# 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 levocetirizine, the scientific conclusions are as follows:

Based on the review of spontaneous post-marketing reports of oculogyration, which showed a close temporal relationship after the use of levocetirizine and included cases of positive de-challenge, the PRAC considered that a causal association between levocetirizine use and oculogyration is plausible. Taking also into account that oculogyration has already been included in the product information of racemic cetirizine, an update of the product information of all medicinal products containing levocetirizine is considered justified.

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 levocetirizine the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing levocetirizine 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 levocetirizine 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 Eye disorders with a frequency 'not known':

**oculogyration**

**Package Leaflet**

- Section 4

The following adverse reaction should be added with a frequency 'not known':

**oculogyration (eyes having uncontrolled circular movements)**

## Annex III

## Timetable for the implementation of this position

**Timetable for the implementation of this position**

| | |
|---|---|
| Adoption of CMDh position: | March 2018 CMDh meeting |
| Transmission to National Competent Authorities of the translations of the annexes to the position: | 05 May 2018 |
| Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder): | 04 July 2018 |