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| --- | --- |
|  | **CMDv validation check list for veterinary medicinal products in MRP/DCP/RUP**  **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 -15 if the dossier was received in advance in the RMS. Otherwise the RMS should send it by day -12 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)** |  |

| **TYPE OF PROCEDURE** | |
| --- | --- |
| Decentralised procedure | |
| Mutual recognition procedure | In that case, has the 6 months time period elapsed between the national procedure and the MR procedure ?  Yes  No |
| **Subsequent recognition procedure** | |

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

PHYSICAL CHECK

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|  | **Electronic submission :** |  | **CESP** |  |  | | |  |  | |
|  | CESP Number : | | |  | | | | | | |
|  | **Technical validation** | | |  | | | | | | |
|  | Result provided by applicant ?  Technically valid (tool like VNeeS checker)? | | | Yes  Yes | |  | No  No | | |  |

|  |  |  |
| --- | --- | --- |
| **Submission format :** | NtA (all parts) | CTD (part II) and NtA (other parts) |

|  |  |  |  |  |  |
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|  | 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 |
| **EU/ASMF number (if applicable) :** | | | |  | |

REGULATORY CHECK

|  |
| --- |
| **LEGAL BASIS OF THE APPLICATION**  This application is submitted in accordance with the following Article in Regulation 2019/6 : |
| **Article 8(1) application**, (i.e. dossier with administrative, quality, safety and efficacy data)  Comments : |
| **Article 18 - Generic application\***  Reference Product (RP) :  ■ Evidence of end of protection period\*\* ? Yes No  ■ Legal basis of the reference product : complete dossier\*\*\* ? Yes No  ■ Date of authorisation of reference product before on/after 1st October 2005  If a generic of a Centrally authorised product:  ■ Same invented name proposed in all MSs? Yes No  *Comments*: |
| **Article 19 - hybrid application**  Reference Product (RP):  ■ Evidence of end of protection period\*\*? 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 strength (quantitative change to the active substance(s))  change in route of administration  change in pharmaceutical form  bioequivalence cannot be demonstrated through bioavailability studies  differences relating to raw materials or in manufacturing processes  other  Comments: |

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

\*\* data protection is defined in articles 39 and 40.

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

|  |
| --- |
| **Article 20 - Fixed combination:**  Comments: |

|  |
| --- |
| **Article 21 - 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. |

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| --- |
| **Article 22 – Well established veterinary use / bibliographic data based application**  Comments: |

**Article 23 application** - (limited market application)

first submission

CVMP eligibility confirmation

re-examination submission (at least 5 years – 6 months after the first authorisation)

Comments :

**Article 25 application** **-** (application in exceptional circumstances)

first submission

re-examination submission (at least 1 year – 3 months after the first authorisation)

Comments :

MRL Status for pharmacologically active substance(s) :

If no MRL has been set:

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

Comments:

Part 1 - Summary of the dossier

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **PART 1A – 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 | Copy of the “Qualification of SME Status” |  |  |  |
| 5.6 | Manufacturing Authorisation required under Annex I (point 4.1) of regulation 2019/6 (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 (including sites involved in sampling and testing for batch release of products manufactured in third countries) |  |  |  |
| 5.9 | GMP certificates(s) ; where applicable a summary of other GMP inspections performed |  |  |  |
| 5.10 | Letter(s) of access to Active Substance Master File(s) (Drug Master File(s)) or copy of Ph. Eur. Certificate(s) of suitability |  |  |  |
| 5.11 | Copy of written confirmation from the CEP holder to the applicant that the manufacturing process has not been modified since the granting of the certificate of suitability by the EDQM |  |  |  |
| 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 | a) List of countries in which a Marketing Authorisation has been granted or revoked for the veterinary medicinal product in the EEA and the equivalent in third countries (required under Annex I, point 6.1) -  b) Copies of all the SPCs for MAs granted by Member States  c) List of countries in which an application has been submitted or refused  d) List of Member States in which the VMP is to be placed on the market |  |  |  |
| 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 | Summary of the Pharmacovigilance system master file and, where appropriate, the risk management system that the Applicant will put in place |  |  |  |
| 5.21 | Evidence and justification to support the claim of new active substance status in the Union for applications based on Articles 8, 23 or 25 of Regulation 2019/6 |  |  |  |

\* NA : not applicable.

|  |
| --- |
| Is Part 1A valid : Yes  No |
| * Have all the appropriate documents been annexed? Yes No   Comments: |

**PART 1B - VMP Product Information**

| 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 1B valid: Yes  No

Comments:

**PART 1C – Critical expert report**

| Present ? |  | RMS Comments |
| --- | --- | --- |
|  | 1. **Quality**  Signature + date  Expert’s CV  Critical |  |
|  | 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 1C valid : Yes  No

Comments:

Part 2 – Quality Documentation

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

Is Part 2 valid ? Yes  No

**Comments:**

Part 3 - Safety documentation (safety and residus tests)

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

| Present ? | Other than biological VMP | RMS Comments |
| --- | --- | --- |
|  | **PART 3 A – Safety tests** | |
|  | 3 A 6. - Environmental risk assessment |  |
|  | **3 B – Residues tests** |  |

Is Part 3 valid ? Yes  No

**Comments :**

Part 4 – Efficacy documentation (Pre-clinical and clinical trial(s))

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

Is Part 4 valid? Yes  No

**Comments :**

*Information for CMS (optional)*

Comparisons table of SPCs provided ? Yes No

Part 2 - 3 - **4 : information on the dossier** (for instance for generic/hybrid 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 |  |
| Date |  |

**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 and SRP/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 and SR/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** |  |
| **Proposed MAH in CMS** |  |
| **FEES** | |
| Proof that fees have been paid or will be invoiced | |

PHYSICAL CHECK

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|  | **Electronic submission :** |  | **CESP** | |  |  | | |  |  | |
|  | CESP Number : | | | |  | | | | | | |
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|  | Sample(s) provided (if requested) | Yes |  | No |  |

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

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | If the applicant is using an ASMF, has the RMS included the ASMF assessment report (for MRP/SRP only) | | Yes |  | No |  |
| EU/ASMF number (if applicable) : | |  | | | | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **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 in CMS in the application form : conforms ? Yes No  ■ Other information 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 |  |
| Date |  |

**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 and SRP/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 and SR/DC procedure**

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**5. Additional information for the applicant**

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