SMA Europe actions around recent Zolgensma safety concerns

Together with the families whose children have received Zolgensma (onasemnogene abeparvovec) gene therapy, SMA Europe is closely following the emerging safety information and is very aware of the worry and uncertainty this may cause for families in our community

10 November 2026

On 6 November, the US Food and Drug Administration (FDA), the regulatory body responsible to monitor drug safety in the United States, has confirmed receiving reports of cases of tumours in children previously treated with Zolgensma, including two cases confirmed to be directly linked to the therapy.

The FDA is investigating the risk and assessing whether further regulatory action is needed. The European Medicine's Agency, responsible to monitor drug safety in Europe, has not yet issued any official statements. We understand that the regulatory evaluation is ongoing and will continue to follow developments closely.

Our priority is to ensure that you receive clear, reliable information and that your concerns are heard.

SMA Europe has strongly urged Novartis to provide timely and transparent information on what is currently known, what remains uncertain, what this may mean for people who have already received treatment. We are pressing involved stakeholders to understand whether any additional monitoring or follow-up may be needed. We are collaborating with experts in our Scientific Advisory Board to help us to assess the emerging scientific information.

You will find official updates on the situation here: SMA Europe | Novartis Gene Therapies | Advancing SMA Treatment

We are actively collecting your questions, worries, and concerns, which you can share by email to secretariat@sma-europe.eu. We will bring them to the attention of Novartis and other appropriate stakeholders and will timely update the community with official, sound information that we can obtain.

This is a difficult and scary time. No one should have to navigate this uncertainty alone. As one united SMA community, we are determined to stand with you, to listen, understand, and take action. You are not alone, and together, we are stronger.

All together, one goal.