EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Consumer goods
Pharmaceuticals

Brussels, October 2008
F2/KK D(2008)

Revision 7.2

NOTICE TO APPLICANTS

Medicinal products for Veterinary Use

VOLUME 6B
Presentation and content of the dossier-Part 1
Summary of the dossier Part 1A
Application form

OCTOBER 2008

This application form will be included in:

The Rules governing Veterinary medicinal products in the European Community

The Notice to Applicants - Volume 6B

Rue de la Loi 200, B-1049 Bruxelles/Wetstraat 200, B-1049 Brussel - Belgium - Office: BREY 10/073.
Telephone: direct line (+32-2)299.15.11, switchboard 299.11.11. Fax: (+32-2)299.80.46.
Karin.Krauss@ec.europa.eu

APPLICATION FORM

SUMMARY OF THE DOSSIER

●●●●●

APPLICATION FORM: ADMINISTRATIVE DATA

The application form is to be used for an application for a marketing authorisation of a medicinal product for veterinary use submitted to (a) the European Medicines Agency under the centralised procedure or (b) a Member State (as well as Iceland, Lichtenstein and Norway) under either a national, mutual recognition procedure or decentralised procedure.

Usually a separate application form for each strength and pharmaceutical form is required. For centralised procedures a combined application form is acceptable (information on each pharmaceutical form and strength should be provided successively, where appropriate).

DECLARATION and SIGNATURE

Product (invented) name:
Strength(s):
Pharmaceutical form:
Active Substance(s):
Applicant:
Person authorised for communication*, on behalf of the Applicant:

It is hereby confirmed that all existing data which are relevant to the quality, safety and efficacy of the veterinary medicinal product have been supplied in the dossier, as appropriate.
It is hereby confirmed that fees will be paid/have been paid according to the national/Community rules**.
On behalf of the applicant,

_____
Signature(s)

_____
NAME*

_____
Function

_____
Place date (yyyy-mm-dd)

* ☐ *Note: please attach letter of authorisation for communication/signing on behalf of the applicant in annex 5.4*
** ☐ *Note: if fees have been paid, attach proof of payment in Annex 5.1 - see information on fee payments in the Notice to Applicants, Volume 6A, Chapter 7.*

Table of contents

[1] As amended by Directive 2004/28/EC

1. TYPE OF APPLICATION

Note: The following sections should be completed where appropriate.

1.1. THIS APPLICATION CONCERNS:

☐ **1.1.1. A CENTRALISED PROCEDURE** (according to Regulation (EC) No 726/2004)

☐ « Mandatory scope » (Article 3(1))
- ❍ Annex (1) (Biotech veterinary medicinal product)
- ❍ Annex (2) (performance enhancers)

☐ « Optional scope » (Article 3(2))
- ❍ Article 3(2)(a) (new active substance)
- ❍ Article 3(2)(b) (significant innovation or interest of animal health at Community level)
- ❍ Article 3 - Immunological veterinary medicinal products for the treatment of animal diseases subject to Community prophylactic measures

Date of acceptance by CVMP:
(yyyy-mm-dd)

☐ « Generic of a centrally authorised veterinary medicinal product» (Article 3(3))

λ Rapporteur:
(Name of CVMP Member)

λ Co-rapporteur:
(Name of CVMP Member)

☐ **1.1.2. A MUTUAL RECOGNITION PROCEDURE** (according to Article 32(2) of Directive 2001/82/EC)

- Reference Member State:
- Date of authorisation: (yyyy-mm-dd):
- Marketing authorisation number:
  (a copy of the authorisation should be provided - see section 4.2)
- Procedure number:

☐ **First use**

- Concerned Member State(s) (specify):

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

Proposed Common Renewal Date:

If a waiver or amendment of PSUR-cycle is applied for, to harmonise with a substance birthdate, please specify:

☐ **Repeat Use 1st Wave** (please also complete section 4.2)

- Concerned Member State(s) (specify):
  For subsequent procedures copy the boxes above

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

Agreed Common Renewal Date:

☐ **1.1.3. A DECENTRALISED PROCEDURE** (according to Article 32(3) of Directive 2001/82/EC)

