



September 25, 2019

Dear HFA and NHF,

We are reaching out to follow-up and provide a timely response to your letter dated September 24, 2019.

The Genentech Patient Foundation sincerely apologizes for the recent quality control issue by MedVantx, our contracted specialty pharmacy vendor, that unacceptably led to the shipment of ancillary supply kits with injection needles of incorrect length to 124 hemophilia A patients being treated with Hemlibra provided by the Genentech Patient Foundation. Since becoming aware of this issue on the afternoon of Wednesday, September 18th, we have moved swiftly to halt MedVantx's distribution of these incorrect needles and to rapidly inform all 124 patients and their 92 healthcare providers.

Below please find an update on where this situation stands as of today, Wednesday, September 25th:

- The Genentech Patient Foundation is an independent 501(c)(3) non-profit that makes many of Genentech's FDA approved medicines available for free to enrolled patients who are unable to afford its medicines. MedVantx is the contracted specialty pharmacy of record for the Genentech Patient Foundation and provides Hemlibra to hemophilia A patients who are enrolled in this program.
- Beginning on August 1st of this year, the Genentech Patient Foundation, through MedVantx, began offering kits to Hemlibra patients containing ancillary supplies for the preparation and administration of Hemlibra. Genentech's instructions for the composition of these kits directed the inclusion of 3/8 inch injection needles. However, 5/8 inch injection needles were incorrectly included.
- Since learning of this issue, we have taken the following actions, with the following results:
 - September 18th: We confirmed that the incorrect needles (5/8 inch long vs. the intended 3/8 inch) had been included in the kits.
 - September 19th: We halted any further shipment of kits and began identifying all potentially impacted patients and providers.
 - September 20th:
 - We began proactive outreach to all 124 patients and their healthcare providers via phone, email and mail from MedVantx pharmacists and/or Genentech Patient Foundation specialists.

- We offered to ship appropriate injection needles to these impacted patients if they were needed to continue treatment. Patients were additionally instructed to identify the 5/8 inch injection needles in the kit and dispose of them in a sharps disposal container.
 - For any patients we were not able to reach, we automatically sent replacement needles.
 - We informed HFA and NHF of the error and emerging action plan.
- As of today, September 25th at 6 pm PST:
 - We have successfully reached 94 patients via phone to inform them of the situation and offer new needles.
 - We have reached an additional 20 patients via email, mail or through their healthcare providers.
 - We are continuing to reach out to the remaining 10 patients who have been sent letters but not yet reached directly via phone or their HCP.

In response to direct questions from the community, please find our answers and additional context below:

- MedVantx obtains and maintains a valid prescription of Hemlibra for all hemophilia A patients we service on behalf of the Genentech Patient Foundation.
- Specialty pharmacies like MedVantx routinely provide patients access to various ancillary medical supplies (including injection needles and syringes) to support overall patient care at home. Patient self-administration needles are considered medical supplies (not prescription drug items) and thus not routinely provided or dispensed pursuant to physician prescription.
- We have not notified the FDA. An FDA product recall would occur if the product (Hemlibra) was defective or potentially harmful. The FDA will be notified about the patient impact through our standard US Drug Safety reporting.
- While 5/8 inch injection needles fall within the appropriate range of lengths that may be used for the administration of subcutaneous medications, our PI states that the needle length is preferably 3/8 inch or maximal length 1/2 inch. Patients who used the 5/8 inch needle should monitor for side effects related to the injection, continue their usual Hemlibra dosing regimen with the appropriately sized needle and notify their healthcare provider of any adverse events.
- No studies have been conducted to evaluate the effects of Hemlibra if it were to be administered intramuscularly.
- We are currently aware of one infant that received Hemlibra with the 5/8 inch injection needle.
- We encourage healthcare professionals, patients and caregivers to report any adverse events in people taking Hemlibra to the FDA at 1-800-FDA-1088, or to Genentech at 1-888-835-2555.
- All patients who inform us that they used an incorrect needle are being referred to Genentech US Drug Safety, which will capture associated potential adverse events. If

we learn of any adverse events caused by the use of an incorrect needle we will share that with the appropriate regulatory bodies.

Finally, while our immediate focus has been and will continue to be getting into contact with patients and providers about this error, we have also initiated a detailed inquiry on both the MedVantx and Genentech Patient Foundation teams to identify how this error was made and to establish additional processes and quality control checks to ensure this situation does not happen again.

Patient safety is of the utmost importance to both the Genentech Patient Foundation and MedVantx, and for this error, we deeply apologize.

Sincerely,

Jack Gallagher
Head of the Genentech Patient Foundation