

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 benazepril / hydrochlorothiazide, the scientific conclusions are as follows:

In view of the available data on psoriasis aggravation from the literature, some cases with a close temporal relationship and a positive de-challenge, and potential class effect with other ACE inhibitors, the PRAC considered a causal relationship between benazepril/hydrochlorothiazide and psoriasis aggravation is at least a reasonable possibility. The PRAC concluded that the product information of products containing benazepril/hydrochlorothiazide should be amended 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 benazepril / hydrochlorothiazide the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing benazepril / hydrochlorothiazide 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 benazepril / hydrochlorothiazide 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 Undesirable effects

The following adverse reaction should be added under the SOC Skin and subcutaneous tissue disorders with a frequency unknown.

Psoriasis aggravation

Frequency

Unknown

Package Leaflet:

Section 4 Possible side effects

Frequency not known (cannot be estimated from available data): **aggravation of psoriasis (skin disease that causes red, itchy scaly patches, most commonly on the knees, elbows, trunk and scalp)**

Annex III

Timetable for the implementation of this position>

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| Adoption of CMDh position: | January 2022 CMDh meeting |
| Transmission to National Competent Authorities of the translations of the annexes to the position: | 13 March 2022 |
| Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder): | 12 May 2022 |