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 epinastine, the scientific conclusions are as follows:

Based on data from post-marketing experience, the PRAC agreed with the MAH's analysis that a causal relationship between epinastine and hypersensitivity reaction including symptoms or signs of eye allergy and extra-ocular allergic reactions, including angioedema, skin rash and redness as well as eye Swelling and/or eyelid oedema cannot be excluded and therefore agrees with these being added as new adverse drug reactions to section 4.8 of the SmPC with the frequency 'not known'. 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 epinastine the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing epinastine 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 epinastine 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

4.8 Undesirable side effects

~~*Increased lacrimation and eye pain have been identified during postmarketing use of Relestat in clinical practice.~~

The following adverse drug reactions were reported during post marketing use of epinastine in clinical practice:

System Organ Class	**Frequency**	**Adverse Reaction**
Immune system disorders	Not known	**Hypersensitivity reaction including symptoms or signs of eye allergy and extra-ocular allergic reactions, including angioedema, skin rash and redness**
Eye disorders	Not known	Increased lacrimation, eye pain, **eye swelling, eyelid oedema**

Package Leaflet

1. Possible side effects

If the following happens, stop using TRADENAME and contact your doctor immediately or go to your nearest hospital:

- asthma (an allergic disease affecting the lungs that causes breathing difficulties)
- **if you experience symptoms of angioedema (swelling of face, tongue or throat; difficulty swallowing; hives and breathing difficulties)**

The following side effects may also occur:

Common (may affect up to 1 in 10 people)
- burning sensation or irritation of the eye (mostly mild)

Uncommon (may affect up to 1 in 100 people)

General side effects:
- headache
- swelling and irritation inside the nose, which may cause a runny or blocked nose and sneezing
- unusual taste in your mouth

Side effects affecting the eye:

- red eyes
- dry eyes
- itchy eyes
- difficulty in seeing clearly
- discharge from the eyes

Not known (frequency cannot be estimated from the available data) ~~Patients have also reported the following side effects:~~

- increased tear production
- eye pain
- **allergic reaction affecting the eyes**
- **swelling of the eyes**
- **swelling of the eyelids**
- **skin rash and redness**

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	June 2018 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	11 August 2018
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	10 October 2018