Recd 3.10.2016

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Mr Robert Meadowcroft
Muscular Dystrophy UK
61A Great Suffolk Street
London
SE1 OBU

30 September 2016
EMA/637355/2016
European Medicines Agency

Dear Mr Meadowcroft,

Subject: Eteplirsen for Duchenne muscular dystrophy

Many thanks for your letter of 20 September 2016 about eteplirsen for Duchenne muscular dystrophy. You seek assurance on two counts: that the European Medicines Agency will deal with the approval of eteplirsen speedily; and that the orphan designation of drisapersen will not adversely affect the Agency's evaluation of eteplirsen.

So far the Agency has not received an application for marketing authorisation for eteplirsen. Until the company sends in the application, it is impossible to say anything about the evaluation timetable.

Conscious that there is no satisfactory treatment for Duchenne muscular dystrophy, the Agency is committed to play its full part in improving the lives of people affected by this devastating condition. The Agency's scientific committees will do their utmost to rigorously and promptly evaluate any evidence presented to support an application for marketing authorisation for candidate medicines, and take into account the perspectives of those affected through our interaction with representatives from patient groups.