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 methyl salicylate/levomenthol, the scientific conclusions are as follows:

A review of post-marketing cases of burns at the application site, some of them serious, found that a causal relationship between the combination methyl salicylate/levomenthol and the event could not be excluded. Therefore, the PRAC considers that the product information should be updated to include the adverse reaction “burns at application site” with a frequency “not known” as the frequency cannot be estimated from the available data. 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 methyl salicylate/levomenthol the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing methyl salicylate/levomenthol 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 methyl salicylate/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

The following adverse reaction should be added under the SOC "General disorders and administration site conditions" with a frequency "**Not known**":

Burns at application site

Package Leaflet

- Section 4

The following adverse reaction should be added under Side effects with frequency **not known (frequency cannot be estimated from the available data):**

Burns at application site

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	January 2018 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	10 March 2018
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	09 May 2018