Application for a Variation to a Registration Certificate for a Homeopathic Medicinal Product

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| *FOR HPRA USE ONLY* |
| CRN:       |

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|  | Registration number(s) allocated by the HPRA HOR:      /     /     / |
|  | Full name, address and telephone number of the registration certificate holder      |
|  | Product name(s)      |
|  | Fee Category[ ]  Variation |
|  | Member States in which the product is registered or registration is pendingAT[ ]  BE[ ]  CY[ ]  CZ[ ]  DE[ ]  DK[ ]  EE[ ]  EL[ ]  ES[ ]  FI[ ]  FR[ ]  HU[ ]  IS[ ] IT[ ]  LI[ ]  LT[ ]  LU[ ]  LV[ ]  NL[ ]  NO[ ]  PL[ ]  PT[ ]  SE[ ]  SI[ ]  SK[ ]  UK[ ]  |
|  | Background *(Please give brief background explanation for the proposed change to the product registration)*     Specify the precise present and proposed details, using additional pages if necessary. If the change affects the Product Specific Details or label, the changed words should be indicated by underline, strikethrough or highlight, and a clean version should be attached. Colour mock-ups need to be provided where the change affects the label or leaflets. |

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| 7. | **PRESENT** | **PROPOSED** |
|  |       |       |
| 8. | I hereby apply to vary the homeopathic registration certificate. I confirm that no changes have been made to the product particulars other than those approved by the Health Products Regulatory Authority. I declare that all changes have been identified and that there are no other changes in the amended documentation.I declare that fees have been/will be paid. *If fees have been paid, attach proof of payment.* |
| Signature of applicant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Print/type name:      Telephone number:      E-mail address:       | Date:      Capacity in which signed:      Fax number:       |

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