- Reference Member State:
- Procedure number:
- Concerned Member State(s) (specify):

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

If a waiver or amendment of PSUR-cycle is applied for, to harmonise with a substance birthdate, please specify:

☐ **1.1.4. A NATIONAL PROCEDURE**

- Member State:
- If available, application number:
- If a waiver or amendment of PSUR-cycle is applied for, to harmonise with a substance birthdate, please specify:

Date (yyyy-mm-dd):

1.2. IS THIS AN APPLICATION FOR A CHANGE TO YOUR EXISTING MARKETING AUTHORISATION LEADING TO AN EXTENSION AS REFERRED TO IN ANNEX II OF REGULATIONS (EC) NO 1084/2003 OR 1085/2003, OR ANY NATIONAL LEGISLATION , WHERE APPLICABLE ?

☐ **No** *(complete sections 1.3 and 1.4.)*

☐ **Yes** *(complete sections below and also complete section 1.4.)*

Please specify:

☐ Change of bioavailability
☐ Change of pharmacokinetics
☐ Change or addition of a new strength /potency
☐ Change or addition of a new pharmaceutical form
☐ Change or addition of a new route of administration
☐ Qualitative change in declared active substance not defined as a new active substance
Note: see definition in the Notice to Applicants, Volume 6A, Chapter 1.
❍ Replacement by a different salt/ester, complex/derivative (same therapeutic moiety)
❍ Replacement by a different isomer, mixture of isomers, of a mixture by an isolated isomer
❍ Replacement of a biological substance or product of biotechnology
❍ Other change(s), please specify:

☐ Change or addition of a food-producing target animal species

Note:
. the applicant of the present application must be the same as the marketing authorisation holder of the existing marketing authorisation
. section 1.3.1 (extension) or section 1.3.2 (not extension) should be completed without prejudice to the provisions of Articles 12, 13, 14 and 25 of Directive 2001/82/EC.

●**For existing marketing authorisation in the Community / Member State where the application is made:**

- Name of the marketing authorisation holder:
- Name, strength, pharmaceutical form of the existing product:
- Marketing authorisation number(s):

1.3. THIS APPLICATION IS SUBMITTED IN ACCORDANCE WITH THE FOLLOWING ARTICLE IN DIRECTIVE 2001/82/EC OR REGULATION (EC) No 726/2004

Note: . section to be completed for any application, including applications referred to in section 1.2
. for further details, consult the Notice to Applicants, Volume 6A, Chapter 1.

1.3.1 ☐ **Article 12(3) - application, (i.e. dossier with administrative, quality, safety and efficacy data*)**

☐ New active substance
Note: constituent of a product not yet authorised by a competent authority or by the Community (for centralised procedure)

☐ Known active substance

Note: . constituent of a product already authorised by a competent authority or the Community
. same or different marketing authorisation holder

** for extensions of complete applications, cross references can only be made to pre-efficacy and efficacy data*

1.3.2 ☐ **Article 13(1) - <u>Generic application</u>**

Note: . application for a generic veterinary medicinal product as defined in Article 13(2)(b) referring to a so-called reference veterinary medicinal product with a Marketing authorisation granted in a Member State or in the Community
. complete administrative and quality data, appropriate safety and efficacy data when applicable see Chapter 1 of the Notice to Applicants, Volume 6A

■ <u>Reference veterinary medicinal product</u> which is or has been authorised for not less than 6/10 years in the EEA:
- Product name, strength, pharmaceutical form:
- Marketing authorisation holder:
- First authorisation: Date (yyyy-mm-dd) Member State (EEA)/Community:

■ <u>Reference veterinary medicinal product</u> authorised in the Community/Member State where the application is made:
- Product name, strength, pharmaceutical form:
- Marketing authorisation holder:
- Marketing authorisation number(s):

■ <u>Veterinary medicinal product used for bioequivalence study (where applicable)</u>
- Product name, strength, pharmaceutical form:
- Marketing authorisation holder:
- Member State of source:

1.3.3 ☐ **<u>Article 13 (3)</u> - so called "hybrid application"**

Note: . application for a veterinary medicinal product referring to a so-called reference veterinary medicinal product with a Marketing Authorisation in a Member State or in the Community (e.g. different pharmaceutical form, different therapeutic use ...)
. complete administrative and quality data, appropriate safety and efficacy data refer to Notice to Applicants, Volume 6A, Chapter 1

