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

|  |  |
| --- | --- |
| **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

|  |
| --- |
|  |

Specific comments (including comments to draft questions)

Part 2 Quality

|  |
| --- |
|  |

Part 3 Safety

|  |
| --- |
|  |

Part 4 Efficacy

|  |
| --- |
|  |

Part 5 Benefit-Risk Assessment

|  |
| --- |
|  |

Summary of Product Characteristics, Package Leaflet and Labelling

|  |
| --- |
|  |

Other Aspects

|  |
| --- |
|  |