

**APPLICATION FOR RENEWAL OF A
MARKETING AUTHORISATION/SIMPLIFIED REGISTRATION
HOMEOPATHIC MEDICINAL PRODUCT**

SEPTEMBER 2011

This application form is recommended to be used for an application for a renewal of a marketing authorisation/registration of a homeopathic medicinal product of human or veterinary use submitted under either a national, mutual recognition procedure or decentralised procedure, if no national specific provisions are in force,

HUMAN <input type="checkbox"/>	VETERINARY <input type="checkbox"/>
MRP/DCP procedure number ¹ : __/__/____/____/____/____	
NATIONAL AUTHORISATION ONLY	<input type="checkbox"/>
NATIONAL REGISTRATION IN MRP/DCP	<input type="checkbox"/>
NATIONAL REGISTRATION ONLY	<input type="checkbox"/>
Reference Member State:	
<input type="checkbox"/> AT <input type="checkbox"/> BE <input type="checkbox"/> BG <input type="checkbox"/> CY <input type="checkbox"/> CZ <input type="checkbox"/> DE <input type="checkbox"/> DK <input type="checkbox"/> EE <input type="checkbox"/> EL <input type="checkbox"/> ES <input type="checkbox"/> FI <input type="checkbox"/> FR <input type="checkbox"/> HU <input type="checkbox"/> IE <input type="checkbox"/> IS <input type="checkbox"/> IT <input type="checkbox"/> LI <input type="checkbox"/> LT <input type="checkbox"/> LU <input type="checkbox"/> LV <input type="checkbox"/> MT <input type="checkbox"/> NL <input type="checkbox"/> NO <input type="checkbox"/> PL <input type="checkbox"/> PT <input type="checkbox"/> RO <input type="checkbox"/> SE <input type="checkbox"/> SI <input type="checkbox"/> SK <input type="checkbox"/> UK	
Concerned Member States:	
<input type="checkbox"/> AT <input type="checkbox"/> BE <input type="checkbox"/> BG <input type="checkbox"/> CY <input type="checkbox"/> CZ <input type="checkbox"/> DE <input type="checkbox"/> DK <input type="checkbox"/> EE <input type="checkbox"/> EL <input type="checkbox"/> ES <input type="checkbox"/> FI <input type="checkbox"/> FR <input type="checkbox"/> HU <input type="checkbox"/> IE <input type="checkbox"/> IS <input type="checkbox"/> IT <input type="checkbox"/> LI <input type="checkbox"/> LT <input type="checkbox"/> LU <input type="checkbox"/> LV <input type="checkbox"/> MT <input type="checkbox"/> NL <input type="checkbox"/> NO <input type="checkbox"/> PL <input type="checkbox"/> PT <input type="checkbox"/> RO <input type="checkbox"/> SE <input type="checkbox"/> SI <input type="checkbox"/> SK <input type="checkbox"/> UK <input type="checkbox"/> NONE	
Is the product currently marketed? Yes <input type="checkbox"/> No <input type="checkbox"/>	
If yes, in which Member States?	
<input type="checkbox"/> AT <input type="checkbox"/> BE <input type="checkbox"/> BG <input type="checkbox"/> CY <input type="checkbox"/> CZ <input type="checkbox"/> DE <input type="checkbox"/> DK <input type="checkbox"/> EE <input type="checkbox"/> EL <input type="checkbox"/> ES <input type="checkbox"/> FI <input type="checkbox"/> FR <input type="checkbox"/> HU <input type="checkbox"/> IE <input type="checkbox"/> IS <input type="checkbox"/> IT <input type="checkbox"/> LI <input type="checkbox"/> LT <input type="checkbox"/> LU <input type="checkbox"/> LV <input type="checkbox"/> MT <input type="checkbox"/> NL <input type="checkbox"/> NO <input type="checkbox"/> PL <input type="checkbox"/> PT <input type="checkbox"/> RO <input type="checkbox"/> SE <input type="checkbox"/> SI <input type="checkbox"/> SK <input type="checkbox"/> UK	

Name of the Homeopathic Medicinal Product: Homeopathic Stock(s) and potencies ³ : Pharmaceutical form(s): Route(s) of administration : Target species ⁴ : MA/Registration number(s) :	Name and address of MA/registration holder: Name and address of Contact ² : Telephone number: Fax number: E-mail: Applicant's reference:
--	--

