27 June 2013
EMA/CHMP/547111/2013
Committee for Medicinal Products for Human Use (CHMP)

# Victrelis

# Boceprevir

# Procedure No. EMEA/H/C/002332/PSUV/020

**Scientific conclusions and grounds recommending the variation to the terms of the Marketing Authorisation**



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**Scientific conclusions**

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

One convincing case of a drug-drug interaction with amlodipine has been reported during the review period of the PSUR. Amlodipine, but also other calcium-channel antagonists, are CYP3A4 substrates and thus their combination with boceprevir, a potent inhibitor of this enzyme, is expected to increase their plasma exposure potentially leading to adverse events such as hypotension. During the PSUR procedure the MAH queried its safety database and identified four cases (including the original case) where a potential drug-drug interaction with calcium channel blockers was suspected, including three cases with a positive dechallenge. Even though the PRAC acknowledges that the number of reported cases remains low at this stage, the PRAC considers it useful to alert physicians to this possible drug interaction involving drugs commonly used in clinical practice. The PRAC therefore recommends to amend the Victrelis SmPC (section 4.5) and Package Leaflet as outlined in Annex I of the PRAC PSUR assessment report.

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

**Grounds recommending the variation to the terms of the Marketing Authorisation**

On the basis of the scientific conclusions for Victrelis the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance boceprevir is favourable subject to the proposed changes to the product information.

The CHMP recommends that the terms of the Marketing Authorisation should be varied.