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| **RECOMMENDATION OF THE COORDINATION GROUP FOR MUTUAL RECOGNITION AND DECENTRALISED PROCEDURES - HUMAN (CMDh) ON THE CLASSIFICATION OF AN UNFORESEEN VARIATIONTO THE TERMS OF THE MARKETING AUTHORISATION** |

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| **Name of the medicinal product in the RMS***(if applicable)* |       |
| **INN (or common name) of the active substance(s)** *(if applicable)* |       |
| **Pharmaceutical form(s) and strength(s)** *(if applicable)* |       |
| **Reference Number for MRP/DCP** *(if applicable)* |       |

**BASIS FOR THE RECOMMENDATION**

Pursuant to Article 5 of Commission Regulation (EC) No 1234/2008, <Member State> forwarded to the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) an application for a recommendation of an unforeseen variation.

The procedure started on <date>.

**Description of the proposed variation application:**

**APPLICANT’S PROPOSAL FOR CLASSIFICATION**

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| **Applicant’s proposal for the classification:** |
| [ ]  IAIN (Immediate Notification) [ ]  IA[ ]  IB [ ]  II |
| **Applicant’s justification for the proposed classification:** |
|       |

**RECOMMENDATION FOR CLASSIFICATION**

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| **Rapporteur’s proposal for the classification:** |
| [ ]  IAIN (Immediate Notification) [ ]  IA[ ]  IB [ ]  II |
| **Justification for the proposed classification**[[1]](#footnote-1)**:** |
|       |

**CONCLUSION**

The Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), having considered the application as set out in the justification, recommends the classification of the proposed unforeseen variation to the terms of the Marketing Authorisation as a type <IAIN/IA/IB/II> variation.

*[Delete one of the 2 options below as appropriate]*

The European Medicines Agency agrees with the above-mentioned recommendation of the CMDh.

The European Commission, CMDv and Rapporteur(s) have been informed consequently.

The European Medicines Agency has a divergent opinion on the classification proposed by the CMDh.

The European Commission has been informed consequently.

The following information will be published on the CMDh website:

| **Section of the Classification Guideline[[2]](#footnote-2)** | **Date issued** | **Summary of the proposed change[[3]](#footnote-3)** | **Proposed classification** | **Proposed conditions, where relevant[[4]](#footnote-4)** |
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| <insert *(e.g. B.I.a.1)*> | <date> |       | <IAIN/IA/IB/II> |       |

1. *In case an identical or similar variation application been published to other centrally/nationally approved products, please indicate reference* [↑](#footnote-ref-1)
2. *The recommendations should be grouped per section of the Classification Guideline to facilitate searching. Within each section the recommendations should be listed in a chronological order.* [↑](#footnote-ref-2)
3. w*ith commercially confidential information deducted in accordance with the principles laid out in the Guidance document on the Principles to be applied for the deletion of commercially confidential information for the disclosure of EMA documents (EMEA/45422/2006)* [↑](#footnote-ref-3)
4. *Conditions to be stated only for Type IA/IAIN variations* [↑](#footnote-ref-4)