Date of national authorisation/registration:	Date of expiry of national authorisation/registration:
Date of first registration in Reference Member State:	Date of first registration in the Concerned Member State to which this application is made:
Date of expiry of current registration in Reference Member State:	Date of expiry of current registration in the Concerned Member State:
Proposed Common Renewal Date:	

APPROVED MANUFACTURERS

Authorised manufacturer(s) (or importer) responsible for **batch release** in the EEA (in accordance with Articles 40 and 51 of Directive 2001/83/EC, as amended, or Articles 44 and 55 of Directive 2001/82/EC (as shown in the package leaflet and where applicable in the labelling or Annex II of the Decision)

Company Name:
Address:
Country:
Telephone:
Telefax:
E-mail:

Further manufacturers responsible for batch release can be detailed in the text field below, in the same format as shown above.

Site(s) in EEA or in countries where an MRA or other Community arrangements apply, where **batch control/testing** takes place, as required by Article 51 of Directive 2001/83/EC as amended or Article 55 of Directive 2001/82/EC, if different from above:

Company Name:
Address:
Country:
Telephone:
Telefax:
E-mail:

Further sites can be detailed in the text field below, in the same format as shown above.

Manufacturer(s) of the homeopathic medicinal product and site(s) of manufacture (including diluent and solvent manufacturing sites):

Company Name:
Address:
Country:
Telephone:
Telefax:
E-mail:

Brief description of functions performed by manufacturer of dosage form/assembler, etc:

Further manufacturers can be detailed in the text field below, in the same format as shown above.

Manufacturer(s) of the dilutions and site(s) of manufacture:

(Note: If different from the manufacturer of the finished homeopathic medicinal product.):

Name:

Company name:

Address:

Country:

Telephone:

Telefax:

E-Mail:

Brief description of functions performed by manufacturer of dosage form/assembler, etc.:

Manufacturer(s) of the homeopathic stock(s)

Note: only the final manufacturer(s) to be mentioned

Substance:

Company Name:

Address:

Country:

Telephone:

Telefax:

E-mail:

Source/Manufacturer(s) of the raw material(s):

Raw material:

Name:

Address:

Country:

Telephone:

Telefax:

E-Mail:

QUALITATIVE AND QUANTITATIVE COMPOSITION IN TERMS OF THE HOMEOPATHIC ACTIVE SUBSTANCE(S) AND THE EXCIPIENT(S)

A note should be given as to which quantity the composition refers (e.g. 1 tablet).

List the active homeopathic substance(s) separately from the excipients

Name of active homeopathic substance*(s)	Quantity	Unit	Reference/Monograph standard
--	----------	------	------------------------------

Name of excipient**(s)	Quantity	Unit	Reference/Monograph standard
------------------------	----------	------	------------------------------

PRESENT PRODUCT INFORMATION TEXT	PROPOSED PRODUCT INFORMATION TEXT

DOCUMENTS APPENDED TO THIS APPLICATION	
Note:	
<ul style="list-style-type: none"> • <i>In case of a human authorisation, delete the complete list of veterinary documents.</i> 	
<ul style="list-style-type: none"> • <i>In case of a veterinary authorisation, delete the complete list of human documents.</i> 	
FOR HUMAN MEDICINAL PRODUCTS ONLY	
Module 1:	
<input type="checkbox"/> 1.0	Cover Letter
<input type="checkbox"/> 1.1	Comprehensive table of content
<input type="checkbox"/> 1.2	Renewal Application Form with the following annexes:
<input type="checkbox"/>	A list of all authorised product presentations for which renewal is sought in tabular format
	Details on contact persons:
<input type="checkbox"/>	<ul style="list-style-type: none"> • Qualified person in the EEA for Pharmacovigilance (only for authorized HoMP)
<input type="checkbox"/>	<ul style="list-style-type: none"> • Contact person in the EEA with overall responsibility for product defects and recalls
<input type="checkbox"/>	<ul style="list-style-type: none"> • Contact person for scientific service in the EEA in charge of information about the medicinal product
<input type="checkbox"/>	List of EU Member States / Norway / Iceland where the product is on the market and indicating for each country which presentations are marketed and the launch date
<input type="checkbox"/>	Chronological list of all post-authorisation submissions since grant of the Marketing authorisation/Registration or last renewal: a list of all approved or pending Type IA/IB and Type II variations, Extensions, Art 61(3) Notifications, USR, giving the procedure number (where applicable), date of submission, date of approval (if approved) and brief description of the change
<input type="checkbox"/>	Chronological list of Follow-up measures, submitted since grant of marketing authorization/registration or last renewal - where applicable
<input type="checkbox"/>	Revised list of all remaining Follow-up measures/post-authorisation commitments
<input type="checkbox"/>	A statement, or when available, a certificate of GMP compliance, not more than three years old, for the manufacturer(s) of the medicinal product listed in the application issued by an EEA competent authority or MRA partner authority. A reference to the Community EudraGMP database will suffice, once this is available - where applicable
<input type="checkbox"/>	For manufacturing sites of the medicinal product not located in the EEA or in the territory of an MRA partner, a list of the most recent GMP inspections carried out by other authorities indicating the date, inspection team and outcome

