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 famotidine, the scientific conclusions are as follows:

In view of available data on interaction between famotidine and posaconazole oral solution from literature, on the information already in place for other EU authorised medicines (posaconazole oral solution, famotidine FDC) and in view of a plausible mechanism of action, the Lead Member State considers that the product information of products containing famotidine should be amended accordingly.

Moreover, in view of available data on interaction with tyrosine kinase inhibitors (TKIs) such as dasatinib, erlotinib, gefitinib, pazopanib with famotidine from the literature, from the PI of dasatinib, erlotinib, gefitinib, pazopanib and in view of a plausible mechanism of action, the Lead Member State considers that the product information of products containing famotidine should be amended 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 famotidine the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing famotidine 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 famotidine 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)

The following changes to the product information of medicinal products containing the active substance famotidine are recommended (new text **underlined and in bold**):

Summary of Product Characteristics

Section 4.5

Interactions should be added as follows:

Co-administration of posaconazole oral-suspension with famotidine should be avoided if possible, since famotidine may reduce the absorption of posaconazole oral-suspension during concomitant use.

Co–administration of famotidine with the tyrosine kinase inhibitors (TKIs) dasatinib, erlotinib, gefitinib, pazopanib may decrease plasma concentrations of TKIs resulting in lower efficacy, therefore co-administration of famotidine with these TKIs is not recommended. For further specific recommendations please refer to the product information of individual TKI medicinal products.

Package Leaflet

Section 2. What you need to know before you take <>

Other medicines and <>

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

- **<Product> may decrease the effect of posaconazole oral suspension (a drinkable medicine used to prevent and treat some fungal infections).**
- **<Product> may decrease the effect of dasatinib, erlotinib, gefitinib, pazopanib (medicines used to treat cancer).**

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	May 2023 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	10 July 2023
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	07 September 2023