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 ibuprofen / pseudoephedrine, the scientific conclusions are as follows:

Based on the review of data on safety and efficacy by the Lead Member State and taking into account any comments provided by the PRAC, the PRAC considers that the risk-benefit balance of medicinal products containing the active substance ibuprofen / pseudoephedrine remains unchanged but recommends that the terms of the marketing authorisation(s) should be varied as follows:

Update of sections 4.4 and 4.8 of the SmPC to add a warning on ischaemic colitis and to add the adverse reaction ischaemic colitis with a frequency unknown. 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 ibuprofen / pseudoephedrine the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing ibuprofen / pseudoephedrine 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 ibuprofen / pseudoephedrine 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 4.4

A warning should be added as follows:

Ischaemic colitis

Some cases of ischaemic colitis have been reported with pseudoephedrine. Pseudoephedrine should be discontinued and medical advice sought if sudden abdominal pain, rectal bleeding or other symptoms of ischaemic colitis develop.

- Section 4.8

The following adverse reaction(s) should be added under the SOC "Gastrointestinal disorders" with a frequency unknown:

- Ischaemic colitis

Package Leaflet

- Section 2

Warnings and precautions

Sudden abdominal pain or rectal bleeding may occur with <invented name>, due to inflammation of the colon (ischemic colitis). If you develop these gastro-intestinal symptoms, stop taking <invented name> and contact your doctor or seek medical attention immediately. See section 4.

- Section 4

Frequency "Not known"

Inflammation of the colon due to insufficient blood supply (ischemic colitis)

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	February 2019 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	6 April 2019
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	5 June 2019

APPENDIX I

PRAC PSUR Assessment Report