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 lactulose, the scientific conclusions are as follows:

In view of available data on hypersensitivity reactions from spontaneous reports, including in some cases a close temporal relationship, a positive de-challenge and/or re-challenge, the PRAC considers a causal relationship between lactulose and hypersensitivity reactions, rash, pruritus and urticaria is at least a reasonable possibility.

The PRAC concluded that the product information of products containing lactulose 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 lactulose the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing lactulose 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 lactulose 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

The following adverse reactions should be added under the SOC Immune system disorders with a frequency Not Known:

hypersensitivity reactions

The following adverse reaction(s) should be added under the SOC Skin and subcutaneous tissue disorders with a frequency Not Known:

Rash, pruritus, urticaria

Package Leaflet

- Section 4 Possible side effects

The following adverse reaction(s) should be added under frequency not known: frequency cannot be estimated from the available data

Allergic reactions, rash, itching, hives.

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	January 2022 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	13 March 2022
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	12 May 2022