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:

In view of available data on risks of QT prolongation/Torsades de pointes from clinical trials and from spontaneous cases, the PRAC considers that electrocardiogram QT prolongation is not sufficiently recognised as being a risk associated with oral bilastine use and that bilastine treatment might not be properly managed in certain patient categories that are at risk. The PRAC therefore concluded that a warning on QT prolongation/Torsade de pointes and the associated risk factors should be added for bilastine oral formulations. In addition, the PRAC recommended to reflect that cases of electrocardiogram QT prolonged have also been reported post-marketing.

The PRAC concluded that the product information of products containing bilastine for oral use should be amended accordingly.

Having reviewed the PRAC recommendation, the CMDh agrees with the PRAC overall conclusions and grounds for recommendation.

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 recommends that the terms of the marketing authorisation(s) should be varied.

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 4.4

A warning should be added as follows:

Cases of Electrocardiogram QT prolonged have been reported in patients using bilastine (see sections 4.8, 4.9 and 5.1). Medicinal products that cause QT/QTc prolongation are suspected to increase the risk of Torsade de pointes.

Therefore, caution should be exercised when administering bilastine to patients who are at increased risk of experiencing QT/QTc-prolongation. This includes patients with a history of cardiac arrhythmias; patients with hypokalemia, hypomagnesaemia, hypocalcemia; patients with known prolongation of the QT interval or significant bradycardia; patients with concomitant use of other medicinal products associated with QT/QTc-prolongation.

- Section 4.8

A footnote (*) is added for electrocardiogram QT prolonged under the table of ADRs from clinical development to reflect that cases have also been reported post-marketing, as follows:

***Electrocardiogram QT prolonged have also been reported post-marketing.**

Package Leaflet

Section 2. What you need to know before you take bilastine

Warnings and precautions

Talk to your doctor or pharmacist before using bilastine if you have moderate or severe renal impairment, **low blood levels of potassium, magnesium, calcium, if you have or had heart rhythm problems or if your heart rate is very low, if you are taking medicines that may affect the heart rhythm, if you have or had a certain abnormal pattern to your heart beat (known as prolongation of the QTc interval on the Electrocardiogram) which can occur in some forms of heart disease** and in addition you are taking other medicines (see ”Other medicines and bilastine”).

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	November 2024 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	30 December 2024
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	27 February 2025