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.