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 adapalene / benzoyl peroxide, the scientific conclusions are as follows:

Based on the review of data presented in this PSUSA, covering the period from 1 October 2014 to 30 September 2017, as well as cumulative data since the European birth date, the PRAC considers that the product information of medicinal products containing the active substance adapalene/ benzoyl peroxide should be updated as follows: update of section 4.8 of the SmPC to add the adverse reaction "application site burn" with a frequency not known and to update the corresponding foot note. 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 adapalene / benzoyl peroxide the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing adapalene / benzoyl peroxide 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 adapalene / benzoyl peroxide 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 4.8

The following adverse reaction should be added under the SOC "Skin and subcutaneous tissue disorders" with a frequency not known:

Tabulated summary of adverse reactions

[…]

- **application site burn****

[…]

****Most of the cases of "application site burn" were superficial burns but cases** ~~whereas in few cases~~**, with second degree burn or severe burn reactions have been reported.**

Package Leaflet

4. Possible side effects

Not known (frequency cannot be estimated from the available data): […] **application site burn** […].

[…] **Application site burns, mostly superficial but more severe cases involving blistering, have been reported.**

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	May 2018 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	14 July 2018
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	12 September 2018