CLL PATIENT ADVOCACY GROUP

E-Bulletin

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CLLPAG UPDATE - ISSUE # 20 SPECIAL EDITION

Federal Regulations Threaten the Availability of New Innovative Drugs for Canadian Patients.

On January 1, 2021 revisions to the *Patented Medicines Regulations* of the Canadian government will come into force, with the objective of lowering the prices of drugs used by Canadian patients. While lower prices are always welcome, the key issue is whether these new regulations will hinder the timely introduction of innovative new medicines to the Canadian market.

This concern is shared by patient groups across Canada and is a question of vital interest to us as a group representing patients with Chronic Lymphocytic Leukemia (CLL) who have benefited from new therapies introduced in the past 5 years.

Our reflection begins with a simple analogy: drug development is like a baseball game in which only home runs count. Developing, testing and gaining regulatory approval for a new drug takes many years and many millions of dollars of investment. If, at any step along the way, a drug fails one of the twin tests of efficacy or safety, the development process stops and the funds invested are lost. Singles, doubles, triples don't count, only home runs: regulatory approval to market the drug.

So why do drug manufacturers take the risk? Because there is a pot of gold at the end of the rainbow: a patent, which grants the manufacturer a monopoly over the drug for a fixed number of years. It is during this period that drug manufacturers recover development costs, earn a return for their investors and accumulate funds for the development of new drugs.

In terms of creating, testing and marketing innovative new drugs, the system has worked well for CLL patients. The past 5 years have seen the introduction of a number of new treatments such as Ibrutinib and Venetoclax that are more effective and have fewer side effects than chemotherapy, prolonging the lives of CLL patients for many years. The availability of different treatment also provides alternatives should a patient experience side effects or should their CLL become resistant to their current therapy. Most importantly, they provide CLL patients with the confidence that, in the absence of a cure, they will be able to live with their disease for many years.

So the system does what it is designed to do: take scientific advances and turn them into approved therapies that prolong lives and improve the quality of life for patients and their families.

But this benefit comes at a cost: higher prices. The pharmaceutical company which holds the patent on a new drug can set the price it wants without worrying about being undercut by competitors, as would occur in a normal market. In the absence of competition to control prices, new drugs tend to be very expensive.

The amended federal regulations are an attempt to address the increasing costs of new drugs. They are also a gamble that drug manufacturers are sufficiently interested in the Canadian market that they will keep introducing innovative medicines for Canadians, despite receiving a price less than in other developed countries.

CLLPAG does not have a crystal ball and nor are we experts on drug policy and pricing. However what we do know is that drug manufacturers are able to choose the countries in which they market their products. Should they find that the new regulations drive prices too low or create too much uncertainty, they will bypass the Canadian market in favour of better opportunities elsewhere.

Canadian patients will be the losers should this occur. Innovative new therapies will become less available. As a result, there will be patients who will die prematurely or suffer a reduced quality of life. They will not have access to alternative therapies should they develop undesirable side effects or if their disease mutates and a new therapy is required. Drug companies can go elsewhere, Canadian patients cannot.

This will be devastating to people like us who need new treatments to survive and/or have improved quality of life. Currently there are no treatments that cure CLL, only that control it. We are hoping for a therapy that cures.

In expressing our concern, CLLPAG is not saying that current drug prices are justified. Like all Canadians, we would welcome lower drug costs, but depriving patients of access to new, effective therapies is not the way to achieve this goal. Unfortunately, that may well be the real impact of the amendments to the *Patented Medicines Regulations*, as there are already indications of manufacturers turning away from the Canadian market.

It is not too late for the federal government to re-examine the more onerous parts of the regulations to ensure that new, innovative and effective drugs keep coming to Canada. CLLPAG has submitted a brief to the Federal government expressing our views.

We suggest that you write you Member of Parliament to request that the government suspend the changes to the *Patented Medicines Regulations* that are scheduled come into effect on January 2021 because:

- The introduction of innovative drugs in the last 5 years has enabled CLL patients to live longer and experience a better quality of life.
- In response to the new regulations, drug manufacturers will simply market their products in countries other than Canada.
- Canadian patients will be deprived of potentially life saving treatments because the amended regulations will reduce the timely introduction to Canada of new and innovative drugs.
- Depriving patients of access to new effective therapies is not the way reduce the cost of drugs to the health system

You can find your MP's e-mail address on the web site of the House of Commons: https://www.ourcommons.ca/Members/en/search

You can find additional information on this issue on the Internet sites of these patients groups

The Best Medicines Coalition https://bestmedicinescoalition.org/issues/pharmaceutical-pricing/

Canadian Organization for Rare Disorders (CORD) https://www.fightforourlives.ca/

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