27 June 2013
EMA/379992/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Aubagio

teriflunomide

On 21 March 2013, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Aubagio 14 mg film-coated tablet intended for the treatment of multiple sclerosis. The Committee also concluded at that time that the active substance, teriflunomide, which is a metabolite of leflunomide, could not be considered a new active substance.

The applicant subsequently requested a re-examination with respect to the new active substance status of teriflunomide. After considering the grounds for the request, the CHMP re-examined the initial opinion and concluded on 27 June 2013 that teriflunomide could be considered to be a new active substance in view of differences between teriflunomide and leflunomide as regards safety.

The approved indication for Aubagio is: "treatment of adult patients with relapsing remitting multiple sclerosis (MS)".

Teriflunomide is a selective immunosuppressant (L04AA31) with anti-inflammatory properties. The exact mechanism by which teriflunomide exerts its therapeutic effect in MS is not fully understood, but it is known to reduce the proliferation of lymphocytes by blocking the mitochondrial enzyme dihydroorotate dehydrogenase (DHO-DH).

The benefit with Aubagio is its ability to reduce the relapse rate in patients with relapsing remitting MS. The most common side effects are upper respiratory tract infections, urinary tract infections, diarrhoea, nausea, paraesthesia (pins and needles), alopecia (loss of hair) and increase in the liver enzyme alanine aminotransferase.

A pharmacovigilance plan for Aubagio will be implemented as part of the marketing authorisation.

Treatment with Aubagio should be initiated and supervised by a physician experienced in the management of multiple sclerosis.

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

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-risk balance for Aubagio and therefore recommends the granting of the marketing authorisation.