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 anastrozole, the scientific conclusions are as follows:

In view of available data on dry eye from the literature, 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 anastrozole and dry eye is at least a reasonable possibility. The PRAC concluded that the product information of products containing anastrozole should be amended accordingly.

In view of available data on tendonitis and tendon rupture from the literature, 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 anastrozole and tendonitis and tendon rupture is at least a reasonable possibility. The PRAC concluded that the product information of products containing anastrozole should be amended accordingly.

In view of available data on memory impairment from the literature, 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 anastrozole and memory impairment is at least a reasonable possibility. The PRAC concluded that the product information of products containing anastrozole should be amended accordingly.

In view of available data on lichenoid eruption from the literature, spontaneous reports including in some cases a close temporal relationship, a positive de-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between anastrozole and lichenoid eruption is at least a reasonable possibility. The PRAC concluded that the product information of products containing anastrozole 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 anastrozole the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing anastrozole 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 (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":

Dry eye

The following adverse reaction should be added under the SOC Skin and subcutaneous tissue disorders with a frequency "not known":

Lichenoid eruption

The following adverse reactions should be added under the SOC Musculoskeletal and connective tissue disorders with a frequency "not known":

Tendonitis

Tendon rupture

The following adverse reaction should be added under the SOC Nervous system disorders with a frequency "not known":

Memory impairment

Package Leaflet

- Section 4.

Side effects with frequency not known (frequency cannot be estimated from the available data)

Dry eye

Lichenoid eruption (small, red or purple itchy bumps on the skin)

Inflammation of a tendon or tendonitis (connective tissues that connect muscles to bones)

Rupture of a tendon (connective tissues that connect muscles to bones)

Memory impairment

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	March CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	11 May 2025
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	10 July 2025