REQUEST FOR A RECOMMENDATION ON THE CLASSIFICATION OF AN UNFORESEEN VARIATION UNDER ARTICLE 5 OF COMMISSION REGULATION (EC) No 1234/2008

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| **human** [ ]  |  |
| [ ]  **NATIONAL AUTHORISATION IN MRP**  **MRP/DCP Number\_/\_/\_\_\_\_/\_\_\_/\_\_/\_\_** [ ]  EU **AUTHORISATION** **MA Number EU/\_/\_ /\_\_** *(If there are several CAPs, the core MA number should be provided for each medicinal product)*[ ]  **NATIONAL AUTHORISATION**[ ]  **PMF EMEA Number: EMEA/H/PMF/\_\_\_\_\_/\_\_**[ ]  **VAMF EMEA Number: EMEA/H/VAMF/\_\_\_\_/\_\_****Nature of Variation:**[ ]  Quality[ ]  active substance[ ]  medicinal product[ ]  Efficacy (including Pharmacokinetics)[ ]  Safety[ ]  Environmental[ ]  Non-clinical[ ]  Clinical[ ]  Pharmacovigilance[ ]  Other (Please specify)**Type of Product:**[ ]  Chemical[ ]  Biological[ ]  Blood Product[ ]  Vaccine[ ]  Biotechnology-derived[ ]  Other Biological[ ]  Advanced Therapy medicinal product[ ]  Other (Please specify):**Is the Product:**[ ]  Sterile[ ]  Non-sterile |

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| **Details of Applicant (NCA, MAH, PMF/VAMF Holder):**Name and address:Name and address of Contact person:Telephone number:Fax number: E-mail: |

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| **Details of Product(s), PMF, VAMF***Information should be repeated if there are several products concerned. For CAPs please attach Annex A of each concerned product.*(Invented)Name(s): Active substance(s):Pharmaceutical form(s): Strength(s): PMF/VAMF name: |

**Detailed description of the proposed variation application:**

Applicant’s explanation as to why this variation is considered to be unclassified:

Are the annexes of the Product information affected by the proposed variation? If yes, please provide relevant affected sections with highlighted changes.

**Applicant’s proposal for the classification:**

[ ]  IAIN (immediate notification) [ ]  IA

[ ]  IB [ ]  II

Applicant’s justification for the proposed classification:

*(Please provide below a detailed justification. No supportive documentation is expected to be attached)*

Has an identical or similar variation application been submitted to a Competent Authority and if so how was it classified?

*(please provide brief background including description of the change, identification of Competent Authority, outcome and dates)*