<input type="checkbox"/>	A declaration by the Qualified Person (QP) of each of the manufacturing authorisation holders (i.e. located in the EEA) listed in the application form where the active substance(s) is used as a starting material, that the active substance(s) is manufactured in accordance with the guidelines on good manufacturing practice for starting materials as adopted by the Community ⁵
<input type="checkbox"/>	Where different, a declaration by the Qualified Person (QP) of the manufacturing authorisation holder(s) listed in the application form as responsible for batch release, that the active substance(s) is manufactured in accordance with the guidelines on good manufacturing practice for starting materials as adopted by the Community ⁵
<input type="checkbox"/> 1.3.1	SPC, Labelling and Package Leaflet
<input type="checkbox"/> 1.4	Information about the expert
<input type="checkbox"/> 1.4.1	Quality (incl. Signature + CV)
<input type="checkbox"/> 1.4.2	Non-clinical (incl. Signature + CV) – if applicable
<input type="checkbox"/> 1.4.3	Clinical (incl. Signature + CV)
Module 2	
<input type="checkbox"/> 2.3	Quality Overall Summary (Quality Expert Statement)
<input type="checkbox"/> 2.4	Non-clinical Overview (Non-clinical Expert Statement) – if applicable
<input type="checkbox"/> 2.5	Clinical Overview (Clinical Expert Statement) – where applicable
Module 5:	
<input type="checkbox"/> 5.3.6	Reports of Post-marketing experience (Periodic Safety Update Report and Summary Bridging Report if applicable) – where applicable

FOR VETERINARY MEDICINAL PRODUCTS ONLY	
<input type="checkbox"/> 1.0	Cover Letter
<input type="checkbox"/> 1.1	Comprehensive table of content
<input type="checkbox"/> 2	Renewal Application Form with the following annexes:
<input type="checkbox"/> 2.1	List of all authorised product presentations for which renewal is sought in tabular format
<input type="checkbox"/> 2.2	Details on contact persons:
<input type="checkbox"/>	<ul style="list-style-type: none"> • Qualified person in the EEA for Pharmacovigilance and the QP for Pharmacovigilance in the MS, if different
<input type="checkbox"/>	<ul style="list-style-type: none"> • Contact person in the EEA with overall responsibility for product defects and recalls
<input type="checkbox"/>	<ul style="list-style-type: none"> • Contact person at the address of the Marketing Authorisation Holder (if different from the address of the contact person during the procedure)
<input type="checkbox"/> 2.3	List of EU Member States / Norway / Iceland where the product is on the market and indicating for each country which presentations are marketed and the launch date
<input type="checkbox"/> 2.4	Chronological list of all post authorisation submissions (variations, extensions etc.), follow-up measures and, for Community Authorisations only, any Specific Obligations submitted since grant of marketing authorisation or last renewal indicating scope, status, date of submission and date when issue has been resolved
<input type="checkbox"/> 2.5	Revised list of all remaining Follow-up measures and, for Community Authorisations only, any Specific Obligations and signed letter of commitment (where applicable)
<input type="checkbox"/> 2.6	Proof of payment of fee, where relevant
<input type="checkbox"/> 2.7	A statement, or when available, a certificate of GMP compliance, not more than three years old, for the manufacturer(s) of the medicinal product listed in the application issued by an EEA competent authority or MRA partner authority.

