Annex I

Scientific conclusions and grounds for the variation to the terms of the Marketing Authorisation(s)

Scientific conclusions

Taking into account the PRAC Assessment Report for the non-interventional imposed PASS final report for the medicinal product(s) containing the active substance domperidone and concerned by the PASS final report, the scientific conclusions are as follows:

The joint database drug utilisation final study report submitted by the MAHs, together with the joint PASS (physician survey) final study report submitted by the MAHs as a separate procedure (EMEA/H/N/PSR/J/0010), comply with their obligation to conduct a drug utilisation study to assess the effectiveness of the risk minimisation measures and to monitor the off-label use of the drug as imposed during the referral under Article 31 of Directive 2001/83/EC for domperidone containing products.

Therefore, in view of available data regarding the joint database drug utilisation final study report, together with the joint PASS (physician survey) final study report submitted as a separate procedure (EMEA/H/N/PSR/J/0010), the PRAC considered that changes to the conditions of the marketing authorisation were warranted.

The CMDh 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 the results of the study for the medicinal product(s) containing the active substance domperidone and concerned by the PASS final report, the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) mentioned above is unchanged subject to the proposed changes to the product information.

The CMDh reaches the position that the marketing authorisation(s) of the products concerned by this PASS final report should be varied.

Annex II

Conditions to the Marketing Authorisation(s)

Changes to be made to the conditions of the marketing authorisation(s) of medicinal product(s) containing the active substance domperidone concerned by the non-interventional imposed PASS final report

The marketing authorisation holder(s) shall remove the following condition(s) (new text **underlined and in bold,** deleted text ~~strike through~~)

~~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.~~

Annex III

Timetable for the implementation of this position

Timetable for the implementation of the position

Adoption of CMDh position:	January 2019 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	16 March 2019
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	15 May 2019