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 nicotine, the scientific conclusions are as follows:

In view of available data on atrial fibrillation from the literature including in 4 cases a close temporal relationship, a positive de-challenge and/or re-challenge and in view of a plausible mechanism of action, the PRAC Lead Member State considers a causal relationship between oral nicotine and atrial fibrillation is at least a reasonable possibility. The PRAC Lead Member State concluded that the product information of products containing nicotine (oral and oromucosal formulations) 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 nicotine the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing nicotine 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 **<u>underlined and in bold</u>**, deleted text ~~strike through~~)

Only for oral and oromucosal formulations

Summary of Product Characteristics

- Section 4.8

If "Atrial fibrillation" is already included in section 4.8 with other frequency, the existing frequency should be maintained.

The following adverse reaction(s) should be added under the SOC cardiac disorders with a frequency not known:

<u>Atrial fibrillation</u>

Package Leaflet

The following adverse reaction should be added if information regarding the adverse reaction is not already in place. In case of existing information regarding atrial fibrillation, these should remain.

4. Possible side effects

Other side effects

Not known:

- **<u>A fast and irregular heartbeat (Atrial fibrillation)</u>**

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	July 2025 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	07 September 2025
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	06 November 2025