23 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. We have been working with urgency to determine any measures to be taken in Roche territories outside the U.S.

After careful consideration Roche has 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. This pause applies to the ambulatory Duchenne population, as we previously discontinued treatment of non-ambulatory individuals.

Patient safety is Roche's highest priority. Based on the totality of available data, Roche believes that the benefit-risk profile remains positive in the ambulatory Duchenne population. As such, in countries that do not reference the FDA for approval and where Elevidys is approved (Brazil and Japan), Roche will continue to supply and ship delandistrogene moxeparvovec to enable treatment of ambulatory patients, according to local regulations.

Roche is working to understand why the FDA has requested that shipments be paused in the ambulatory patient population, and is in contact with the appropriate health authorities globally to determine next potential steps. We understand the profound impact this will have on the Duchenne community, especially on the families awaiting treatment, and recognize that you may have questions regarding these updates. We have included a few questions and answers below, and are here to help if you have more questions.

Thank you for your ongoing partnership as we do our best to support the understanding and implementation of these measures.

Sincerely,

S Blum

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

M-XX-00021296
July 2025

Frequently asked questions

I've already received treatment with delandistrogene moxeparvovec. Should I be worried?

- The clinical trial programme for delandistrogene moxeparvovec has shown that the treatment can support stabilisation or slowing of disease progression alongside improvements in motor function, with a consistent and manageable safety profile. The meaningful value that can be derived from treatment with delandistrogene moxeparvovec has led to numerous regulatory approvals around the world.
- Please contact your local treating physician with any questions that you might have relating to previous treatment with delandistrogene moxeparvovec.

What happens if treatment is planned but we change our minds about having it?

- We encourage you to discuss your situation with your healthcare provider as they are in the best position to work together with you and your family to decide what is best for you.

How long do you expect this pause to continue? Will you resume accepting new orders for treatment with delandistrogene moxeparvovec?

- At this time we do not have an answer for how long this pause will continue.
- What we can tell you is that we will share important updates and announcements with both the Duchenne community and physicians as we have them.