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:

Based on the review of two publications that found loss of efficacy of calcium carbonate when co-administered as phosphate binder with famotidine in haemodialysis patients, PRAC recommended amending section 4.5 of the SmPC to add information on concomitant use in haemodialysis patients.

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) >

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 4.5

Risk of loss of efficacy of calcium carbonate when co-administered as phosphate binder with famotidine in haemodialysis patients

<Package Leaflet>

Other medicines and <Product>

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

- calcium carbonate, when used as a medicine for high blood phosphate levels (hyperphosphataemia) in patients on dialysis

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	May 2018 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	14 July 2018
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	12 September 2018