■ <u>Reference veterinary medicinal product</u> which is or has been authorised for not less than 6/10 years in the EEA:
- Product name, strength, pharmaceutical form:
- Marketing authorisation holder:
- First authorisation: Date (yyyy-mm-dd): Member State (EEA)/Community:

■ <u>Reference veterinary medicinal product authorised</u> in the Community/Member State where the application is made:
- Product name, strength, pharmaceutical form:
- Marketing authorisation holder:
- Marketing authorisation number(s):

■ <u>Veterinary medicinal product used in bioequivalence studies, where applicable</u>
- Product name, strength, pharmaceutical form:
- Marketing authorisation holder:
- Member State of source:

■ Difference(s) compared to the reference veterinary medicinal product:

☐ Changes in the active substance(s)
☐ Change in therapeutic indications
☐ Change in pharmaceutical form
☐ Change in strength (quantitative change to the active substance(s))
☐ Change in route of administration
☐ Bioequivalence cannot be demonstrated through bioavailability studies

1.3.4 ☐ **Article 13(4) - Similar biological application**

Note: . application for a product referring to a reference biological product
. complete administrative and quality data , appropriate safety and efficacy data
refer to Notice to Applicants, Volume 6A, Chapter 1

■ Reference product which is or has been authorised for not less than 6/10 years in the EEA:

- Product name, strength, pharmaceutical form:
- Marketing authorisation holder:
- First authorisation: Date (yyyy-mm-dd): Member State (EEA)/Community:

■ Reference veterinary medicinal product authorised in the Community/Member State where the application is made:

- Product name, strength, pharmaceutical form:
- Marketing authorisation holder:
- Marketing authorisation number(s):

■ Veterinary medicinal product used in bioequivalence studies, where applicable

- Product name, strength, pharmaceutical form:
- Marketing authorisation holder:
- Member State of source:

1.3.5 ☐ **Article 13a – Well established veterinary use**

Note: . for further details, consult the Notice to Applicants, Volume 6A, Chapter 1
. for extensions of bibliographical applications, cross references can only be made to pre-efficacy and efficacy data

1.3.6 ☐ **Article 13b - Fixed combination:**

Note: . complete administrative and complete quality, pre-efficacy and efficacy data on the combination only
. for extensions of fixed combination applications, cross references can only be made to pre-efficacy and efficacy data

1.3.7 ☐ **Article 13c - Informed consent application**

Note: . application for a veterinary medicinal product possessing the same qualitative and quantitative composition in terms of active substances and the same pharmaceutical form of an authorised product where consent has been given by the existing marketing authorisation holder to use their data in support of this application
. complete administrative data should be provided with consent to pharmaceutical, pre-efficacy and efficacy data
. the authorised product and the informed consent application can have the same or different MAH

Authorised product in the Community / Member State where the application is made:

- Product name, strength, pharmaceutical form
- Marketing authorisation holder:
- Marketing authorisation number(s):

☐ Attach letter of consent from the marketing authorisation holder of the authorised product (Annex 5.2)

1.3.8 ☐ Article 13d – Immunological Veterinary Medicinal Product for which the results of certain trials are not being submitted

1.4 MRL status (only for food producing species)

When the veterinary medicinal product is intended for use in food-producing animals, please provide the following information as available at the time of submission of the application[1].

Maximum Residue Limits (MRL) according to Council Regulation (EEC) No 2377/90 has been published in the Official Journal of the European Communities:

Substance(s)	Annex	Species	Target tissue(s)	Remarks	OJ date of publication

Application for a Maximum Residue Limit has been made to the EMEA:

Substance(s)	Date of submission	Species	Remarks

[1] *All substances contained in the product are subject to this requirement if they are pharmacologically active in the dose in which they are administered to the animal. Excipients not included in any of the Annexes of Council Regulation (EEC) No 2377/90 should also be listed and an appropriate justification given.*

1.5 CONSIDERATION OF THIS APPLICATION IS ALSO REQUESTED UNDER THE FOLLOWING ARTICLE IN DIRECTIVE 2001/82/EC OR REGULATION (EC) NO 726/2004

