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 bilastine, the scientific conclusions are as follows:

During the reporting interval a cumulative review of hypersensitivity reactions including the terms rash, pruritus, localised oedema/local swelling, erythema, urticaria, dyspnoea, angioedema, anaphylactic reaction and anaphylactic shock was performed. The causality was assessed as possible in most of the cases, and as probable in a few cases; furthermore most of the cases reported were medically confirmed, and time of onset considered plausible in relation to bilastine administration; a positive dechallenge was present in most cases. On the basis of evaluation, the PRAC concluded that hypersensitivity reactions should be included in the product information for bilastine.

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 bilastine the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing bilastine 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 bilastine 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 Undesirable effects:

Frequency not known (cannot be estimated from the available data): Palpitations**,** ~~and~~ tachycardia **and hypersensitivity reactions (such as anaphylaxis, angioedema, dyspnoea, rash, localised oedema/local swelling, and erythema)** have been observed during the post-marketing period.

Package Leaflet

Section 4: Possible side effects

Frequency not known: cannot be estimated from the available data

- palpitations (feeling your heart beat)
- tachycardia (fast heart beat)
- **Allergic reactions the signs of which may include difficulty in breathing, dizziness, collapsing or losing consciousness, swelling of your face, lips, tongue or throat, and/or swelling and redness of the skin. If you notice any of these serious side effects, stop taking the medicine and seek urgent medical advice straight away.**

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	October CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	25 November 2017
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	24 January 2018