|  |  |
| --- | --- |
|  | **CMDv validation check list for veterinary medicinal products in MRP/DCP**  **Reference Member State(RMS)** |

Note : this check list, once filled in by the RMS should be sent before the start of the validation phase, i.e. at day -14 if the dossier was received in advance in the RMS. Otherwise the RMS should send it between day -14 and day -10 at the latest. In any case, the CMS should be informed about the expected date at which they should be in receipt of the check list.

| **IDENTIFICATION OF THE PRODUCT** | |
| --- | --- |
| Procedure number |  |
| **Product (invented) name** |  |
| **Applicant (name)** |  |

| **FEES** |
| --- |
| Proof that fees have been paid or will be invoiced |

PHYSICAL CHECK

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|  |  | | |  | |  |  | | |  |
|  | **Electronic submission :** |  | **CESP** |  | **CD/DVD** | | |  | **Eudralink** | |
|  | CESP Number : | | |  | | | | | | |
|  | Eudralink – date of submission : | | |  | | | | | | |
|  | **Technical validation** | | |  | | | | | | |
|  | Result provided by applicant ?  Technically valid (tool like VNeeS checker)? | | | Yes  Yes | |  | No  No | | |  |
|  | **Paper copy submission** | | | | | | | | | |
|  | Are all the volumes present and their contents presented in an acceptable format ? | | | Yes | |  | No | | |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Sample(s) provided (if requested) | Yes |  | No |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **ACTIVE SUBSTANCE in case ASMF is used** | | | | | |
| ASMF received : | Yes |  | No |  | Original letter of access |
| Current edition  Critical Summary |

REGULATORY CHECK

|  |
| --- |
| **LEGAL BASIS OF THE APPLICATION**  This application is submitted in accordance with the following Article in Directive 2001/82/EC : |
| **Article 12(3)- application**, (i.e. dossier with administrative, quality, safety and efficacy data)  New active substance  Known active substance  Comments : |
| **Article 13(1) - Generic application\***  Reference Product (RP) :  ■ Evidence of licence for 8/10 years\*\*? Yes No  ■ Legal basis of the reference product : complete dossier\*\*\* ? Yes No  *Comments*: |
| **Article 13 (3) - so called “hybrid application”**  Reference Product (RP):  ■ Evidence of licence for 8/10 years\*? Yes No  ■ Legal basis of the reference product : complete dossier\*\* ? Yes No  ◼ Difference(s) compared to the reference veterinary medicinal product :  changes in the active substance(s)  changes 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  Comments: |
| **Article 13(4) - Similar biological application**  Reference Product (RP) :  ■ Evidence of licence for 8/10 years\*? Yes No  ■ Legal basis of the reference product : complete dossier ? Yes No  Comments: |

\* If the reference product is a centrally authorised VMP, then the name of the generic product should be the same within all CMS.

\*\* The 8 year rule for submitting generic applications will not come into effect until 2013 (applies to products for which an application has been submitted on 30 October 2005 or later).

\*\*\* The legal basis of the reference product cannot be a generic, but can be WEU, fixed combination or informed consent.

|  |
| --- |
| **Article 13a – Well established veterinary use**  Comments: |
|  |
| **Article 13b - Fixed combination:**  Comments: |
|  |
| **Article 13c - Informed consent application**\*  Letter of consent from the marketing authorisation holder of the authorised product.  Comments:    \* The legal basis of the reference product should be a complete dossier, cannot be a generic. |

|  |
| --- |
| **EXTENSION** : **Application for a change to the existing marketing authorisation leading to an extension as referred to in annex II of Commission Regulation (EC) No 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products, or any national legislation , where applicable ?**  Extension of the same product/MA  New product / MA  Nature of extension:  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 master cell bank from a different source, when 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  Comments: |

MRL Status for pharmacologically active substance(s) :

If no MRL has been set:

