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Co-ordination group for Human Use
EMEA/H/N/PSR/J/0015

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 for non-interventional imposed PASS final report appendix

Active substance(s): domperidone

Basis for Position

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

The evaluation procedure started on 8 January 2018.

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 17 January 2019.

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 authorization holder(s) shall remove the below condition:

   The Marketing Authorisation Holders shall perform a drug utilisation study to assess the effectiveness of the risk minimisation measures and to monitor off-label use. The study shall be conducted in more than one Member State and the protocol shall be submitted to the PRAC within 3 months of the commission decision for this procedure.

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 MAHs together with its annexes and appendix(ces).