

NO PEGASYS®?
NO PROBLEM!



INTRODUCTION & AIMS



In 2024, a global shortage of Pegasys® became real. A number of factors including a change in ownership of the rights and manufacturing; clinical demand across the world was higher than expected, and inaccurate planning and calculations by the previous owner led to this.

In Canada, stock did exist, but how much and where was unknown. There was a Tier 3 shortage - the worst level. What was available to replace it?

Our Mission, should the *Canadian Drug Agency(CDA)* accept it, was that **all** Canadian MPN patients, through the *Special Access Program*, have access to and be transferred over to **BESREMI®** before any interruption in their MPN treatment.

HOW DID WE ACCOMPLISH THIS?

On December 13, 2024, the first of weekly *Checkpoint Meetings* took place with:

- FORUS Therapeutics President & CEO
- FORUS Therapeutics Director; Medical & Scientific Affairs
- Leukemia & Lymphoma Society of Canada(LLSC) Manager, Community Strategic Partnership
- President of the Canadian MPN Doctors Group
- Canadian MPN Network Board Chair
- Canadian MPN Advocacy Chair

- The **CDA** did reach out to this group individually, which began a valuable relationship with the federal government agency.
- This group met throughout Christmas holidays to locate the most urgent need of Pegasys. Prioritizing they most exceptional individuals was necessary.
- Weekly meetings - even through holidays like Christmas and Easter, some part of this group met and developed plans.
- A letter to all Canadian MPN patients was collaboratively written and sent out:
 - To all Canadian Support Group Coordinators to disperse
 - On all FB pages for Canadian patients to respond to
 - To all medical staff across Canada in each province treating MPN patients in Canada to make them aware of our plan

TO ALL CANADIAN MPN PATIENTS

We understand that many of you have been waiting for updates regarding the Pegasys drug shortage in Canada. We hope the information provided here will help ease some of your stress and anxiety.
Currently, Pegasys is categorized as a Tier 3 shortage in Canada, which is the most serious level of drug shortage recognized by Health Canada.
The Canadian MPN Network, the (LLSC), and FORUS Therapeutics have been meeting weekly ... The Canadian MPN group representing the Canadian MPN physicians have been part of the meetings ... In collaboration with Dr. Sirhan, President of the Canadian MPN Group, we are advocating ... with prioritization for exceptional individuals. ... If you are in this situation, we encourage you to speak to your doctor and ask them to work with ... and initiate a pharmacy-pharmacy transfer.
In terms of Besremi, in December FORUS Therapeutics submitted the Exceptional Importation Compliance forms to Health Canada. Health Canada has reassured us that the submission is being processed expeditiously and has personally met with all involved groups to provide updates and clarify any uncertainties.
Many of you have been proactive in contacting your physicians, us, and Health Canada to share the human impact of the Pegasys shortage. ... At this time, the situation is fluid and moving quickly. ... Thank you for your patience and understanding.

If you would like to read the full letter, see **Patti Saluk**, Board Chair, CMPNN

RESULTS

- As of March 15, 2025, Health Canada **permitted the Exceptional, Temporary Importation and Sale of US-authorized BESREMI** (ropeginterferon alfa-2b-njft) injection.
- This Special Importation was granted until January 2026. Health Canada stated the submission and efforts by all came from the heart, which made all the difference in their decision.
- By March 17, 2025, the **first MPN patient** in Alberta, Canada, received their first dosage of **BESREMI®**.
- The *Checkpoint Meeting Group*, along with provincial government partners, also had stock of Pegasys® relocated to where needed.
- Another letter was sent to Canadian MPN Canadian Patients with the successful updates.



CONCLUSIONS

- ★ **FORUS THERAPEUTICS** has submitted the application for regulatory authority from Health Canada.
- ★ **COLLABORATION** with others rather than trying to accomplish something on your own is KEY to success.
- ★ **PERSISTENCE, DETERMINATION**, simple **HARD** and **HEARTFELT WORK**



For more details on how this was really accomplished, see **Patti Saluk**, Board Chair, Canadian MPN Network

