Part 1: Administrative information
Application form
USER GUIDE FOR THE ELECTRONIC APPLICATION FORM FOR A MARKETING AUTHORISATION (Veterinary)
June 2015

Version 1.0

PURPOSE AND GENERAL RULES

This user guide has been prepared in order to facilitate the work of applicants when completing the electronic application form as part of an application for a marketing authorisation / extension of a medicinal product for veterinary use.

How to fill in the electronic application form?

The electronic application form has been prepared to be filled in by the applicant in case of an application made either by national route or by mutual recognition, decentralised or centralised procedures.

In the case of a mutual recognition or decentralised procedure an application form should be filled in for all competent authorities where the application is made.
Since some information may differ between Member States (e.g. name of the product, marketing authorisation holder (MAH), legal status, contact persons etc…), the appropriate sections should be replicated where necessary. Fields can be duplicated by clicking on a boxed "+" symbol. For relevant sections, the applicant is requested to specify to which Member State the information relates.

Where EEA is indicated in the application form, the applicant should understand EEA countries therefore including EU countries.
For national, mutual recognition and decentralised procedures, a completed separate application form is usually required for each strength and pharmaceutical form. For centralised procedures a combined application form for all strengths and pharmaceutical forms is recommended, the relevant sections should be replicated as necessary.

Fields relevant for certain types of applications or related to legal basis do only appear after ticking the concerned box.

Square boxes indicate that multiple choices are possible while round boxes indicate that one choice excludes the other possibilities.

Some fields have to be filled in by choosing a value from a drop-down list that is based on a controlled dictionary. Further information on the dictionaries used is provided in this document.

The e-submissions website (http://esubmission.ema.europa.eu/eaf/index.html) provides further guidance on:
- Technical aspects of the electronic application form, in particular the technical user guide and Questions & Answers documents relating to practical and technical aspects of the electronic Application Forms;
- Information on the dictionaries, including instructions on requesting additional terms to some of the lists.

Which language should be used?

- English should be used for a centralised procedure.
- English should be used for a mutual recognition or decentralised procedures, except in some
Member States where the national language should be used. - National language should be used preferably in the case of a national application, except if subsequent mutual recognition procedure is already considered and if the national competent authority where this application is made accepts English.
Language requirements apply also to the annexes to the application form therefore, as applicable, translations may have to be provided.
Further guidance can be found in http://www.hma.eu/uploads/media/HR_GUI-28_Dossier_languages.pdf.

ADMINISTRATIVE DATA

DECLARATION and SIGNATURE

In this declaration, data must be identical to the information provided in other sections, as well as in the supportive documents provided (e.g. annexes to the application form, proposed product information, other parts of the dossier).

When this section is completed the data should be populated to corresponding fields in other sections of the application form by clicking on the respective push-button "Populate data in section 2.2.1. and 2.6.1."

Product (Invented) name

In case of an application under the mutual recognition (MRP) or decentralised (DCP) procedure the product name used in the reference Member State should be listed. Please refer to the CMDv document "Clarification Paper – Agreeing Product Name During the Decentralised Procedure". Here should be quoted only the product or invented name in the box and not the FULL name of the product. A list of the different proposed invented names and marketing authorisation holders in the concerned Member States should be appended to the application form in annex 5.18.

For an application under the centralised procedure, the invented name should be agreed by CVMP prior submission. Please refer to the EMA website for further information (http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/landing/veterinary_medicines_regulatory.jsp&mid=).

Pharmaceutical form

The pharmaceutical form should be selected in the drop-down list, which includes the pharmaceutical forms described in the Standard terms published in the European Pharmacopoeia that provides standardised nomenclatures and quality standards for medicinal substances and products (https://www.edqm.eu/en/standard-terms-590.html). Only the full term should be mentioned (not the short term).

For centralised procedure only: If the application is made for several pharmaceutical forms in a single application form, the pharmaceutical form field should be duplicated and all pharmaceutical forms included.

Strength (s)
Active Substance(s)

The two fields "Strength" and "Active substance" should be considered as linked and corresponding values listed in the same order for both fields. Strength is to be entered as a free text and active substance selected from the drop-down list (based on a controlled dictionary).

To see the drop-down list click on "Add Active Substance(s)". If the product contains more than one active substance, each active substance should be added.

Duplicate the field by clicking on +.

For the Centralised Procedure only, if the concerned pharmaceutical form has several strengths that are applied for in the same application form, the field should be duplicated and all strengths included.

