Canadian Hemophilia Society
Help Stop the Bleeding

December 3, 2024

The Honourable Mark Holland
Minister of Health of Canada
House of Commons
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by e-mail

Dear Minister Holland,

I am writing on behalf of the bleeding disorder community regarding the recent announcement by the Public Health Agency of Canada (PHAC) to end the Blood Safety Contribution Plan as of April 1, 2026. The Canadian Hemophilia Society (CHS) is deeply concerned that hemovigilance in Canada is not at the highest standard and that the situation will worsen.

The bleeding disorder community understands better than anyone the consequences of lax hemovigilance. In the 1980s, 700 people with bleeding disorders were infected with HIV through blood products. Another 500 Canadians were infected by fresh components. Three-quarters of those people died in the ensuing years as a result of their infections. Approximately 20,000 more were infected with the hepatitis C virus. Many died. The public cost of programs to compensate these people is more than a billion dollars. The human cost is incalculable. It has taken many years and much effort to restore faith in Canada's blood system. An ineffective hemovigilance system would endanger that renewed trust.

PHAC claims that "mandatory reporting for unexpected and severe outcomes are reported to blood operators under the regulatory oversight of Health Canada." While true, hemovigilance should be just as concerned with rare, minor and unexplained adverse reactions. If these events had been reported and analyzed in the 1970s and early 1980s, quicker action could have been taken to mitigate the extent of the blood tragedy. Only the power of a surveillance system reporting all adverse events, analyzed in an integrated manner, linked to hospitals, blood operators and public health reporting, will allow appropriate action to be taken in time to avoid the long-term consequences of a new pathogen.

The Commission of Inquiry on the Blood System in Canada, led by Justice Horace Krever, after four years of hearings and study, published its Final Report in November 1997 with 50 recommendations. The goal was to reduce the risk of such a tragedy ever happening again. Justice Krever's report has become a blueprint for blood safety and hemovigilance around the world.

Among several recommendations regarding vein-to-vein surveillance for adverse reactions, recommendation 40 states, "*It is recommended that there be an active program of post-market surveillance for blood components and blood products*." Recommendation 43 states, "*It is recommended that the Bureau of Biologics and Radiopharmaceuticals be given sufficient resources to carry out the functions properly.*"

Other recommendations call on the different actors in the blood system—the blood system operators, Public Health, the Provinces and Territories, and physicians—to play their respective roles in an integrated hemovigilance system.

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The reformed blood safety system that was put in place after 1997 has succeeded in avoiding a repetition of the blood tragedy. For example, Public Health, international surveillance systems, those in the Provinces and Territories and the blood operators quickly recognized the emerging threat from West Nile Virus in the early 2000s and instituted safety measures, including donor deferral and donor testing. More recently, the combined resources of the blood system were able to provide valuable information to guide public policy on the ebb and flow of the COVID pandemic.

New pathogens emerge to threaten blood safety every year. In 2024, the blood system is actively following babesiosis, Lyme disease, malaria, chikungunya, dengue fever, hepatitis A, hepatitis E, influenza A (H5N1), leishmania, West Nile Virus, Zika virus and anaplasmosis, in addition to the better-known transfusion-transmitted risks such as HIV, and hepatitis B and C. These threats do not respect borders. Surveillance cannot be left to individual provinces and territories. A hemovigilance system must be national, and work locally with provinces and territories, and with international partners.

After discussions with Canada's blood operators, Canadian Blood Services and Héma-Québec, and the National Advisory Committee on Blood and Blood Products, which advises the Provinces and Territories, it has become clear that the sunsetting of the Blood Safety Contribution Plan will exacerbate already existing shortcomings in Canada's hemovigilance system, including the loss of …

- funding for essential personnel, such as Transfusion Safety Officers and adverse event data entry staff;
- a standardized adverse reaction reporting format and national hemovigilance reporting portal into which to enter hemovigilance data as not all provinces have their own hemovigilance monitoring systems;
- the national Transfusion-Transmitted Injuries Surveillance System (TTISS) database;
- the ability to audit national data.

The Canadian Hemophilia Society joins the blood operators, Canadian Blood Services and Héma-Québec, and others who view the discontinuation of the Blood Safety Contribution Program as a serious setback to Canada's hemovigilance system. Moreover, this decision was made, it appears, without any external consultation. Those most affected by potential failures to safeguard the blood system, patients, were certainly not consulted.

If the objectives of the Blood Safety Contribution Plan do not align with PHAC's mandate and priorities, as it claims, then it is time to create a national body with the mandate, and to provide it with the resources it needs, as recommended by the Commission of Inquiry.

We respectfully urge you to take the necessary steps to address this serious issue.

Sincerely,

Emil Wijnker, President

Cc: Nathalie Fagnan, CEO, Héma-Québec
Vincent Laroche, President, Québec's *Comité consultatif national en médecine transfusionnelle*
Graham Sher, CEO, Canadian Blood Services
Andrew Shih, Chair, National Advisory Committee on Blood and Blood Products