15 October 2020
EMA/CHMP/521586/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Plegridy

peginterferon beta-1a

On 15 October 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Plegridy. The marketing authorisation holder for this medicinal product is Biogen Netherlands B.V.

The CHMP recommended the addition of a new route of administration (intramuscular use) for an existing formulation (125 micrograms in 0.5 ml) already authorised for subcutaneous use. The recommended indication for intramuscular use is the same as the currently authorised indication for Plegridy and is as follows:

> Plegridy is indicated in adult patients for the treatment of relapsing remitting multiple sclerosis.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR) and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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