Applicant details

The same applicant should apply in all concerned Member States. For MRP and DCP applications, the applicant should be the same as the marketing authorisation holder (MAH)/applicant in the reference Member State (RMS).

The name of the applicant should be included in the field 'Applicant', while contact person on behalf of the applicant should be indicated in the fields "Title", "First Name" and "Surname" of this section.

Person authorised for communication, on behalf of the Applicant

Letter of authorisation for communication/signing on behalf of the applicant should be attached in Annex 5.4. Person signing the application form should have the letter of authorisation referred to above.

1. TYPE OF APPLICATION

1.1 This application concerns

1.1.1. A Centralised procedure

Article 3 of Regulation (EC) No 726/2004 defines the eligibility of applications for evaluation under the centralised procedure through which medicinal products must or may be authorised by the Union. The eligibility to centralised procedure should be confirmed by the CVMP well in advance of the submission of the application for the marketing authorisation.

The basis for eligibility should be indicated in line with the CVMP acceptance/confirmation of the eligibility to the centralised procedure, indicating also the date of acceptance/confirmation of eligibility. Only one eligibility basis should be indicated. If the product falls under 'mandatory' eligibility scope, this scope should be indicated, even if the product falls also under an 'optional' scope.

The rapporteur and co-rapporteur appointed by the CVMP should be indicated in this section (Title, First name, Surname).

For further guidance on the procedure for confirmation of eligibility to centralised procedure and rapporteur appointment please refer to the website of European Medicines Agency (http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/landing/veterinary_medicines_regulatory.jsp&mid=).

1.1.2. A Mutual recognition procedure

The applicant should indicate the reference Member State, details of the marketing authorisation (date of authorisation and marketing authorisation number), procedure number, and for each "wave" of mutual recognition procedure concerned Member State(s) and the proposed (or agreed) common renewal date.

The procedure number is the Mutual Recognition Procedure number allocated by the reference Member State.

"First Use" means the first mutual recognition procedure.
All the concerned Member States should be indicated (by replication of the box).

"Repeat use" means a new use ("wave") of the same mutual recognition or decentralised procedure made to include new concerned Member State(s).
When applying for a repeat use, the applicant should complete "first use/wave" by stating the Member States which have recognised the marketing authorisation during the first use (or during the decentralised procedure) and complete, when necessary, section 4.2 indicating the Member States where the application has (have) been withdrawn during the "first use/wave". For each subsequent use the applicant should indicate the rank (2nd, third, fourth…) and states the Member States which have recognised the marketing authorisation during the first use/wave and subsequent finalised use of the procedure. Last "wave" should reflect the current application.

Further information on previous applications should be provided in section 4 of the application.

1.1.3. A Decentralised procedure

The applicant should indicate the reference Member State, procedure number allocated by the RMS, and concerned Member State(s) and proposed common renewal date.
For repeat-use of decentralised procedure, please complete section 1.1.2.

1.1.4. A National procedure

The Member State in which the application is made should be mentioned. Optionally procedure number allocated prior to the submission should be indicated.

1.2. Application for a change to 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

Certain changes to a marketing authorisation are considered to fundamentally alter the terms of a marketing authorisation and therefore cannot be considered as a variation. For these changes, set out in Annex I of Regulation (EC) No 1234/2008, a new application must be made that shall be evaluated in accordance with the same procedure as for the initial marketing authorisation to which it relates.
Applications for changes or additions falling under the scope of Annex I of Commission Regulation (EC) No 1234/2008 ("extension application") can only be submitted by the marketing authorisation holder. In this case, the applicant must be the same as the marketing authorisation holder of the existing marketing authorisation.
Reference should be made to the following guidance:

http://www.hma.eu/uploads/media/063_Q_A_Referring_to_data_in_another_dossier_EMA-CMDv-69345-2011.pdf

The same procedure should be followed, not the same legal basis.

1.2.1 Changes applied for

The applicant should specify which of the changes set out in Annex I of Commission Regulation (EC) No 1234/2008 this application concerns:

- a qualitative change in declared active substance not defined as a new active substance (indicating the type of change),
- change in bioavailability,
- change in 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

Multiple concomitant changes are possible in a single application form if applied for at the same time. All changes applied for should be indicated, therefore all relevant boxes should be ticked (e.g. change of pharmaceutical form and change of strength).
The European Commission has published a guideline to clarify the terms 'pharmaceutical form' and 'strength' and to include relevant examples for this classification: Guideline on the categorisation of new applications versus variation applications.

