APPLICATION FORM FOR RENEWAL OF A MARKETING AUTHORISATION

HUMAN ☐ **VETERINARY** ☐

NATIONAL AUTHORISATION IN MRP/DCP ☐ **MRP/DCP procedure number[1]: __/_/____/___/__/__**

EU AUTHORISATION ☐

NATIONAL AUTHORISATION ONLY ☐

Reference Member State:

☐AT ☐BE ☐BG ☐CY ☐CZ ☐DE ☐DK ☐EE ☐EL ☐ES ☐FI ☐FR ☐HR
☐HU ☐IE ☐IS ☐IT ☐LI ☐LT ☐LU ☐LV ☐MT ☐NL ☐NO ☐PL ☐PT
☐RO ☐SE ☐SI ☐SK ☐UK

Concerned Member States:

☐AT ☐BE ☐BG ☐CY ☐CZ ☐DE ☐DK ☐EE ☐EL ☐ES ☐FI ☐FR ☐HR
☐HU ☐IE ☐IS ☐IT ☐LI ☐LT ☐LU ☐LV ☐MT ☐NL ☐NO ☐PL ☐PT
☐RO ☐SE ☐SI ☐SK ☐UK ☐NONE

Is the product currently marketed? Yes ☐ No ☐ If yes, in which Member States[2]?

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☐RO ☐SE ☐SI ☐SK ☐UK

(Invented)Name: Active substance(s): Pharmacotherapeutic classification (Group + ATC code): Pharmaceutical form(s) and strength(s)[3]: Route(s) of administration[3] : Target species[3]: MA number(s) [3]:	Name and address of MA holder: Name and address of Contact[4]: Telephone number: Fax number: E-mail: Applicant's reference:

Date of first authorisation in Reference Member State/EU: Date of expiry of current authorisation in Reference Member State/EU:	Date of first authorisation in the Concerned Member State to which this application is made: Date of expiry of current authorisation in the Concerned Member State:

[1] Human Medicinal Products: Number to be completed by the Marketing Authorisation Holder, reflecting the correct sequential MRP/DCP Number according to Volume 2A, Chapter 2, 7. Numbering System for the Procedures for Mutual Recognition and Decentralised Procedure as published on the Website of the European Commission (http://ec.europa.eu/health/documents/eudralex/vol-2/index_en.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] For centrally authorised products a list of EU Member States / Norway / Iceland where the product is on the market should be provided in a separate appendix

[3] For centrally authorised products this information, including packaging and pack size(s), should be provided in tabular format in a separate appendix (cf. Annex A to CHMP/CVMP Opinion)

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

	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.

For blood products and vaccines:
State laboratory or laboratory designated for official **batch release**, as accordance with Articles 111(1), 113, 114 (1)-(2) and 115 of Directive 2001/83/EC as amended.

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 EU 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 **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 **active substance(s)**
Note: All manufacturing sites involved in the manufacturing process of each source of active substance should be listed. Broker or supplier details alone are not sufficient

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

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

QUALITATIVE AND QUANTITATIVE COMPOSITION IN TERMS OF THE ACTIVE SUBSTANCE(S) AND THE EXCIPIENT(S)
(For centrally authorised products the composition should be provided separately in tabular format as part of the Quality Expert Statement.)

A note should be given as to which quantity the composition refers (e.g. 1 capsule).
List the active substance(s) separately from the excipients

Name of active substance*(s)	Quantity	Unit	Monograph standard
Name of excipient*(s)	Quantity	Unit	Monograph standard

**Only one name should be given, in the following order of priority: INN, Ph. Eur., National Pharmacopoeia, common name, scientific name. The active substance should be declared by its recommended INN, accompanied by its salt or hydrate form if relevant.*

Details of any overages should **not** be included in the formulation but stated below:
- active substance(s)
- excipient(s)

(If revised product information (SmPC, 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).

