# 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 1-propanol / 2-propanol / lactic acid, the scientific conclusions are as follows:

Based on available data on risk(s) from spontaneous reports including in some cases a close temporal relationship, a positive de-challenge and/or re-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between 1-propanol/ 2-propanol/ lactic acid and skin irritations such as erythema and burning sensation is possible.

Update of section 4.8 of the SmPC is required to add the adverse reactions "erythema" (replacing redness in SmPC) and "burning sensation" as additional examples of skin irritations with a frequency very rare. 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 1-propanol / 2-propanol / lactic acid the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing 1-propanol / 2-propanol / lactic acid 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 1-propanol / 2-propanol / lactic acid 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 reactions should be added under the SOC *Skin and subcutaneous tissue disorders* with a frequency *Very rare:*

Skin irritations such as **erythema**, ~~redness~~ dryness, contact allergies, **burning sensation**.

**Package Leaflet**

- Section 4

Dryness, irritation, ~~erythema,~~ **redness** or **burning sensation** of the skin may occur. Allergic contact dermatitis or contact allergies are very rare.

## Annex III

## Timetable for the implementation of this position

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|---|---|
| Adoption of CMDh position: | May 2020 CMDh meeting |
| Transmission to National Competent Authorities of the translations of the annexes to the position: | 13 July 2020 |
| Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder): | 10 September 2020 |