1.5.1 ☐ Exceptional Circumstances

Note: Article 26(3) of Directive 2001/82/EC and Article 39(7) of Regulation (EC) 726/2004

1.5.2 ☐ Accelerated Review

Note: centralised procedure only according to Regulation (EC) No 726/2004 Article 39(8)
Date of acceptance by CVMP:

(yyyy-mm-dd)

1.5.3 ☐ Article 13(5) of Directive 2001/82/EC (one year of data exclusivity for an extension to another food-producing species within five years of the initial authorisation)

2. MARKETING AUTHORISATION APPLICATION PARTICULARS

2.1. Name(s) and ATC vet code

2.1.1 Proposed (invented) name of the veterinary medicinal product in the Community/ Member State/ /Iceland/Lichtenstein/ Norway:

☐ If different (invented) names in different Member States are proposed in a mutual recognition or decentralised procedure, these should be listed in Annex 5.18

2.1.2 Name of the active substance(s):

Note: 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 (for further details, consult the Guideline on the SPC)*

2.1.3 Pharmacotherapeutic group (Please use current ATC Vet code):

ATC Vet Code: **Group:**

Please indicate if the application for the ATC Vet Code is still pending: ☐

2.1.4 Target species:

2.2. Strength, pharmaceutical form, route of administration, container and pack sizes

2.2.1 Strength and Pharmaceutical form (use current list of standard terms - European Pharmacopoeia)

***Pharmaceutical form*:**

Active substance(s):

***Strength(s)*:**

2.2.2 Route*(s)* of administration (use current list of standard terms - European Pharmacopoeia)

2.2.3 Container, closure and administration device(s), including description of material from which it is constructed. (use current list of standard terms - European Pharmacopoeia)

For each type of pack give:

2.2.3.1 Package size(s):
Note: for mutual recognition and decentralised procedures, all package sizes authorised in the Reference MemberState should be listed

2.2.3.2 Proposed shelf life:

2.2.3.3 Proposed shelf life (after first opening container):

2.2.3.4 Proposed shelf life (after reconstitution or dilution):

2.2.3.5 Proposed storage conditions:

2.2.3.6 Proposed storage conditions after first opening:

☐ Attach list of Mock-ups or Samples/specimens sent with the application, as appropriate (see Notice to Applicants, Volume 6A, Chapter 7) (Annex 5.17).

2.3 Legal status

2.3.1 Proposed administration:

☐ only by a veterinary surgeon
☐ by a veterinary surgeon or under their direct responsibility
☐ other

2.3.2 Proposed dispensing/classification

☐ subject to medical prescription
☐ not subject to medical prescription
☐ subject to other controls
specify:

2.3.3 For veterinary products subject to medical prescription:

☐ veterinary product on prescription which **may** be renewed (if applicable)
☐ veterinary product on prescription which **may not** be renewed (if applicable)
☐ veterinary product on **special** prescription
☐ veterinary product on **restricted** prescription

(Not all the listed options are applicable in each member state. Applicants are invited to indicate which categories they are requesting, however, the member states reserve the right to apply only those categories provided for in their national legislation.)

2.3.4 Supply for products <u>not</u> subject to medical prescription

- ☐ supply through pharmacies only
- ☐ supply through non-pharmacy outlets and pharmacies (if applicable)
- ☐ supply/administration by veterinary surgeons only
- ☐ supply by pharmacies and/or veterinary surgeons for animals under their care
- ☐ supply through authorised distributor
- ☐ general sale

2.3.5 Promotion for products <u>not</u> subject to medical prescription

☐ promotion to health care professionals only

☐ promotion to the general public and health care professionals

2.4. Marketing authorisation holder / Contact persons / Company

2.4.1 Proposed marketing authorisation holder/person legally responsible for placing the product on the market in the Community / each MS:

(Company) Name:
Address:
Country:
Telephone:
Telefax:
E-Mail:
Contact person at this address (for centralised procedure only)
☐ Attach proof of establishment of the applicant in the EEA (Annex 5.3)

Has SME status been assigned by the EMEA?

