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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/PSUSA/00010055/201909

Period covered by the PSUR: 12/09/2018 To: 12/09/2019

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for alemtuzumab, the scientific conclusions of CHMP are as follows:

During the reporting period, three case reports were identified indicating a potential causal association of progressive multifocal leukoencephalopathy (PML) and alemtuzumab. PML is a severe demyelinating disease of the central nervous system that is caused by reactivation of the polyomavirus JC, which occurs almost exclusively in immunosuppressed individuals. On the basis of this, updated risk minimizing measures are warranted. The PRAC recommends an update of the SmPC, section 4.4 and the patient information leaflet.

Cases of pericarditis with a potential causal association with alemtuzumab were identified during the reporting period. Due to the severity of pericarditis and the cases identified, an update of the SmPC is warranted to include a warning of the risk of pericarditis. The PRAC recommends an update of the SmPC, section 4.4.

During the Article 20 referral procedure, Acquired haemophilia A was found to be related to treatment with alemtuzumab. Taken the severity of Acquired haemophilia A into consideration, the PRAC suggests an update of the SmPC section 4.4 to re-enforce awareness of this risk.

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

Grounds for the variation to the terms of the marketing authorisation

On the basis of the scientific conclusions for alemtuzumab the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing alemtuzumab is unchanged subject to the proposed changes to the product information

The CHMP recommends that the terms of the marketing authorisation should be varied.