



A Statement from Genentech on HEMLIBRA Particles

During a routine examination of drug product batches, as part of our quality assurance systems and processes, hardly visible, translucent particles were identified in Hemlibra® (emicizumab-kxwh), outside our particle specification.

These particles are inherent to the drug product and based on toxicology and safety assessments and review of available data, the benefit/risk profile of Hemlibra remains unchanged as a result. They consist of protein (Hemlibra drug substance) and silicone oil (PDMS, polydimethylsiloxane). Silicone oil is a non-toxic, organic polymer that is included in all parenteral medicines. Translucent particles are commonly observed and present in other approved biologics.

We informed health authorities in March 2019. The U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), Swissmedic, Health Canada, and the Ministry for Health, Labour and Welfare (MHLW) in Japan all agreed with our assessment that the benefit/risk profile of Hemlibra remains unchanged, and have supported the continued distribution of Hemlibra to patients to avoid therapy interruption. We have submitted the results of our final analysis to the health authorities and continue to engage with these health authorities.

We are committed to producing high quality products for our patients, which is why we have rigorous manufacturing monitoring, controls and testing in place for all our medicines, including Hemlibra.

Please contact your healthcare provider or Genentech Medical Communications at 1-800-821-8590 for additional inquiries.