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 magnesium sulfate / sodium sulfate / potassium sulfate, the scientific conclusions are as follows:

In view of available data on risk of arrhythmia from spontaneous reports including in some cases a close temporal relationship time to onset (TTO) 1 day, and in view of a plausible mechanism of action, the PRAC considers a causal relationship between magnesium sulfate / sodium sulfate / potassium sulfate and arrhythmia is at least a reasonable possibility. The PRAC concluded that the product information of products containing magnesium sulfate / sodium sulfate / potassium sulfate should be amended accordingly.

Having reviewed the PRAC recommendation, the CMDh agrees with the PRAC overall conclusions and grounds for recommendation.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for magnesium sulfate / sodium sulfate / potassium sulfate the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing magnesium sulfate / sodium sulfate / potassium sulfate is unchanged subject to the proposed changes to the product information.

The CMDh recommends that the terms of the marketing authorisation(s) should be varied.

Taking into account the PRAC recommendation, the CMDh is of the opinion that the risk-benefit balance of medicinal products containing magnesium sulfate / sodium sulfate / potassium sulfate remains unchanged but recommends by consensus that the terms of the marketing authorisation(s) should be varied as follows:

Update of section 4.8 of the SmPC to add the adverse reaction "Cardiac arrhythmia*" with a frequency "not known". The Package leaflet is updated 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 4.8

The following adverse reaction "Cardiac arrhythmia*" should be added under the SOC Cardiac disorders with a frequency "not known":

SOC Cardiac disorders
Cardiac arrhythmia*
Palpitations*
*Clinical consequences of dehydration and/or electrolyte imbalance

Package Leaflet

- Section 4 Possible side effects

Not known (cannot be estimated from the available data)

Abnormal or irregular heartbeat (arrhythmia)

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	March 2025 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	12 May 2025
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	10 July 2025