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 cefadroxil, the scientific conclusions are as follows:

Based on the reviewed literature on the concomitant use of cefadroxil with probenecid which indicated that probenecid interacts with multiple types of cephalosporins and competitively inhibits renal tubular secretions of cefadroxil thus increasing its plasma concentration, and also taking into account that the interaction with probenecid is already included in the product information of other cefadroxil containing products, the PRAC considered that the interaction with probendecid should be added to section 4.5 of the summary of product characteristics of all cefadroxil containing products. The package leaflet is updated 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 cefadroxil the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing cefadroxil 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 cefadroxil are currently authorised in the EU or are subject to future authorisation procedures in the EU, the CMDh recommends that 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

[The following text should be added as follows]

The concomitant administration of probenecid reduces the renal elimination of cefadroxil; therefore, plasma concentrations of cefadroxil may be increased when given in combination with probenecid.

Package Leaflet

- Section 2

[The following text should be added as follows]

Taking other medicines

[…]

Probenecid (for gout)

Annex III

Timetable for the implementation of this position>

Timetable for the implementation of this position

Adoption of CMDh position:	March 2018 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	5 May 2018
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	4 July 2018