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 busulfan, the scientific conclusions are as follows:

In view of available data on pulmonary hypertension from the literature, spontaneous reports including in 9 cases a close temporal relationship and in view of a plausible mechanism of action, the PRAC considers a causal relationship between busulfan and pulmonary hypertension is at least a reasonable possibility. The PRAC concluded that the product information of products containing busulfan 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 busulfan the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing busulfan 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 should be added under the SOC Respiratory, thoracic and mediastinal disorders with a frequency Not known:

Pulmonary hypertension

Package Leaflet

Section 4

The following side effect should be added with a frequency Not known:

- **increased blood pressure in the blood vessels of the lungs (pulmonary hypertension)**

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	27 February 2025 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	14 April 2025
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	12 June 2025