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 haemophilus type b conjugate vaccines, the scientific conclusions are as follows:

Based on the number of cases received of rash generalised reported for haemophilus type b conjugate vaccines, their temporal association, and the fact hypersensitivity and rash are listed, the PRAC considers that rash generalised should be included in the tabulated list of adverse reactions in section 4.8 of the SmPC, with an unknown frequency. The package leaflet should be 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 haemophilus type b conjugate vaccines the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing haemophilus type b conjugate vaccines 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 haemophilus type b conjugate vaccines 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 added under the SOC Skin and subcutaneous tissue disorders with a frequency unknown: **rash generalised**.

Package Leaflet

- Section 4

The following adverse reaction(s) should be added with a frequency unknown: **rash generalised**.

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	October 2017 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	25 November 2017
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	24 January 2018