



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food and feed safety, innovation
Animal nutrition, veterinary medicines

Brussels, 29.11.2017

Revision 8

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

November 2017

This application form will be included in:

The Rules governing Veterinary medicinal products in the European Union

The Notice to Applicants - Volume 6B Administrative information

Revision 8

Mandatory use of electronic Application Forms for Centralised Procedure

APPLICATION FORM

SUMMARY OF THE DOSSIER



APPLICATION FORM: ADMINISTRATIVE DATA

For all applications for a marketing authorisation of a medicinal product for veterinary use submitted to a Member State (as well as Iceland, Lichtenstein and Norway) under either a national, mutual recognition procedure or decentralised procedure and for submissions to the European Medicines Agency under the centralised procedure use the electronic Application form available from: <http://esubmission.ema.europa.eu/eaf/index.html>

Usually a separate application form for each strength and pharmaceutical form is required.

For centralised procedures a combined electronic application form should be used (information on each pharmaceutical form and strength should be provided successively, where appropriate).

DECLARATION and SIGNATURE

Product (invented) name:

Strength(s):

Pharmaceutical form(s):

Full name of the active substance(s) (including salt or hydrate, if applicable):

Applicant:

Address:

It is hereby confirmed that all existing data which are relevant to the quality, safety and efficacy of the medicinal product have been supplied in the dossier, as appropriate and that such data are not subject to regulatory data exclusivity in the Union.

It is hereby confirmed that fees will be paid/have been paid according to the national/European Union rules**.

On behalf of the applicant

Signature(s)

Title: First name: * Surname:

Function

Address: date (yyyy-mm-dd)

Email:

* 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

Declaration and signature

1. TYPE OF APPLICATION

- 1.1 This application concerns
- 1.2 Application for a change to your existing marketing authorisation leading to an extension as referred to in Annex I of Regulation (EC) no 1234/2008, or any national legislation
- 1.3 According to Directive 2001/82/EC¹ or Regulation 726/2004
- 1.4 Maximum Residue Limit (MRL) status)
- 1.5 Consideration of the application under Article 26(3) of Directive 2001/82/EC, Article 39(7) or Article 39(8) of Regulation 726/2004

2. MARKETING AUTHORISATION APPLICATION PARTICULARS

- 2.1 Name(s) and ATC vet code
- 2.2 Strength, pharmaceutical form, route of administration, container and pack sizes
- 2.3 Legal status
- 2.4 Marketing authorisation holder, Contact persons, Company
- 2.5 Manufacturers
- 2.6 Qualitative and quantitative composition

3. SCIENTIFIC ADVICE

4. OTHER MARKETING AUTHORISATION APPLICATIONS

- 4.1 For national/MRP/DCP applications, please complete the following in accordance with Article 12 of Directive 2001/82/EC
- 4.2 Marketing authorisation applications for the same product in the EEA
- 4.3 For multiple/duplicate applications of the same medicinal product
- 4.4 Marketing authorisation applications for the same product outside the EEA

5. ANNEXED documents (where appropriate)

¹ As amended by Directive 2004/28/EC
Revision 8 (November 2017)

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/confirmation by CVMP: (yyyy-mm-dd)

EMA product number:

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

CVMP Rapporteur:

CVMP co-rapporteur:

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

Procedure type: (from the first procedure or wave to the last one)

○ First use ○ Repeat Use (please also complete section 4.2)

▪ 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:

▪ Concerned Member State(s) (specify):

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"/>	IT	<input type="checkbox"/>
EL	<input type="checkbox"/>	ES	<input type="checkbox"/>	FI	<input type="checkbox"/>	FR	<input type="checkbox"/>	HR	<input type="checkbox"/>	HU	<input type="checkbox"/>	IE	<input type="checkbox"/>	IS	<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"/>								

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

Proposed (or agreed) Common Renewal Date:

(For subsequent procedures or waves, copy the procedure section above)

○ **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	<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"/>	HR	<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"/>								

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

Proposed Common Renewal Date:

○ **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 birth-date, please specify:

1.2. APPLICATION FOR A CHANGE TO YOUR EXISTING MARKETING AUTHORISATION LEADING TO AN EXTENSION AS REFERRED TO IN ANNEX I OF COMMISSION REGULATION (EC) NO 1234/2008, OR ANY NATIONAL LEGISLATION, WHERE APPLICABLE ?

