4 August 2025

Dear Healthcare Professional,

Shortage notification of PEGASYS® peginterferon alfa-2a 135 micrograms/0.5 mL injection pre-filled syringe (AUST R: 91836) and PEGASYS® peginterferon alfa-2a 180 micrograms/0.5 mL injection pre-filled syringe (AUST R: 91837) and alternative supply arrangement under Section 19A of the *Therapeutic Goods Act 1989.*

Echo Therapeutics, the supplier **of PEGASYS® peginterferon alfa-2a 135 mcg (AUST R: 91836) & 180 mcg (AUST R: 91837)** wishes to notify you of a shortage of both presentations and the availability of alternative supply arrangements during this shortage.

Echo Therapeutics has been able to arrange supply of alternative products **PEGASYS® peginterferon alfa-2a 135 micrograms/0.5 mL injection (Ireland)** and **PEGASYS® peginterferon alfa-2a 180 micrograms/0.5 mL injection pre-filled syringe** on a temporary basis. These products are NOT registered in Australia, and supply is authorised under an approval granted by the Therapeutic Goods Administration (TGA) under Section 19A of the *Therapeutic Goods Act 1989* until 31 January 2026 for the following indications:

Chronic Hepatitis C (CHC)

The combination of Pegasys and ribavirin is indicated for the treatment of chronic hepatitis C in patients who have received no prior interferon therapy (treatment-naïve patients) and patients who have failed previous treatment with interferon alfa (pegylated or non-pegylated) alone or in combination therapy with ribavirin.

The combination of Pegasys and ribavirin is also indicated for the treatment of chronic hepatitis C patients with clinically stable human immunodeficiency virus (HIV) co-infection who have previously not received interferon therapy.

Pegasys monotherapy is indicated for the treatment of chronic hepatitis C in treatment-naïve patients. Patients must be 18 years of age or older and have compensated liver disease.

Chronic Hepatitis B (CHB)

PEGASYS is indicated for the treatment of chronic hepatitis B in adult patients with evidence of viral replication and liver inflammation and compensated liver disease.

PEGASYS® peginterferon alfa-2a 135 micrograms/0.5 mL injection pre-filled syringe (Ireland) and **PEGASYS® peginterferon alfa-2a 180 micrograms/0.5 mL injection pre-filled syringe (Ireland)** are registered and marketed in Ireland and therefore the labelling, although similar, is not identical. The approved Section 19A products and the Australian products are identical in active ingredient, strength, and formulation.

Please note that **PEGASYS® peginterferon alfa-2a 135 micrograms/0.5 mL injection pre-filled syringe (Ireland)** is supplied in a single pack containing one single pre-filled syringe.

PEGASYS® peginterferon alfa-2a 180 micrograms/0.5 mL injection pre-filled syringe (Ireland) is supplied as a pack of 4 pre-filled syringes. This is the same quantity as the ARTG-registered presentation of **PEGASYS®**.

Please refer to the Australian Product Information for **PEGASYS® peginterferon alfa-2a 135 micrograms/0.5 mL injection pre-filled syringe (AUST R: 91836) and PEGASYS® peginterferon alfa-2a 180 micrograms/0.5 mL injection pre-filled syringe (AUST R: 91837)** available at https://www.ebs.tga.gov.au when prescribing **PEGASYS® peginterferon alfa-2a 135 micrograms/0.5 mL injection pre-filled syringe (Ireland)** or **PEGASYS® peginterferon alfa-2a 180 micrograms/0.5 mL injection pre-filled syringe (Ireland).**

Patients should be advised to disregard the CMI/patient leaflet for **PEGASYS® peginterferon alfa-2a 135 micrograms/0.5 mL injection pre-filled syringe (Ireland)** and **PEGASYS® peginterferon alfa-2a 180 micrograms/0.5 mL injection pre-filled syringe (Ireland)** contained within the pack and refer to the Australian Consumer Medicines Information available from the Echo Therapeutics' website.

Adverse Event Reporting

Reporting any suspected adverse event is important for the continued monitoring of the safety of all medicines. Any adverse events which are experienced with **PEGASYS® peginterferon alfa-2a 135 micrograms/0.5 mL injection pre-filled syringe (Ireland)** or **PEGASYS® peginterferon alfa-2a 180 micrograms/0.5 mL injection pre-filled syringe (Ireland)** should be reported by healthcare professionals and patients to Echo Therapeutics on 1300 848 328 or by email drugsafety@echotherapeutics.net. Alternatively, this information can be reported directly to the TGA.

Please forward this information to relevant staff members in your organisation.

For additional information, please contact Echo Therapeutics on 1300 848 328 or email connect@echotherapeutics.net.

Yours sincerely,

Jude D'Silva
Managing Director
Echo Therapeutics Pty Ltd