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 levosimendan the scientific conclusions are as follows:

In view of available data on hypersensitivity reactions from spontaneous reports including in 10 cases a close temporal relationship, a positive de-challenge and/or re-challenge the PRAC considers a causal relationship between levosimendan, and hypersensitivity reactions is at least a reasonable possibility. The PRAC concluded that the product information of products containing levosimendan 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 levosimendan the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing levosimendan 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

Table 3 Summary of Adverse Reactions **identified with levosimendan in clinical trials and post-marketing data** ~~SURVIVE Clinical Study, REVIVE Programme, and LIDO/RUSSLAN/300105/3001024 Clinical Studies combined~~

The following adverse reaction should be added under the SOC Immune system disorders with a frequency "not known".

Hypersensitivity

Package Leaflet

- Section 4

The following adverse reaction should be added with a new subheading for frequency "not known".

Not known (frequency cannot be estimated from the available data):
Hypersensitivity (symptoms may include rash and itching).

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	May 2025 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	6 July 2025
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	4 September 2025