PRESENT **PRODUCT INFORMATION** TEXT	PROPOSED **PRODUCT INFORMATION** TEXT

DOCUMENTS APPENDED TO THIS APPLICATION

Note:

- *In case of a human authorisation, delete the complete list of veterinary documents.*
- *In case of a veterinary authorisation, delete the complete list of human documents.*

FOR HUMAN MEDICINAL PRODUCTS ONLY

Module 1:	
☐ 1.0	Cover Letter
☐ 1.1	Comprehensive table of content (not applicable for centrally authorised medicinal products)
☐ 1.2	Renewal Application Form with the following annexes:
☐	A list of all authorised product presentations for which renewal is sought in tabular format
	Details on contact persons:
☐	• Qualified person in the EEA for Pharmacovigilance
☐	• Contact person in the EEA with overall responsibility for product defects and recalls
☐	• Contact person for scientific service in the EEA in charge of information about the medicinal product
☐	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
☐	Chronological list of all post-authorisation submissions since grant of the Marketing authorisation or last renewal: a list of all approved or pending Type IA/IB and Type II variations, Extensions, Art 61(3) Notifications, USR and PSUR, giving the procedure number (where applicable), date of submission, date of approval (if approved) and brief description of the change.
☐	Chronological list of conditions and Specific Obligations (for centrally authorised products) submitted since grant of marketing authorisation or last renewal indicating scope, status, date of submission and date when issue has been resolved (where applicable)
☐	Revised list of all remaining conditions and any Specific Obligations (for centrally authorised products) (where applicable)
☐	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 EudraGMP database will suffice, once this is available
☐	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

☐	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 EU[5]
☐	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 EU
☐ 1.3.1	SmPC, Labelling and Package Leaflet
☐ 1.3.3	Specimen (for centrally authorised products only)
☐ 1.4	Information about the expert
☐ 1.4.1	Quality (incl. Signature + CV)
☐ 1.4.2	Non-clinical (incl. Signature + CV) – where applicable
☐ 1.4.3	Clinical (incl. Signature + CV)
☐ 1.8.1	Summary of Pharmacovigilance System (where applicable)
☐ 1.8.2	Risk Management Plan (where applicable)
Module 2	
☐ 2.3	Addendum to Quality Overall Summary
☐ 2.4	Addendum to Non-clinical Overview –(where applicable)
☐ 2.5	Addendum to Clinical Overview

[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 EU, 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).

FOR VETERINARY MEDICINAL PRODUCTS ONLY	
☐ 1.0	Cover Letter
☐ 1.1	Comprehensive table of content
☐ 2	Renewal Application Form with the following annexes:
☐ 2.1	List of all authorised product presentations for which renewal is sought in tabular format
☐ 2.2	Details on contact persons:
☐	• Qualified person in the EEA for Pharmacovigilance and the QP for Pharmacovigilance in the MS, if different
☐	• Contact person in the EEA with overall responsibility for product defects and recalls
☐	• Contact person at the address of the Marketing Authorisation Holder (if different from the address of the contact person during the procedure)
☐ 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
☐ 2.4	Chronological list of all post authorisation submissions (variations, extensions etc.), conditions and, any Specific Obligations (for centrally authorised products) submitted since grant of marketing authorisation or last renewal indicating scope, status, date of submission and date when issue has been resolved
☐ 2.5	Revised list of all remaining conditions and, any Specific Obligations (for centrally authorised products) (where applicable)
☐ 2.6	Proof of payment of fee, where relevant
☐ 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.
☐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.
☐ 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 EU[6]
☐ 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 EU [6]
☐ 3	SPC, Labelling and Package Leaflet

[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 EU, 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).

☐ 4	Quality expert statement (incl. Signature + CV), including:
☐ 4.1	Currently authorised specifications for the active substance and the finished product
☐ 4.2	Qualitative and quantitative composition in terms of the active substance(s) and the excipient(s)
☐ 5	Clinical expert statement (incl. Signature + CV)
☐ 6	Safety expert statement (incl. Signature + CV)
☐ 7	Periodic Safety Update Report and Summary Bridging Report if applicable
☐ 8	Declaration of current TSE status

I hereby make application for the above Marketing Authorisation 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 or Article 41(1) 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