MASAC Medical Advisory #: 430

Sanofi is notifying healthcare professionals about a voluntary recall of one lot (# EY0330) of ALTUVIIIO [antihemophilic factor (recombinant), Fc-VWF-XTEN] after it came to our attention that the label contains erroneous text regarding product dose potency.

Overview of situation
ALTUVIIIO lot #EY0330 of 2000 IU nominal vial potency was erroneously labelled with an actual potency of 2132 IU/mg on the finished product and cartons, instead of the correct value of 1811 IU/vial. The nominal value of 2000 IU/vial is correct and the actual potency is still within FDA-approved manufacturing specifications.

Prescriber Action
The dose of ALTUVIIIO lot #EY0330 is consistent with the recommended dosing in the USPI and is not expected to have a clinical impact on patients who are on a prophylactic regimen, as the FVIII activity levels should remain in the protective range to prevent spontaneous bleeding.

Please work with your pharmacy and your distributors to notify any of your patients who may have received this lot of ALTUVIIIO and instruct them to discontinue use of and return all product from this lot. Please note that the pharmacies have been notified about the recall. If your patient needs treatment before receiving replacement product, the dose should be calculated based on vial potency of 1811 IU/vial and/or per clinical judgement.

Background: Therapeutic Indication
ALTUVIIIO [antihemophilic factor (recombinant), Fc-VWF-XTEN fusion protein-ehtl] is a recombinant DNA-derived, Factor VIII concentrate indicated for use in adults and children with hemophilia A (congenital factor VIII deficiency) for:
• Routine prophylaxis to reduce the frequency of bleeding episodes
• On-demand treatment & control of bleeding episodes
• Perioperative management of bleeding

Cause for the Recall and Mitigating Actions Taken by Sanofi
Sanofi decided to voluntarily recall the batch to avoid having incorrectly labelled units on the market. Out of an abundance of caution, the vials that have been distributed are being recalled and will be replaced.

Supportive Evidence for the Mitigation Measures for Prescribers
The dose of ALTUVIIIO lot #EY0330 is consistent with the recommended dosing in the USPI and is not expected to have a clinical impact on patients who are on a prophylactic regimen, as the FVIII activity levels should remain in the protective range to prevent spontaneous bleeding.

In bleeding situations, per the USPI, e.g. surgery and acute bleeding episodes, it is expected that the patient will be protected. For perioperative management, FVIII levels are typically monitored during the perioperative period to determine if and when additional doses may be needed to maintain haemostasis.

Patient Monitoring
No specific measure is required. Please refer to the Prescribing Information for details regarding the treatment with ALTUVIIIO. For further information, please contact your local Sanofi Medical Information Hotline at (1-800-633-1610, option 1).

PHYSICIANS: Please distribute this information to all providers in your area who treat patients with hemophilia and bleeding disorders.

CHAPTERS: Please distribute this information to your membership.
Please sign up for the Patient Notification System (PNS) to be notified directly about the latest recall or withdrawal of recombinant and plasma products. The system is confidential and time sensitive. It is administered by an independent third-party organization and is free of charge. To enroll in the PNS, please call (888) UPDATE-U or go online at http://www.patientnotificationsystem.org.