- ❍ No
- ❍ Yes
  EMEA-SME Number:
  Date of expiry: (yyyy-mm-dd)
  ☐ Attach copy of the 'Qualification of SME Status' (Annex 5.21)

2.4.2 Person/company authorised for communication on behalf of the applicant during the procedure in the Community/each MS:

Name:
Company name:
Address:
Country:
Telephone:
Telefax:
E-Mail:

☐ If different to 2.4.1 above,
Attach letter of authorisation (Annex 5.4)

2.4.3 Person/Company authorised for communication between the marketing authorisation holder and the competent authorities after authorisation if different from 2.4.2 in the Community/each MS:

Name:
Company name:
Address:
Country:
Telephone:
Telefax:
E-Mail:

☐ If different to 2.4.1 above,
Attach letter of authorisation (Annex 5.4)

2.4.4 Qualified person in the EEA for Pharmacovigilance

Name:
Company name:
Address:
Country:
24 H Telephone:
Telefax:
E-Mail:

☐Attach C.V. of qualified person (Annex 5.5). See also Annex – point 5.20

2.5 Manufacturers

Note: ALL manufacturing and control sites mentioned throughout the whole dossier MUST be consistent regarding their names, detailed addresses and activities.

2.5.1 Authorised manufacturer(s) (or importer) responsible for batch release in the EEA in accordance with Article 55 and Article 53 of Directive 2001/82/EC (as shown in the package leaflet and where applicable in the labelling or Annex II of the Commission Decision):
Company Name:
Address:
Country:
Telephone:
Telefax:
E-Mail:

- Manufacturing Authorisation number:
- ☐ Attach copy of manufacturing authorisation(s) (Annex 5.6)
- ☐ Attach justification if more than one manufacturer responsible for batch release is proposed (Annex 5.7)

<u>For Vaccines :</u>
Details of the state laboratory or laboratory designated for that purpose (OMCL) where the official batch protocol review (Article 81 of Directive 2001/82/EC) or the official control authority batch release Article 82 of Directive 2001/82/EC) takes place.

Name:
Address:
Country:
Telephone:
Telefax:
E-Mail:

2.5.1.1 Contact person in the EEA for product defects and recalls *)*

Name:
Address:
Country:
24H contact telephone number:
Telefax:
E-Mail:

2.5.1.2 <u>Batch control/Testing arrangements</u>
Site(s) in EEA or in countries where an MRA or other Community arrangements apply where batch control/testing takes place (if different from 2.5.1) as required by Article 55 of Directive 2001/82/EC:
Name of the Company:
Address:
Country:
Telephone:
Telefax:
E-Mail:

Brief description of control test carried out by the laboratory(ies) concerned:

2.5.2 Manufacturer(s) of the veterinary medicinal product and site(s) of manufacture:
(Note: including manufacturing sites of any diluent/solvent presented in a separate container but forming part of the veterinary medicinal product)

Name:
Company name:
Address:
Country:
Telephone:
Telefax:
E-Mail:

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

☐ Attach flow-chart indicating the sequence and activities of the different sites and activities involved in the manufacturing process, including testing sites (Annex 5.8)

- <u>If the manufacturing site is in the EEA</u>,
  Manufacturing authorisation number (under Article 44 of Directive 2001/82/EC):

☐ Attach manufacturing authorisations required under Article 44 of Directive 2001/82/EC (Annex 5.6)

Name of qualified person:
(if not mentioned in manufacturing authorisation)

• If the manufacturing site is outside the EEA,
- ☐ Where MRA or other Community arrangements apply, attach equivalent of manufacturing authorisation (Annex 5.6)

Has the site been inspected for GMP Compliance by an EEA authority or by an authority of countries where Mutual Recognition Agreements (MRA) or other Community arrangements apply within the terms of the agreement?

☐ no ☐ yes

☐ If yes, please provide in Annex 5.9 for each site a statement from the competent authority which carried out the inspection, including:

- last GMP inspection date
- name of competent authority which carried out the inspection
- category of products and activities inspected
- outcome: GMP compliant: ☐ no ☐ yes

- Has the site been inspected for GMP Compliance by any other authority including those of countries where MRA or other Community arrangements apply but not within the respective territory?

