Pegasys® supply update 20 May 2025

Dear Clinicians and Patients

As you are aware, we have been navigating our constrained supplies of Pegasys® over the last 10 months due to the change in manufacturing site and constrained allocations during the global shortage. Please share this communication with all relevant Health Care Professionals.

Approval of the Austrian manufacturing facility

We have some good news to share: the new manufacturing facility in Austria has been approved and we worked very efficiently with the TGA to follow with the required TGA approvals soon after. This means we will start to receive Australian & New Zealand stock later this year. At this stage the timeline we have been given is **November 2025**.

Current status (May 2025) of the Australian/New Zealand labelled Pegasys® 135mcg and 180mcg

As of this Monday 19th May 2025, we are now out of the 180mcg presentation at our warehouse, which was anticipated, as per our communications via the TGA shortages website notifications and previous communication with you. **We are also now down to 1 month's supply of the 135mcg presentation**. The timelines were always evolving as we did not have confirmation of future supplies and changes in short term demand were always difficult to predict

Note: The TGA Medicines Shortages website section will be updated accordingly as the situation evolves, we urge all stakeholders who require urgent updates to refer to the TGA Medicines Shortages section for the latest update. This can be accessed here https://apps.tga.gov.au/Prod/msi/search?shortagetype=All

The challenge was finding a solution for the gap in supply until the new Australian stock arrives in November.

Section 19A: TGA Approved Irish-labelled stock of Pegasys® during the shortage:

I have more good news to share with you but will still need your help as we manage this next period. We have successfully negotiated with Pharma& (the owners of Pegasys®) to secure some European stock, specifically Irish-labelled stock. The teams at Echo Therapeutics and Pharma& have worked with the TGA to get a special approval to allow this stock to be used for patients across Australia via the Section 19a pathway which allows for unregistered stock to be used locally. This Irish labelled Pegasys® allocation, is sourced from the new manufacturing plant that will be supplying Australia in the near future and meets the requirements of the TGA as mentioned earlier. Pharma& has placed Echo Therapeutics in a queue to receive this allocation, which is expected to arrive by July 2025.

Additional information regarding ordering instructions, such as ordering codes and PBS items codes, will be provided closer to July 2025 (this is awaiting PBS approval as at May 2025).

Your crucial support and patience would be much appreciated as we navigate the S19A Irish labelled stock during the shortage, and through to resumption of full supply.

With your help and support, we can initially look to utilise the current remaining 135mcg Australian stock. This will be followed by the Irish-labelled stock scheduled for July 2025, for all patients to reduce supply disruptions until future Australian stock is available. **Importantly the majority of this Irish stock will be the 180mcg presentation.**

So, the situation means juggling the available presentations (currently mainly 135mcg) and incoming Irish presentation (mainly 180mcg) with patients' individual doses, frequency and clinical needs.

Please note, this has been an evolving situation and Echo Therapeutics has lobbied very diligently to secure Pegasys® for Australian patients. The situation in some countries in Europe and other parts of the world has been more dire with no stock for many months. Nonetheless, while we have a near-term solution, we will still be faced with challenges which may require clinicians and patients needing to explore dosing and management strategies for individual needs.

Supply of the Irish stock will continue via JustMeds, our home delivery partner, to ensure fair and equitable supply to as many patients as possible. We anticipate this will also prevent stockpiling of stock and significantly reduce the risk of unapproved export, which has happened across Europe and other parts of the globe.

What happens when Echo resumes supply of Australian labelled stock later this year?

It is important to note, that once the new Australian labelled Pegasys® arrives (scheduled to arrive November 2025), Echo intends to continue servicing patients via JustMeds (Pegasys® home deliver program), allocating and monitoring stock levels until **consistent** supply is established. We commit to our continued transparent communication during this period.

Your support will still be required through this period as the quantity, timing and schedule of deliveries of Australian labelled stock is still evolving as at May 2025. This is because all countries globally require a build-up of stock to a level that is efficient and equitable, for all patients worldwide.

Thank you for your understanding, your resilience and continuing to help us manage all of these changes as they come to light. The team at Echo Therapeutics has been doing a lot of work behind the scenes to secure some of the stock allocations, to try and ensure equitable supply and to always try to avoid patients going without this important medicine for their needs.

By the end this week, we will also share a short video with Haematologist, Dr Cecily Forsyth and Nathalie Cook OAM, from the patient advocacy group Myeloproliferative Neoplasms Alliance Australia (MPNAA) about some suggested strategies to consider.

Warm regards

Jude

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