ANNEX IV

SCIENTIFIC CONCLUSIONS AND GROUNDS FOR THE VARIATION TO THE TERMS

OF THE MARKETING AUTHORISATION(S)

[This Annex IV refers to CAPs]

**Scientific conclusions**

Taking into account the PRAC Assessment Report on the PSUR(s) for {name of active substance(s)}, the scientific conclusions of PRAC are as follows:

[Copy-paste from the relevant paragraphs of section (Final assessment conclusions and actions) of the PSUR PRAC AR, with regards to the scientific grounds recommending the variation to the terms of the Marketing Authorisation(s).
Avoid the use of abbreviations].

[Please select option 1 or 2]

[OPTION 1: CHMP agrees]

Having reviewed the PRAC recommendation, the CHMP agrees with the PRAC overall conclusions and grounds for recommendation.

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

On the basis of the scientific conclusions for {name of active substance(s)} the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing {name of active substance(s)} is unchanged subject to the proposed changes to the product information.

The CHMP recommends that the terms of the Marketing Authorisation(s) should be varied.

[OPTION 2: CHMP disagrees]

Having reviewed the PRAC recommendation, the CHMP does not agree with the PRAC overall conclusions and grounds for recommendation.

Detailed explanation of the scientific grounds for the differences from the PRAC recommendation

[Detail the differences between the PRAC recommendation and the CHMP opinion, if any, and provide scientific grounds for the changes.]

[If a report presenting the justification for the divergences from the PRAC recommendation is produced by the CHMP, it should be appended to the CHMP opinion and reflected on the cover page.]

Taking into account the PRAC recommendation <and the CHMP discussion>, the CHMP is of the opinion

[In case of recommendation to maintain the marketing authorisation]

<that the risk-benefit balance of medicinal products containing {name of active substance(s)} remains unchanged and recommends by <consensus><majority decision> the maintenance of the marketing authorisation(s).>

[In case of recommendation to vary the marketing authorisation]

<that the risk-benefit balance of medicinal products containing {name of active substance(s)} remains unchanged but recommends by <consensus><majority decision> that the terms of the marketing authorisation(s) should be varied as follows:

[The scope of changes to the SmPCs and package leaflets should be highlighted here with a detailed description of the new text underlined and deleted text marked as strikethrough.]

<Update of section {n} <and {n}> of the SmPC to add <the adverse reaction {x} with a frequency {y}> <a warning on {z}><…>. <The Package leaflet is updated accordingly.>>

[In case changes to the conditions of the marketing authorisation are recommended, these should also be highlighted here with a detailed description of the new text underlined and deleted text marked as strikethrough.]

<The conditions imposed to the marketing authorisation are as follows:>

[In case the CHMP departs from the PRAC on follow-up requirements, choose as applicable]

<In addition, the MAH(s) should also address the following issues in the next PSUR:

* [list]>

<In addition, the MAH(s) should submit an updated RMP within {x} months in order to address the following issues:

* [list]>