☐ no ☐ yes

☐ If yes, please provide summary information in Annex 5.9

including:
- last GMP inspection date (yyyy-mm-dd)
- name of competent authority which carried out the inspection
- categories of products and activities inspected
- outcome: ☐ positive ☐ negative

2.5.3 Manufacturer(s) of the active substance(s) and site(s) of manufacture

Note: All manufacturing sites involved in the manufacturing process of each source of active substance should be listed. Brokers or supplier details alone are not acceptable. For biotech products include all sites of storage of master and working cell bank and preparation of working cell banks.

Substance:
Name:
Address:
Country:
Telephone:
Telefax:
E-Mail:
Brief description of manufacturing steps performed by manufacturing site:

☐ Attach flow-chart indicating the sequence and activities of the different sites involved in the manufacturing process, including batch control sites (Annex 5.8)

☐ For each active substance, attach a declaration from the Qualified Person of the manufacturing authorisation holder(s) in Section 2.5.1 and from the Qualified Person of the manufacturing authorisation holder(s) listed in Section 2.5.2 where the active substance is used as a starting material (Annex 5.19) that the active substance manufacturer(s)[2] referred to in Section 2.5.3 operate in compliance with the detailed guidelines on good manufacturing practice for starting materials.

• Has a Ph.Eur. Certificate of suitability been issued for the active substance(s):

☐ no ☐ yes

If yes,
- substance:
- name of the manufacturer:
- reference number:
- date of last update (*yyyy-mm-dd*):
☐ Provide copy in Annex 5.10

• Is a Active Substance Master File (European Drug Master File) to be used for the active substance(s) reference/original?

☐ no ☐ yes

If yes,
- substance:
- name of the manufacturer:
- reference number for EMEA / competent authority:
- date of submission (*yyyy-mm-dd*):
- date of last update (*yyyy-mm-dd*):
- ☐ attach letter of access for Community/Member State authorities where the application is made (see "European DMF procedure for active ingredients) (Annex 5.10)
- ☐ attach copy of written confirmation from the manufacturer of the active substance to inform the applicant in case of modification of the manufacturing process or specifications according to Annex I of Directive 2001/82/EC (Annex 5.11)

[2] According to Article 50a of Directive 2001/82/EC, manufacture includes complete or partial manufacture, import, dividing up, packaging or presentation prior to its incorporation into a veterinary medicinal product, including re-packaging or re-labelling as carried out by a distributor.

2.5.4 Contract companies used for bioavailability or bioequivalence trials

For each contract company, state where analytical tests are performed and where efficacy data are collected and give:

Name:
Address:
Country:
Telephone:
Telefax:
Email:

Duty performed according to contract:
Name and country of origin of the original/reference product:

2.6 Qualitative and quantitative composition

2.6.1 Qualitative and Quantitative composition in terms of the active substance(s) and the excipient(s):

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

List the active substance(s) separately from the excipient(s):

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

etc.

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

etc.

*Note: * only one name for each substance 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 (for further details, consult the Guideline on the SPC)*

Details of any overages should not be included in the formulation columns but stated below:

- active substance(s):
- excipient(s):

2.6.2 List of materials of animal origin contained or used in the manufacturing process of the veterinary medicinal product?

NONE ☐

Name	Function*			Animal origin susceptible to TSE**	Other animal origin	Certificate of suitability for TSE (state number)
	AS	EX	R			
1.	☐	☐	☐	☐	☐	☐
2.	☐	☐	☐	☐	☐	☐
3.	☐	☐	☐	☐	☐	☐
4.	☐	☐	☐	☐	☐	☐

etc.

* AS= active substance, EX=excipient (incl. starting materials used in the manufacture of the active substance/excipient), R=reagent/culture medium (incl. those used in the preparation of master and working cell banks)

** as defined in section 2 (scope) of the Note for Guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products

☐ If a Ph. Eur. Certificate of Suitability for TSE is available according to Resolution AP/CSP (99)4 of the Council of Europe attach it in Annex 5.12

2.6.3 Does the veterinary medicinal product contain or consist of Genetically Modified Organisms (GMOs) within the meaning of Directive 2001/18/EC ?

