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 nadroparin, the scientific conclusions are as follows:

In view of available data on cross-reactivity between nadroparin and low molecular weight heparins and/or unfractionated heparins from the literature and spontaneous reports, the PRAC considers a causal relationship between nadroparin and cross-reactivity reactions is at least a reasonable possibility and that contraindication on hypersensitivity is necessary. The PRAC concluded that the product information of products containing nadropain should be amended accordingly.

The CMDh agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the Marketing Authorisation(s)

On the basis of the scientific conclusions for nadroparin the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing nadroparin is unchanged subject to the proposed changes to the product information.

The CMDh reaches the position that the marketing authorisation(s) of products in the scope of this single PSUR assessment should be varied. To the extent that additional medicinal products containing nadroparin are currently authorised in the EU or are subject to future authorisation procedures in the EU, the CMDh recommends that the concerned Member States and applicant/marketing authorisation holders take due consideration of this CMDh position.

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 4.3

The contraindication should be amended as follows:

Nadroparin is contraindicated in cases of:

- hypersensitivity to the active substance nadroparin, **heparin or its derivatives, including other low molecular weight heparins,** or any of the excipients listed in section 6.1

Package Leaflet

Section 2

Do not use [name of the product]

- If you are allergic to the active substance **nadroparin, heparin or a similar product (such as enoxaparin, bemiparin, dalteparin),** or to any of the other ingredients of this medicine (listed in section 6).

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	December 2021 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	31 January 2022
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	30 March 2022