22 June 2017
EMA/715525/2017
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): hydrochlorothiazide / irbesartan

Procedure No. EMEA/H/C/PSUSA/00001653/201609

Period covered by the PSUR: 30 September 2013 to 29 September 2016

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for hydrochlorothiazide / irbesartan, the scientific conclusions of CHMP are as follows:

In the approved EU SmPC for irbesartan + hydrochlorothiazide products the risk of thrombocytopenia is included as an adverse drug reaction (ADR) reported with the use of hydrochlorothiazide alone; however, in the PRAC Recommendation issued at the conclusion of the latest irbesartan PSUSA procedure (EMEA/H/C/PSUSA/001782/201508) the ADR of thrombocytopenia was identified and included in the EU SmPC for irbesartan single ingredient. To be consistent with this PRAC recommendation the MAH should include thrombocytopenia also in the table of adverse reactions reported with the use of irbesartan alone in the product information of irbesartan + hydrochlorothiazide combination products.

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 hydrochlorothiazide / irbesartan the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing hydrochlorothiazide / irbesartan 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.