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| |  |  |  | | --- | --- | --- | |  |  | **Veterinary Medicines Directorate**  Woodham Lane, New Haw  Addlestone, Surrey  KT15 3LS  United Kingdom  Tel: +44 (0)1932 336911  Fax: +44 (0)1932 336618  Search for VMD on GOV.UK |   **APPLICATION FOR THE RENEWAL OF A**  **VETERINARY HOMEOPATHIC REMEDY REGISTRATION**  **An incomplete application form may delay the application process.**  **If submitting in hard-copy, please use block capitals.**    **Further guidance about this application type is available in Veterinary Medicines Guidance Note (VMGN) No. 7 entitled ‘Guidance on the Homeopathic Registration Scheme’.**  **SECTION 1 – ADMINISTRATIVE DETAILS** |

**1. Product Name:**

**2. Vh No.**

**3.** **Name and Address of Registration Holder:**

Company Name:

Address:

**4.** **Contact Details for this Application:**

Name:

Email Address:

**5.** **Invoice Details:** Email address of where the invoice should be sent to.

Email Address:

**6.** **e-Issuing Details:** Email address of where the registration documentation should be sent to (if different from 4 above).

Email Address:

**SECTION 2 – REGISTRATION DATES**

**7.** Please state the date the registration was first approved / issued:

**8.** Please state the date the registration is due for renewal:

**SECTION 3 – ADDITIONAL INFORMATION**

**9.** Applicants should confirm below that they have read and complied with the requirements set out in Annex 1. If not, applicants should provide justification for any missing data or non-compliance as without this the application will not be validated.

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| |  | | --- | |  |   **SECTION 4 – DECLARATION** |  |  |

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| I apply for the application as described above. I confirm that the information given in support of this application is correct at the time of submission. | | | | |
| Signature |  | Job Title |  |  |
|  |  | |  | |
| Name in BLOCK LETTERS |  | Date |  |  |
| **If any information provided in this application is later found to be false or incorrect, the Secretary of State may suspend or revoke the authorisation.** | | | | |

**ANNEX 1**

Before completing the renewal application form please check your registration documents to ensure that the VMD has been informed of all changes in particulars relating to this product.

Please send one copy of your renewal application form and the following information to the VMD at least six month prior to the date of renewal.

**Administrative requirements**

* Anapplication form
* Colour mock-ups of the current labels and package leaflet (if applicable); *these must be submitted electronically. Failure to do so will result in your application being deferred at validation.*
* Any data that has been requested as a condition on a previous application, e.g. variation.
* Any other data that is necessary to bring the Veterinary Homeopathic Registration in line with Directive 2001/82/EC as amended.
* Details of all variationsapplied for in the last five years including:
* The date of application.
* The nature of the application.
* The date of approval or refusal.
* Confirmation that no other applications are currently underway on this product:

Changes to a registration cannot be made during the renewal process; in order to ensure a registration is as up-to-date as possible; any changes to the registration must be made by way of a variation(s), which must be submitted and approved prior to the submission of the renewal application. Therefore, it is the applicant’s responsibility to ensure that this is done in time for the renewal to be submitted and approved before the registration ceases to be valid.

If any changes are identified during the renewal procedure, the renewal may be granted subject to a condition(s), i.e. the applicant may be asked to submit a variation following the conclusion of the renewal procedure in order to change the registration accordingly, which may be charged for and processed as per normal procedures.

Please note that a renewal application will not be accepted while the registration is subject to on-going variation procedures (including Type IA procedures), and variation applications will not be accepted while the registration is subject to a current renewal procedure.

**Pharmacovigilance requirements**

* A Periodic Safety Update Report. For further information about what is required, please see Section 6 of Part I of [Volume 9b](http://ec.europa.eu/health/files/eudralex/vol-9/vol_9b_2011-10.pdf) or contact Reena Agrawal on 01932 338430, or via email at: [r.agrawal@vmd.defra.gsi.gov.uk](mailto:r.agrawal@vmd.defra.gsi.gov.uk) . Reena works in the Pharmacovigilance team at the VMD.

**Quality requirements**

* The applicant should provide a declaration stating that all aspects of the manufacture and control of the remedy remain unchanged.
* A list of sites should be provided, covering all suppliers and manufacturing, assembly, control and release sites.
* For the suppliers of the homeopathic materials, a declaration should be provided by the manufacturer of the remedy that confirms that the suppliers of the homeopathic materials operate in accordance with the requirements of GMP for starting materials.
* For the sites of manufacturer, assembly, control and release of the remedy, manufacturing authorisations and GMP certificates should be provided.
* A declaration of the current TSE status with updated EDQM certificates of suitability, if appropriate (compliance with the actual version of the TSE guideline). See <http://www.vmd.gov.uk/General/AppsPage/format.pdf> and <http://www.vmd.gov.uk/General/AppsPage/notes.pdf>

**Safety Requirements**

The safety of the remedy for people handling/administering the homeopathic remedy should be reviewed talking into account any relevant information that has come to light in the reporting period, e.g. appropriate and sufficient warnings on the product literature in relation to any human adverse reactions.