This guideline on categorisation should be read in conjunction with the European Directorate for the Quality of Medicines and Healthcare (EDQM) guidance: Standard terms: Introduction and guidance for use and Regulation (EC) No 1234/2008.
In case of doubt, the MAH is advised to contact the concerned Competent Authority in advance of the submission.

1.3 This application is submitted in accordance with the following article in Directive 2001/82/EC

The section should be completed for each application and only one box should be ticked.

The applicant should indicate the "legal basis" of the application – the corresponding Article of Directive 2001/82/EC, according to which the application is made. Please refer to Notice to Applicants, Volume 6A, Chapter 1 for further guidance.

For applications for a change to an existing marketing authorisation leading to an extension as referred to in Annex I of Regulation (EC) No 1234/2008. For extensions, cross references to safety and residue data, environmental risk assessment or pre-clinical and clinical data of the existing marketing authorisation could be made.

1.3.1 Article 12(3) application

For applications made according to Article 12(3) of Directive 2001/82/EC, the applicant should indicate whether it concerns a new active substance (at time of submission) or a known active substance. In case the claim of a new active substance is made, the corresponding justification should be provided as Annex 5.22 to the Application Form and the corresponding box in section 1.4.1 ticked.

1.3.2 Article 13(1) generic application

For applications made according to Article 13(1) of Directive 2001/82/EC the applicant should indicate under:

- *"Veterinary medicinal product which is or has been authorised in accordance with Union provisions in force* (acquis communautaire) *for not less than 6/10years in the EEA"* – a reference medicinal product for which data protection has expired;
- *"Veterinary medicinal product authorised in the Union/Member State where the application is made or European reference medicinal product"* – a reference medicinal product with the same pharmaceutical form(s) (please see Article 13(2) of Directive 2001/82/EC regarding immediate release oral forms), strength(s) and route of administration, on which the product information of the generic product is based);
- *"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"* – a reference medicinal product used as the reference product in bioequivalence studies.

Reference product boxes can be replicated when information is different in the Member States.

All 3 subsections must be filled out, otherwise the applicant should justify.

The reference medicinal products listed above must belong to the same Global Marketing Authorisation, contain the same active substance(s) as the generic product and being authorised on the basis of a complete dossier. When there are any differences between products indicated under second and third indent of this section, the applicant should justify in Part 1C the relevance of the bioequivalence data.

Please refer to Notice to Applicants, Volume 6A, Chapter 1 for further guidance.

For each of the reference medicinal products in this section the applicant should indicate all the particulars listed in the application form:

- Product (invented) name
- Pharmaceutical form(s)
- Strength(s)
- Name of the marketing authorisation holder
- Marketing authorisation number
- Date of authorisation
- The EEA (including EU) Member State or EU that has granted the marketing authorisation

For the product to which the bioequivalence has been demonstrated the applicant should also indicate the Member State in which the product has been sourced for the bioequivalence studies and the references numbers/ EudraCT numbers of those studies.

1.3.3. Article 13(3) hybrid application

For applications made according to Article 13(3) of Directive 2001/82/EC the applicant should indicate:

- *"Veterinary medicinal product which is or has been authorised in accordance with Union provisions in force* (acquis communautaire) *for not less than 6/10 years in the EEA"* – medicinal product for which regulatory data protection periods have expired;
- *"Veterinary medicinal product authorised in the Union/Member State where the application is made or European reference medicinal product"* – medicinal product, on which the product information of the hybrid product is based;
- Differences (several possible) to the reference medicinal product on which the product information of the hybrid product is based:
  - change 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.
- 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"* – medicinal product used as the reference product in bioequivalence studies.

Reference product boxes can be replicated when information is different in the Member States.

All subsections must be filled out, otherwise the applicant should justify.

For each of the products in this section the applicant should indicate all the particulars listed in the application form.

The products referred to must belong to the same Global Marketing Authorisation, contain the same active substance(s) and be authorised on the basis of a complete dossier. When there are any differences between products indicated under second and third indent of this section, the applicant should justify in Part 1C the relevance of the bioequivalence data.

Please refer to Notice to Applicants, Volume 6A, Chapter 1 for further guidance.

