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:

Based on review of literature and spontaneous reporting, the PRAC considered that a causal relationship between headache and nadroparin cannot be excluded and therefore recommends that this is added to section 4.8 of the SmPC with a frequency unknown. The Package Leaflet is updated 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 4.8

The following adverse reaction should be added under the SOC Nervous system disorders with a frequency unknown: **headache.**

Package Leaflet

- Section 4

The following adverse reaction should be added with a frequency unknown: **headache.**

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	December CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	26 January 2019
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	27 March 2019