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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: ibrutinib

Procedure No. EMEA/H/C/PSUSA/00010301/201605

Period covered by the PSUR: 13 November 2015 to 12 May 2016

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Scientific conclusions

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

Following a cumulative review, 17 cases of Progressive Multifocal Leukoencephalopathy (PML) have been identified and assessed. Although some cases are confounded by previous or concomitant therapy with other drugs listing PML in the Summary of product characteristic (SmPC), the role of ibrutinib, also in light of its biological plausibility as an immunosuppressant, cannot be excluded.

Since PML is a very serious clinical event which benefits from early diagnosis and intervention, health care professionals using ibrutinib would benefit from a warning with regards to the possibility of events of PML when using ibrutinib in the context of a prior or concomitant immunosuppressive therapy. Therefore, an update of section 4.4 of the SmPC to reflect the potential for this risk is recommended.

The MAH should update the Risk Management Plan to included PML as an important potential risk and provide appropriate risk minimisation measures via the next type II variation affecting the RMP or with the next PSUR whichever occurs earlier.

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 ibrutinib the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing ibrutinib is unchanged subject to the proposed changes to the product information

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