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 bemiparin, the scientific conclusions are as follows:

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

Update of section 4.3 of the SmPC to amend a contraindication regarding hypersensitivity. 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 bemiparin the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing bemiparin 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 bemiparin are currently authorised in the EU or are subject to future authorisation procedures in the EU, the CMDh recommends that 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:

Hypersensitivity to the active substance, or to any of the excipients listed in section 6.1.

Hypersensitivity to heparin **or its derivatives, including other low molecular weight heparins**, or substances of porcine origin.

Package Leaflet

Section 2- What you need to know before you use Zibor

Do not use Zibor:

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

- if you have had an allergic reaction after being given any medicine containing heparin.

- if you are allergic to any substance derived from pigs.

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	January 2023 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	13 March 2023
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	11 May 2023