Valid application for MRL made to EMA  Yes Date ….  No

6 month elapsed between valid application for MRL an application for MA  Yes  No

Comments:

Part I - Summary of the dossier

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **PART IA – Administrative information**  **Annexed documents ( where appropriate)** | | **RMS comments** | | |
|  | | **Valid** | **Invalid** | **N.A.** |
| 5.1 | Proof of payment |  |  |  |
| 5.2 | Informed consent letter of MAH of authorised VMP. |  |  |  |
| 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 EudraGMP 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 |  |  |  |
| 5.9 | Statement (or GMP Certificate issued by an EEA inspectorate, when available) from the competent authority which carried out the inspection of the manufacturing site(s) (not older than 3 years). References to EudraGMP will suffice when available. |  |  |  |
| 5.10 | Letter(s) of access to Active Substance Master File(s) (Drug Master File(s)) or copy of Ph. Eur. Certificate(s) of suitability |  |  |  |
| 5.11 | Copy of written confirmation from the manufacturer of the active substance to inform the applicant in case of modification of the manufacturing process or specifications according to Annex I of Directive 2001/82/EC. |  |  |  |
| 5.12 | Ph. Eur. Certificate(s) of suitability for TSE |  |  |  |
| 5.13 | Written consent(s) of the competent authorities regarding GMO release in the environment. |  |  |  |
| 5.14 | Scientific Advice given by CVMP or Member State |  |  |  |
| 5.15 | Copy of Marketing Authorization(s) required under Article 12(3) n of Directive 2001/82/EC in the EEA and the equivalent in third countries on request. |  |  |  |
| 5.16 | Letter from Commission services regarding multiple applications. |  |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 5.17 | List of Mock-ups or Samples/specimens sent with the application, as appropriate (see EMA/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).  *QP template provided ?* |  |  |  |
| 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 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. |  |  |  |

\* NA : not applicable.

|  |
| --- |
| Is Part IA valid : Yes  No |
| * Have all the appropriate documents been annexed? Yes No   Comments: |

**PART IB - SPC, Labelling and package leaflet**

| Present ? |  | RMS Comments |
| --- | --- | --- |
|  | Proposed SPC in English |  |
|  | Proposed labelling in English |  |
|  | Proposed Package Leaflet in English |  |
|  | Editable files of proposed SPC, labels and product literature provided (Word format) in English version |  |

Is Part IB valid: Yes  No

Comments:

**PART IC – Detailed and critical summaries**

| Present ? |  | RMS Comments |
| --- | --- | --- |
|  | 1. **Quality**  Signature + date  Expert’s CV  Critical and summary table |  |
|  | 2. **Safety**  Signature + date  Expert’s CV  Critical and summary table |  |
|  | **Environmental risk assessment (ERA)**  Signature + date  Expert’s CV  Critical and summary table |  |
|  | **3. Residues** - if applicable  Signature + date  Expert’s CV  Critical and summary table |  |
|  | 4. **Efficacy**  Signature + date  Expert’s CV  Critical and summary table |  |

Is Part IC valid : Yes  No

Comments:

Part II – Quality Part

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Are all the volumes present and their contents presented in an acceptable format ? | Yes |  | No |  |

Is Part II valid ? Yes  No

**Comments:**

Part III - Safety and residues tests

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Are all the volumes present and their contents presented in an acceptable format ? | Yes |  | No |  |

| Present ? | Pharmaceutical VMP | RMS Comments |
| --- | --- | --- |
|  | **PART III A – Safety tests** | |
|  | III A 6. - Environmental risk assessment |  |
|  | **III B – Residues tests** |  |

Is Part III valid ? Yes  No

**Comments :**

Part IV - Pre-clinical and clinical trial

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Are all the volumes present and their contents presented in an acceptable format ? | Yes |  | No |  |

Is Part IV valid? Yes  No

**Comments :**

*Information for CMS (optional)*

Comparisons table of SPCs provided ? Yes No

Part II - III - **IV : information on the dossier** (for instance for abridged application : new/own studies/data as *in vivo* bioequivalence, phase II ERA…)

**RMS CONCLUSIONS**

|  |  |
| --- | --- |
| **THIS APPLICATION WAS CHECKED BY** | |
| Reference Member State |  |
| Person responsible for validation |  |
| Name  Telephone |  |
| E-mail |  |

**1. STATUS OF THE APPLICATION in RMS**

The application is considered valid.

