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 PSURs for ibuprofen / levomenthol, the scientific conclusions are as follows:

In view of available data on photosensitivity reactions from literature, spontaneous reports including at the minimum 2 cases with a close temporal relationship and conclusions from PSUSA-00010649-202002 (regarding ibuprofen, ibuprofen lysin and combination ibuprofen caffeine), the PRAC considers a causal relationship between ibuprofen / levomenthol and photosensitivity reactions is at least a reasonable possibility. Therefore, the PRAC concluded that the product information (PI) of products containing ibuprofen / levomenthol should be amended accordingly.

The PRAC also came to the conclusion that the PI of products containing ibuprofen / levomenthol that have photosensitivity already listed as an ADR (irrespective of approved frequency) should not submit a variation to modify this already existing information. However, if other linked terms to photosensitivity reactions are used in the PI, this should be assessed on an individual basis in accordance with the MedDRA terminology.

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 / levomenthol the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing the active substance(s) ibuprofen / levomenthol is favourable 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 / levomenthol are currently authorised in the EU or are subject to future authorisation procedures in the EU, the CMDh recommends that such marketing authorisations are varied accordingly.

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: Undesirable effects

SOC Skin and subcutaneous tissue disorders

photosensitivity reactions - frequency unknown

Package Leaflet

Section 4. Possible side effects

skin becomes sensitive to light - frequency unknown

Annex III

Timetable for the implementation of this position

Timetable for the implementation of the agreement

Adoption of CMDh agreement:	March 2021 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the agreement:	09 May 2021
Implementation of the agreement by the Member States (submission of the variation by the Marketing Authorisation Holder):	08 July 2021