

# Canada's Vaccine Development Capacity and the Federal Government's Management of COVID-19

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## ABSTRACT

Why is Canada lagging the rest of the world in developing and rolling out a COVID-19 vaccine? Why is Canada down the priority list of countries to receive supplies of vaccine? Why does Canada not have the capability to produce vaccine for COVID-19? Despite numerous outreach efforts by the industry over the years, successive governments, including this one, have done little to nothing to create a favourable pharmaceutical policy environment. They have made no effort to work with the innovative industry to encourage a partnership which would deliver tremendous value to the healthcare system and the economy and give Canadians early access to new medicines and vaccines.

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## DISCLOSURE

None declared.

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## Introduction

I have been closely following the COVID-19 vaccine issue in Canada and felt compelled to write about it. As President and CEO of GlaxoSmithKline Canada for 16 years, I was intimately involved in the production and distribution of the Canadian vaccine for the H1N1 pandemic in 2009. All of the vaccine for that pandemic was produced in the GSK vaccine factory in Quebec City, which still produces millions of doses of Canada's annual flu vaccine.

Although there were a few glitches, the H1N1 campaign was a tremendous success. The vaccine was developed, rolled out and administered to millions of Canadians in just several months. I give great credit to the Chief Public Health Officer at that time, David Butler-Jones and the Deputy Minister of Health, Morris Rosenberg, for their leadership and collaboration during that pandemic.

So why is Canada lagging the rest of the world in developing and rolling out a COVID-19 vaccine? Why is Canada down the priority list of countries to receive supplies of vaccine? Why does Canada not have the innovative capability to develop a vaccine for COVID-19?

## Canadian Pharmaceutical Industry

The issues we are facing today in Canada with respect to having early access to a COVID-19 vaccine have their roots dating back 50 years. In 1968 Pierre Trudeau and his government effectively eliminated pharmaceutical patents by implementing a regime of compulsory licensing. The objective was to lower pharmaceutical prices and encourage the establishment of a Canadian domestic industry. It was a massive failure. It led to a number of multinational innovative companies immediately closing down their research centres in Canada.

It also led to the creation of a powerful generic industry that does no innovative research and has now evolved into a commodity business competing globally on price. The generic industry oligopoly emerged with Apotex and Novopharm dominating the landscape. For over 3 decades, under very favourable market conditions for

those companies, Canadians ended up paying the highest prices in the world for generic drugs.

The pharmaceutical policy environment in Canada for the innovative industry has been quite unfriendly. Successive governments have created an environment which has discouraged innovative pharmaceutical investment in research, development, and manufacturing in Canada. This puts the Canadian CEO's of global companies in a weak position to attract investment to Canada from their corporate head offices.

Although the Mulroney and Harper Conservative governments supported the innovative industry by improving the patent (and data protection) landscape, Canada only partially recovered, and to this day does not have globally competitive patent protection for innovative medicines. This regime has led to many brand name pharmaceutical products losing their patent cover and market position early.

In addition to weaker patent protection compared with other Western countries, Health Canada continues to be one of the slowest regulatory agencies in approving new medications and vaccines. Meanwhile, the pricing regime has deteriorated over the years with governments focused on ratcheting down the prices of innovative medicines. In fact, on January 1, 2021 the Trudeau government will enact new PMPRB (Patented Medicines Pricing Review Board) regulations to drive prices down further. Not a good move during a pandemic, because it is the industry that is ultimately going to defeat the virus.

Unfortunately, many policy makers only see medicines and vaccines as a cost to the health care system. They do not recognize the value those medicines bring to the system in reducing costs in other healthcare silos. Governments have also never recognized the value the industry brings to the innovative economy, despite the fact that Canada continues to lag the world in innovation, and is in real need of upping its game. The last global survey saw Canada slip down the innovation list even further.

Despite numerous outreach efforts by the industry over the years, successive governments, including this one, have done little to nothing to create a favourable pharmaceutical policy environment. They have made no effort to work with the innovative industry to encourage a partnership which would deliver tremendous value to the healthcare system and the economy and give Canadians early access to new medicines and vaccines. So, not surprisingly, the industry has shifted its investment elsewhere to more positive environments. Good examples are the U.S., the U.K. and Europe.

### Pandemic Management Failures

Many want to praise the federal government for all the money they have distributed to Canadians during the pandemic. Many of the programs have been beneficial and truly needed. It is hard not to be a bit cynical though. Canadian taxpayers, our children and grandchildren will be paying for all this spending. And governments of all stripes would have and could have done the same in terms of spending billions of dollars rolling out these programs under these circumstances. That is the easy part. But almost everything else regarding the pandemic has been poorly handled by our federal government.

