



ASSURING THE SAFETY, QUALITY AND EFFICACY
OF VETERINARY MEDICINES

APPLICATION FORM FOR AN EXCEPTIONAL MARKETING AUTHORISATION



APPLICATION FORM: ADMINISTRATIVE DATA

Limited Marketing Authorisation Application (Attach evidence Annex 3.0)

Provisional Marketing Authorisation Application (Attach evidence Annex 3.1)

NB: The supporting data, including Expert Reports, should be submitted in accordance with the Notice to Applicants. An index should be provided which gives the location of each section within the dossier (Including the location of any references or published literature submitted in support of the application).

DECLARATION and SIGNATURE

Product (invented) name:

Strength(s):

Pharmaceutical form:

Active Substance(s):

Target Species:

Route(s) of administration:

Indication(s):

**Date of company meeting
with VMD:**

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.

On behalf of the applicant,

Signature(s)

NAME*

Function

Place date (yyyy-mm-dd)

1. 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 Council Regulation (EEC) No 470/2009 has been published in the Official Journal of the European Communities:

Substance(s)	MRL status	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) No470/2009 should also be listed and an appropriate justification given.

2.1 Marketing authorisation holder / Contact persons / Company

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

(Company) Name:
Address:
Country:
Telephone:
Telefax:
E-Mail:

Attach proof of establishment of the applicant in the EEA (Annex 3.3)

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

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

If different to 2.1.1 above,
Attach letter of authorisation (Annex 3.4)

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

2.1.4 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 3.5). See also Annex – point 3.14

2.2 Manufacturers

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

2.2.1 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 3.6)

For Vaccines :

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:

2.2.2 Contact person in the EEA for product defects and recalls

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

2.2.3 Batch control/Testing arrangements

Site(s) in EEA or in countries where an MRA or other Community arrangements apply where batch control/testing takes place (if different from 2.2.1) 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:

2.2.4 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.:

If the manufacturing site is in the EEA,

Manufacturing authorisation number (under Article 44 of Directive 2001/82/EC):

Attach manufacturing authorisations required under Article 44 of Directive 2001/82/EC (Annex 3.6)

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 3.6)

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 3.7 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 3.7

- 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

2.2.5 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:

- For each active substance, attach a declaration from the Qualified Person of the manufacturing authorisation holder(s) in Section 2.2.3 and from the Qualified Person of the manufacturing authorisation holder(s) listed in Section 2..2.4 where the active substance is used as a starting material that the active substance manufacturer(s)¹ referred to in Section 2.2.5 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 3.8

- Is an Active Substance Master File (ASMF) 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 ASMF procedure for active ingredients) (Annex 3.8)

- 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 3.9)

¹ 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.

2.3 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 3.10

2.3.1 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 3.11)

3. ANNEXED DOCUMENTS (WHERE APPROPRIATE)

- 3.0** Evidence that the product is intended for use in a Limited Market.
- 3.1** Evidence that the Provisional Marketing Authorisation criteria has been met.
- 3.2** Overall benefit: risk discussion for the proposed product.
- 3.3** Proof of establishment of the applicant in the EEA.
- 3.4** Letter of authorisation for communication on behalf of the applicant/MAH
- 3.5** Curriculum Vitae of the Qualified Person for Pharmacovigilance
- 3.6** 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.
- 3.7** 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.
- 3.8** Letter(s) of access to Active Substance Master File(s) (Drug Master File(s)) or copy of Ph. Eur. Certificate(s) of suitability
- 3.9** 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.
- 3.10** Ph. Eur. Certificate(s) of suitability for TSE
- 3.11** Written consent(s) of the competent authorities regarding GMO release in the environment.
- 3.12** Mock-ups of the proposed packaging, or text.
- 3.13** Detailed description of the Pharmacovigilance system.

[#263506 v2]