20 September 2018
EMA/832773/2018
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/00000985/201801

Period covered by the PSUR: January 2017 to 27 January 2018

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact

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 a review of 336 cases of Complication of device insertion, a small number of cases reported Ozurdex implant-related retina injury, which in some cases caused a permanent vision impact such as central scotoma.

Therefore, it was recommended to update the ADR of “Complication of device insertion” to

“Complication of device insertion resulting in ocular tissue injury” in the next revision of the CCDS to further clarify this event.

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.