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 fluvastatin, the scientific conclusions are as follows:

There were respectively 81 and 553 cases of diarrhoea reported during the reporting period and cumulatively. Because of the seriousness of certain cases of diarrhoea and in view of the data presented in the reviewed PSUR(s) for fluvastatin, the PRAC considered that changes to the product information of medicinal products containing fluvastatin were warranted.

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 fluvastatin the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing fluvastatin 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 fluvastatin 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 **<u>underlined and in bold</u>**, deleted text ~~strike through~~)>

Summary of Product Characteristics

- Section 4.8

The following adverse reaction(s) should be added under the SOC gastrointestinal disorders with a frequency 'not known':

<u>Diarrhoea</u>

Package Leaflet

- Section 4

<u>Diarrhoea</u> frequency **<u>Not known</u>**

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	May 2018CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	14 July 2018
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	12 September 2018