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 phosphocreatine, the scientific conclusions are as follows:
In view of available data on urticaria from spontaneous reports, including in two cases a close temporal relationship, a positive de-challenge and/or re-challenge, the PRAC considers a causal relationship between phosphocreatine and urticaria is at least a reasonable possibility. The PRAC concluded that the product information of products containing phosphocreatine 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 phosphocreatine the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing phosphocreatine 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.

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 should be added under the SOC Skin and subcutaneous tissue disorders with a frequency unknown:

Urticaria

Package Leaflet

4. Possible side effects

Not known (frequency cannot be estimated from the available data):

Itchy rash (urticaria)

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	July 2025 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	7 September 2025
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	6 November 2025