



August 12, 2026

Dear Members of the Pompe Community,

At Sanofi, we recognize that some patients are facing delays in their Pompe treatments, and we understand the concern and uncertainty this can create for people living with rare diseases and their families.

We are writing to share an update regarding the supply of Sanofi therapies for Pompe and provide information on what we know, what we are doing, and what you can expect from us. We recognize that behind every disruption is a patient and we do not take that lightly. We apologize for any impact these interruptions may have. Our teams are working as quickly as possible to restore full site operations to meet the needs of patients around the world.

On June 22, 2026, the U.S. Food and Drug Administration (FDA) issued a Warning Letter to Sanofi's manufacturing facility in Waterford, Ireland. The necessary actions we are taking in response to the FDA letter have contributed to intermittent release interruptions of Nexviazyme® and Myozyme® in some markets, with the timing and extent of impact varying by country and by product, depending on available inventory, local demand, and the timing of upcoming shipments. As a result, some patients have experienced or may experience interruptions of upcoming infusions.

Despite our ongoing efforts, these intermittent release interruptions may continue for the next few months. We will provide updates as the situation evolves and are committed to working with the patient advocacy community. We are also working closely with our Sanofi colleagues across the globe and regulatory authorities to manage available supply, minimize patient impact, and support continuity of care wherever possible. It is important to note that every batch released from Waterford continues to meet all established requirements for safety, strength, and purity.

Your local Sanofi team will be your primary point of contact for country-specific updates.

If you have questions about your specific treatment plan, please speak with your healthcare professional.

What to expect

We will continue to share updates with you in collaboration with the International Pompe Association as the situation evolves. We owe it to every patient that relies on Sanofi treatments to resolve this with urgency.

We appreciate your patience as we work through this situation and are grateful you have put your trust in our team. We are fully committed to the Pompe community, every patient, family, and healthcare professional who relies on us.

Sincerely,

Alaa Hamed, Head Global Medical Affairs – Rare Diseases Specialty Care
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