Productnaam

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| Concerned Member State’s Comments on Lead Member State’s Preliminary assessment report |

**Note**

Comments should be uploaded to the PSUR Repository.

NB: Only **one set of comments** should be sent by the Concerned Member State (CMS). In case a PRAC member would like to raise (additional) comments, these should be included in the MS comments of their delegation.

# This Document is Sent By

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| --- | --- |
| Name of contact point of the Member State  |  |
| Names of the assessor(s)  |  |
| Date of comments  |  |
| Name of EMA Procedure Manager.. |  |

# This report concerns

|  |  |
| --- | --- |
| Name of active substance(s)........ |  |
| Procedure Number  | PSUSA/……/………… |

[ ]  We fully endorse the Lead MS assessment, and have no further comments

[ ]  We do not fully endorse the Lead MS assessment, and have the following comments:

General comments on the PSUR assessment

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Specific comments (including comments to draft questions)

## Signal and risk evaluation

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## Benefit evaluation

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## Benefit-Risk Assessment

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## Summary of Product Characteristics, Package Leaflet and Labelling

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## Other Aspects

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## Additional PRAC member’s comments [[1]](#footnote-1)

Name PRAC member:

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1. If applicable, see section 3.7.2 of CMDh SOP on the processing of PSUR single assessment for nationally authorised products: “Member States and MAH(s) have 30 days to provide any comments and respond to the Request for supplementary information, if applicable. PRAC members should include their comments in the MS comments of their delegation, i.e. only one (set of) comment(s) should be sent by each delegation.” [↑](#footnote-ref-1)