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Co-ordination Group for Mutual Recognition and Decentralised Procedures – Veterinary

CMDv validation check list for Renewals of veterinary medicinal products

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 -7. 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)	

Date of submission :	
Date of first authorisation in Reference Member State/EU :	
Proposed Common Renewal Date:	

PHYSICAL CHECK

☐	Paper copy submission				
	Are all the volumes present and their contents presented in an acceptable format ?	Yes	☐	No	☐
☐	Electronic submission				

	DOCUMENTS APPENDED TO THIS APPLICATION	**RMS comments**		
		Valid	**Invalid**	**N.A.**
1.0	Cover Letter	☐	☐	☐
1.1	Comprehensive table of content	☐	☐	☐
2	Renewal Application Form with the following annexes:	☐	☐	☐
2.1	List of all authorised product presentations for which renewal is sought in tabular format	☐	☐	☐
2.2	Details on contact persons: • Qualified person in the EEA for Pharmacovigilance and the QP for Pharmacovigilance in the MS, if different • Contact person in the EEA with overall responsibility for product defects and recalls • Contact person at the address of the Marketing Authorisation Holder (if different from the address of the contact person during the procedure)	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
2.3	List of EU Member States / Norway / Iceland where the product is on the market and indicating for each country which presentations are marketed and the launch date	☐	☐	☐
2.4	Chronological list of all post authorisation submissions (variations, extensions etc.), conditions and, any Specific Obligations (for centrally authorised products) submitted since grant of marketing authorisation or last renewal indicating scope, status, date of submission and date when issue has been resolved	☐	☐	☐
2.5	Revised list of all remaining conditions and, any Specific Obligations (for centrally authorised products) (where applicable)	☐	☐	☐
2.6	Proof of payment of fee, where relevant	☐	☐	☐
2.7	A statement, or when available, a certificate of GMP compliance, not more than three years old, for the manufacturer(s) of the medicinal product listed in the application issued by an EEA competent authority or MRA partner authority.	☐	☐	☐
2.8	In addition, for manufacturing sites of the medicinal product not located in the EEA or in the territory of an MRA partner, a list of the most recent GMP inspections carried out by other authorities indicating the date, inspection team and outcome.	☐	☐	☐
2.9	A declaration by the Qualified Person (QP) of each of the manufacturing authorisation holders (i.e. located in the EEA) listed in the application form where the active substance(s) is used as a starting material, that the active substance(s) is manufactured in accordance with the guidelines on good manufacturing practice for starting materials as adopted by the EU	☐	☐	☐
2.10	Where different, a declaration by the Qualified Person (QP) of the manufacturing authorisation holder(s) listed in the application form as responsible for batch release, that the active substance(s) is manufactured in accordance with the guidelines on good manufacturing practice for starting materials as adopted by the EU	☐	☐	☐
3	SPC, Labelling and Package Leaflet Editable files of proposed SPC, labels and product literature	☐ ☐	☐ ☐	☐ ☐

	provided (Word format) in English version			
4	Quality expert statement (incl. Signature + CV), including:	☐	☐	☐
4.1	Currently authorised specifications for the active substance and the finished product	☐	☐	☐
4.2	Qualitative and quantitative composition in terms of the active substance(s) and the excipient(s)	☐	☐	☐
5	Clinical expert statement (incl. Signature + CV)	☐	☐	☐
6	Safety expert statement (incl. Signature + CV)	☐	☐	☐
7	Periodic Safety Update Report and Summary Bridging Report if applicable	☐	☐	☐
8	Declaration of current TSE status	☐	☐	☐

*NA : not applicable.

Are all documents provided valid : Yes ☐ No ☐

Comments:

Information for CMS (optional)

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 40.

☐ 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 40 of the procedure

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4. Additional information for the applicant

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CMDv validation check list for veterinary medicinal products

Concerned Member State(CMS) :

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IDENTIFICATION OF THE PRODUCT	
Product (invented) name	
Procedure number	
MAH in CMS *(FR : the VMP has its MA so it is a MAH, not a proposed one)*	

FEES
☐ Proof that fees have been paid or will be invoiced

PHYSICAL CHECK					
☐	Paper copy submission				
	Are all the volumes present and their contents presented in an acceptable format ?	Yes	☐	No	☐
☐	Electronic submission				

Other CMS validation points

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 40.

☐ 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 40

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4. Additional information for the applicant

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