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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): dexamethasone (centrally authorised product indicated in uveitis and macular oedema)

Procedure No. EMEA/H/C/PSUSA/00000985/201701

Period covered by the PSUR: 28 January 2016 – 27 January 2017

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for dexamethasone (centrally authorised product indicated in uveitis and macular oedema), the scientific conclusions of CHMP are as follows:

Following the completion of non-interventional (observational) post-authorisation safety study 206207-025 to evaluate the long-term safety of Ozurdex in real-world clinical practice, it has been concluded that patients receiving more than 2 injections experience more adverse reactions. Although the reported adverse events are consistent with the known safety profile and do not raise any new safety concerns, the MAH proposes to update the SmPC sections 4.2 and 4.8 to reflect these changes. With further amendments, the PRAC agrees with the Product Information updates.

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 dexamethasone (centrally authorised product indicated in uveitis and macular oedema) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing dexamethasone (centrally authorised product indicated in uveitis and macular oedema) 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.