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Ottawa Moves to Reduce Price of Drug after Cancer Patients Complain of Gouging
Lisa Priest, The Globe and Mail, January 31, 2008

A cancer drug will be subject to retroactive price controls after its cost to patients jumped almost ninefold – to as much as \$4,200 a month.

The Patented Medicine Prices Review Board ruled that it has jurisdiction over the multiple myeloma drug thalidomide and can regulate its cost.

The next step is for the board to scrutinize the drug's price with an eye to determining whether it is excessive – as patients and at least one cancer agency have charged.

If the price of the half-century-old drug, which can be made for less than a dime per capsule in a Brazilian government laboratory, are found to have been too high over the past 13 years, governments could receive refunds. Today, one capsule costs about \$35.

According to E. Richard Gold, a lawyer who specializes in patents, the decision closes a loophole. Since the drug is not licensed by Health Canada and was available only under its special-access program, it avoided price regulation.

"This is a loophole, that if it had been followed, other companies with relatively small markets would have followed it and it would have created an inequity in the Canadian system where some drugs are controlled and some aren't," said Dr. Gold, director of the Centre for Intellectual Property Policy at McGill University. "... The patients want the drug and ought to have a price that's fair. There's no justification in terms of policy on why this would not be regulated."

Known by the trade name Thalomid, the drug is used for multiple myeloma, a cancer of the blood's plasma cells found in bone marrow. The price of the drug has been increasing since 2000. Those who did not qualify for U.S.-based manufacturer Celgene Corp.'s free-drug program or other special access programs had to pay.

Donna Reece, a Toronto-based hematologist who specializes in multiple myeloma, diagnosed in an estimated 2,000 Canadians last year, said that about 30 per cent of her patients pay for the drug.

"Thalomid is critical to good multiple myeloma care," Dr. Reece said. "... There are patients who do get the drug free and we're thankful for that, but I think there's a large segment that are not eligible for financial support and the price is high."

Dennis Hemus, 60, took the drug for two years, beginning in 2005, and although it was covered by the BC Cancer Agency, he repeatedly contacted Health Canada and politicians with concerns over the price.

"There will be people out there who will not be taking it because of cost and it won't be prescribed to them because of cost," Mr. Hemus said from his home in Windermere, B.C. "That's one of the tragedies."

In 2000, the BC Cancer Agency paid \$120 for 30 capsules of 50 milligrams each. By summer 2006, it was paying \$1,050, said Susan O'Reilly, vice-president of cancer care for the agency. The typical dose is four 50-milligram tablets a day. The agency switched to another drug for new patients, in part because of cost.

"This drug is a very old drug, it's a drug that probably costs a few cents per pill to manufacture," Dr. O'Reilly said. "I found it unacceptable that a drug company would just inflate the price of this drug. They have their reasons; partly they want to fund research in other drugs."

Known for causing horrific birth defects more than 40 years ago, thalidomide has made a spectacular comeback. The mechanism that caused the birth defects – the damaging of blood-vessel growth – has been found to help starve some tumours. It also helps stimulate the immune system to attack cancer cells.

Reached in Summit, N.J., Celgene Corp.'s vice-president of corporate communications, Brian Gill, said that most Canadian patients have received Thalomid free through various programs and that the company is "fully committed" to ensuring patients get it.

As for its price, Mr. Gill said that "worldwide, the cost of Thalomid has been priced based on its therapeutic value, which is in line with other innovative therapies that are helping turn these incurable cancers into chronic diseases."

At issue was whether thalidomide could be subject to price controls. Celgene Corp. had argued that since it does not have a notice of compliance from Health Canada that would allow the drug to be marketed here, it is not under the board's jurisdiction.

But in a Jan. 21 decision, the Patented Medicine Prices Review Board disagreed, saying it "sees no reason why Canadians purchasing medicines through [Health Canada's special-access program] are any less deserving or needful of protection by the board."

Indeed, thalidomide is one of the most requested drugs under the special-access program, which provides unlicensed drugs to those with serious or life-threatening conditions when conventional therapies fail. The drug is also used in other cancers and autoimmune diseases, with more than 25,000 requests for it from 2002 to 2007, according to Health Canada figures.

With the exception of Saskatchewan, British Columbia and Alberta, no other cancer agencies finance oral cancer drugs; thalidomide is no longer funded by any provincial cancer agency.

Though the drug's patent expired in 1976, another was approved in 2006. Sylvie Dupont, secretary of the Patented Medicine Prices Review Board, stressed that the decision dealt only with jurisdiction.

"The board has not reviewed the prices. None of this has been done so far, so we have to, on the other hand, be careful," Ms. Dupont said. "The board has found one thing and one thing only – that it has jurisdiction."

That decision concluded the board “has jurisdiction to make a remedial order concerning the pricing of Thalomid from and after Jan. 12, 1995.” The process of price controls begins with the board scrutinizing the drug's price by comparing it to others in its therapeutic class. If there are no comparators, they look at prices paid for it in Germany, France, Italy, Sweden, Switzerland, Britain and the United States. The Canadian price can never be the highest of those countries; typically, it is set at the median.

If the price is found to be excessive, the board can compel the company to repay excessive monies retroactively, typically to the federal government, which can disperse it to the provinces.

Dr. O'Reilly of the BC Cancer Agency called it a “fair decision.

“I will assume there will be consequences in terms of a price adjustment. I would welcome that.”