- **No** (complete sections 1.3 and 1.4.)
- **Yes**

Please specify:

- qualitative change in declared active substance not defined as a new active substance
 - 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
 - modification of the vector used to produce the antigen or the source material, including a new master cell bank from a different source, where the clinical/safety characteristics are not significantly different;
 - change to the extraction solvent or the ratio of herbal drug to herbal drug preparation
- 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

- 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.

This section should be completed without prejudice to the provisions of Articles 12, 13, 14 and 25 of Directive 2001/82/EC.

For an existing marketing authorisation in the European Union / 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

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.
- . information on active substance status (new/known) should be provided in section 2.1.2

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

**for extensions of full applications, cross references can only be made to safety and clinical data*

1.3.2 ○ Article 13(1) - Generic application

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 European Union
- . complete administrative and quality data, appropriate safety and clinical data when applicable see Chapter 1 of the Notice to Applicants, Volume 6A

Reference veterinary medicinal product:

Note: The chosen reference medicinal product must be a medicinal product authorised in the Union on the basis of a complete dossier in accordance with the provisions of Article 12 of Directive 2001/82/EC.

■ *Veterinary medicinal product which is or has been authorised in accordance with Union provisions in force for not less than 6/8/10 years in the EEA:*

- Product name, strength(s), pharmaceutical form(s):
- Marketing authorisation holder:
- Date of authorisation (yyyy-mm-dd):
- Marketing authorisation granted by:
 - Union
 - Member State (EEA):
- Marketing authorisation number(s):
- Procedure number for MRP/DCP (if applicable):

Note: This section defines the reference medicinal product chosen for the purposes of establishing the expiry of the data protection period.

■ *Veterinary medicinal product authorised in the Union/Member State where the application is made or European reference medicinal product:*

- Product name, strength(s), pharmaceutical form(s):

- Marketing authorisation holder²:
- Marketing authorisation(s) granted by:
 - Union
 - Member State (EEA):
- Marketing authorisation number(s):
- Procedure number for MRP/DCP (if applicable):
 - **Veterinary medicinal product which is or has been authorised in accordance with Union provisions in force and to which bioequivalence has been demonstrated by appropriate bioavailability studies:**

Note: Should be in accordance with the notion of global marketing authorisation, if different from the medicinal product identified above:

- Product name, strength(s), pharmaceutical form(s):
- Marketing authorisation holder²:
- Date of authorisation (yyyy-mm-dd):
- Marketing authorisation(s) granted by:
 - Union
 - Member State (EEA):
- Marketing authorisation number(s):
- Procedure number for MRP/DCP (if applicable):
- Member State of source:
- Bioavailability study(ies) reference number(s):

Note: Section to be duplicated for each product used for the demonstration of bioequivalence.

1.3.3 ○ **Article 13 (3) - 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 European Union (e.g. different pharmaceutical form, different therapeutic use ...)
- complete administrative and quality data, appropriate safety and clinical data
- refer to Notice to Applicants, Volume 6A, Chapter 1

Reference medicinal product:

Note: The chosen reference medicinal product must be a medicinal product authorised in the Union on the basis of a complete dossier in accordance with the provisions of Article 12 of Directive 2001/82/EC.

■ **Veterinary medicinal product which is or has been authorised in accordance with Union provisions in force for not less than 6/8/10 years in the EEA:**

- Product name, strength(s), pharmaceutical form(s):
- Marketing authorisation holder:
- Date of authorisation (yyyy-mm-dd):
- Marketing authorisation(s) granted by:
 - Union
 - Member State (EEA):
- Marketing authorisation number(s):
- Procedure number for MRP/DCP (if applicable):

Note: This section defines the reference medicinal product chosen for the purposes of establishing the expiry of the data protection period.

