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 ofloxacin (systemic use) the scientific conclusions are as follows:

Delirium

In view of available data on delirium from number of cases detected, literature and high-quality data, a positive de-challenge and in view of a plausible mechanism of action, the Lead Member State considers a causal relationship between ofloxacin (systemic use) and delirium is established. The Lead Member State concluded that the product information of products containing Ofloxacin (systemic use) 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 ofloxacin (systemic use) the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing ofloxacin (systemic 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 ofloxacin (systemic 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 4.8. Undesirable effects

Table of ADRs, under SOC Psychiatric disorders

Frequency rare: Delirium

Package Leaflet

Section 4: Possible side effects:

Side effects of rare frequency may include:

Delirium (acute confusional state)

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	December 2021 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	31 January 2022
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	31 March 2022