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 diclofenac (topical formulations), the scientific conclusions are as follows:

Based on the review of data from safety databases and presented in the PSURs, the PRAC considers "burning sensation" and "application site burning" to be undesirable effects of topical diclofenac, regardless of the route of administration. These are considered to be reflected in the summary of product characteristics by the wording "dermatitis", "application site burn" or "burning sensation" for cutaneous topical diclofenac medicinal products; by the wording "eye pain", "application site burn" or "burning sensation" for ophthalmic topical diclofenac medicinal products and by the wording "irritation of the oral cavity and "application site burn" for oromucosal topical diclofenac medicinal products. The PRAC recommends that any marketing authorisation holder that does not have these listed adverse reactions should update section 4.8 of the summary of product characteristics to add the adverse reaction "Burning sensation at the application site" with frequency 'not known' for cutaneous topical containing medicinal products; "Burning sensation in the eye" with frequency 'not known' for ophthalmic topical diclofenac containing medicinal products; and "Burning sensation in the mouth" with a frequency 'not known' for oromucosal topical diclofenac containing medicinal products. The Package Leaflet is updated accordingly.

Based on the review of data from safety databases and presented in the PSURs, the PRAC considers the safety topic "dry skin" to be an undesirable effect of cutaneous topical diclofenac administration. However, all the identified serious cases of "dry skin" were in the context of other skin reactions already reflected in the cutaneous topical diclofenac medicinal products' summary of product characteristics as common undesirable effects: (Rash, eczema, erythema, dermatitis (including dermatitis contact), pruritus). Therefore, the PRAC recommends that any marketing authorisation holder of cutaneous topical diclofenac medicinal products, that does not have these listed adverse reactions should update section 4.8 of the summary of product characteristics to add the adverse reaction "Dry skin" with a frequency 'not known'. 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 diclofenac (topical formulations) the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing diclofenac (topical formulations) 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 diclofenac (topical formulations) 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~~)

All MAHs with a marketing authorisation for cutaneous topical diclofenac products, that do not currently have "Rash, eczema, erythema, dermatitis (including dermatitis contact), pruritus", "application site burn" or "burning sensation" listed in section 4.8 of the respective Summary of Product Characteristics

Summary of Product Characteristics

- Section 4.8

The following adverse reactions should be added under the SOC 'skin and subcutaneous tissue' with a frequency 'not known':

Burning sensation at the application site

Dry skin

Package Leaflet

- Section 4

Not known:

Burning sensation at the application site

Dry skin

All MAHs with a marketing authorisation for ophthalmic topical diclofenac products, that do not currently have "eye pain", "application site burn" or "burning sensation" listed in section 4.8 of the respective Summary of Product Characteristics

Summary of Product Characteristics

- Section 4.8

The following adverse reaction should be added under the SOC 'Eye disorders' with a frequency 'not known':

Burning sensation in the eye

Package Leaflet

- Section 4

Not known:

Burning sensation in the eye

All MAHs with a marketing authorisation for oromucosal topical diclofenac products, that do not currently have "Irritation of the oral cavity ", "application site burn" listed in section 4.8 of the respective Summary of Product Characteristics

Summary of Product Characteristics

- Section 4.8

The following adverse reaction should be added under the SOC 'Gastrointestinal disorders' with a frequency 'not known':

Burning sensation in the mouth

Package Leaflet

- Section 4

Not known:

Burning sensation in the mouth

Annex III

Timetable for the implementation of this position>

Timetable for the implementation of this position

Adoption of CMDh position:	May 2019 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	11 July 2019
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	09 September 2019