CVMP Member Comments on Rapporteur’s Reports

**Note**

The completed form should be named procedure number-CVMP member-country code-DXX comments.

The commenting MS should send an e-mail to the rapporteur and All CVMP (list-v-cve@eudra.org), and always cc EMA-IRIS@id.ema.europa.eu, by replying or forwarding the original email received from the rapporteur, including a link to any uploaded comment form.

This document is sent by

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

This comment concerns

|  |  |
| --- | --- |
| **Product name**  |  |
| Procedure number  | EMA/VRA/0000xxxxxx |
| Day in procedure  | **<D43/D50> <D79>** |

[ ]  We fully endorse the CVMP Rapp assessment, and have no further comments

[ ]  We do not fully endorse the CVMP Rapp assessment, and have the following comments:

Overall comments

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Specific comments (including comments to draft questions)

Part 2 Quality

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Part 3 Safety

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Part 4 Efficacy

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Part 5 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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