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 furosemide/spironolactone, the scientific conclusions are as follows:

In view of available data on reduced plasma concentration of furosemide with concomitant aliskiren exposure from the literature and in view of a plausible mechanism of action, the PRAC considers a causal relationship between aliskiren and reduced plasma concentration of furosemide is at least a reasonable possibility. The PRAC concluded that the product information of products containing furosemide 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 furosemide/spironolactone the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing furosemide/spironolactone 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 4.5

An interaction should be added as follows:

Aliskiren reduces the plasma concentration of furosemide given orally. Reduced effect of furosemide might be observed in patients treated with both aliskiren and oral furosemide, and it is recommended to monitor for reduced diuretic effect and adjust the dose accordingly.

Package Leaflet

- Section 2

Other medicines and <product name>

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

Your doctor may need to change your dose and/or to take other precautions if you are taking one of the following medicines:

- **Aliskiren – used to treat high blood pressure**

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	November CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	2 January 2024
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	22 February 2024

APPENDIX I

PRAC PSUR Assessment Report