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 ivermectin (topical use), the scientific conclusions are as follows:

Based on a cumulative safety review performed by the marketing authorisation holder, a total of 214 cases of hypersensitivity have been identified associated with the topical use of ivermectin. The reports include one serious case from post-authorisation sources and two from clinical trials. Given the number of cases reported as allergy or with symptoms of allergy, it is considered necessary to update the product information to add the adverse reactions dermatitis contact (allergic or irritant) with a frequency of not known.

Therefore, in view of the data presented in the reviewed PSUR(s), the PRAC considered that changes to the product information of medicinal products containing ivermectin (topical use), were warranted.

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 ivermectin (topical use) the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing ivermectin (topical use) 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 ivermectin (topical use) 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(s) should be added under the SOC Skin and subcutaneous tissue disorders with a frequency not known:

- Dermatitis contact (allergic or irritant)

Package Leaflet

4. Possible side effect

[...]

Common side effect (may affect up to 1 in 10 people):

- Burning feeling of the skin
- Uncommon side effects (may affect up to 1 in 100 people):
- Irritation of the skin
- Itching of the skin
- Dry skin

Not known side effect (frequency cannot be estimated from the available data)

- Redness **of the skin**
- **Inflammation of the skin**

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	December 2016 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	28 January 2017
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	29 March 2017