28 March 2019
EMA/241761/2019
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): glimepiride / pioglitazone hydrochloride, metformin / pioglitazone, pioglitazone

Procedure No.: EMEA/H/C/PSUSA/00002417/201807

Period covered by the PSUR: 01 August 2016 to 31 July 2018

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for glimepiride / pioglitazone hydrochloride, metformin / pioglitazone, pioglitazone, the scientific conclusions of CHMP are as follows:

The MAH provided updates on new information related to the important identified and important potential risks as listed in the summary of safety concerns. The data presented during the current reporting period did not provide new information that would allow for further reduction, mitigation, or characterisation of these risks. Based on the data presented, the risk minimisation measures in the approved product information are considered adequate for the listed safety concerns.

Given the accumulation of data since the implementation of the additional risk minimization measures, the PRAC agreed with the MAH's proposal to remove the additional risk minimisation measures. As a consequence, the conditions or restrictions with regards to the safe and effective use of the medicinal product should be updated to remove the additional risk minimisation measures. The RMP has been updated in accordance.

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 glimepiride / pioglitazone hydrochloride, metformin / pioglitazone, pioglitazone the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing glimepiride / pioglitazone hydrochloride, metformin / pioglitazone, pioglitazone 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.