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

Based on the review of literature and data from safety databases, the PRAC considered that a causal relationship between cefuroxime sodium (for intracameral use) and *macular oedema* cannot be excluded and therefore recommends updating the Product Information by listing this adverse reaction with a frequency “unknown”.

In addition, based on case reports of medication error with a wrong solution being used in drug reconstitution, the PRAC considered that an update of the section 4.2 of the SmPC to add an additional reminder is required and that the type of the solvent used for reconstitution should be on the outer package.

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 (for intracameral use) the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing cefuroxime sodium (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 (for intracameral use) 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 4.2

Method of administration

X must be administered after reconstitution by intraocular injection in the anterior chamber of the eye (intracameral use), by an ophthalmic surgeon, in the recommended aseptic conditions of cataract surgery. Only sodium chloride 9 mg/ml (0.9 %) solution for injection must be used when reconstituting X (see section 6.6).

Section 4.8

Macular oedema (frequency unknown)

Package Leaflet

Section 4

Macular oedema (blurry or wavy vision near or in the centre of your field of vision) (frequency unknown)

Labelling

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

{CARTON}

After reconstitution with 5 ml of solvent (sodium chloride 9mg/ml (0.9%) solution), 0.1 ml solution contains 1 mg of cefuroxime.

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	30 January 2019 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	17 March 2019
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	15 May 2019