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

<table>
<thead>
<tr>
<th>HUMAN</th>
<th>VETERINARY</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ NATIONAL AUTHORISATION IN MRP</td>
<td></td>
</tr>
<tr>
<td>MRP/DCP Number / / _____ / / / / /</td>
<td></td>
</tr>
<tr>
<td>☐ EU AUTHORISATION</td>
<td></td>
</tr>
<tr>
<td>MA Number EU / / / /</td>
<td></td>
</tr>
<tr>
<td>(If there are several CAPs, the core MA number should be provided for each medicinal product)</td>
<td></td>
</tr>
<tr>
<td>☐ NATIONAL AUTHORISATION</td>
<td></td>
</tr>
<tr>
<td>☐ PMF EMEA Number: EMEA/H/PMF/ _____ / /</td>
<td></td>
</tr>
<tr>
<td>☐ VAMF EMEA Number: EMEA/H/VAMF/ _____ / /</td>
<td></td>
</tr>
</tbody>
</table>

**Nature of Variation:**
- ☐ Quality
  - ☐ active substance
  - ☐ medicinal product
- ☐ Efficacy (including Pharmacokinetics)
- ☐ Safety
- ☐ Residue
- ☐ 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
- ☐ For companion animal
- ☐ For food-producing animal
Details of Applicant (NCA, MAH, PMF/VAMF Holder):

Name and address:

Name and address of Contact person:

Telephone number:
Fax number:
E-mail:

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):

Species (Vet only):

Withdrawal periods – if appropriate (Vet only):

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:**

- [ ] IA\(^{in}\) (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)