<input type="checkbox"/> 2.8	In addition, for manufacturing sites of the medicinal product not located in the EEA or in the territory of an MRA partner, a list of the most recent GMP inspections carried out by other authorities indicating the date, inspection team and outcome.
<input type="checkbox"/> 2.9	A declaration by the Qualified Person (QP) of each of the manufacturing authorisation holders (i.e. located in the EEA) listed in the application form where the active substance(s) is used as a starting material, that the active substance(s) is manufactured in accordance with the guidelines on good manufacturing practice for starting materials as adopted by the Community ⁶
<input type="checkbox"/> 2.10	Where different, a declaration by the Qualified Person (QP) of the manufacturing authorisation holder(s) listed in the application form as responsible for batch release, that the active substance(s) is manufactured in accordance with the guidelines on good manufacturing practice for starting materials as adopted by the Community ⁶
<input type="checkbox"/> 3	SPC, Labelling and Package Leaflet
<input type="checkbox"/> 4	Quality expert statement, including:
<input type="checkbox"/> 4.1	Currently authorised specifications for the active substance and the finished product
<input type="checkbox"/> 4.2	Qualitative and quantitative composition in terms of the active substance(s) and the excipient(s)
<input type="checkbox"/> 5	Clinical expert statement
<input type="checkbox"/> 6	Safety expert statement
<input type="checkbox"/> 7	Periodic Safety Update Report and Summary Bridging Report if applicable
<input type="checkbox"/> 8	Declaration of current TSE status

I hereby make application for the above Marketing Authorisation/Registration to be renewed. I declare that the quality of the product, in respect of the methods of preparation and control, has been regularly updated by variation procedure to take account of technical and scientific progress in accordance with Article 23 of Directive 2001/83/EC or Article 27 (1) of Directive 2001/82/EC or Article 16 of Regulation (EC) No 726/2004. The product conforms with current CHMP/CVMP quality guidelines where relevant. I confirm that no changes have been made to the product particulars other than those approved by the Competent Authority.

Fees paid or will be paid, if applicable Amount/Currency:

Main Signatory _____ Status (Job title) _____

Print name _____ Date _____

Second Signatory _____ Status (Job title) _____
(where appropriate)

Print name _____ Date _____

¹ **Human Medicinal Products:** Number to be completed by the Marketing Authorisation Holder, reflecting the correct sequential Mutual Recognition Procedure Number according to Volume 2A, Chapter 2, 7. Numbering System for the Procedures for Mutual Recognition as published on the Website of the European Commission (<http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/homev2.htm>)
Veterinary Medicinal Products: Renewal number to be issued by the Reference Member State before submission of the application according to the corresponding CMD(v) Best Practice Guide (<http://www.hma.eu>)

² As specified in section 2.4.3 in Part 1A. If different, attach letter of authorisation

³ If more than one potency please specify

⁴ Only for veterinary homeopathic medicinal products

⁵ Note: Where more than one Qualified Person (QP) is involved, a single declaration by one of the QPs that the active substance(s) used as a starting material are manufactured in accordance with the guidelines on good manufacturing practice for starting materials as adopted by the Community, may be submitted provided that:

- The declaration makes it clear that it is signed on behalf of all the involved QPs.
- The arrangements are underpinned by a technical agreement as described in Chapter 7 of the GMP Guide and the QP providing the declaration is the one identified in the agreement as taking specific responsibility for the GMP compliance of the active substance manufacturer(s).

⁶ Note: Where more than one Qualified Person (QP) is involved, a single declaration by one of the QPs that the active substance(s) used as a starting material are manufactured in accordance with the guidelines on good manufacturing practice for starting materials as adopted by the Community, may be submitted provided that:

- The declaration makes it clear that it is signed on behalf of all the involved QPs.
- The arrangements are underpinned by a technical agreement as described in Chapter 7 of the GMP Guide and the QP providing the declaration is the one identified in the agreement as taking specific responsibility for the GMP compliance of the active substance manufacturer(s).

** the following order of priority should be used: Scientific Latin name of the Ph. Eur. or of National Pharmacopoeia, or , in absence of a monograph, a scientific Latin name (botanical scientific name...) followed by the homeopathic name*

*** Only one name of each substance should be given in the following order of priority: INN, Ph. Eur., National Pharmacopoeia, Common name, Scientific name.*

(If revised product information (SPC, Labelling and/or Package Leaflet) is proposed to take account of issues raised by the expert, specify the precise present and proposed wording, underlining or highlighting the changed words. Alternatively, such listing may be provided as a separate document attached to the application form).