22 April 2021
EMA/CHMP/213204/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Aubagio

teriflunomide

On 22 April 2021, 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 Aubagio. The marketing authorisation holder for this medicinal product is sanofi-aventis groupe.

The CHMP adopted a new 7 mg strength (film-coated tablet) and an extension to the existing indication as follows:[2]

> Aubagio is indicated for the treatment of adult **patients and paediatric** patients **aged 10 years and older** with relapsing remitting multiple sclerosis (MS) (please refer to section 5.1 for important information on the population for which efficacy has been established).

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
[2] New text in **bold**

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