The government defunded our pandemic early warning system (GPHIN) which was state of the art globally. It would have warned us early on about COVID-19. By killing it they were flying blind and could not react soon enough to stop the arrival of the virus. We could have and should have closed the border sooner.

Despite all the talk about documenting learnings from the SARS epidemic and the H1N1 pandemic, virtually none of the key learnings seem to have been documented and we have had to re-invent the wheel to a great degree. One of the learnings was to have a stockpile of PPEs and antivirals. The current government threw the outdated stockpile of PPE'S in the dumpster in 2019 and did not restock. We then had to scramble to find sufficient new sources and quantities but quickly recognized we had outsourced most of that production to other countries, particularly China.

And why is it that we cannot have more rapid tests available? The PCR testing is effective and accurate, but it is slow and resource intensive. We just do not have the capacity to do widespread PCR testing. So rapid tests would be useful in some instances. They are not as accurate but if they were good enough for the NBA and NHL in allowing them to successfully run their seasons, they should be good enough for us.

Unfortunately, Canada is also experiencing a record number of drug shortages, especially during COVID-19. Most of our medicines now come from other countries, such as China and India. Are these secure sources of supply?

During the H1N1 pandemic it was agreed by everyone that Canada should never have just one local supplier of pandemic vaccine. Great idea, but there was no follow up planning to ensure we had vaccine manufacturing capability or secure sources of supply for the next pandemic. And here we are, scrambling for early access to vaccine.

It would have been nice to have at least a couple of the new vaccines tested in Canadian clinical trials. Not one of them has been used in a major Canadian clinical trial. We need to ask ourselves why? Is it because of the poor relationship our government has with the key pharmaceutical companies?

It appears that many countries are well ahead of us with respect to vaccine access. Countries such as Spain, Mexico, Indonesia, India, Germany, the U.K., etc. In the US, Operation Warp Speed, led by the former head of vaccines for GSK, will begin to vaccinate the American population by December.

We now know that Canada should receive about 6 million doses of the Pfizer and Moderna vaccines by the end of March. That means we can begin to vaccinate 3 million people. By that time, the U.S. will have vaccinated 110 million people. The Prime Minister recently told media that the hope is that the majority of us should be vaccinated by the end of September. A few minutes later the deputy public health officer stated that it will

probably be the end of 2021. The Canadian public should, and probably will be, outraged.

The delay is due to Canada's slow-off-the-mark efforts to negotiate the purchase of COVID-19 vaccine supply from global pharmaceutical companies with existing vaccines capability and products in development. Instead, the government dithered and naively tried to find a way to develop a vaccine in Canada from scratch. The federal government threw millions of dollars at 3 or 4 Canadian organizations which had never produced a vaccine and had little hope of producing one in time for COVID-19.

One of the first vaccines that the government bet on was the CanSino Chinese vaccine in partnership with the National Research Council, who were supposed to manufacture it. With all of our issues with China, why would anyone bet on a partnership for a life-saving vaccine with them? It was a dramatic failure as China never delivered the materials for the clinical trial. It went nowhere.

As a result of our poor positioning on the priority list, the government knows it has a real political problem and is shifting blame for their failures to other countries, pharmaceutical companies, and the other parties. On November 25, a government minister stated on Power Play on CTV that GSK had closed its Canadian manufacturing for vaccines during the Harper years, which is blatantly false. GSK and Sanofi continue to manufacture multiple vaccines in Canadian plants.

We are fortunate that the National Vaccine Task Force, made up of prominent experienced research and industry experts made the recommendation to secure contracts with 7 different global pharmaceutical companies. Thankfully, the government followed this recommendation, or otherwise we would wait longer.

But most other Western countries have published plans detailing how many doses they expect, how they will distribute them, and who will get them. Meanwhile, we have none of that. In fact, the government only recently appointed someone to plan the rollout. The lack of transparency of the federal government is shocking. We clearly do not have a plan yet and we are supposed to

obtain approval of the Pfizer vaccine by December. The federal government must develop and communicate the COVID-19 vaccine plan specifics to the provinces and the public as soon as possible. While we wait for a vaccine, more people will get sick and more will die. Delays matter.

There are 3 key things the federal government can do to make a real difference in the future:

1. Establish a constructive working relationship with the innovative pharmaceutical industry to build a secure domestic source of supply and appropriate stockpiles for vaccines, pharmaceuticals, and PPEs so we will be ready for other emergencies.
2. Delay or cancel the implementation of the new PMPRB pricing regulations as a signal to industry that things have changed.
3. Build a policy platform that will make Canada globally competitive to attract innovation and investment. The Mulroney government took an initial step by improving patent protection and in return Canada saw a dramatic increase in investments from the industry.