EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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): natalizumab

Procedure No. EMEA/H/C/PSUSA/00002127/201908

Period covered by the PSUR: 06 August 2018 To: 06 August 2019

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**Scientific conclusions**

Taking into account the PRAC Assessment Report on the PSUR(s) for natalizumab, the scientific conclusions of CHMP are as follows:

The MAH conducted a retrospective analysis on the impact of plasma exchange/plasmapheresis (PLEX) on the outcome (2-year survival post-PML) of natalizumab-associated progressive multifocal leukoencephalopathy (PML). This analysis suggested that PLEX is not associated with a statistically significant effect on survival and appears to have no impact on improving post-PML outcomes. As PLEX is frequently used in clinical practise for treatment of PML, PRAC agreed that physicians should be informed about the new data on PLEX via an update of the sections 4.4 and 5.2 of the SmPC.

Further, the MAH proposed updating the adverse drug reaction (ADR) frequencies of some adverse events (from "common" to "very common") in the section 4.8 of SmPC and Package Leaflet. The changes in ADR frequencies are to correct typographical errors and are considered acceptable.

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 natalizumab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing natalizumab is unchanged subject to the proposed changes to the product information

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