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 cefoperazone, the scientific conclusions are as follows:

In view of available data on Coagulopathy and Haemorrhage from clinical trial(s), the literature, spontaneous reports and in view of a plausible mechanism of action, the PRAC Lead Member State considers a causal relationship between cefoperazone and Haematuria is at least a reasonable possibility. The PRAC Lead Member State concluded that the product information of products containing cefoperazone should be amended 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 cefoperazone the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing cefoperazone 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 cefoperazone 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 4.8

The following adverse reaction(s) should be added under the SOC Renal and urinary disorders with a frequency unknown:

Haematuria

Package Leaflet

- Section 4.

Blood in urine (haematuria)

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	September/2021 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	31 October 2021
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	30 December 2021