Application for a Registration Certificate for a Homeopathic Medicinal Product

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

*For guidance on completing this form, please see notes at the end of the form.*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Registration number(s) allocated by the HPRA HoR: /// | | | | |
|  | Full name, address and telephone number of the proposed registration certificate holder | | | | |
|  | Product name | | | | |
|  | Homoeopathic stock(s) | Please state dilution of each stock | | | |
|  |  |  | | | |
|  |  |  | | | |
|  |  |  | | | |
|  |  |  | | | |
|  |  |  | | | |
|  |  |  | | | |
|  |  |  | | | |
|  |  |  | | | |
|  | Pharmaceutical form | 1. Route of Administration | | | |
| 7a | Legal Status | | | | |
| 7b | Method of Sale and Supply | | | | |
|  | Specification of Stocks  Stock Name | | Specification | Dilution | Unit |
|  |  | |  |  |  |
|  |  | |  |  |  |
|  |  | |  |  |  |
|  |  | |  |  |  |
|  |  | |  |  |  |
|  |  | |  |  |  |
|  |  | |  |  |  |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Other constituents  Quantity/Dose | | | | | | | | |
| 9a | Diluent | | Specification | | | Modifier | % quantity | | Unit |
|  |  | |  | | |  |  | |  |
|  |  | |  | | |  |  | |  |
| 9b | Pharmaceutical Base Ingredient | |  | | |  |  | |  |
|  |  | |  | | |  |  | |  |
|  |  | |  | | |  |  | |  |
|  |  | |  | | |  |  | |  |
|  |  | |  | | |  |  | |  |
|  |  | |  | | |  |  | |  |
|  |  | |  | | |  |  | |  |
|  | Method of Manufacture (Brief Description): | | | | | | | | |
|  | Finished Product Specification | | | | | | | | |
|  | Special Warnings if necessary | | | | | | | | |
|  | Storage Conditions | | | | | | | | |
|  | Nature of container and closure | | | | | | | | |
|  | Container | Shelf-life unopened | | | Shelf-life opened | | | Pack size (unit) | |
|  |  |  | | |  | | |  | |
|  |  |  | | |  | | |  | |
|  |  |  | | |  | | |  | |
|  |  |  | | |  | | |  | |
|  |  |  | | |  | | |  | |
|  | Name(s) of manufacturers and site(s) of manufacture of (a) the stock(s) and (b) the pharmaceutical base and (c) the finished product. | | | | | | | | |
|  | 1. The stock | | | c) The finished product | | | | | |
|  | 1. The pharmaceutical base | | | | | | | | |

|  |  |  |
| --- | --- | --- |
|  | Assembler(s): | 1. Importer: |
|  | Distributor (where applicable): | 1. 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  Renewal  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 CY CZ DE DK EE EL ES FI FR HU IS  IT  LI LT LU LV NL NO PL PT SE SI SK UK | |
|  | **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 for a period of five years and 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 the Registration of Homeopathic 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. through pharmacies only, through pharmacies on foot of a medical prescription, through non-pharmacy outlets or through practitioners only.

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, a 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 months (M) or weeks (W).

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.