1.3.4. Article 13(4) similar biological application

For applications made according to Article 13(4) of Directive 2001/82/EC the applicant should indicate:

- *"Veterinary medicinal product which is or has been authorised in accordance with Union provisions in force* (acquis communautaire) *for not less than 6/(8)/10 years in the EEA"* – medicinal product for which data protection periods have expired;
- *"Veterinary medicinal product authorised in the Union/Member State where the application is made or European reference medicinal product"* – medicinal product on which the product information of the biosimilar product is based;
- Differences (several possible) to the reference medicinal product on which the product information of the biosimilar product is based:
  - 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(s) of administration,
  - other changes
- "*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*" – medicinal product used as the reference product in comparability tests and studies.
- Reference product boxes can be replicated when information is different in the Member States.

For each of the products in this section the applicant should indicate all the particulars listed in the application form.

The reference medicinal product to which comparability tests and studies have been conducted must be authorised in the EEA. When a non-EEA authorised comparator has been used for certain clinical or in vivo non-clinical studies in the comparability programme, it must be clearly identified but should not be additionally listed under third indent of this section of the application form. The "Guideline on similar biological medicinal products" should be consulted on the acceptability of a Non-EU comparator.

The products referred to must belong to the same Global Marketing Authorisation, and be authorised on the basis of a complete dossier. When there are any differences between products indicated under the second and third indent of this section, the applicant should justify the relevance of the comparability data. Please refer to Notice to Applicants, Volume 6A, Chapter 1 for further guidance.

1.3.5. Article 13a - Well-established use application

Further details and justification for the type of application should be provided. Please refer to Notice to Applicants, Volume 6A, Chapter 1 for further guidance.

1.3.6. Article 13b - Fixed combination application

This applies for fixed combinations of known substances. If not, section 1.3.1 is suitable for combinations including new active substances. Please refer to Notice to Applicants, Volume 6A, Chapter 1 for further guidance.

1.3.7. Article 13c- Informed consent application

The applicant should indicate the medicinal product for which the marketing authorisation holder has provided the consent and from which all pharmaceutical, safety and clinical data form the basis of the informed consent application. Letter of consent from the marketing authorisation holder of the authorised product, should be provided in Annex 5.2 to the application form.

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

The applicant should duly substantiate the request not to provide the field trials.

1.4 MRL status (Only for food-producing species)

Only to be completed when the target species is/are (a) food-producing animal(s).

All substances contained in the product are subject to this requirement (included in Table I of the Annex to Regulation (EU) No 37/2010) if they are pharmacologically active in the dose in which they are administered to the animal. Therefore, it applies to the active substances as well as other pharmacologically active substances contained in the products such as preservatives, adjuvants or other excipients.

Excipients not included in Table 1 of the Annex to Regulation (EU) No 37/2010 should also be listed and an appropriate justification given on why they do not fall within the scope of Regulation (EC) No 470/2009.

1.5 Consideration of this application requested under the following article of Directive 2001/82/EC or Regulation (EC) No 726/2004

1.5.1 Exceptional Circumstances

Provision foreseen according to Article 26(3) of Directive 2001/82/EC and Article 39(7) of Regulation (EC) No 726/2004. The applicant should indicate if marketing authorisation under exceptional circumstances is requested.

1.5.2 Accelerated Review

Article 39(8) of Regulation (EC) No 726/2004 is applicable to the centralised procedure only. The CVMP agreement on accelerated assessment procedure should be obtained in advance of the submission of the application for marketing authorisation. The applicant should indicate on the application form if accelerated assessment has been requested and agreed, together with the date of acceptance by the CVMP.

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)

The applicant should indicate if this request is made. Further details and justification for the request should be provided.
Please refer to Notice to Applicants, Volume 6A, Chapter 1 for further guidance.

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*

The information is identical to the one in section "Declaration and signature" since populated automatically. It does reflect the invented name proposed in the RMS.
If different (invented) names in Member States are proposed in the MRP or DCP, the box should be ticked and these should be listed in Annex 5.18.

2.1.2 Name of the active substance(s)

The information is identical to the one in section "Declaration and signature" since populated automatically.
The active substance(s) should be declared by its/their recommended International Non propriety Name (INN), accompanied by its salt or hydrate form if relevant (for further details, consult the product information templates on the EMA website:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000185.jsp&mid=WC0b01ac058002d9b0). Where no INN is available the Ph. Eur. name, the name of a national pharmacopoeia, a common name or scientific name should be provided. If the INN has not yet been published by WHO, the applicant should confirm that the approval of the INN is pending.
If there is more than one active substance, this field should be duplicated.