☐ No ☐ Yes

If yes, does the product comply with Directive 2001/18/EC ?

☐ No ☐ Yes

☐ *Attach a copy of any written consent(s) of the competent authorities to the deliberate release into the environment of the GMOs for research and development purposes where provided for by Part B of the above-mentioned Directive (Annex 5.13)*

3. SCIENTIFIC ADVICE

3.1. Was there formal scientific advice given by the CVMP for this veterinary medicinal product?

☐ No ☐ Yes

If yes,

Date (*yyyy-mm-dd*):
Reference of the scientific advice letter:
☐ Attach copy of the scientific advice letter (Annex 5.14)

3.2. Was there scientific recommendation(s) given by Member State(s) for this veterinary medicinal product?

☐ No ☐ Yes

If yes,

Member State(s): Date(s) (*yyyy-mm-dd*):

4. OTHER MARKETING AUTHORISATION APPLICATIONS

4.1 FOR NATIONAL APPLICATIONS ONLY, PLEASE COMPLETE THE FOLLOWING IN ACCORDANCE WITH ARTICLE 12(1) OF DIRECTIVE 2001/82/EC:

4.1.1 Is there another Member State(s) where an application for the same* product is pending?

☐ yes ☐ no
If yes, section 4.2. must be completed

4.1.2 Is there another Member State(s) where an authorisation is granted for the same* product?

☐ yes ☐ no
If yes, section 4.2 must be completed and copy of authorisation provided

Are there any differences which have therapeutic implications between this application and the applications/authorisations for the same product in other Member States (for national applications, Article 21 or 22 of Directive 2001/82/EC shall apply).

☐ yes ☐ no
If yes, please elaborate:

**Note: "same product" means same qualitative and quantitative composition in active substance(s) and having the same pharmaceutical form from applicants belonging to the same mother company or group of companies or which are "licensees".*

4.1.3 Is there another Member State(s) where an authorisation was refused/ suspended/ revoked by competent authorities for the same* product?

☐ yes ☐ no

If yes, section 4.2 must be completed

4.2. Marketing authorisation applications for the <u>same</u> product in the EEA (Same qualitative and quantitative composition in active substance(s) and having the same pharmaceutical form from applicants belonging to the same mother company or group of companies or which are "licensees").

Note: refer to Commission Communication 98/C229/03

☐ <u>Authorised</u>
country:
date of authorisation (*yyyy-mm-dd*):
invented name:
authorisation number:

☐ Attach marketing authorisation (Annex 5.15)

☐ <u>Pending</u>
country:
date of submission (*yyyy-mm-dd*):

☐ <u>Refused</u>
country:
date of refusal (*yyyy-mm-dd*):

☐ <u>Withdrawn (by applicant before authorisation)</u>
country:
date of withdrawal (*yyyy-mm-dd*):
invented name:
reason for withdrawal:

☐ <u>Withdrawn (by applicant after authorisation)</u>
country:
date of withdrawal (*yyyy-mm-dd*):
authorisation number:
reason for withdrawal:
invented name:

☐ <u>Suspended/revoked (by competent authority)</u>
country:
date of suspension/revocation (*yyyy-mm-dd*):
reason for suspension/revocation:
invented name:

4.3 For multiple applications of the same veterinary medicinal product:

Multiple applications for:
Name of the other product(s):
Date of application(s) (*yyyy-mm-dd*):
Applicant(s):

☐ Attach copy of correspondence with the European Commission, for centralised procedures only (Annex 5.16)

4.4. Marketing authorisation applications for the same product outside the EEA (i.e. from applicants belonging to the same mother company or group of companies OR which are "licensees". (Same qualitative and quantitative composition in active substance(s) and having the same pharmaceutical form.)

☐ Authorised
country:
date of authorisation (*yyyy-mm-dd*):
invented name:

☐ Pending
country:
date of submission (*yyyy-mm-dd*):

☐ Refused
country:
date of refusal (*yyyy-mm-dd*):

☐ Withdrawn (by applicant before authorisation)
country:
date of withdrawal:
invented name:
reason for withdrawal (*yyyy-mm-dd*):

☐ Withdrawn (by applicant after authorisation)
country:
date of withdrawal (*yyyy-mm-dd*):
authorisation number:
reason for withdrawal:
invented name:

☐ Suspended/revoked (by competent authority)
country:
date of suspension/revocation (*yyyy-mm-dd*):
reason for suspension/revocation:
trade name:

5. ANNEXED DOCUMENTS (WHERE APPROPRIATE)

☐ **5.1** Proof of payment

☐ **5.2** Informed consent letter of marketing authorisation holder of authorised veterinary medicinal product.

