14 September 2018
EMA/603587/2018
Veterinary Medicines Division

Change of applicant re-validation Checklist form (V)

Change of applicant re-validation checklist		
GENERAL CONSIDERATIONS		
Product name		
Procedure number		
OLD applicant details		**NEW** applicant details

Comments

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Cover Letter and Annexes		
COVER LETTER		
A letter explicitly requesting the change of applicant is submitted. The procedure number and the product are correctly identified.	Select	
The letter is signed by both the previous and new applicant.	Select	
A confirmation that complete and up-to-date file concerning the veterinary medicinal product, or a copy of this file, has been made available to, or has been transferred to, the new applicant.	Select	*This statement needs to be included in the cover letter.*
The applicant should confirm that this application does not fall under the scope of a duplicate application as per Article 82 of Regulation (EC) No 726/2004.	Select	*The applicant needs to provide a statement confirming that the application does not fall under the scope of a duplicate application as per Article 82 of Regulation (EC) No 726/2004. This statement needs to be included in the cover letter.*
If the application is a duplicate application, or creates a duplicate application, the applicant should present the relevant authorisation from the Commission as per Article 82 of Regulation (EC) No 726/2004indicating the new applicant.	Select	*The application form needs to be updated accordingly. The applicant needs to provide the relevant authorisation from the Commission as per Article 82 of Regulation (EC) No 726/2004 indicating the new applicant (refer to section 4. of the application form and Annex 5.16). In case of a duplicate application ensure that SIAMED is updated with the relationship to the relevant product(s).*
If applicable, a confirmation that the minor use/minor species (MUMS)/limited market classification, if still valid, has already been transferred, or that notification of its transfer has been submitted.	Select	*The MUMS/limited market classification is connected to the product/indication and therefore transferable together with the product with no implication on financial incentives/data requirements. If the MUMS/limited market classification is still valid at the time of change of transfer of applicant, it should be transferred to the new applicant. To acknowledge such a transfer, the EMA requires a letter from the original sponsor/applicant informing the agency of the transfer of the classification product and the MUMS/limited market classification from the original sponsor/applicant to a sponsor/ applicant established in the Union (EEA). This letter should state the document reference number of the MUMS outcome letter confirming the MUMS classification. The letter should be submitted to VetMUMSapplications@ema.europa.eu*
The Applicant should confirm that the only changes introduced in the eAF are limited to the following sections: - Declaration and signature; - 2.4 Marketing Authorisation Holder/contact persons/company; - 2.5.1.1 Contact person in the EEA for product defects and recalls (if applicable); - 4. Other Marketing Authorisation applications (if applicable).	Select	*The applicant needs to provide a statement confirming that the only changes implemented in the eAF are limited to these sections. This statement can be part of the Cover Letter. In case other changes are related to the responses to LoQ/LoOI submitted in parallel, this should be clearly explained in the cover letter.*

Application Form and Annexes		
ADMINISTRATIVE DATA		
The applicant's details should be consistent throughout the application form (on the declaration and signature page under "applicant" and in section 2.4.1) and in the product information (SPC section 7, Labelling sections 15 and 2, and PL section 1).	Select	*The "Applicant" (1st page of AF) and "proposed MAH" (section 2.4.1) must be the same. Ensure that the company name is present in this section.*
The **'Declaration and signature'** page should be signed by the person authorised for communication, on behalf of the new applicant. The same contact person is declared in section 2.4.2 of the application form and a letter of authorisation is attached (Annex 5.4).	Select	*The letter of authorisation should be provided on headed paper, signed and with a recent date.* *If the contact person is different, or letter not provided/not correct, request corrected application form/letter.*
Annex 5.4 Letter of authorisation. A letter of authorisation should be provided on headed paper. It should be recent and signed.	Select	*If the person authorised for communication is the CEO/President/Director/Vice-President, Annex 5.4 is not necessary. The details of the person in Annex 5.4 should be the same as in section 2.4.2 or 2.4.3 of the application form.*
The details of the contact persons listed under sections 2.4.1 to 2.4.5 and 2.5.1 must be provided and updated in SIAMED if different.	Select	*Ask the applicant to confirm the addresses and ask vet.applications to update SIAMED if required.*
1.3 RELATED ARTICLE IN THE DIRECTIVE 2001/82/EC		
1.3.7 Article 13c – Informed consent application. If the initial submission was an informed consent, an updated Annex 5.2 is submitted.	Select	
2.4 MARKETING AUTHORISATION HOLDER / CONTACT PERSONS / COMPANY		
2.4.1 Proposed marketing authorisation holder. The name and address of the proposed new MAH is exactly the same as in the Annex 5.3 Proof of Establishment (PoE).	Select	*Annex 5.3 has to be provided and the details should be exactly the same as in section 2.4.1. as far as they are given in the PoE. Ignore section for national/decentralised applicant (should be kept unticked/empty).*
Annex 5.3 Proof of establishment. Does the Annex 5.3 is provided and establish the applicant as being in the EEA?	Select	*Submitted proof of establishment should not be older than 6 months. It can be in any language as long as EN translation is provided).*

