

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 amantadine, the scientific conclusions are as follows:

In view of available data on suicidal ideation and suicide attempt/completed suicide from case reports, including cases of close temporal relationship and positive de-challenge, the PRAC considers that the product information of products containing amantadine should be amended accordingly.

Update of section 4.4 of the SmPC to add (Laboratoire and Hikma) or to amend (Alliance, Novartis and Hexal) the warning/precaution regarding suicidality. The Package leaflet is updated 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 amantadine the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing amantadine 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 4.4

The following warning should be added (Laboratoire and Hikma) /amended (Alliance, Novartis and Hexal):

Cases of suicidal ideation and behaviour have been reported during treatment with amantadine. Patients should be monitored for signs of suicidal ideation and behaviour and treatment initiated as needed. Patients (and caregivers of patients) should be advised to seek medical advice if any signs of suicidal ideation or behaviour emerge.

< Existing advice that prescriptions should be written for the smallest quantity should be kept. >

Package Leaflet

- Section 2

Subsection: Warnings and precautions

Cases of suicidal thoughts and actions have been reported during treatment with amantadine. If you have thoughts or attempts of harming or killing yourself, contact your doctor immediately.

Annex III

Timetable for the implementation of this position

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Adoption of CMDh position:	September 2024 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	4 November 2024
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	2 January 2025