

Very brief summary of transcript

The new Pegasys factory in Austria has received its certification and is now operating, but there is currently a shortage of Pegasys in Australia.

To address this, Echo Therapeutics has negotiated with Ireland to supply interferon to help fill the gap until the new Australian supply arrives, likely in November.

The Irish supply will be quality-controlled and repackaged for Australian patients, who may need to obtain new prescriptions for the 180 microgram syringes. Patients are advised to work closely with their haematologists to manage their dosage and supply during this transition period, and the MPN Alliance Australia is available to provide support and advice.

Full transcript

Hello, I'm Cecily Forsyth, a haematologist with a subspecialty interest in myeloproliferative neoplasms. And I'm joined tonight by Nathalie Cook, one of the MPN patient volunteers from the MPN Alliance Australia. Hello, Nathalie.

Nathalie:

And hello Cecily. Thank you for joining me again for a video for patients. So I've heard that there's information online and MPN Facebook pages that the new Pegasys factory in Austria has received its certification and it's now operating. And yet the TGA, the Therapeutic Goods Administration website, advises that there's currently a shortage of Pegasys in Australia from now until the end of September.

And this is all a bit unsettling for the MPN community, and it would be great if you could please clarify what all that this means for Australian patients.

Cecily:

Okay, I think first of all, it is really important to acknowledge that this is an unsettling time for patients on interferon. And we really understand that: haematologists, nurses, MPN patient support people, families, we get how stressful it is. So we really want to try and provide up- to- date information and a plan for the future. And we want people to discuss that with their haematologist so they know what to expect.

So thank you to everybody who has multi- dosed, who has not hoarded supplies, who has listened to the updates and really thought about what's happening. You know, we really, really appreciate everybody's efforts to help get us through from now until this shortage is over.

So firstly, the new factory by Pharma& in Austria has absolutely got all the approvals that are needed and they are now manufacturing pegylated interferon, what we know as Pegasys here in Australia.

Unfortunately, Australia is a little bit down in the queue to receive Pegasys because we've run out of pegylated interferon later than most European and North American countries. So we are further down in the queue to be resupplied. So yes, Pharma& are busy making interferon, which is great news. In Australia, we have to wait our turn to be resupplied.

So at the moment, we have run out of 180 microgram syringes in Australia, and we have about a month's supply of 135 microgram syringes left. So yes, we are going to have a shortage and that shortage will continue possibly till the end of the year. But we have got a few things up our sleeve, as I'm sure you're going to ask me about.

Nathalie:

Thanks Cecily. So I remember that usually Australian authorities, namely the TGA, the Therapeutic Goods Administration, need to approve medicines for Australian use. So even though the factory has European authority approvals, does it now also need to get Australian approvals?

Cecily:

Absolutely. Every medicine that is used in Australia has to be approved and made sure it is safe for patients. So there's a very rigorous system in Australia. So what has actually been happening for the last few months is that Echo Therapeutics, who provide Pegasys for Australian patients, have been working with the TGA to fast-track those approvals and to get those approvals happening really early. So as soon as stock for Australia is available from Austria, that process is streamlined, and we just go ahead as soon as that stock is here.

So we're actually really grateful to a number of people. Some of the haematologists throughout Australia who lobbied the TGA, the staff at TGA, you know, who work really tirelessly trying to actually get approvals happening and to understand what it's like for patients, and Echo Therapeutics, who've also lobbied really hard to make sure that as soon as the supply for Australia is available, that it is actually available for patients right away.

Nathalie:

Great. That's indeed fantastic news, So does that mean that there'll only be a small gap in Pegasys availability here in Australia?

Cecily:

How long this gap is going to be is really unknown. And, you know, large parts of Europe were out of pegylated Interferon for many, many months before we have run out now, or running out. So we are further down in the queue for us to receive Australian supply, and it may be November before Australian supply is back with certainty and in a normal manner. But in fact, Echo Therapeutics have negotiated with an overseas country, actually happens to be Ireland, for a supply of interferon to come from Ireland that we will be able to access to help fill in the gap between when we run out of 135 microgram

syringes, probably within a month and when we get the new supply dedicated to Australia from Pharma&.