2.1.3 Pharmacotherapeutic group (Please use current ATC vet code)

The applicant should include the ATC vet code agreed by the WHO.
When a WHO agreed ATC vet code is not available, the most complete code corresponding to the claimed therapeutic use of the product should be given. This section should be duplicated where needed.
The two fields "ATC vet code" and "Group" are linked and should be both completed.

When the agreed ATC vet code is not yet available but the application for it has been submitted to the WHO, this should be indicated on the application form by ticking the box "If no ATC vet code has been assigned, please indicate if an application for the ATC vet code has been made".
If an ATC vet code is published by the WHO, but it is not used in the application, a justification should be provided.

2.1.4 Target species

The section should be filled in according to the target species Controlled Term List on the EUTCT website http://eutct.ema.europa.eu/eutct/displayWelcome.do.including any sub-category and indicating species in singular or plural as per official language use.
A drop-down list is available. The boxes can be replicated if needed.

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)

The values for “Pharmaceutical form”, “Strength” and “Active Substance” fields are populated automatically from “Declaration and signature” section. The fields are not editable here.

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

The route of administration should be chosen from the List of Standard Terms published by the European Directorate for the Quality of Medicines and Healthcare (EDQM)
(https://www.edqm.eu/en/standard-terms-590.html)

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)

The container should be selected from the List of Standard Terms published by the European Directorate for the Quality of Medicines and Healthcare (EDQM).

This subsection should be duplicated in order to include all types of pack.

For each type of pack give different package sizes.

Note. For mutual recognition and decentralised procedures, all package sizes authorised in the Reference Member State should be listed.

For each container the proposed container, closure and administration device (if applicable) should be indicated.
The subsections should be duplicated, if necessary.
Both, container and closure system have a dropdown field to select the correct option (The dropdown lists are based on a controlled dictionary).

- **Proposed shelf life Sections:** For each container indicate (if applicable):

- Proposed shelf life (before first opening of the container)
- Proposed shelf life (after first opening of the container)
- Proposed shelf life (after reconstitution or dilution)

Two sub-sections (rows) have been implemented:

- The row on the left side includes free text field to enter numbers
- The row on the right side includes dropdown fields with standard units list (seconds, minutes, hours,)

The information should be identical to Part 2.
Proposed storage conditions Section and Proposed storage conditions after first opening Section have a dropdown field to select the correct option (The dropdown lists are based on a controlled dictionary).

Indicate if a list of Mock-ups or samples/specimens sent with the application is attached as appropriate (see EMA/CMDv websites). The list should contain short description (names) of mock-ups or samples / specimens sent and be provided (Annex 5.17) to the application form.

2.3. Legal status

For products authorised by MRP/DCP, legal status is regulated at national level. Differences in proposed prescription status are acceptable among Member States.
The legal status may differ from one presentation to another but not all Member States accept more than one legal status at one marketing authorisation.

In the centralised procedure for veterinary medicinal products, the CVMP decides whether the product requires a prescription or not. Further sub-categories can be applied at the national level, based on the main category agreed at the European level and product information of the concerned product.

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 MS

For MRP/DCP applications the proposed marketing authorisation holder can be different in the Member State. The fields can be duplicated in order to indicate the proposed marketing authorisation holder per MS.
Proof of establishment of the applicant in EEA must be provided as Annex 5.3 and must have the same name and address (if mentioned) as in the application form.
In the centralised procedure, if the applicant has an SME status confirmed by the EMA, the copy of "Qualification of SME Status" should be included as Annex 5.21 and the EMA SME number should be indicated on the application form.

2.4.2 Person/company authorised for communication on behalf of the applicant <u>during the procedure</u> in the European Union/each MS

Contact details of section 2.4.1. can automatically be populated into section 2.4.2. when identical.
In mutual recognition and decentralised procedures, if more than one person/company is authorised for communication the related fields can be duplicated in order to indicate more than one person/company.
In centralised procedure, only one contact person can be indicated.

2.4.3 Person/company authorised for communication between the marketing authorisation holder and the competent authorities <u>after authorisation</u> if different from 2.4.2 in European Union/each MS

In mutual recognition and decentralised procedures, if more than one person/company is authorised for communication the related fields can be duplicated in order to indicate more than one person/company.
In centralised procedure, only one contact person can be indicated.

