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:

Ischaemic optic neuropathy

Based on the review of post-marketing and literature data on ischaemic optic neuropathy and taking into consideration that ischaemia could be explained by the biological vasoconstrictor mechanism of pseudoephedrine and that other ischaemic adverse effects are already listed in pseudoephedrine containing products, the PRAC proposes to add "ischaemic optic neuropathy" in section 4.8 of the SmPC, with frequency "unknown" and a warning in section 4.4, both regarding pseudoephedrine use. The PIL should be 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 optic neuropathy

Cases of ischaemic optic neuropathy have been reported with pseudoephedrine. Pseudoephedrine should be discontinued if sudden loss of vision or decreased visual acuity such as scotoma occurs.

- Section 4.8

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

- Ischaemic optic neuropathy

Package Leaflet

- Section 2

Warnings and precautions

Reduction of blood flow to your optic nerve may occur with <invented name>. If you develop sudden loss of vision, stop taking <invented name> and contact your doctor or seek medical attention immediately. See section 4.

- Section 4

Frequency "Not known"

Reduced blood flow to the optic nerve (Ischaemic optic neuropathy)

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	February / 2020 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	12 April 2020
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	11 June 2020