**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 paroxetine, the scientific conclusions are as follows:

In view of available data on leukopenia from clinical trial(s), the literature, spontaneous reports, and a positive de-challenge and/or re-challenge, the Lead Member State considers a causal relationship between paroxetine and leukopenia is at least a reasonable possibility. The PRAC concluded that the product information of products containing paroxetine 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 paroxetine the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing paroxetine 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(s) should be added under the SOC Blood and lymphatic system disorders with a frequency Uncommon:

**Leukopenia**

**Package Leaflet**

- PIL section 4:

Other possible side effects during treatment

Uncommon
**Reduction in white blood cell count**

**Annex III**

**Timetable for the implementation of this position**

**Timetable for the implementation of this position**

| | |
|---|---|
| Adoption of CMDh position: | September 2023 CMDh meeting |
| Transmission to National Competent Authorities of the translations of the annexes to the position: | 29 October 2023 |
| Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder): | 28 December 2023 |