26 March 2026

Dear Members of SMA Europe,

In response to your request for important updates regarding risdiplam (Evrysdi®), we are writing to share a welcome regulatory update.

The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion for an update to the European label for the risdiplam tablet.[1] This update **expands the current label** and will **allow the risdiplam tablet to be administered via nasogastric (NG) and gastrostomy (G) feeding tubes after being dispersed (mixed) in water.**

Acting on Your Feedback

At Roche, we believe that innovation is most meaningful when it is guided by the people it serves. Pursuing this label amendment was a priority for us following helpful feedback from the SMA community, who advocated for a label expansion for greater inclusivity for people dependent on feeding tubes. The label update will allow more people living with SMA the flexibility to choose the treatment that best fits their needs.

What Happens Next

This approval and corresponding label update applies across all 27 European Union member states, as well as Iceland, Norway, and Liechtenstein. We are updating our patient and medical materials so that healthcare professionals and families have the most current instructions as soon as possible.

Our expectation is that this update will be implemented immediately where tablets are already reimbursed. For the remaining countries where the tablet is not yet available, please be assured that our teams are working diligently with local authorities to secure access as quickly as possible.

We remain deeply grateful for your partnership, and for the feedback that helps us refine our work.

Sincerely,

Carlos Mayer

Carlos Mayer, on behalf of the Roche Global SMA Team
Global Patient Partnership

1. Evrysdi Summary of Product Characteristics 2026. Available at: https://www.ema.europa.eu/en/documents/product-information/evrysdi-epar-product-information_en.pdf. Last accessed: March 2026.

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