Genentech
A Member of the Roche Group

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®:

Each PEGASYS® ProClick™ Autoinjector Monthly Convenience Pack contains:	NDC
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
Each PEGASYS® Single Use Vial Package contains:	
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

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 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,

Hal Barron, MD

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