

Letter to Patients - Pegasys® (Peginterferon alfa-2a supply status March 2025)

Dear Patient

I would like to provide you with an update on Pegasys® (Peginterferon alfa-2a) supply in Australia.

The change of manufacturing from Roche (previous manufacturer of Pegasys®) to Pharma& (new Austrian manufacturer) has been in motion for the last few years. Pharma& have built a new manufacturing site in Austria to make this complex biologic drug to ensure ongoing supplies for patients in need globally. Approval of the site by European authorities is in progress.

However, in the meantime, demand for Pegasys has increased, and as you may be aware, there is now a worldwide shortage of Pegasys®. We were given a final allocation of previously made Pegasys® in December 2024. We are now down to under 3 months' supply and do not have a clear line of sight as to when new supplies will arrive.

Since 2022, Echo Therapeutics has been the only supplier of Pegasys® in Australia. Last year as you are aware, due to global shortages, we learned of Pegasys® being exported without our consent. To reduce the risk of unauthorised export, we partnered with JustMeds to ensure Pegasys® is supplied directly to you. This has resulted in our supplies lasting longer than expected, especially when compared to other countries' supplies. We thank you for your understanding and appreciate your support with this immense change and the way you have adapted to it.

So, what is Echo Therapeutics doing to get supplies:

- Firstly, the JustMeds solution will continue for the near to medium term to keep managing our supplies. From all accounts this is running smoothly for the majority of patients.
- Following European approval of the new Austrian manufacturing facility, Echo Therapeutics will provide the TGA with the updated information. We have already engaged the TGA and they are aware of the need for a fast approval. We hope this local approval will follow 2-3 months after European approval or sooner.

- Should there be a supply interruption in Australia, we are also planning to get some European stock to help cover that period, as the new European stock will be available sooner than our Australian stock. We do not know how much, how soon or what that stock will look like. We are hoping for something quite similar looking (English labelled and both the 135 mcg and 180 mcg presentations), but this is all yet to be confirmed. The TGA will need to approve the EU labelled stock via a process called section 19A. Again, we have asked for urgent review and approval, once we understand our allocation. We will also seek special PBS funding, to ensure your costs remain the same.
- In the meantime, we encourage you to talk with your haematologist or prescribing clinician to discuss strategies for optimising the Pegasys® you already have. MPN AA (Patient group Myeloproliferative Neoplasms Alliance Australia) along with Dr Cecily Forsyth have made a short video about the situation along with some practical strategies and topics to discuss with your health care professional, to help 'stretch' the remaining stock until new supplies are available.

Once again, I thank you for your understanding during this difficult time. We at Echo Therapeutics are doing our best as the local supplier and will keep you updated via the MPN AA portal as we learn more. I wish to acknowledge the volunteer team at MPN AA who help us get these communications to you. We do not have any financial or other commercial arrangements with the MPN AA patient group.

Regards

Jude

A handwritten signature in cursive script that reads "Jude D'Silva".

Jude D'Silva

Managing Director

Echo Therapeutics Pty Ltd