☐ **5.3** Proof of establishment of the applicant in the EEA.

☐ **5.4** Letter of authorisation for communication on behalf of the applicant/MAH

☐ **5.5** Curriculum Vitae of the Qualified Person for Pharmacovigilance

☐ **5.6** Manufacturing Authorisation required under Article 44 of Directive 2001/82/EC (or equivalent, outside of the EEA where MRA or other Community arrangements apply). A reference to EudraGMP will suffice when available.

☐ **5.7** Justification for more than one manufacturer responsible for batch release in the EEA

☐ **5.8** Flow-chart indicating all sites involved in the manufacturing process of the veterinary medicinal product or active substance (including sites involved in sampling and testing for batch release of products manufactured in third countries). Note: ALL manufacturing and control sites mentioned throughout the whole dossier MUST be consistent regarding their names, detailed addresses and activities

☐ **5.9** Statement (or GMP Certificate issued by an EEA inspectorate, when available) from the competent authority which carried out the inspection of the manufacturing site(s) (not older than 3 years).
References to Eudra GMP will suffice when available. Where applicable a summary of other GMP inspections performed in the last 2 years.

☐ **5.10** Letter(s) of access to Active Substance Master File(s) (Drug Master File(s)) or copy of Ph. Eur. Certificate(s) of suitability

☐ **5.11** Copy of written confirmation from the manufacturer of the active substance to inform the applicant in case of modification of the manufacturing process or specifications according to Annex I of Directive 2001/82/EC.

☐ **5.12** Ph. Eur. Certificate(s) of suitability for TSE

☐ **5.13** Written consent(s) of the competent authorities regarding GMO release in the environment.

☐ **5.14** Scientific Advice given by CVMP or Member State

☐ **5.15** Copy of Marketing Authorization(s) required under Article 44 of Directive 2001/82/EC in the EEA and the equivalent in third countries on request (a photocopy of the pages which give the marketing authorization number, the date of authorisation and the page which has been signed by the authorizing competent authority will suffice).

☐ **5.16** Correspondence with European Commission regarding multiple applications.

☐ **5.17** List of Mock-ups or Samples/specimens sent with the application, as appropriate (see Notice to Applicants, Volume 6A, Chapter 7)

☐ **5.18** List of proposed (invented) names and marketing authorisation holders in the concerned member states

☐ **5.19** Manufacturing authorisation holders are obliged to only use as starting materials active substances that have been manufactured in accordance with GMP so a declaration is expected from each of the manufacturing authorisation holders that use the active substance as a starting material. In addition, as the QP responsible for batch certification takes overall responsibility for each batch, a further declaration from the QP responsible for batch certification is expected when the batch release site is a different site from the above.

In many cases only one manufacturing authorisation holder is involved and therefore only one declaration will be required. However, when more than one manufacturing authorisation holder

is involved rather than provide multiple declarations it may be acceptable to provide a single declaration signed by one QP. This will be accepted 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 responsibilty for the GMP compliance of the active substance manufacturer(s). Note: These arrangements are subject to inspection by the competent authorities.

Applicants are reminded that a Qualified Person is at the disposal of a manufacturing authorisation holder according to Art. 41(50) of Directive 2001/83(82)/EC and located in the EEA. Therefore declarations from personnel employed by manufacturers in third countries, including those located within MRA partner countries are not acceptable.

According to Article 50a (1) of Directive 2001/82, manufacture includes complete or partial manufacture, import, dividing up, packaging or presentation prior to its incorporation into a medicinal product, including re-packaging or re-labelling as carried out by a distributor.

☐ **5.20** Detailed description of the Pharmacovigilance system and, where appropriate, the risk management system that the Applicant will put in place.

☐ **5.21** Copy of the 'Qualification of SME Status'.