# 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 disodium hydrogen phosphate / sodium dihydrogen phosphate, phosphate sodium, the scientific conclusions are as follows:

In view of available data from literature and spontaneous reports, the PRAC considers a causal relationship between disodium hydrogen phosphate / sodium dihydrogen phosphate, phosphate sodium and electrolyte imbalances (hyperphosphatemia, hypokalemia, hypernatremia, hypocalcemia). The PRAC concluded that the product information of Enemac 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 disodium hydrogen phosphate / sodium dihydrogen phosphate, phosphate sodium the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing disodium hydrogen phosphate / sodium dihydrogen phosphate, phosphate sodium 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 4.4**

A warning should be added as follows:

**Since [product name] contains sodium phosphate, its use involves a risk of elevated levels of sodium and phosphate in blood and diminished levels of calcium and potassium, which can lead to hypernatremia, hyperphosphatemia, hypocalcemia and hypokalemia, which can appear with clinical symptoms like tetany and kidney failure.**

- **Section 4.8**

The following adverse reaction(s) should be added under the SOC Metabolic and nutrition disorders with a frequency rare:

***Metabolic and nutrition disorders***

**Hyperphosphatemia, hypokalemia, hypernatremia, hypocalcemia and calcification of tissues can occur rarely**

**Package Leaflet**

- **Section 4**

**high blood phosphate levels, low blood potassium levels, high blood sodium levels, low blood calcium levels**

## Annex III

## Timetable for the implementation of this position

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|---|---|
| Adoption of CMDh position: | September 2025 CMDh meeting |
| Transmission to National Competent Authorities of the translations of the annexes to the position: | 2 November 2025 |
| Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder): | 1 January 2026 |