

March 21, 2012

## IMPORTANT DRUG INFORMATION

***Subject: Information for Healthcare providers on a potential shortage of the pre-filled syringe (PFS) form of PEGASYS® (pegylated interferon alfa-2a) administration***

Dear Health Care Provider:

We are contacting you to inform you of a potential supply constraint with PEGASYS® (peginterferon alfa-2a) 180mcg/0.5ml prefilled syringe (PFS). These potential supply constraints are limited to only the PFS form of PEGASYS® administration, as a result of increased demand for PEGASYS® PFS and a production constraint of the PFS glass syringe barrels.

This increased market demand and the supply constraints of PFS may lead to potential limited availability of the PFS form of PEGASYS® administration in the next 6 months; Genentech anticipates that the potential shortage of the PFS will resolve by September 2012.

### **Recommendations to ensure continuity of therapy with PEGASYS®:**

To help ensure continuity of PEGASYS® treatment, two alternate forms of PEGASYS® administration are available and should be considered for use with new and existing PEGASYS patients:

- PEGASYS® (peginterferon alfa-2a) ProClick™ autoinjector to administer the recommended weekly fixed dose of 180 mcg or 135 mcg
- Vials to administer the recommended weekly dose of 180 mcg or less

### **Alternate delivery methods available in the US market for PEGASYS®:**

<b>Each PEGASYS® ProClick™ Autoinjector Monthly Convenience Pack contains:</b>	<b>NDC</b>
A box containing four 180 mcg per 0.5 mL PEGASYS® ProClick™ single use autoinjectors	0004-0365-30
A box containing four 135 mcg per 0.5 mL PEGASYS® ProClick™ single use autoinjectors	0004-0360-30
<b>Each PEGASYS® Single Use Vial Package contains:</b>	
A box containing 180 mcg per 1 mL solution in a single use vial	0004-0350-09

In order to help avoid a potential PFS shortage and maintain continuity of PEGASYS® therapy, if PEGASYS is chosen for a new patient, we recommend healthcare providers initiate them on PEGASYS® ProClick™. In addition, we recommend healthcare providers consider switching appropriate existing PFS patients to PEGASYS® ProClick™ at the next available opportunity or refill. Patients who require a dose lower than 135 mcg of PEGASYS® will be required to use the PFS or administer the appropriate reduced dose from the 180 mcg/1 mL vial.

The above action by healthcare providers will assist in our endeavor to reserve sufficient quantities of PFS for patients with a clinical need to remain on the PFS (e.g. those requiring dose adjustments outside of the fixed PEGASYS® ProClick™ doses of 180mcg and 135mcg).

Please note that the switch recommendation does NOT apply to patients enrolled in clinical trials.

PEGASYS® ProClick™ and vials are not affected by the supply constraints for the PFS.

While we regret the potential supply constraint for the PFS, switching between PFS and PEGASYS® ProClick™ forms of PEGASYS® administration does not result in any change to the benefit-risk of PEGASYS®. In a crossover, user-handling study from the registration trials, patients were randomized to PEGASYS® 180 mcg once weekly by either PEGASYS® ProClick™ or PFS for 3 weeks and were then switched to the alternative delivery method for 3 weeks. Overall safety and tolerability were similar between PEGASYS® ProClick™ and the PFS.

The Wholesale Acquisition Cost (WAC) of the PEGASYS® ProClick™ device is equivalent to the WAC cost of the PFS.

Genentech is committed to supporting you and your patients in the appropriate use of PEGASYS® ProClick™ through all the PEGASSIST support resources and patient2education programs. New patients as well as existing patients switching from PFS to PEGASYS® ProClick™ will need to be appropriately trained on the PEGASYS® ProClick™ injection instructions. As a supplement to the instructions for use (IFU), the following resources are available to reinforce the appropriate injection instructions for PEGASYS®:

- PEGASYS® patient self-injection brochures and injection DVDs
- PEGASYS® self-injection training kit (demonstration devices)
- In person and web-based patient education classes
- 24/7 nurse educator call center (1-877-734-2797)
- [www.PEGASYS.com](http://www.PEGASYS.com)

We will continue to provide assistance with training staff to assist patients in the appropriate use of PEGASYS® ProClick™ as well as direct training for patients as deemed necessary by you or your staff. If you have any questions regarding the PEGASYS® support resources and patient education programs that supplement the PEGASYS® instructions for use, please contact your local PEGASYS® representative or call the Genentech Customer Service line at 1-800-551-2231.

If you or your patients have any further questions about the information in this letter, please contact the Genentech Resource Center at 1-877-436-3683. If you have medical questions about PEGASYS®, please contact our Medical Communications/Information Department at 1-800-821-8590. You are encouraged to report side effects associated with the use of PEGASYS® to Genentech at 1-888-835-2555 or to the FDA's MedWatch Safety Information and Adverse Event Reporting Program, which can be found at [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

For the PEGASYS® indication and important safety information including Boxed WARNINGS and Medication Guide, please see the attached full prescribing information.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Hal Barron', with a long horizontal flourish extending to the right.

**Hal Barron, MD**

**Executive Vice President, Global Development and Chief Medical Officer  
Genentech, A Member of the Roche Group**