**Template letter for MHRA on Early Access Programme**

On the next page we have some suggested text to send to the MHRA about why it is important they grant a broad label for givinostat.

The best email address to use is: [MHRACustomerServices@mhra.gov.uk](mailto:MHRACustomerServices@mhra.gov.uk), but the address of the MHRA’s main office is at the top of the letter if you’d prefer to post this.

We expect the MHRA will make their decision in early 2025, and we want them to mirror the decision of the FDA in the US, and grant it a broad label so as many boys as possible can access it. You can find the FDA announcement, approving it for all patients with DMD who are six-years-old and above, here: <https://www.fda.gov/news-events/press-announcements/fda-approves-nonsteroidal-treatment-duchenne-muscular-dystrophy>

It would be devastating if this was only approved for boys who are ambulant. In your message to the MHRA, help them to understand why retaining muscle function beyond just walking is important.

**Consider the text on the other page a guide, try and personalise it to you, your family, and your situation as much as possible.**

If you need any help, let our Senior Policy Manager Will Pender know (will@duchenneuk.org).

YOUR ADDRESS AND CONTACT DETAILS

DATE

FAO: Givinostat assessment team

MHRA  
10 South Colonnade

Canary Wharf

London

E14 4PU

Greetings,

I am a [RELATIONSHIP HERE] of a person with a rare muscle-wasting disease called Duchenne muscular dystrophy (DMD). The MHRA is currently assessing a DMD treatment called givinostat, which has already been approved by the FDA in the United States. I am writing to you to urge you to grant givinostat a licence in the UK, and to mirror the terms of the FDA’s licence by making givinostat available to everyone with DMD over the age of six.

DMD, the most common form and severe form of muscular dystrophy, is a horribly cruel and devastating disease which affects almost exclusively males. You can find out more about DMD at the website of Duchenne UK ([www.duchenneuk.org/about-duchenne-muscular-dystrophy](http://www.duchenneuk.org/about-duchenne-muscular-dystrophy)).

Boys with DMD start off ambulant, but as their muscles weaken will need to rely on a wheelchair. A treatment which can retain muscle function is not only important to keep boys walking, but to also keep their arms, heart and lungs healthy. A broad label, for all patients aged six and over, would help enable that.

Thank you for reading my message.

[YOUR NAME HERE]