² Should be considered the “same” as the one identified above, as per the Commission Communication (98/C 299/03) (i.e. belonging to the same mother company or group of companies or which are “licencees”)

■ ***Veterinary medicinal product authorised in the Union/Member State where the application is made or European reference medicinal product:***

- Product name, strength(s), pharmaceutical form(s):
- Marketing authorisation holder²:
- Marketing authorisation(s) granted by:
 - Union
 - Member State (EEA) :
- Marketing authorisation number(s):
- Procedure number for MRP/DCP (if applicable):

■ **Difference(s) compared to this reference 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

■ ***Veterinary medicinal Product which is or has been authorised in accordance with Union provisions in force used for the demonstration of bioequivalence (if applicable) and/or in other studies.***

- Study reference number:
- Product name, strength(s), pharmaceutical form(s):
- Marketing authorisation holder²:
- Marketing authorisation(s) granted by:
 - Union
 - Member State (EEA):
- Marketing authorisation number(s):
- Procedure number for MRP/DCP (if applicable):
- Member State of source:

Note: Section to be duplicated for each product used for the demonstration of bioequivalence and/or in other 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 (safety) and clinical data refer to Notice to Applicants, Volume 6A, Chapter 1*

Reference medicinal product:

Note: The chosen reference medicinal product must be a medicinal product authorised in the Union on the basis of a complete dossier in accordance with the provisions of Article 12 of Directive 2001/82/EC.

■ ***Veterinary medicinal product which is or has been authorised in accordance with Union provisions in force for not less than 6/8/10 years in the EEA:***

- Product name, strength(s), pharmaceutical form(s):
- Marketing authorisation holder:
- Date of authorisation (yyyy-mm-dd):
- Marketing authorisation(s) granted by:
 - Union
 - Member State (EEA) :

- Marketing authorisation number(s):
- Procedure number for MRP/DCP (if applicable):

Note: This section defines the reference medicinal product chosen for the purposes of establishing the expiry of the data protection period.

■ ***Veterinary medicinal product authorised in the Union/Member State where the application is made or European reference medicinal product:***

- Product name, strength(s), pharmaceutical form(s):
- Marketing authorisation holder²:
 - Marketing authorisation(s) granted by:
 - Union
 - Member State (EEA):
- Marketing authorisation number(s):
- Procedure number for MRP/DCP (if applicable):

■ **Difference(s) compared to this reference medicinal product:**

- change(s) in the raw material(s)
- change(s) in the manufacturing process(es)
- change in therapeutic indication(s)
- change in pharmaceutical form(s)
- change in strength (quantitative change to the active substance(s))
- change in route of administration(s)
- other

■ ***Veterinary medicinal product which is or has been authorised in accordance with Union provisions in force and to which comparability tests and studies have been conducted:***

Note: The chosen reference medicinal product must be a medicinal product authorised in the Union and should be used throughout the comparability programme for quality, safety and clinical studies.

- Product name, strength(s), pharmaceutical form(s):
- Marketing authorisation holder²:
- Date of authorisation (yyyy-mm-dd):
- Marketing authorisation(s) granted by:
 - Union
 - Member State (EEA):
 - Marketing authorisation number(s):
 - Procedure number for MRP/DCP (if applicable):

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 safety and clinical data*

1.3.6 ○ Article 13b - Fixed combination:

*Note: . complete administrative and complete quality, safety and clinical data on the combination only
 . for extensions of fixed combination applications, cross references can only be made to safety and clinical data
 This applies for fixed combinations of known substances; section 1.3.1 is applicable for combinations including new active substances.*

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, safety and clinical data
 - . the authorised product and the informed consent application can have the same or different MAH

Authorised product in the Union/ 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 application¹.

Maximum Residue Limits (MRL) according to Commission Regulation (EU) No 37/2010:

Pharmacological active substance	Marker residue	Animal species	MRL	Target tissues	Other provisions	Therapeutic classification

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

Pharmacological active substance	Date of submission	Species	Remarks

¹All 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 Regulation (EU) No 37/2010 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 Article 39(8) of Regulation (EC) No 726/2004

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 each extension to another food-producing species within five years of the initial authorisation)

1.5.4 ○ Article 77(5) of Directive 2001/82/EC and Article 49(3) of Regulation (EC) No 726/2004
(other requirements for the PSUR submission cycle)

Please attach justification for requesting deviation from the 'standard' PSUR cycle as stated in legislation (Annex 5.24).

