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 aciclovir, the scientific conclusions are as follows:

In view of available data on dosing strategies in obese patients from the literature and spontaneous reports, the PRAC finds that while no specific dosing strategy can be recommended over another at this point in time, the dosing information in obese patients needs to be updated to indicate that dosing on actual body weight may lead to an increased plasma concentration compared to non-obese patients and that dose reduction should therefore be considered; conversely, dosing based on ideal body weight may lead to a lower plasma concentration of aciclovir compared to non-obese. The PRAC concluded that the product information of all products containing aciclovir for intravenous use 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 acyclovir for intravenous use, the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing aciclovir for intravenous use is unchanged subject to the proposed changes to the product information.

The CMDh recommends that the terms of the marketing authorisation(s) for aciclovir for intravenous use 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 4.2

The posology regarding dosing of obese patients should be added or amended as follows. The reference to Section 5.2 highlighted in blue only applies to those MAHs whose SmPCs contain pharmacokinetic information on obesity in section 5.2.

~~Obese patients should be dosed at the recommended adult dose using ideal body weight, rather than actual body weight.~~

In obese patients who receive aciclovir intravenously based on their actual body weight, increased plasma concentrations may be obtained (see 5.2 Pharmacokinetic properties). A dose reduction should therefore be considered in obese patients, especially in patients with renal impairment or in elderly patients.

- Section 4.4

Warnings regarding dosing of obese patients should be removed from section 4.4.

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	30 January 2025 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	16 March 2025
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	15 May 2025