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 mizolastine, the scientific conclusions are as follows:

Vomiting has been noted in association with mizolastine use in post marketing experience. Cumulatively there have been 32 cases reported (7 serious and 25 non-serious), while during the interval there were 10 cases (1 serious and 9 non-serious). Cumulatively 8 cases with positive de-challenge and 2 cases with both positive de-challenge and re-challenge have been reported.

Based on the review of the post-marketing cases, taking into consideration the number of cases, temporal association and presence of both positive de-challenge and re-challenge the PRAC concluded that a possible causal relationship may exist and therefore recommends adding “vomiting” with frequency “not known” in section 4.8 of the summary of product characteristics (SmPC).

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 mizolastine the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing mizolastine 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 mizolastine 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 4.8

The following adverse reaction(s) should be added under the SOC Gastrointestinal disorders with frequency "Not known":

Gastrointestinal disorders

Not known: **vomiting**

Package Leaflet

Section 4: Possible side effects

Not known: **Vomiting**

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	July 2018 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	08 September 2018
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	07 November 2018