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 lanthanum, the scientific conclusions are as follows:

In view of available data on risk of bowel obstruction, ileus and faecal impaction from the literature and also spontaneous reports, and in view of a plausible mechanism of action, the PRAC considers that lanthanum treatment of subjects with bowel obstruction should be contraindicated. The PRAC concluded that the product information of products containing lanthanum carbonate 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 lanthanum the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing lanthanum 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 4.3

The contraindication should be added as follows:

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1

Hypophosphataemia

Bowel obstruction

- Section 4.4

Lanthanum treatment in patients predisposed to gastrointestinal obstruction, ileus, subileus and perforation; for example, those with altered gastrointestinal anatomy (e.g., diverticular disease, peritonitis, history of gastrointestinal surgery, gastrointestinal cancer and gastrointestinal ulceration), hypomotility disorders (e.g., constipation, diabetic gastroparesis) and in subjects with medications known to potentiate these effects, should only be used after careful consideration. **In subjects with ongoing bowel obstruction, lanthanum treatment is contraindicated (see section 4.3)**

Package Leaflet

2. What you need to know before you take [Product name]

Do not take [Product name]

- if you are allergic to lanthanum carbonate hydrate or any of the other ingredients of this medicine (listed in section 6)

- if you have too little phosphate in your blood (hypophosphataemia)

- if you have blockage of the bowel (bowel obstruction)

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	November 2024 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	06 January 2025
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	27 February 2025