August 16, 2023

Alain Baumann, CEO, World Federation of Hemophilia

Dear Alain Baumann:

We are writing to inform you that Takeda has identified and addressed a manufacturing issue that impacted BAXJECT II and BAXJECT II Hi-Flow reconstitution devices that were produced by our contract manufacturer between October 2021 and January 2022. These devices were co-packaged for use in conjunction with certain Takeda hemophilia medications (RECOMBINATE, RIXUBIS, ADVATE, ADYNOVATE and FEIBA) and shipped to countries where these medications are approved for use with these specific devices. We've identified the countries with impacted BAXJECT II and BAXJECT II Hi-Flow device lots in market, and we are systematically working with regional and local health authorities to correct this issue and to ensure hemophilia patients have access to their medicines.

Device reports indicated that particles were observed near the luer port of the reconstitution device prior to administration of the medicine, either when the luer port cap was removed as part of the reconstitution preparation process or in the syringe after the medicine was reconstituted. No reports led to serious adverse events or death, and no adverse events were attributable to the presence of particles. No particles have been identified in the active medicine. Only the devices produced by the contract manufacturer between October 2021 and January 2022 are impacted. The safety profiles of RECOMBINATE, RIXUBIS, ADVATE, ADYNOVATE and FEIBA remain consistent with the product labels.

Takeda is committed to providing reliable and high-quality therapies for patients. We are actively working with regional and local health authorities to address the impacted BAXJECT II and BAXJECT II Hi-Flow reconstitution devices in their respective countries. Corrective efforts may vary by country, as determined by that country's health authority. Regardless of the local actions taken, we are working to achieve continuity of supply for hemophilia patients, and we are communicating directly with healthcare professionals, patient organizations and other key stakeholders.

If you receive questions from patients about the replacement of BAXJECT II and BAXJECT II Hi-Flow reconstitution devices, we encourage you to ask them to consult with their treating physician. We will continue to keep you updated and thank you for your ongoing support.

Sincerely,

Hampton Shaddock
Head, Global Therapeutic Policy & Patient Advocacy GPLS

Tineke Zuurbier
Head of Public Affairs & Advocacy, Plasma Derived Therapies