FOR INFORMATION ONLY

2. MARKETING AUTHORISATION APPLICATION PARTICULARS

2.1. Name(s), ATC vet code and Target Species

2.1.1 Proposed (invented) name of the veterinary medicinal product in the European Union/ 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 Active substance(s):

Full name of the active substance(s), if applicable including salt or hydrate*:

Base/active moiety of the active substance(s) (if different from above):

Substance type (e.g. chemical substance, recombinant biological substance):

For applications submitted in accordance with Article 12(3) of Directive 2001/82/EC:

Claim for new active substance(s)**

Note: active substance(s) not yet authorised in a veterinary medicinal product by a competent

authority or by the European Union (for centralised procedure).

Please provide evidence and justification to support the claim of new active substance in annex 5.22

Known active substance

*Note: *active substance should be indicated here as full substance. If the substance is included in the product as a salt or hydrate, the corresponding base /active moiety should be indicated in the additional field;*

Name should be based on the following order of priority: INN, Ph.Eur., National Pharmacopoeia, common name, scientific name.

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

ATC vet code:

Group:

If no ATC vet code has been assigned, please indicate if an application for an ATC vet code has been made:

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) (as used for expression of strength*):
Strength(s):

Note: * for active substances presented in the form of salt or hydrate, the expression of strength should be based on base/active moiety

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)

(Duplicate section 2.2.3. as needed)

For each container give:

Description:

Container	Material	Closure
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Administration device if applicable

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 Member State 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 CMDv website) (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 not 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 distributors
 general sale

2.3.5 Promotion for products not subject to medical prescription

- promotion to veterinary professionals only
Member States:
 promotion to the general public and veterinary professionals
Member States:

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 European Union / each Member State:

Centralised procedure

(Company) Name:

Address:

Postcode:

Country:

Telephone:

E-Mail:

Contact person at this address:

Title: First name: Surname:

National procedure including mutual recognition/decentralised procedure

Member State(s):

(Company) Name:

Address:

Postcode:

Country:

Telephone:

E-Mail:

(Repeat section for different proposed marketing authorisation holders in the Member States)

Attach proof of establishment of the applicant/MAH in the EEA (Annex 5.3)

Has SME status been assigned by the EMA?

No

Yes

EMA-SME Number:

Date of expiry: (yyyy-mm-dd)

Attach copy of the 'Qualification of SME Status' (Annex 5.21)

Proof of Payment (when relevant; not applicable for centralised procedure)

Have all relevant fees been prepaid to competent authorities?

Yes (for fees paid, attach proof of payment in Annex 5.1)

No

For Member State(s):

Billing address (when relevant)

Company name:

VAT number:

Address:

Postcode:

Country:

Telephone:

E-Mail:

Purchase order (PO) number:

2.4.2 Person/Company authorised for communication on behalf of the applicant during the procedure in the European Union/each Member State:

Name:

Company name:

Attach letter of authorisation (Annex 5.4)

Address:

Country:

Telephone:

E-Mail:

If different to 2.4.1 above, attach a 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 European Union/each Member State:

Name:

Company name:

Address:

Country:

Telephone:

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

Title:

First name:

Surname:

Company name:

Address:

Postcode:

Country:

24 H Telephone:

E-Mail:

The above-mentioned qualified person resides³ and operates in the EEA

The qualified person is registered with Eudravigilance

Detailed description of the pharmacovigilance system (see also annex 5.20)

³ For the purposes of this application form, a Qualified person Responsible for Pharmacovigilance “resides” in the place where he/she makes his/her home, where he/she lives, can be traced, located, identified for all legal and contractual obligations, whether or not it is owned by him/her or he/she is permanently dwelling there.

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 a) 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

Postcode:

Country:

Telephone:

E-Mail:

Manufacturing Authorisation number:

Attach copy of manufacturing authorisation(s) (Annex 5.6)

or

Enter Eudra GMDP document reference number:

If available:

Attach latest GMP certificate (Annex 5.9)

Or Enter Eudra GMDP document reference number:

2.5.1 b) Official batch release for Vaccines :

Details of the Official Medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official batch release (in accordance with Articles 81 and 82 of Directive 2001/82/EC as amended)

Laboratory name:

Address:

Postcode:

Country:

Telephone:

E-Mail:

2.5.1.1 Contact person in the EEA for product defects and recalls

Title:

