EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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 substances: ombitasvir / paritaprevir / ritonavir

Procedure no.: EMEA/H/C/PSUSA/00010367/201507

Period covered by the PSUR: 19 December 2014 to 15 July 2015

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for ombitasvir / paritaprevir / ritonavir, the scientific conclusions of CHMP are as follows:

Based on one plausible, unconfounded, spontaneous report of angioedema, one possible case from clinical trials using a regimen of three direct-acting antiviral agent (3-DAA), in which the patient complained about left mouth and lip swelling, three additional reports retrieved from Eudravigilance (using angioedema as Standard MedDRA Queries) where one of the cases presented a temporal plausible association and a positive dechallenge and given the potential severity of angioedema, the PRAC considered that there is sufficient evidence to include angioedema in section 4.8 of the summary of product characteristics, with a frequency rare. The Package Leaflet should be updated accordingly.

Therefore, in view of the data presented in the reviewed PSUR, the PRAC considered that changes to the product information of medicinal products containing ombitasvir / paritaprevir / ritonavir were warranted.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the marketing authorisation

On the basis of the scientific conclusions for ombitasvir / paritaprevir / ritonavir the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing ombitasvir / paritaprevir / ritonavir is unchanged subject to the proposed changes to the product information

The CHMP recommends that the terms of the marketing authorisation should be varied.