2.4.4 Qualified person in the EEA for Pharmacovigilance

In mutual recognition and decentralised procedures, if more than one Qualified person in the EEA for Pharmacovigilance is assigned and/or for different Member States, related fields can be duplicated in order to indicate more than one Qualified person and/or different Member States.

In centralised procedure, only one qualified person can be indicated.

2.5. -Manufacturers

For each company two “addresses” are described:
Address 1 field to enter building name/number or street and
Address 2 field to enter city/town.

For manufactures there are two options:

- Option #1:- The administrative address and manufacture address are the same
- Option #2:- The administrative address and manufacture address are different: in this case administrative and manufacturing facility address (for responsible for batch release in the EEA) fields are separate.

Note: ALL manufacturing and control sites mentioned throughout the whole dossier (Annex 5.8, Part 2, the Application form section 2.5 and Product Information) MUST be consistent regarding their names, detailed addresses and activities. Sites should not be included in one part of the dossier and left out in another for the reason of their activity.

In the centralised procedure, for manufacturing sites in section 2.5 of the application form, it is recommended to enter the EUDRA GMP certificate reference number, if it exists, instead of attaching the GMP certificate in Annex 5.9. Similarly, it is recommended to enter the EUDRA GMP Manufacturing Authorisation reference number, if it exists, instead of attaching a copy of the manufacturing authorisation(s) or other proof of GMP compliance in Annex 5.6.

2.5.1.a)- Authorised manufacturer(s) (or importer(s)) 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):

For both options, Authorised Manufacturers can be replicated, if necessary. The manufacturer country field has a dropdown to select each one, based on a controlled list of countries.

2.5.1 b) Official batch release for Vaccines:

The applicant may provide details of the Official Medicines Control Laboratory (OMCL) designated for the purpose of Official Control Batch Release (OCABR) in accordance with Article 82 of Directive 2001/82/EC as amended or the OMCL/Competent Authority responsible for release under Article 81 of Directive 2001/82/EC (Official Batch Peer review (OBPR)) if marketed in Member States requiring routine batch control for release onto their market.

There is only a short list of immunological veterinary medicinal products (IVMPs) that are subject to OCABR, the remaining products are subject to Art 81 of Directive 2001/82/EC in those member states implementing official batch release.

2.5.1.1 Contact person in the EEA for product defects and recalls

For 24H Telephone and Telefax fields, the phone number of the relevant functional office including the international area codes should be included.

Only one contact person per marketing authorisation should be indicated.

2.5.1.2. Batch control/Testing arrangements

Unless a MRA or other Community arrangement is in operation with the third country concerned, applicants are reminded that each production batch has to undergo all the controls required by Art 55 of Directive 2001/82/EC as amended, in the EEA.

A brief description of control tests carried out by the laboratory (ies) concerned is available in the dropdown field based on a controlled dictionary (e.g., Quality control testing - Biological, Quality control testing Chemical/Physical,…).

2.5.2 Manufacturer(s) of the veterinary medicinal product and site(s) of manufacture

(Note: including manufacturing sites of any diluents / solvent presented in a separate container but forming part of the veterinary medicinal product, quality control/ in-process testing sites, immediate and outer packaging and importer(s). For each site provide the relevant information.)

Sites mentioned in sections 2.5.1 and 2.5.1.2 should only be repeated here when they have an additional function in the manufacturing of the medicinal product.

A brief description of functions performed for each manufacturer(s) concerned is available in the dropdown field based on a controlled dictionary (e.g., Primary packaging, quality control testing, Processing of medicinal product, etc.).

The term “Processing of medicinal product” covers the manufacture of the finished product. “This terminology is based on the agreed terms used in the EU format for MIAs and GMP certificates included in the Compilation of Community Procedures on Inspections and Exchange of Information.

Note. More information about the functions performed is available on. http://eutct.ema.europa.eu/eutct

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

Note: All manufacturing sites involved the manufacturing process of each source of active substance, including quality control/ in-process testing sites, should be listed. Broker 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 relevant information.

The values for Active Substance are populated from “Declaration and Signature section” (please refer to the administrative data in the user guide).
A brief description of manufacturing steps performed by manufacturing site for each manufacturer(s) concerned is available in the dropdown field based on a controlled dictionary (e.g., Manufacture of active substance, Manufacture of active substance intermediate, Packaging of active substance, etc.)

