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 ropivacaine, the scientific conclusions are as follows:

In view of available data on anaphylactic shock from spontaneous reports including 3 cases with possible causality, and a probable/ likely case described in literature, and that anaphylactic shock can be part of an allergic reaction/ anaphylactic reaction which is already labelled in the product information and a known risk for ropivacaine, the Lead Member State considers a causal relationship between ropivacaine and anaphylactic shock is at least a reasonable possibility. The Lead Member State concluded that the product information of products containing ropivacaine 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 ropivacaine the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing ropivacaine 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 ropivacaine 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(s) should be amended under the SOC Immune system disorders with a frequency rare:

Allergic reactions (anaphylactic reactions, **anaphylactic shock,** angioneurotic oedema and urticaria)

Package Leaflet

- PIL Section 4:

Important side effects to look out for:

Sudden life-threatening allergic reactions (such as anaphylaxis, **including anaphylactic shock**) are rare, affecting 1 to 10 users in 10,000. Possible symptoms include sudden onset of rash, itching or lumpy rash (hives); swelling of the face, lips, tongue or other parts of the body; ~~and~~ shortness of breath, wheezing or difficulty breathing**; a feeling of loss of consciousness**. If you think that [product name] is causing an allergic reaction, tell your doctor immediately.

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	May 2023 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	9 July 2023
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	7 September 2023