The application is considered valid and the procedure can start, but the issues in section 3 below need to be addressed before day 30/50 (MRP/DCP).

The application is considered invalid and the procedure cannot start before the issue in section 2 below have been addressed.

**2. Validation issue(s) preventing the procedure from starting**

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**3. Validation issue(s) not preventing the procedure from starting but which have to be addressed by day 30/50 of the MR/DC procedure**

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**4. Additional information for the applicant**

**Please note that once the application has been validated, a consolidated amended dossier taking into account all of the amendments during validation should be submitted. A signed statement should be provided that the only changes to the dossiers are as a result of validation issues and that the dossiers in the CMS are identical.**

|  |  |
| --- | --- |
|  | **CMDv validation check list for**  **veterinary medicinal products**  **Concerned Member State(CMS) :** |

| **IDENTIFICATION OF THE PRODUCT** | |
| --- | --- |
| **Product (invented) name** |  |
| **Procedure number** |  |
| **Route(s) of administration** |  |
| **Number of pack types** |  |
| **Proposed MAH in CMS** |  |
| **FEES** | |
| Proof that fees have been paid or will be invoiced | |

PHYSICAL CHECK

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | | |  | | |  |  | | |  |
|  | **Electronic submission :** |  | **CESP** | |  | **CD/DVD** | | |  | **Eudralink** | |
|  | CESP Number : | | | |  | | | | | | |
|  | Eudralink – date of submission : | | | |  | | | | | | |
|  | **Paper copy submission** | | | | | | | | | | |
|  | Are all the volumes present and their contents presented in an acceptable format ? | | | Yes | | |  | No | | |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Sample(s) provided (if requested) | Yes |  | No |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | RMS assessment report submitted  (for MRP only) | Yes |  | No |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | If the applicant is using an ASMF, has the RMS included the ASMF assessment report (for MRP only) | Yes |  | No |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **ACTIVE SUBSTANCE in case ASMF is used** | | | | | |
| ASMF received : | Yes |  | No |  | Original letter of access |
| Current edition |

|  |
| --- |
| **ABRIDGED APPLICATION**  ■ Legal basis :  ■ Name of Reference Product n CMS in the application form : conforms ? Yes No  ■ Other informations on the Reference Product :  MA number :  *Comments*: |

| **Other CMS validation points** |
| --- |
| ■ Comparisons table of SPCs provided ? Yes No  **Informed consent application**  ■ Attach letter of consent from the marketing authorisation holder of the authorised product in the CMS  (Annex 5.2) : Yes No |

**CMS CONCLUSIONS**

|  |  |
| --- | --- |
| **THIS APPLICATION WAS CHECKED BY** | |
| Person responsible for validation |  |
| Name  Telephone |  |
| E-mail |  |

**1. STATUS OF THE APPLICATION in CMS**

The application is considered valid.

The application is considered valid and the procedure can start, but the issues in section 3 below need to be addressed before day 30/50 (MRP/DCP).

The application is considered invalid and the procedure cannot start before the issue in section 2 below have been addressed.

**2. Validation issue(s) preventing the procedure from starting**

.

.

**3. The RMS is asked to provide MIRP according to the CMDv guidance CMDv/GUI/006**

YES NO

**4. Validation issue(s) not preventing the procedure from starting but which have to be addressed by day 30/50 of the MR/DC procedure**

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**5. Additional information for the applicant**

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