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:

The results of a non-clinical study of the excretion of ^{14}C-bilastine in the milk of lactating rats following a single oral administration at 20 mg/kg (PBC040-105) became available during this PSUR. In this study the radiolabelled bilastine was rapidly absorbed and radioactivity was transferred to milk. The radioactivity in milk decreased in parallel with plasma. The C_{max} and AUC_{0-t} values in milk were 0.407 and 0.536-fold lower than those in plasma, respectively. In line with the “guideline on risk assessment of medicinal products on human reproduction and lactation: from data to labelling” (EMEA/CHMP/203927/2005), as no data are available in humans, the PRAC considered that the product information (PI) should be updated to reflect the results of this study.

Therefore, in view of the data presented in the reviewed PSUR(s), the PRAC considered that changes to the product information of medicinal products containing bilastine, were warranted.

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 such marketing authorisations are varied 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 4.6

[The existing information on lactation should be revised as follows]

[..]

Breast-feeding

~~It is unknown whether bilastine is excreted in human milk.~~ The excretion of bilastine in milk has not been studied in **humans**~~animals~~. **Available pharmacokinetic data in animals have shown excretion of bilastine in milk (see section 5.3).** A decision on whether to discontinue/abstain from <Invented name> therapy must be made taking into account the benefit of breast- feeding for the child and the benefit of bilastine therapy for the mother.

[…]

- Section 5.3

[The following paragraph should be added after information on reproduction]

[…]

In a lactation study, bilastine was identified in the milk of nursing rats administered a single oral dose (20 mg/kg). Concentrations of bilastine in milk were about half of those in maternal plasma. The relevance of those results for humans is unknown.

[…]

Package Leaflet

No amendments to the package leaflet are considered needed.

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	October 2016 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	25 November 2016
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	24 January 2017