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 on the PSUR(s) for domperidone, the scientific conclusions are as follows:

In view of available data on acute hypertension episodes in patients with phaeochromocytoma from the literature and spontaneous reports, including in some cases a close temporal relationship, a positive de-challenge and/or re-challenge; and in view of a plausible mechanism of action, the PRAC considers a causal relationship between domperidone and acute hypertension episodes in patients with phaeochromocytoma is at least a reasonable possibility. The PRAC concluded that the product information of products containing domperidone should be amended accordingly.

Having reviewed the PRAC recommendation, the CMDh agrees with the PRAC overall conclusions and grounds for recommendation.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for domperidone the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing domperidone is unchanged subject to the proposed changes to the product information

The CMDh recommends that the terms of the marketing authorisation(s) should be varied.

Taking into account the PRAC recommendation, the CMDh is of the opinion

that the risk-benefit balance of medicinal products containing domperidone remains unchanged but recommends by consensus that the terms of the marketing authorisation(s) should be varied as follows:

Update of section 4.3 of the SmPC to add a contraindication regarding confirmed or suspected pheochromocytoma. The Package leaflet is updated accordingly.

Annex II

Amendments to the product information of the nationally authorised medicinal product(s)

Amendments to be included in the relevant sections of the Product Information (new text **underlined and in bold**, deleted text ~~strike through~~)

Summary of Product Characteristics

- Section 4.3

The contraindication should be added as follows:

Confirmed or suspected pheochromocytoma due to the risk of severe hypertension episodes.

Package Leaflet

- Section 2. What you need to know before you take <X>

Do not take <X>:

if you have or may have a rare tumour of the adrenal gland (pheochromocytoma) because it could elevate your blood pressure.

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	July 2025 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	08 September 2025
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	06 November 2025