Nathalie:

Fantastic. Well, that's good news. So will the Irish supply be quality controlled in the same way that the Australian supply is?

Cecily:

Look, absolutely. It will have, the packaging will be a little bit different, because it will meet the Irish guidelines for approval, and it will be overseas supply. Some patients may be used to that already. I think Respirin Forte is a common antibiotic. We've used overseas supply for quite some time for that drug when there were shortages. So many drugs that we've had shortages, we obtain from overseas. So in the case of Pegasys, we will be obtaining Irish supply. It will still be coming in a four- pack box. It will still be coming from JustMeds. But yes, if you look closely on it, it will be clear that that is stock from Ireland. I don't think it's going to be green or anything exotic like that. But yes, it will be, you know, it will be Irish stock, and it will be labelled with some differences from how stock in Australia would look. But it is the same drug from Pharma&. It will be transported according to all protocols for transporting the drug. It will be quality controlled in exactly the same way. It's the same product. It was just labelled for Ireland, not for Australia.

Nathalie:

And I also understand that there'll be Australian labels put over the Irish stock because it'll have information about it being a product for the Irish market. And that I think Echo Therapeutics will put labels on top of that. And I also heard that they might be in separate packaging. Patients will still pay the PBS price, but each syringe will be packaged in a separate box, but they'll still get the four.

Cecily:

That's right. They're going to be sort of repackaged in Australia by JustMeds. I understand that in Ireland the syringes are packaged individually.

And so that will be repackaged, and there will be a label indicating that, yes, this is Pegasys, and that it's authorised product and quality controlled. But it will still be very easy to see that it has come from an Irish stock. And yes, JustMeds will be sending that out. And I think that it will be a little bit different, you know, compared to what we have at the moment.

At the moment, we have 135 microgram and the majority of patients in Australia use the 135 microgram syringes. But when we get the Irish supply, we will be using the 180 micrograms. So we will predominantly be getting the 180 microgram syringes. So there will be a few little differences.

Nathalie:

Okay, great. And so I imagine that patients will need to get a new script from their haematologist. So if their usual dose has been, or their usual script has been for the 135 micrograms, they'll need to obtain another script so that they've got a 180 script. So maybe they should ask their haematologist for a script for each so that they can send them into JustMeds, depending on what supplies are available and they can fill the script for them.

Cecily:

Look, I think it is going to be a little bit challenging. And you're quite right. It's going to be a little bit of negotiation about scripts. And that is going to require cooperation from everybody. I realise that no patient wants to be ringing up for a second script for a different strength. But unfortunately, that we may well have to negotiate that with many patients who are normally on 135 moving to the 180s. So it is sensible to plan in advance so that you're not on the very last day when you're desperate for supply trying to suddenly get a script.

You know, so plan in advance when you see your haematologist say:

- I understand that we're going to very likely have 180s between July and September/November. So for July to November please could I have a script for 180s?
- And what do you think I should do? You know, if I'm on a dose, say, for example, of 45 micrograms every two weeks, how should I manage this out of a 180? What can I do? And get some advice about whether you stay on exactly the same dose, whether a 67.5 might be rounded to 60 and you get three doses out of the one 180 microgram vial. Just have a bit of a chat to your haematologist asking can I multidose? And how can I eek out my interferon to last for as long as possible.

We want to minimise the number of patients who have to switch to an alternate drug like hydroxycarbamide.

Nathalie:

Great, thank you. So there's lots of possibilities and it's really on an individual basis that each patient can discuss that with their own haematologist, isn't it?

Cecily:

There's some people as we mentioned in our last chat, for whom tight control is really important. There's some people who are on 180 micrograms a week. There's nothing you can do about stretching that supply out in general. I mean, some haematologists might say, look, you could go to 10 every 10 days. But if you're on a big dose, because you've got very proliferative disease, you haven't got much flexibility. If you are well controlled on a smaller dose, then maybe stretching time between doses or rounding it up so that you use the syringe as least number of times as possible (for sterility and safety).