First Name:

Surname:

Address:

Country:

24H contact telephone number:

E-Mail:

2.5.1.2 Batch control/Testing arrangements

Site(s) in EEA, or in countries where an MRA or other European Union arrangements apply, where batch control/testing takes place as required by Article 55 of Directive 2001/82/EC:

Company Name:

Address:

Postcode:

Country:

Telephone:

E-Mail:

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

- Attach copy of manufacturing authorisation(s) or proof of GMP compliance (Annex 5.6)
or
 Enter Eudra GMDP document reference number:

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, quality control sites, in-process testing sites, immediate and outer packaging and importer(s). For each site provide the following information:

Company name:

Address:

Postcode

Country:

Telephone:

E-Mail:

Brief description of functions performed:

- 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)

• Site is in the EEA:

- Manufacturing authorisation number

Attach manufacturing authorisation(s) (Annex 5.6)

or

Enter EudraGMDP document reference number:

- Name of qualified person:

(if not mentioned in manufacturing authorisation)

- Site is outside the EEA:
If available, D-U-N-S number⁴

Attach document equivalent of manufacturing authorisation in accordance with Article 12 (m) of Directive 2001/82/EC (Annex 5.6)

Has the site been inspected for GMP Compliance by an EEA authority or by an authority of countries where MRA or other European Union arrangements apply within the terms of the agreement?

no yes

If yes, please

Attach latest GMP certificate in Annex 5.9

or

Enter Eudra GMDP document reference number:

- Has the site been inspected for GMP compliance by any other authority (including those of countries where MRA or other European Union arrangements apply but not within their respective territory)?

no yes

If yes, please provide summary information in Annex 5.9 (and, if available a GMP certificate or a statement from the competent authority which carried out the inspection).

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, including quality control/in-process testing sites, 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 when relevant. For each site provide the following information:

Active substance:

Name:

Address:

Postcode:

Country:

Telephone:

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 Qualified Person declaration that the active substance is manufactured in compliance with the detailed guidelines on good manufacturing practice for starting materials (Annex 5.19).

- Has the site been inspected for GMP Compliance by an EEA authority or by an

⁴ The Data Universal Numbering System (D-U-N-S) is a system developed by Dun & Bradstreet (D&B) which assigns a unique digit numeric identifier to a single business entity. It is used in this case to facilitate the identification of manufacturing sites outside of EEA

authority of countries where MRA or other European Union arrangements apply within the terms of the agreement?

no yes

If yes, please

Attach latest GMP certificate in Annex 5.9

or

Enter Eudra GMDP document reference number

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

no yes

If yes, please provide summary information in Annex 5.9 (and, if available a GMP certificate or a statement from the competent authority which carried out the inspection)

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

no yes Provide copy in Annex 5.10

If yes, please provide the following:

- name of the CEP holder:

- name of the manufacturer if different from the above::

- CEP number:

- date of last update (yyyy-mm-dd):

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

no yes

If yes, please provide the following information:

- name of the ASMF holder:

Address:

Postcode:

Country:

Telephone:

E-Mail:

- name of the manufacturer if different from the above:

- EU ASMF reference number if available:

- National ASMF reference number (when applicable and only if EU ASMF reference number is not available)

- Applicant part version number:

- date of submission (yyyy-mm-dd):

- date of last update (yyyy-mm-dd):

- attach letter of access for European Union/Member State authorities where the application is made (see "Guideline on Active Substance Master File") (Annex 5.10)

- attach copy of 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)

• Is an EMA certificate for a Vaccine Antigen Master File (VAMF) issued or submitted in accordance with Directive 2001/82/EC (Annex I), being used for this MAA?

no yes Provide copy in Annex 5.23

If yes,

- substance name:
- name of the VAMF Certificate Holder/ VAMF Applicant:
- reference number of Application/ Certificate:
- date of submission (if pending) (yyyy-mm-dd):
- date of approval or last update (if approved) (yyyy-mm-dd):

(Section to be copied as per however many VAMFs may be cross-referenced)

2.5.4 Contract companies used for all clinical trial (s) (including bioavailability and bioequivalence trials) included in the application or used for the validation of blood product manufacturing processes.

