20 October 2025

The Honourable Marjorie Michel
Minister of Health
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The Honourable Mélanie Joly
Minister of Industry
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Dear Ministers,

I am working with a group of Canadians who have Type 1 diabetes and are unable to safely or effectively use recombinant DNA and analogue insulin products. We represent people between the ages of 15 and 75 years, and we come from across the country. I was a cofounder and leader of the Society for Diabetic Rights which led a national campaign to secure access to animal insulin and some of us have been active in these ongoing efforts for over 25 years.

In 2003, the House Standing Committee on Health (HESA) after two days of hearings, made a number of recommendations to Health Canada to support access to animal-sourced insulin. These included:

- Adjustments to the Special Access Program (SAP) to remove financial and other barriers to insulin access;
- Reporting "annually to the Standing Committee on Health through the House of Commons on the status of animal-sourced as well as human recombinant insulins; and
- Partnering with the Canadian Food Inspection Agency (CFIA) to facilitate "the provision of tissue for insulin purification through the relationship established between the Agency and the abattoirs."

Health Canada did not act on all recommendations. But the report had an impact on the ministry, which immediately took steps to secure ongoing access by Canadians to animal insulin. These actions included:

- inviting Wockhardt (UK) to apply for market authorization for two Hypurin porcine insulin products;
- relaxing the requirements of the Special Access Program for those who required or preferred bovine animal insulin, also obtained from Wockhardt;
- issuing an It's Your Health bulletin, in consultation with the Society for Diabetic Rights and others, about the availability of recombinant human and analogue as well as animal-sourced insulins in Canada;
- contacting the World Health Organization to request that animal insulin be listed on the Essential Medicines List; and
- consistently maintaining ongoing dialogue with those who required ongoing access to animal insulin.

In 2008, Health Canada appointed me to the Expert Advisory Panel on Insulin. It concluded that some people who require insulin "have better metabolic and symptomatic control when receiving animal-sourced insulins rather than synthetic human insulin or insulin analogues." The panel recommended that "animal-sourced insulins should continue to be made available to patients with diabetes mellitus." Health Canada stated that "more than one approach needs to be considered" and agreed "with the Panel's recommendation that animal-sourced insulin preparations should continue to be made available to patients."

Health Canada, in particular Julia Hill and Dr Agnes Klein, both from the Biologic and Genetic Therapies (now Radiopharmaceutical Drugs) Directorate, have provided invaluable support in these efforts. Dr Klein over many years has reflected both a personal and professional commitment to ensuring patients who need animal insulin can get it. However, as recent events have demonstrated, much more attention to this issue is now urgently needed. This is because imported animal insulin will no longer be available. This is the purpose of my letter.

Wockhardt UK announced earlier this year that it will discontinue supplying its pork insulin products to Canada. The company has also indicated it will no longer participate in the Special Access Program so those who need pork insulin will not have this option. The Drug Shortages Unit has been given responsibility to address concerns about the discontinuation. It has stated that, "Health Canada is a federal regulator and not a manufacturer or distributor of drugs and health products. Wockhardt UK is the only manufacturer of animal-sourced insulin in the world. There are no domestic manufacturers of this product in Canada."

Insulin withdrawals and discontinuations can be traumatic for people who need this medicine. Unfortunately, Health Canada does not seem adequately aware of the seriousness of the issue. For example, it is advising patients who will be affected by Wockhardt's decision to "discuss alternative treatments" with their doctors and to report "any problems or adverse events…to Health Canada." Similarly, the Canadian Society of Endocrinology and Metabolism has issued an advisory about the discontinuation of Hypurin insulin products, asserting that "Recent studies have shown no harm in switching patients from animal-derived insulin to synthetic forms." The advisory references a 1991 study by AJ Garber, et.al., which was excluded from the 2001 Cochrane systematic review of animal and human insulin because it was non-randomised and short-term[1]. In addition, the claim that "no studies" have shown harm is false, as was revealed during the 2003 HESA hearings, not to mention the reports of thousands of patients around the world, including many in Canada.

