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 cefuroxime sodium (except for intracameral use), the scientific conclusions are as follows:

Serious cases of eye disorders (including macular oedema, retinal oedema, retinal detachment, retinal toxicity, visual impairment, visual acuity reduced, vision blurred, corneal opacity and corneal oedema) have been reported during the interval in relation to off-label intracameral administration of cefuroxime sodium-containing products subject to this procedure. Considering the serious risks linked to the continued off-label use abovementioned, despite the availability of intracameral formulation, the PRAC concluded that the summary of product characteristics should be amended to include a warning in this regard. No corresponding changes to the Package leaflet are considered warranted as these medicinal products have only been reported to be used intracamerally by ophthalmologists for in-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 cefuroxime sodium (except for intracameral use) the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing cefuroxime sodium (except for intracameral use) 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 cefuroxime sodium (except for intracameral use) are currently authorised in the EU or are subject to future authorisation procedures in the EU, the CMDh recommends that such marketing authorisations are varied accordingly.

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]

Intracameral use and eye disorders

<Invented name> is not formulated for intracameral use. Individual cases and clusters of serious ocular adverse reactions have been reported following unapproved intracameral use of cefuroxime sodium compounded from vials approved for intravenous/intramuscular administration. These reactions included macular oedema, retinal oedema, retinal detachment, retinal toxicity, visual impairment, visual acuity reduced, vision blurred, corneal opacity and corneal oedema.

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	December CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	27 January 2018
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	28 March 2018