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 {active substance(s) as EURD list entry}, the scientific conclusions are as follows:

{text}

[OPTION 1: CMDh agrees]

Having reviewed the PRAC recommendation, the CMDh 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 {active substance(s) as EURD list entry} the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing {active substance(s) as EURD list entry} is unchanged subject to the proposed changes to the product information

The CMDh recommends that the terms of the marketing authorisation(s) should be varied.

[OPTION 2: CMDh disagrees]

Having reviewed the PRAC recommendation, the CMDh 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

{text}

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

[In case of recommendation to maintain the marketing authorisation]

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

<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.>>

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

[In case the CMDh departs from the PRAC on follow-up requirements]

<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]>

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>**

**<Package Leaflet>**

<Annex III>

**<Conditions to the Marketing Authorisation(s)>**

Annex <III> <IV>

**Timetable for the implementation of this position**

**Timetable for the implementation of this position**

|  |  |
| --- | --- |
| Adoption of CMDh position: | {Month Year} CMDh meeting |
| Transmission to National Competent Authorities of the translations of the annexes to the position: | {DD/MM/YYYY}  |
| Implementation of the positionby the Member States (submission of the variation by the Marketing Authorisation Holder): | {DD/MM/YYYY}  |