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Co-ordination group for Human Use
EMEA/H/N/PSR/0001

Position of the Co-ordination Group for Mutual Recognition and Decentralised Procedures for human use on non-interventional imposed Post-Authorisation Safety Study (PASS) final report for

Medicinal product(s)

Invented name(s): See PRAC assessment report appendix

Active substance(s): trimetazidine

Basis for recommendation

Pursuant to Article 107p of Directive 2001/83/EC, the Marketing Authorisation Holder(s) to the European Medicines Agency the final report for non-interventional imposed post-authorisation safety study (PASS) for the nationally authorised medicinal product(s) mentioned above containing active substance (for details see PRAC assessment report appendix).

The evaluation procedure started on 15 October 2015.

The steps taken for the assessment of the non-interventional imposed PASS final report are detailed in the appended Pharmacovigilance Risk Assessment Committee (PRAC) assessment report.

The recommendation was adopted by the PRAC on 11 February 2016.

Position

1. The CMDh, having considered in accordance with Article 107q(2) of Directive 2001/83/EC the results of the study on the basis of the PRAC recommendation and the PRAC assessment report as appended, reaches its position by consensus on the variation to the terms of the Marketing Authorisation(s) for the medicinal products mentioned above concerning the following change(s):

   The marketing authorisation holder (s) shall remove the below condition:

PhV 1 The MAH should perform a drug utilization study to verify the compliance of prescribers regarding the restricted indication after marketing authorisation changes. The final study protocol will be submitted within 60 days from Commission decision to MSs/RMS to be finally agreed prior to starting the study. The final study report will be submitted to NCAs/RMS by:	30 September 2014

The Icelandic and the Norwegian CMDh member(s) agree(s) with the above-mentioned position of the CMDh.

2. The scientific conclusions are set out in Annex I.

3. The changes to the conditions to the marketing authorisation(s) of the medicinal products mentioned above are set out in Annex II.

4. The timetable for the implementation of this CMDh position is set out in Annex III.

This position is forwarded to Member States, to Iceland and Norway, to the MAH together with its annexes and appendix(ces).