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 ebastine, the scientific conclusions are as follows:

Based on the positive causality rates of the cases reported in the signal "weight increased/appetite increased" in association with ebastine, together with theoretical and literature evidence supporting the influence of antihistamines targeting the H1 receptor in weight gain and appetite stimulation, the PRAC considers that the adverse reaction 'Increased appetite' and 'Weight increased' should be included in section 4.8 of the summary of product characteristic with a frequency not known. The package leaflet is updated accordingly.

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 ebastine the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing ebastine 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 ebastine 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 should be added under the SOC Metabolism and nutrition disorders with a frequency "not known":

Increased appetite

The following adverse reaction should be added under the SOC Investigations with a frequency "not known":

Weight increased

Package Leaflet

Section 4: Possible side effects

Frequency not known: cannot be estimated from the available data

• […]

● weight increased

● increased appetite

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this 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