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

Name:
Address:
Postcode
Country:
Telephone:
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):

Dosage form unit 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
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For salts and hydrates only, corresponding to (indicate base/active moiety):

etc.

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

Note: * active substance should be indicated first as full substance. If the substance is included in the product as a salt or hydrate, this corresponding base/active moiety should be indicated in the additional field;

Name should be given in the following order of priority: INN, Ph.Eur., National Pharmacopoeia, common name, scientific name

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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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:

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

No Yes

If yes,

Member State(s):

Date(s) (yyyy-mm-dd):

Attach copy of the scientific advice (Annex 5.14)

4. OTHER MARKETING AUTHORISATION APPLICATIONS

4.1 FOR NATIONAL/MRP/DCP APPLICATIONS, PLEASE COMPLETE THE FOLLOWING IN ACCORDANCE WITH ARTICLE 12 (N) 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".*

*** This is covering applications submitted at an earlier time or in parallel to this application if not already listed under 1.1.2 or 1.1.3.*

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 SAME 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

Authorised

country:

date of authorisation (yyyy-mm-dd):

invented name:

marketing authorisation number:

Attach marketing authorisation (Annex 5.15)

Submitted (which are not considered as multiple/duplicate applications – see section 4.3)

country:
date of submission (yyyy-mm-dd):
procedure number for MRP/DCP (if applicable):

Refused

country:
date of refusal (yyyy-mm-dd):
procedure number for MRP/DCP (if applicable):

Withdrawn (by applicant before authorisation)

country:
date of withdrawal (yyyy-mm-dd):
invented name:
reason for withdrawal:
procedure number for MRP/DCP (if applicable):

Withdrawn (by applicant after authorisation)

country:
date of withdrawal (yyyy-mm-dd):
authorisation number:
reason for withdrawal:
invented name:
procedure number for MRP/DCP (if applicable):

Suspended/revoked (by competent authority)

country:
date of suspension/revocation (yyyy-mm-dd):
reason for suspension/revocation:
invented name:
procedure number for MRP/DCP (if applicable):

4.3 FOR MULTIPLE APPLICATIONS OF THE SAME VETERINARY MEDICINAL PRODUCT:

Multiple applications (submitted simultaneously or subsequently to the initial application/MA) for:

Name of the other product(s):
Date of application(s) (yyyy-mm-dd):
Applicant(s):
Procedure number for MRP/DCP (if applicable):

Attach copy of letter from the Commission services, 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):

reason for refusal

Withdrawn (by applicant before authorisation)

country:

date of withdrawal (yyyy-mm-dd):

invented name:

reason for withdrawal:

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:

invented 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 Empty
- 5.6 Manufacturing Authorisation required under Article 44 of Directive 2001/82/EC (or equivalent, outside of the EEA where MRA or other European Union arrangements apply). A reference to EudraGMDP will suffice when available.
- 5.7 Empty
- 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 GMP certificate(s); Where applicable, a summary of other GMP inspections performed.
- 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 Authorisation(s) required under Article 12(3) n 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 authorisation number, the date of authorisation and the page which has been signed by the authorising competent authority will suffice).
- 5.16 Letter from the Commission services regarding multiple applications.
- 5.17 List of Mock-ups or Samples/specimens sent with the application, as appropriate (see CMDv website)
- 5.18 List of proposed (invented) names and marketing authorisation holders in the concerned member states
- 5.19 For each active substance, attach a declaration(s) from the Qualified Person of the manufacturing authorisation holder in Section 2.5.1 and from the Qualified Person of each of the manufacturing authorisation holders (i.e. located in EEA) listed in Section 2.5.2 where the active substance is used as a starting material that the active substance is manufactured in compliance with the detailed guidelines on good manufacturing practice for starting materials. Alternatively, such declaration may be signed by one Qualified Person on behalf of all QPs involved (provided this is clearly indicated). The declaration should refer to an audit and the date of the audit.
- 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'.
- 5.22 Evidence and justification to support the claim of new active substance status in the European Union for applications based on Article 12(3) of Directive 2001/82/EC.
- 5.23 Copy of EMA certificate for a Vaccine Antigen Master File.
- 5.24 Justification for requesting deviation from the 'standard' PSUR cycle as stated in legislation.

FOR INFORMATION ONLY