a minority of cases.

How well does the drug work?

Will the drug make you feel better? Drugs are sometimes approved using what are called hard clinical endpoints, such as do you live longer and/or is your quality of life better. But drugs are also approved based on surrogate endpoints.

Surrogate endpoints are measures of things like changes in blood chemistry, blood pressure or how hard you can blow into a machine. These are supposed to predict what matters to patients—things like survival and quality of life—and sometimes they do as with drugs for HIV/AIDS that lower viral load, which correlates with improved mortality. But often surrogate endpoints don't. For example, only a minority of cancer drugs approved by the U.S. Food and Drug Administration on the basis that they shrunk the size of the tumor, a surrogate endpoint, actually helped people live longer.

The Summary Basis of Decision documents will tell you whether clinical or surrogate endpoints were used, and it turns out that more than 50 percent of the drugs approved by Health Canada between 2012 and 2022 used surrogate endpoints. So, how much benefit you will get might be questionable.

How quickly was the drug approved?

You might want to learn about how long it took Health Canada to approve the drug. There are studies showing that the faster a drug is approved, the more likely it is that safety problems will show up once it is on the market.

Information about how fast a drug was approved used to be available by writing to publications@hc-sc.gc.ca for annual reports, and using the

information in those reports to calculate review times. But in August 2022, an unannounced decision was made to cancel the annual reports. So, as of now, there is no information covering the period after March 31, 2022. It's unclear if the annual reports will be resumed.

How does one drug compare to another?

You might notice that the drug you've been prescribed for your problem is not the same one that your friend was prescribed for the identical problem. You may want to know which drug, on average, does a better job.

The Patented Medicine Prices Review Board (PMPRB) used to rank the additional therapeutic value of new drugs compared to existing ones on a scale from breakthrough to slight/no therapeutic value. Those rankings were done by an independent panel of experts and published each year in the PMPRB's annual report. At least they were up until the long-delayed report for 2022, which didn't come out until February 2024. That report did not contain any rankings and the PMPRB has not said that publicly available information about rankings is going to come back.

Orphan drugs

If you have an orphan or rare disease (one that affects fewer than one in 2,000 people) you often don't have very many, or even any, treatment options. In those cases, you will want to know when new drugs are available that might help you.

Starting in 2018 Health Canada published an annual report that listed the new orphan drugs that it approved. But the last report covered 2021; since then, there have not been any new editions. So, now there is no new easily available information about new orphan drugs.

Finding out safety and effectiveness information about drugs shouldn't be a hit and miss affair. Health Canada needs to do a much better job of providing all the information that concerned patients (and their caregivers) need in order to make sure that patients get the best possible results from the drugs that they use.

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