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 pravastatin, the scientific conclusions are as follows:

In view of available data on muscle rupture from the literature, spontaneous reports including in 62 cases a close temporal relationship, a positive de-challenge (14 cases) and/or re-challenge (2 cases) and in view of a plausible mechanism of action, the PRAC considers a causal relationship between pravastatin and muscle rupture is at least a reasonable possibility. The PRAC concluded that the product information of products containing pravastatin 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 pravastatin the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing pravastatin 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

Musculoskeletal and connective tissue disorders: […];

Frequency: **not known**

Muscle rupture

Package Leaflet

Section 4

Side effects of unknown frequency (frequency cannot be estimated from the available data)

[…] **Muscle rupture** […]

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	**December 2023 CMDh meeting**
Transmission to National Competent Authorities of the translations of the annexes to the position:	**29 January 2024**
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	**28 March 2024**