

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 apomorphine, the scientific conclusions are as follows:

In view of available data on **increased risk of hypotension and loss of consciousness with concomitant use of ondansetron** from clinical trial(s), the literature, and in view of a plausible mechanism of action, the PRAC considers a causal relationship between apomorphine and increased risk of hypotension and loss of consciousness with concomitant use of ondansetron is at least a reasonable possibility.

The PRAC concluded that the product information of products containing apomorphine should be amended accordingly as detailed below.

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 apomorphine the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing apomorphine is unchanged subject to the proposed changes to the product information.

The CMDh reaches the position that the marketing authorisation(s) of products in the scope of this single PSUR assessment should be varied. To the extent that additional medicinal products containing apomorphine are currently authorised in the EU or are subject to future authorisation procedures in the EU, the CMDh recommends that the concerned Member States and applicant/marketing authorisation holders take due consideration of this CMDh position.

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 or amended as follows:

Concomitant use with ondansetron (see section 4.5)

- Section 4.5

An interaction should be added or amended as follows:

Concomitant use of apomorphine with ondansetron may lead to severe hypotension and loss of consciousness and is therefore contraindicated (see section 4.3). Such effects might also occur with other 5-HT₃ antagonists.

Package Leaflet

2.What you need to know before you use [product name]

Do not use [Product name]

If you are taking ondansetron (medicine to treat nausea and vomiting)

Other medicines and [Product name]

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Check with your doctor or pharmacist before taking your medicine:

If you are taking ondansetron (medicine to treat nausea and vomiting), as this may result in severe drop in blood pressure and loss of consciousness.

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	July 2023 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	3 September 2023
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	2 November 2023