Application Form and Annexes		
2.4.1 Contact at the MAH address. A contact person should be identified at the MAH address.	Select	*Data needs to be correct (especially phone number as Courier will call company / contact person to deliver Commission Decision) & complete for SIAMED entry (otherwise templates will not work)* *Name, Address, Telephone number, personalized email address should be included.*
2.4.1 SME status. The previous applicant had an SME status.	Select	*Check SIAMED and update as appropriate.*
2.4.1 SME status. The current applicant has an SME status.	Select	*Check SIAMED and update as appropriate.* *If current applicant has SME status, please clearly indicate in the Excel FCN.*
Annex 5.21 Qualification of SME status. If SME status has been assigned by the EMA to the new applicant, Annex 5.21 and a valid SME number should be provided.	Select	*Annex 5.21: (related to section 2.4.1) The qualification for SME status should be provided and be valid at the start of the procedure. If the company is claiming SME status but do not have a letter or number, contact SME office and inform the financial workflow. Flag to Scientific/Content Lead (S/CL). Check in SIAMED if SME status is correctly entered. In case of doubts, or if the SME number contains a "C" (meaning consultant) e.g. EMA/SME/C/XXX/XX/XX contact SME office to confirm.*
2.4.1 SME status. SME status will expire before the end of the procedure.	Select	*If SME status is valid, please ensure that SIAMED correctly reflects this information and flag to S/CL and SME office. If SME status is close to expiry (less than 1 year), flag to SME office and if not re-confirmed, need to update SIAMED once no longer applicable – flag to S/CL when SME status will expire.*
2.4.2 Person authorised for communication on behalf of the applicant for the procedure. A name and full contact details (personal e-mail address, full address in the EEA and telephone number) should be provided.	Select	*Data needs to be correct & complete for SIAMED entry. Name, Address, Telephone number, personalised email address should be included. If different from section 2.4.1, a letter of authorisation needs to be provided (Annex 5.4).*
2.4.3 Person authorised for communication on behalf of the applicant after authorisation. A name and full contact details (personal e-mail address, full address and telephone number) should be provided, if applicable.	Select	*Data needs to be correct & complete for SIAMED entry. Name, Address, Telephone number, personalised email address should be included. If different from 2.4.2, a letter of authorisation needs to be provided (Annex 5.4).*
2.4.4 Qualified Person for Pharmacovigilance. It is a legal requirement that the QPPV resides and operates in the EEA. The QPPV must also be registered with Eudravigilance. The confirmation boxes must be ticked.	Select	*Data needs to be correct & complete for SIAMED entry. Name, Address, Telephone number, personalised email address should be included.* *It might be that the email address is in a format such as EUQppv@company.com but in that case it should be confirmed with the company that it is a dedicated email address which will reach the QPPV 24h/day.*
Annex 5.20 Detailed Description of the Pharmacovigilance System. An updated DDPS should be provided. The DDPS should include the CV of the qualified person.	Select	*If CV of qualified person is missing (no inclusion in Annex 5.20) issue VSI and immediately flag issue to S/CL.*
2.5 MANUFACTURERS		
2.5.1 Authorised site responsible for batch release. The site(s) responsible for batch release should remain unchanged.	Select	*Ensure that the details in the eAF correspond to those already entered in SIAMED at the time of validation. If this site is based in UK, flag to S/CL.*
2.5.1.1 Contact person for product defects and recalls. The name of the person responsible for product defects and recalls in the EEA with correct contact details (full address in the EEA, 24H telephone number and e-mail address) must be provided.	Select	*Person has to be located in the EEA. Data needs to be correct & complete for SIAMED entry (otherwise templates will not work). Name, Address, Telephone number, personalised email address should be included.*

Application Form and Annexes		
Annex 5.10 Letter(s) of access to an ASMF or copy of Ph. Eur. Certificate of Suitability. In case an ASMF or a CEP is used for the manufacture of active substance, an updated Letter of Access (ASMF) and/or Declaration of Access (CEP) should be provided for the new applicant.	Select	*The ASMF holder details should correspond to those in the updated Letter of Access and updated ASMF holder's Cover Letter.*
Annex 5.11 Written confirmations from the manufacturers of the active substances to inform the Applicant in case of modification of the manufacturing process or specifications.	Select	*This statement can sometimes be found annexed to the letter of access.*
If an ASMF is used the ASMF holder needs to submit an **updated part 1**.	Select	*Including Cover letter; the Annex 4 - withdrawal of access letter (for the previous applicant); Annex 2 - updated letter of access; Commitment to inform the new applicant in case of modification of the manufacturing process or specifications.*
4. OTHER MARKETING AUTHORISATION APPLICATIONS		
4.3 Multiple/Duplicate applications. Section 4.3 is mandatory for duplicates/informed consents.	Select	*Pay attention when preparing the FCN as duplicates filed on patent grounds will receive a reduced fee.*
Annex 5.16 Letter from commission. Should contain the following: - The name of the (proposed) MAH relevant for the application: should be exactly the same as the applicant for the multiple. - The name of the co-marketer is not relevant - The name of the product relevant for the application must be the same as in the AF. In case the AS is given it must be the same as the ref MP.	Select	*Flag to S/CL if the letter contains a statement with a condition.* *The application should be blocked and issue escalated to S/CL if the letter contains a statement that the conditions are not fulfilled.*

Part 1		
SPC, LABELLING AND PACKAGE LEAFLET		
An update complete **Product Information** (latest QRD) should be provided in English for all of the applied forms and strength.	Select	*Changes are expected in SPC section 7, Labelling sections 15 and 2, and PL section 1.* *Word version should be provided in folder 'add-info'.* *PDF version should be provided in part 1b-spc-pl.*
MOCK-UPS		
Updated **mock-ups** should be provided (English worst case scenario).	Select	*Mock-up for PL not needed, only labelling (outer and inner).*