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 modafinil, the scientific conclusions are as follows:

In view of available data on Drug Abuse and Drug Dependence in patients with history of psychiatric disorders from the literature and 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 that the existing warning on Abuse, misuse, diversion should be updated to include patients with history of psychiatric disorders. The PRAC concluded that the product information of products containing Modafinil should be amended 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 modafinil the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing modafinil 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 modafinil 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

- Section 4.4

A warning should be amended as follows:

Abuse, misuse, diversion ***and dependence***

~~*Whilst*~~ ***There have been*** *studies with modafinil* ***that*** *have demonstrated a potential for dependence. The possibility of dependence with long-term use cannot be entirely excluded.*

Caution should be exercised in administering modafinil to patients with ***a history of psychiatric disorders (see above),*** *history of alcohol, drug or illicit substance abuse.*

Package Leaflet

No amendment is required.

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	April 2022 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	6 June 2022
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	5 August 2022