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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): alemtuzumab

Procedure No. EMEA/H/C/003718/PSR/S/0051

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Scientific conclusions

Taking into account the PRAC Assessment Report for the non-interventional imposed PASS final study report for the medicinal product(s) mentioned above, the scientific conclusions of CHMP are as follows:

The existing obligation to conduct the PASS cat 1 *Non interventional post-authorisation safety study (PASS): In order to investigate the incidence of mortality in patients treated with Lemtrada compared to a relevant patient population, the MAH shall submit the results of a post-authorisation safety study comparing Lemtrada to an adequate contro*l is now fulfilled and can be removed as a condition in Annex IID. The Annex IID is updated accordingly. Please note, that this assessment is without prejudice to the final outcome of the separate ongoing procedure EMEA/H/C/003718/PSR/S/0050 for the DUS PASS.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for the results of the study for the medicinal product(s) mentioned above, the CHMP is of the opinion that the benefit-risk balance of these medicinal product(s) is unchanged, subject to the proposed changes to the product information.

The CHMP is of the opinion that the terms of the marketing authorisation(s) of the medicinal product(s) mentioned above should be varied.