29 July 2025

Dear members of the World Duchenne Organization,

We are sharing a community letter in response to your request for updates about our Duchenne programme.

Last week the FDA requested that Sarepta voluntarily halt all shipments of delandistrogene moxeparvovec in the U.S. After careful consideration Roche decided to voluntarily and temporarily pause all new orders of delandistrogene moxeparvovec to countries outside the U.S. that reference the FDA for local approval, and in Named Patient Supply (NPS) countries. Following further discussions with health authorities that did not reference the FDA, Roche subsequently voluntarily and temporarily halted new orders and shipping in all Roche territories outside of the US.

On 28 July the FDA recommended removing the pause in shipments for ambulatory individuals with Duchenne. Following this recommendation Roche is ready to immediately resume new orders and shipments of Elevidys for ambulatory patients outside of the US and in close collaboration with health authorities.

Patient safety is Roche's highest priority. Based on the totality of available data, Roche believes that the benefit-risk profile is positive in the ambulatory patient population. We are actively working with physicians and patient organisations to provide updates and developments on the Duchenne programme, and will continue to work in close collaboration with health authorities.

We understand that this news may have caused confusion and uncertainty for the Duchenne community. Thank you for your ongoing partnership as we do our best to support the understanding and implementation of these latest developments.

Sincerely,

S Blum

Sandra Blum, on behalf of the Roche Global DMD team
Global Patient Partnership Leader

M-XX-00021365
July 2025