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:

During the covered period erythema and skin exfoliation (scaling) were among the most frequently reported adverse drug reactions. Erythema and skin exfoliation (scaling) are not listed as adverse drug reactions in section 4.8 of the SmPC for adapalene 0.3% /BPO 2.5%, but only for adapalene 0.1% /BPO 2.5%. The PRAC concluded that the product information of products containing adapalene 0.3% /BPO 2.5% should be amended accordingly.

Having reviewed the PRAC recommendation, the CMDh agrees with the PRAC overall conclusions and grounds for recommendation.

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 recommends that the terms of the marketing authorisation(s) should be varied.

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 of medicinal products containing the active substances adapalene 0.3% /BPO 2.5% (new text **underlined and in bold**, deleted text ~~strike through~~)

Summary of Product Characteristics

Section 4.8

The following adverse reactions should be added under the SOC skin and subcutaneous tissue disorders with a frequency common:

- **Erythema**
- **Skin exfoliation (scaling)**

Package Leaflet

- 4. Possible side effects

Common

- **Reddening of the skin**
- **Scaling**

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	30 May 2024
Transmission to National Competent Authorities of the translations of the annexes to the position:	15 July 2024
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	12 September 2024