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)*