Application for a Registration Certificate for a Homeopathic Veterinary Medicinal Product

This form is to be used only in respect of products which meet all the criteria of Article 86 of Regulation (EU) 2019/6 from 28 January 2022. For all other products, the standard HPRA application for authorisation of a veterinary medicinal product form should be used. For guidance on completing this form, please see notes at the end of the form.

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|  | Registration number(s) *allocated by the HPRA*  HoVR      /     / | |
|  | 1. Full name, address and telephone number of the proposed registration certificate holder | |
|  | 1. LOC ID of the proposed registration certificate holder      1. Trading Style (if different) | |
|  | 1. Contact details for person to communicate with during the procedure | |
|  | 1. Contact details for person responsible for pharmacovigilance      1. Pharmacovigilance System Master File (PSMF) reference number | |
|  | Proposed product name | |
|  | Homoeopathic stock(s) | Please state dilution of each stock |
|  |  |
|  | Pharmaceutical form | 1. Route of administration |
|  | Target species | |
|  | Proposed route of sale and supply | |

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|  | Justification of homeopathic nature on the basis of adequate bibliography | | | | | | | | | | |
|  | Specification of stocks  Stock Name | | Specification | | | | | Dilution | | | Unit |
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|  | Other constituents Quantity/Dose | | | | | | | | | | |
| 11a | Diluent specification | | | | Modifier | | % quantity | | | Unit | |
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|  | | | |  | |  | | |  | |
| 11b | Pharmaceutical base ingredient | | | | | | | | | | |
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| 12 | Method of Manufacture (brief description) | | | | | | | | | | |
| 1. 131 | Finished product specification | | | | | | | | | | |
|  | Proposed withdrawal period and justification (if applicable) | | | | | | | | | | |
|  | Special warnings if necessary | | | | | | | | | | |
|  | Storage conditions | | | | | | | | | | |
|  | Nature of container and closure | | | | | | | | | | |
| Container | Shelf-life unopened | | | | Shelf-life opened | | | Pack size (unit) | | |
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|  | Name(s) of manufacturers and site(s) of manufacture of (a) the stock(s) and (b) the pharmaceutical base and (c) the finished product. Include LOC ID all sites. | | | | | | | | | | |
|  | 1. The stock | | | c) The finished product | | | | | | | |
|  | 1. The pharmaceutical base | | | | | | | | | | |
|  | Assembler(s) | | | Importer | | | | | | | |
|  | Distributor (where applicable) | | | Address of storage premises | | | | | | | |
|  | 1. Site and arrangements for batch release | | | | | | | | | | |
|  | 1. Site and arrangements for quality control (if different) | | | | | | | | | | |
|  | Fee Category  New application  Transfer  Variation  All stocks already approved  Formulation already approved | | | | | | | | | | |
|  | Master Files or Homoeopathic Registrations to which cross reference is made | | | | | | | | | | |
|  | Member States in which the product is registered or registration is pending  AT  BE  BG  CY  CZ  DE  DK  EE  EL  ES  FI  FR  HU  IS  IT  LI  LT  LU  LV  MT  NL  NO  PL  PT  RO  SE  SI  SK  UK (NI) | | | | | | | | | | |
|  | I/We apply for the grant of a Registration Certificate to the proposed holder named above in respect of the product(s) to which the product particulars above refer and in accordance with the other particulars annexed as may have been subsequently amended and authenticated by me/us, the said certificate to be subject to the following provisions:   * The product shall be sold or supplied in accordance with the said product particulars except in so far as may from time to time be approved by the Health Products Regulatory Authority. * The specification of the constituents and of the finished product shall be in accordance with the information contained in or furnished in connection with the application. * The product is to be manufactured only in accordance with the methods set out in this application or furnished in connection with the application. * No material information has been omitted.   Signed: Date:  State capacity in which signed: | | | | | | | | | | |

HOW TO COMPLETE THE APPLICATION FORM

Please complete a separate application form for each series of dilutions and for each pharmaceutical form for which you seek registration. (For example, a series of dilutions prepared as Arnica tablets 6x, 6c, 30c and 200c may be covered in a single application form. A second form would be required for Arnica drops 6c and 30c.)

For combination products, please complete a separate form for each formulation.

Provisional registration number Assigned by the HPRA: See Guide to Registration of Homeopathic Veterinary Medicinal Products.

Non-proprietary name Use the correct pharmacopoeial name of the homeopathic stock, the type of dosage form and the dilution.

Route of administration E.g. oral, topical, ophthalmic.

Method of sale and supply Give details, e.g. as companion animal medicine, via licensed merchant, via pharmacy only, or on veterinary prescription (refer to the relevant national legislation).

Stock name and specification Describe the stock using the correct scientific name, e.g. Q index. The specification should be that of a relevant pharmacopoeia, or where no monograph exists, an in-house specification. Please use the following abbreviations:

Ph. Eur. – European Pharmacopoeia,

GHP – German Homeopathic Pharmacopoeia;

HPUS – United States Homeopathic Pharmacopoeia.

Dilution State the degree of dilution, e.g. 6, 30, etc.

Unit State the scale of potency, i.e. X for decimal, C for centesimal.

Diluent State the name and specification of diluents used to dilute the stock (e.g. Ethanol BP or Lactose Ph.Eur.). The quantity should be listed as ‘qs’ in the modifier column.

Pharmaceutical base ingredient List all excipients present in the final pharmaceutical form; include the specification and quantity per unit dose for tablets or % quantity for liquids, creams etc.

Method of manufacture This refers to the final dosage form. A brief description is required and should include the method of dilution used. Reference to a pharmacopoeia alone is not acceptable.

Special warnings if necessary For some dosage forms a special warning regarding use may be required.

Storage conditions Precise details should be given, e.g. ‘Do not store above 25oC’. Terms such as ‘Room Temperature’ or ‘In a cool place’ are not acceptable.

Nature of container and closure A brief description of the container and closure should be given, e.g. ‘amber glass tablet bottle, with polypropylene screw on cap’.

Shelf life unopened container The shelf life of the unopened container should be expressed in months (M) or years (Y).

Shelf life after opening for the first time Shelf life after opening may be in months or weeks.

Pack size The pack size should contain numbers of units only, right aligned. If a decimal place is required it should occupy only one box.

Unit Where applicable enter the unit of measure, e.g. as mg, or ml. in the Unit box. No entry is required in the unit box for solid dosage forms.

Name(s) and site(s) of manufacture All relevant sections to be completed. If the manufacturer of the stock and base (e.g. lactose tablets) differs from that of the final dosage form, please give details of both.

Site and arrangements for quality control Name the site and organisation responsible for quality control of the finished product.

LOC IDs All sites of manufacture, distribution, etc., must be registered in the EMA's Organisation Management Service (OMS) as part of SPOR data management services. If your organisation is not already registered does you need to register it. Further information is available at <https://iris.ema.europa.eu/locations/>.