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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 symptomatic multiple myeloma)

Procedure No. EMEA/H/C/PSUSA/00010480/201909

Period covered by the PSUR: 15 September 2018 – 15 September 2019

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**Scientific conclusions**

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

Following a Members State's request for PRAC advice for another systemic dexamethasone product, the PRAC advised that a warning regarding the risk of pheochromocytoma crisis should be included in section 4.4 of the SmPC and in the corresponding section of the PL, given that several other nationally authorised corticosteroids, including dexamethasone products, already contain warnings on pheochromocytoma crisis.

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 symptomatic multiple myeloma) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing dexamethasone (centrally authorised product indicated in symptomatic multiple myeloma) 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.