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|  | <CHMP><CAT><PRAC> Member Comments on <CHMP><CAT><PRAC> Rapporteur’s Reports |

**Note**

* Free text comments or short comments can be sent to CHMP/CAT/PRAC using secure e-mail (EUDRALINK).

Product Shared Mailbox: product.name-xxxx@ema.europa.eu and product initial MAA dedicated mailbox: MAAxxxx@ema.europa.eu (xxxx refers to the product number EMA/H/C/xxxx) should always be copied.

* Use this template only if you wish to provide additional, more extensive comments.

# This Document is Sent By

|  |  |
| --- | --- |
| Name of Committee Member  |  |
| Names of Assessors  |  |
| Date of comments  |  |

# This report concerns

|  |  |
| --- | --- |
| Product name  |  |
| Procedure Number  |  |
| Title of Report  |  |

[ ]  We fully endorse the CHMP/CAT/PRAC Rapp assessment, and have no further comments

[ ]  We do not fully endorse the CHMP/CAT/PRAC Rapp assessment, and have the following comments:

General comments

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Specific comments (including comments to draft questions)

## Quality Aspects

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## Non-clinical Aspects

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## Clinical Pharmacology

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## Clinical Efficacy

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## Clinical Safety

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## Periodic Safety Update Report

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## Risk Management Plan/ Post-authorisation Safety Studies/ Conditions

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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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