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 soybean phospholipids (oral use), the scientific conclusions are as follows:

In view of available data on increased blood pressure, palpitations, dizziness, and nausea and vomiting from the literature, spontaneous reports including cases with a close temporal relationship and positive de-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between soybean phospholipids (oral use) and increased blood pressure, palpitations, dizziness, and nausea and vomiting is at least a reasonable possibility. The PRAC concluded that the product information of products containing soybean phospholipids (oral use) 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 soybean phospholipids (oral use) the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing soybean phospholipids (oral use) 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 soybean phospholipids (oral use) 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 reaction should be added under the SOC Investigations with a frequency "not known":

Increased blood pressure

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

Palpitations

The following adverse reaction should be added under the SOC Nervous system disorders with a frequency "not known":

Dizziness

The following adverse reactions should be added under the SOC Gastrointestinal disorders with a frequency "not known":

~~stomach complaints~~ **Nausea; Vomiting**

Package Leaflet

- Section 4

Not known: frequency cannot be estimated from the available data

- Increased blood pressure

- Palpitations

- Dizziness

- Nausea; Vomiting ~~stomach complaints~~

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	June 2022 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	08 August 2022
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	06 October 2022