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 nimodipine the scientific conclusions are as follows:

In view of available data on hypoxia from clinical trials, the literature, spontaneous reports including in some cases a close temporal relationship, a positive de-challenge and re-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between nimodipine and hypoxia is at least a reasonable possibility. The PRAC concluded that the product information of products containing nimodipine 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 nimodipine the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing nimodipine 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 **hypoxia*** should be added under the SOC Respiratory, thoracic and mediastinal disorders with a frequency 'not known'

***Applies to the indication SAH** *(Note to MAHs: should only be used if the product has other indications than SAH - with a combined ADR table).*

Package Leaflet

- Section 4 Possible side effects

The following adverse reaction should be added: **low level of oxygen in body tissues***

***Applies to the indication subarachnoid hemorrhage** *(Note to MAHs: should only be used if the product has other indications than subarachnoid hemorrhage).*

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	June 2024 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	12 August 2024
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	10 October 2024