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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): epoetin theta

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Scientific conclusions

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

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Five cases of pure red cell aplasia were reported including three with positive neutralising antibodies tests (all by subcutaneous route). One case of pure red cell aplasia is particularly relevant because the patient had only received epoetin theta by subcutaneous route during one year but has no previous treatment with another erythropoietin stimulating agents. The role of epoetin theta cannot be excluded given the treatment duration (>1 year), the route of administration (subcutaneous) and the fact that no switch for another type of erythropoietin stimulating agents has been performed.

Based on the above findings, the PRAC consider that the sections 4.4 and of 4.8 of the summary of product characteristics of epoetin theta should be updated to reflect that neutralising anti erythropoietin antibody-mediated pure red cell aplasia (PRCA) associated with epoetin theta therapy has been now reported in post marketing setting. The package leaflet should be updated accordingly.

Therefore, in view of the data presented in the reviewed PSUR(s), the PRAC considered that changes to the product information of medicinal products containing epoetin theta were warranted.

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 epoetin theta the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing epoetin theta 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.