So everybody's situation is different. They need to be thinking about it, thinking about what is easy and getting some help. The MPN Alliance Australia, the MPN advocates on your panel, they're just fantastic. And they will really help people with all of these decisions, about what to ask their haematologist and how to tackle these differences and, get through this hopefully as safely and quickly as possible.

Nathalie:

Great. Thanks Cecily. And there's even little practical things that people can do, for example, that they can look at the syringe and they can get a marker pen and roughly put marks to divide it up into the dose that's been decided with them and their haematologist for that particular syringe. So that might be a helpful way to help people roughly deliver the right dose for themselves.

Cecily:

Absolutely. And I think where it does get a little bit difficult is the 180 coming from Ireland doesn't have a mark below the 90. So people need to remember that when we look at interferon, it's a long-acting drug. So that if you look at the dose you have over a two or three month period, it doesn't really matter if you're dividing the 180 into 60s, or if you have 70 one week and 50 the next week and then the last, 60. Because over the two to three months, that dose will be the whole syringe. So yes, I think exactly as you suggest, a bit of a marker pen, roughly aiming for aiming for that line is fine. And if you overshoot and you have a bit more one week, yes, you might have a few more symptoms, flu like symptoms, but in general, it won't cause a dramatic change in your counts because that's not the way interferon works. So we don't all have to be absolutely accurate. We just have to do the best we can in a sensible manner.

I'm dividing this syringe into three, you know, get a marker. Look ok that's the marker of one third, roughly, and that is fine.

Nathalie:

Great. And that's also one of the advantages of the pegylated interferon because it is long acting compared to the old roferon that was much shorter acting, isn't it?

Cecily:

Absolutely. Very much so. Yes. And, you know, what patients have done and how much they've embraced multi-dosing, has been really fantastic. And it has helped keep Australian supply at a level where very few patients are going to need to transition to hydroxycarbamide, which is really fantastic news for the MPN population.

Nathalie:

Fantastic. So, when will the new factory be supplying Australia directly, so that we won't need to rely on the stock coming from Ireland?

Cecily:

I think that's hard to answer. And I think what I feel is really important is to say that everything we're talking about tonight is a guide.

And we are hoping that there will be Irish stock available in July. And we will all be delighted when it gets on the plane and it arrives. But we always say that is the aim at the moment is July.

We are in a queue from Pharma&. And at this stage, it is expected to be November, where the Australian supply for Australian directed, labelled, not detouring via Ireland supply, arrives. But again, we have to just wait. And when that is here, we will let everybody know with great joy. But that is the expectation. The timeline we have at the moment is about a month of 135 microgram syringes and then July before new supply, predominantly 180s, arrives from Ireland. And then we think about November before Australian directed supplies from Pharma& arrive.

Nathalie:

Great. And what about delivery? So after this temporary shortage of Pegasys is over, will delivery still be provided by JustMeds? Or will patients go back to their old arrangements with their local pharmacies?

Cecily:

So just to sort of clarify for patients. JustMeds will still be the supplier of the Irish stock. They will still supply stock until we are back with no supply shortages. Once their supply is back with no shortages, patients can choose to get their interferon wherever they would like. And for some patients, actually, the convenience of JustMeds delivery system may actually appeal. And for other patients, they will just get the supply from their hospitals or their local pharmacy once we are back in the time where supply is plentiful.

Nathalie:

Great. Thanks, Cecily. So that's fantastic news that we're not going to have a period with no Pegasys, as was feared earlier on. So that's great that we can get that extra supply from Ireland in the interim before the continuous supply comes straight from the factory in Austria later in the year. That's great.

Cecily:

And that summarises it very well, Nathalie. And just thank you to everybody, JustMeds, thank you to all the haematologists who continue to assist their patients. Thanks to the patients. Thank you to Echo for doing their best. And thanks to the TGA. So lots and lots of people to actually thank. It is still going to be tight. It is going to be concerning. We know there will be people who will be struggling with interferon supply. And please reach out to the MPN Alliance Australia to see if there's anything they can do to help and for advice and reach out to your haematologists because we're really hoping that as few people as possible will be really badly impacted by this. You know, we want to make it as smooth as possible for everybody.

Nathalie:

And thank you again, Cecily, for your time and expertise. Much appreciated.