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 naproxen, the scientific conclusions are as follows:

Based on the review of data presented in this PSUSA, covering the period from August 2014 to August 2017, as well as cumulative data since the European birth date, the PRAC considers that the product information of naproxen containing medicinal products for systemic use should be updated as follows: update of section 4.5 of the SmPC to add the interaction with low dose acetylsalicylic acid. The package leaflet is updated 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 naproxen the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing naproxen 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 naproxen are currently authorised in the EU or are subject to future authorisation procedures in the EU, the CMDh recommends that 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 4.5

A statement should be added as follows:

Acetylsalicylic acid

Clinical pharmacodynamic data suggest that concomitant naproxen usage for more than one day consecutively may inhibit the effect of low-dose acetylsalicylic acid on platelet activity and this inhibition may persist for up to several days after stopping naproxen therapy. The clinical relevance of this interaction is not known.

Package Leaflet

- Section 2

Talk to your doctor or pharmacist first, if you are taking any of these other medicines:

[...]

- **Aspirin / acetylsalicylic acid to prevent blood clots.**

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	April 2018 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position :	9 June 2018
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	8 August 2018