



05 April 2022
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



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	<i>This statement needs to be included in the cover letter.</i>
The applicant should select the correct option whether the application is/is not a duplicate application.	Select	
The Applicant should confirm that the only changes introduced in the eAF are limited to the following sections: <ul style="list-style-type: none"> - 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	<i>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.</i>

Application Form and Annexes

ADMINISTRATIVE DATA

<p>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 (In QRD 8.2: SPC section 7, Labelling sections 15 and 2, and PL section 1. In QRD 9.0: SPC section 6, Labelling sections 13 and 8, and PL section 16).</p>	<p>Select</p>	<p><i>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.</i></p>
<p>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).</p>	<p>Select</p>	<p><i>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.</i></p>
<p>Annex 5.4 Letter of authorisation. A letter of authorisation should be provided on headed paper. It should be recent and signed.</p>	<p>Select</p>	<p><i>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.</i></p>
<p>The details of the contact persons listed under sections 2.4.1 to 2.4.4 and 2.5.1 must be provided and updated in SIAMED if different.</p>	<p>Select</p>	<p><i>Ask the applicant to confirm the addresses and ask vet.applications to update SIAMED if required.</i></p>
<p>1.3 RELATED ARTICLE IN REGULATION (EU) 2019/6</p>		
<p>1.3.7 Article 21 – Informed consent application. If the initial submission was an informed consent, an updated Annex 5.2 is submitted.</p>	<p>Select</p>	
<p>2.4 MARKETING AUTHORISATION HOLDER / CONTACT PERSONS / COMPANY</p>		
<p>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).</p>	<p>Select</p>	<p><i>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).</i></p>
<p>Annex 5.3 Proof of establishment. Does the Annex 5.3 is provided and establish the applicant as being in the EEA?</p>	<p>Select</p>	<p><i>Submitted proof of establishment should not be older than 6 months. It can be in any language as long as EN translation is provided).</i></p>

Application Form and Annexes		
2.4.1 Contact at the MAH address. A contact person should be identified at the MAH address.	Select	<i>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.</i>
2.4.1 SME status. The previous applicant had an SME status.	Select	<i>Check SIAMED and update as appropriate.</i>
2.4.1 SME status. The current applicant has an SME status.	Select	<i>Check SIAMED and update as appropriate. If current applicant has SME status, please clearly indicate in the Excel FCN.</i>
Annex 5.5 Copy of the Qualification of SME status. If SME status has been assigned by the EMA to the new applicant, Annex 5.5 and a valid SME number should be provided.	Select	<i>Annex 5.5: (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.</i>
2.4.1 SME status. SME status will expire before the end of the procedure.	Select	<i>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.</i>
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	<i>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).</i>
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	<i>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).</i>
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	<i>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.</i>
Annex 5.20 Summary of the Pharmacovigilance System Master File and, where applicable, the Risk Management System that the applicant will put in place. An updated PSMF should be provided. The PSMF should include the CV of the qualified person.	Select	<i>If CV of qualified person is missing (no inclusion in Annex 5.20) issue VSI and immediately flag issue to S/CL.</i>
2.5 MANUFACTURERS		
2.5.1 Authorised site responsible for batch release. The site(s) responsible for batch release should remain unchanged.	Select	<i>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.</i>
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	Select	<i>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.</i>

contact details (full address in the EEA, 24H telephone number and e-mail address) must be provided.		
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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	<i>The ASMF holder details should correspond to those in the updated Letter of Access and updated ASMF holder's Cover Letter.</i>
Annex 5.11 Confirmation in writing from CEP holder to the applicant that the manufacturing process has not been modified since the granting of the certificate of suitability by the European Directorate for the Quality of Medicines and Healthcare.	Select	<i>This statement can sometimes be found annexed to the letter of access.</i>
If an ASMF is used the ASMF holder needs to submit an updated part 1 .	Select	<i>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.</i>
4. OTHER MARKETING AUTHORISATION APPLICATIONS		
4.3 Multiple/Duplicate applications. Section 4.3 is mandatory for duplicates/informed consents.	Select	<i>Pay attention when preparing the FCN as duplicates filed on patent grounds will receive a reduced fee.</i>

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	<p><i>Changes are expected in</i></p> <ul style="list-style-type: none"> <i>QRD 8.2: SPC section 7, Labelling sections 15 and 2, and PL section 1.</i> <i>QRD 9.0: SPC section 6, Labelling sections 13 and 8, and PL section 16.</i> <p><i>Word version should be provided in folder 'add-info'. PDF version should be provided in part 1b-spc-pl.</i></p>