Note. More information about the manufacturing steps performed is available on. http://eutct.ema.europa.eu/eutct

Note: When Centralised procedure is selected in Section 1 – Only the drop down field will be visible and mandatory, the free text field will not be visible.
When other procedures selected in Section 1 – both free text field and drop down field will be visible and either one is mandatory.

Several items are available on the electronic application form and should be selected based on the following criteria:

Item # 1: GMP inspection evidence from EEA or state with MRA etc.
Indicate if the site has 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 agreement.

In case of YES provide the EU-GMP Certificate reference number or attach latest GMP certificate.

Item # 2: other GMP inspection evidence

Item # 3: CEP
Indicate if a Ph. Eur. Certificate of suitability has been issued for the active substance(s):

In case of YES provide the Name of the CEP holder, the Name of the manufacturer if differs from the above and the CEP number.

Indicate if an Active Substance Master File has been used for the active substance(s).

Item # 4: ASMF
In case of YES attach letter of access for European Union/Member State authorities where the application is submitted (see "European ASMF procedure for active ingredients") (Annex 5.10).

In case of modification of the manufacturing process or specifications according to Annex 1 of Directive 2001/82/EC attach copy of confirmation from the manufacturer of the active substance to inform the applicant.

VAMF
Indicate if an EMA certificate for a Vaccine Antigen Master File (VAMF) has been issued or submitted in accordance with Directive 2001/82/EC Annex I, Part III.

2.5.4 Contract companies used for clinical trial(s), bioavailability or bioequivalence trials

For each contract company state where analytical tests are performed and where clinical data are collected.

Duty performed according to contract: a brief description of the duty performed according to the contract should be given.

For each contract company, clearly indicate where analytical tests are performed and where clinical data are collected. The subsections should be replicated, if necessary.

2.6. Qualitative and quantitative composition

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

The Qualitative and quantitative composition in terms of the active substance(s) and the excipient(s) should be consistent with the composition presented in Part 2A.
"Quantity/Unit" should not be understood too strictly since, for example, in the case of radiopharmaceutical products, interval of concentration might be indicated or for some excipients used "q.s.p." for a pH, an interval of values will have to be indicated. Under "reference/monograph standard" should be indicated the current Ph. Eur reference or the reference to an in-house monograph when no Ph. Eur monograph exists.
For liquids, the concentration per 1 ml should be given in addition to the container size/volume of the product.

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

If a substance is listed, it should be clear that if no Certificate of suitability for TSE is available, appropriate data should be included in relevant sections of the dossier (Part 2C).

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

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

If 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(s) given by the CVMP for this veterinary medicinal product?

If yes, provide date and reference of the scientific advice letter.

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

If yes, provide date and member State(s).

In any case, attach a copy of the scientific advice letter (Annex 5.14).

These sections may be replicated where needed.

4. OTHER MARKETING AUTHORISATION APPLICATIONS

4.1. For National / MRP / DCP applications, 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**?*

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?*

Where differences are identified by the applicant concerning authorisations granted in other Member States through a national procedure /MRP/ DCP, the applicant should explain clearly if different therapeutic indications have been granted in those Member States and on which grounds.

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

If yes, section 4.2 must be completed.

* "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.

4.2. 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.

For each case (authorised, pending, refused, withdrawn, suspended or revoked), all the information should be linked to one country and the whole section could be duplicated. This whole section 4.2 should be updated by the applicant as soon as a change occurs during the procedure.

In case of refusal, withdrawal by the Applicant, suspension or revocation by a Competent Authority, the reason for refusal, withdrawal, suspension or revocation should be clearly specified.

4.3. For multiple / duplicate applications of the same veterinary medicinal product

Multiple / duplicate applications (submitted simultaneously or subsequently to the original product) for:
All the information should be linked to one duplicate and the whole section should be replicated for each duplicate application.
A copy of letter from Commission services is required for validation in the centralised procedure.

Moreover, in case of parallel multiple applications, the applicant is requested to use the same legal basis as for the original authorisation application.

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.)
Note: refer to Commission Communication 98/C229/03.

For each case (authorised, pending, refused, withdrawn, suspended or revoked) all the information should be linked to one country and the whole section could be duplicated. In case of refusal, withdrawal, suspension or revocation, the reason for each case should be clearly specified.

5. ANNEXED DOCUMENTS (where appropriate)

All annexes provided should be identified by the correct identification number.