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 clevidipine, the scientific conclusions are as follows:

In view of available data from the literature and spontaneous report including in some cases a close temporal relationship and in view of a plausible mechanism of action, the PRAC Lead Member State considers a causal relationship between clevidipine and blood triglycerides increase is at least a reasonable possibility. The PRAC Lead Member State concluded that the product information of products containing clevidipine 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 clevidipine the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing clevidipine 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 **"Investigation"** with a frequency **"uncommon":**

"Blood triglycerides increased"

Package Leaflet

4. Possible side effects

Uncommon side effects

-blood triglycerides increased

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:	11/08/2024
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	10/10/2024