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 terazosin, the scientific conclusions are as follows:

In view of available data on nasal congestion from the literature and spontaneous reports, the PRAC considers a causal relationship between terazosin and "Nasal congestion" is at least a reasonable possibility. The PRAC concluded that the product information of products containing terazosin 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 terazosin the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing terazosin 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 Respiratory, thoracic and mediastinal disorders with a frequency not known:

Nasal congestion

Package Leaflet

Section 4

Not known (frequency cannot be estimated from the available data):

Blocked nose

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	July 2024 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	8 September 2024
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	7 November 2024

APPENDIX I

PRAC PSUR Assessment Report