Alternative treatments are not an option for many of those using animal insulin who experience severe hypoglycaemia unawareness or are unable to effectively manage their condition, both of which increase the risk of death and undermine quality of life. Some users also experience a debilitating immune response to recombinant and analogue insulins, described by Eli Lilly in 1990 as "arthralgia-arthritis-myalgia syndrome" and which only ceases upon changing to animal-sourced insulin[2]. Although this appears to be a rare immune response, MedEffect has received 79 reports of myalgia with a suspected link to recombinant and/or analogue insulins and only one possible link to beef insulin (1986-2022). There are 25

[1] Richter B, Neises G. 'Human' insulin versus animal insulin in people with diabetes mellitus. Cochrane Database of Systematic Reviews 2003, Issue 3. Art. No.: CD003816. DOI: 10.1002/14651858.CD003816.
[2] Insulin chemistry and pharmacology; insulin allergy, resistance, and lipodystrophy. Rifkin, H., & Porte, D., Jr. (Eds.). (1990). Ellenberg and Rifkin's diabetes mellitus: Theory and practice (4th ed.). Elsevier Science Publishing Co, Inc., New York, New York, 1990; 497-513.

reports of arthralgia with a suspected link to recombinant and/or analogue insulins and one suspected link to an unspecified (likely animal) insulin type (1980-2021). Among the group I'm working with currently, there are at least two people who experience this immune response, myself and a 15-year girl whose mother is working hard to find ways to continue accessing pork insulin.

Although insulin was famously discovered at the University of Toronto, Canada now imports every single drop of this vital medicine, and we have no manufacturing capacity whatsoever. This situation exposes a vulnerable population of approximately half a million insulin users to fluctuations in the market that are beyond their control. Since the mid-1990s 62 different types of insulin have been withdrawn from the market, not a single one for reasons of safety or effectiveness. Most of these were older and more affordable animal insulins. The global insulin market, dominated by three large multinationals (Eli Lilly, Novo Nordisk and Sanofi), is unstable for a variety of reasons (including challenges in production capacity, supply chain problems, and marketing decisions).

More recently, Novo Nordisk has initiated the withdrawal of Levemir and Actrapid, two widely used insulin products, affecting people with diabetes in a number of countries including South Africa, the United States, India, and Canada. These products are being withdrawn because the company has opted to dedicate its resources to the production of GLP-1s. Novo Nordisk is now laying off 11% of its global workforce and there are concerns it may exit the insulin market altogether.

If this occurs, Canadians who require insulin will be severely impacted. Although Health Canada is aware of the pending withdrawals and has concerns about the company's long-term plans, it doesn't appear to have a plan to respond. This is not much different than it was 22 years ago when MP Judy Wasylycia-Leis commented during the HESA hearings on insulin that, "with respect to supply, most depressing or shocking of all is the thought that Health Canada, which is the body that is supposed to redress problems from the marketplace, is supposed to protect patients in the face of the vagaries of the marketplace, is saying, we can't do anything." In response, Julia Hill, representing Health Canada, reported that "financing for production of animal insulin" fell within the purview of Industry Canada. During the hearing, she said she had just learned that "in 1990 the minister for Investment Canada accepted a decision by Novo Nordisk to stop supplying animal insulin when orders dropped below the threshold of 1 million vials in a 12-month period. So that was an Industry Canada decision that took place about 13 years ago." It is significant that this threshold was agreed to by Industry Canada, not Health Canada and that Health Canada was not even aware that such a deal had been made it. Nevertheless, on the basis of the agreement, Novo Nordisk began withdrawing all of its animal insulin products in the mid-1990s.

We need a different approach. Insulin products are being discontinued, or withdrawn from the Canadian market, by three foreign manufacturers which control its supply. As a matter of urgency Canada needs to explore potential options to protect the health of a significant group of diabetics who will be affected by industry decisions. One possibility would be to provide federal funding to the nonprofit Canadian Critical Drug Initiative for the production of animal and biosimilar analogue insulins. CCDI is a partnership among three levels of government and the University of Alberta to support "an integrated research, development, and manufacturing initiative" whose purpose is to "increase the domestic production of critical medicines." Insulin surely fits that definition.

We would like to meet with your two ministries to discuss the options, both immediate and long term. In the very short term, we need a plan to ensure pork insulin is available without the heavy cost burden, delays and stress associated with importation. But a long-term solution is essential. We believe the domestic production of insulin is needed so that Canadians are no longer negatively impacted by unpredictable markets and the commercial priorities of global manufacturers. There are a group of us who would like to meet with you as soon as possible to explore this idea.

Yours very truly,

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Cc:
The Honourable Pierre Poilievre, Leader of the Official Opposition
Yves-François Blanchet, Leader Bloc Quebecois
Don Davies, Leader New Democratic Party
Elizabeth May, Leader Green Party of Canada
The Honourable Gary Anandasangaree, Minister of Public Safety / MP Scarborough-Guildwood-Rouge Park
Jenny Kwan, MP Vancouver East
Bruce Fanjoy, MP Carleton
Anna Roberts, MP King-Vaughan

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