EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Work instructions

Title: Handling of Veterinary e-submissions		
Applies to: Veterinary applications team		
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1. Changes since last revision

New WIN.

2. Records

- SIAMED database is updated as appropriate.
- The original paper cover letter or any other paper original documents received with the date of receipt stamp is scanned into DREAM and stored in temporary filing area in Vet Applications team's filing cabinets by the date of submission, and discarded after 6 months have elapsed from the date of issue/submission

3. Instructions

3.1. Purpose

The purpose of this WIN is to provide guidance on handling electronic submission and technical validation of dossiers for centralised veterinary medicinal products, MRL applications and referrals.

The steps described below apply to submission at all stages of the procedure.

3.2. Scope

The WIN applies to the Vet Applications team in the Veterinary Regulatory and Organisational Support service (V-VM-ROS).

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3.3. Responsibilities

It is the responsibility of the Head of Department (delegated to the Service Head), to ensure that this procedure is adhered to within V-VM-ROS. The responsibility for the execution of a particular part of this procedure is identified in the right-hand column of section **3.5 "Instructions".**

3.4. Definitions

A-IS-BSU	Business Support Services in the Administration Division (here: Mailroom)
AA	Administrative assistant (here: in vet applications team, appointed by the Head of V-VM-ROS specifically to routinely screen the Vet.applications mailbox for submission of applications. This staff member has one back-up also appointed specifically for this role by the Head of V-VM-ROS)
AST	Assistant
HDep	Head of Department
HDiv	Head of Division
HSer	Service Head
PM	Project Manager within V-VM-DEM responsible for coordination of the Initial MA/ Extension/ Annual Reassessment procedure, or for scientific input to a post-authorisation procedure
ProcM	Procedure Manager responsible for coordination of post-authorisation procedures (variations, transfers, renewals, post-authorisation measures)
SOP	Standard Operating Procedure
V-VM	Veterinary Medicines (Department)
V-VM-APH	Animal and Public Health (Service)
V-VM-DEM	Development and Evaluation of Veterinary Medicines (Service)
V-VM-ROS	Veterinary Regulatory and Organisational Support (Service)
VO	Validating Officer within V-VM-ROS appointed to validate the particular application for initial marketing authorisation or extension.
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3.5. Instructions

Step	Action	Responsibility
1.0	**Receipt of e-submission**	
1.1	***Submission via EMA e-Submission Gateway / Web Client***	AA
	Receive auto-forwarded email in vet.applications inbox from esubmission.vnees[1] (All public folders/Chrono In/EMAILS/esubmission.vnees) with message "You received a new vnees submission" and follow the enclosed link to the staging area.	
	Submission via CD/DVD	
	Receipt of the package containing cover letter, CD/DVD from the mailroom, electronically sign the receipt on the hand-held PDA.	
	Submission via EudraLink / e-mail to vet.applications	
	On the day of receipt, Vet Applications to press "confirm" button in EudraLink message view to acknowledge receipt.	
1.2	Save the submission folder received on the desktop or temporary drive (not necessary for CD/DVD submission), unzipping attachments, if necessary. Proceed to 2.0	AA
2.0	**Technical validation**	
2.1	Upload submission from temporary drive or CD/DVD into EURS: • Log into EURS using Administrator credentials. • For creation of new product dossier, right click on "eSubmission management PRODUCTION", New Dossier - "Title": Enter product number with 7 digits - "Directory" should be shown as Y:\vnees - "Dossier type": choose between VNeeS, VNeeS-ASMF, VNeeS-Referrals - "Invented name": Enter name of the product - "Applicant name": Enter name of the applicant. For MRLs enter "N/A – MRL" (MRLs can have more than one applicant) - "INN": Enter INN name. For vaccines, enter "vaccine". For products with more than one active substance, enter "fixed combination".	AA

[1] Receipt of this email means that the applicant has received both an MDN (Message Delivery Notification) meaning that the transmission has reached the Agency and an acknowledgment XML message, meaning that the right file name to send the application has been used. In case of error in the sending process, the applicant would receive an error message and be asked to contact Gatewaysupport@ema.europa.eu.

Step	Action	Responsibility
	• For creation of application submission, right click on the product folder, Import non-eCTD Submission - "Directory": Select relevant directory where the folder should be copied from. - "Validation criteria": should be shown as "no validation" - "Settings": should be "finish without confirmation" - Select "Next" • Then fill in the submission attributes as follows (*except for referrals, see below*): - "Title": enter Date of receipt (YYYY-MM-DD) - "Application number": Enter the number assigned to the application in SIAMED (e.g. IB-0001) - "Submission type": Enter submission type as "type II, type IA, Type IB, Renewal,…." - "Submission description": "Initial/Updated initial/Responses to VSI/Responses to LoQ/Responses to LoOI" • For *referrals*, set the attributes as follows: - "Title": enter Date of receipt by EMA (YYYY-MM-DD) - "Application number": Enter the number assigned to the application as per referrals tracking table (e.g. V-A-XXX) - "Submission type": Enter submission type as "Art xx(x)" *Article Number should read either of the following: Art 33(4), Art 34, Art 35, Art 13, Art 30 (3), Art 78* - "Submission description": Enter "Submission description – Company – Resubmission (if applicable)" *Can be one of the following: Responses to LoQ, Responses to LoOI, Dossier Product name (eg. Dossier Fiprex cat 52.5 mg spot on), Re-examination submission*.	
2.2	Send EURS link via email to PM/ProcM/Procedure AST/VO. If different from procedure assistant, include the responsible V-VM-ROS AST and request SIAMED entry as soon as possible. Copy product shared mailbox. *NB: The email subject should contain product name, procedure number , submission unit type (eg. Responses to LoQ)*	AA
2.3	For initial submission, enter procedure in SIAMED; and assign the necessary resources to the procedure (at minimum project manager/procedure manager and procedure assistant should be assigned straight away).	AST

Step	Action	Responsibility
	Confirm procedure entry to PM/ProcM. For subsequent submissions in a procedure, liaise with the relevant PM or ProcM for an update of SIAMED where necessary.	AA
2.4	Check for presence of the VNeeS checker report in the submission (excluding Referrals). Check that it is the currently applicable checker version[2] and that the report outcome is valid. If appropriate, run the technical validation tool - VNeeS checker - on application (except referrals). Save such technical validation report in the procedure folder in DREAM if different from the report provided by the applicant.	VO/ProcM
2.5	Is the submission (technically) valid? If yes, go to step 3. If no, go to step 2.6.	
2.6	Assess whether the submission is to be rejected as non-compliant: Check cover letter for justification for non-compliance.	VO/ProcM
2.7	Has non-compliance been sufficiently justified by applicant? If yes, go to step 3.0 If no, go step 2.8	
2.8	Request resubmission from the applicant in the correct format as soon as possible.	VO/ProcM
2.9	Has the applicant resubmitted the dossier in the correct format within the agreed timeframe? If yes, go to step 3.0 If no, go step 2.10	
2.10	Is this an Initial Marketing Authorisation Application or an Extension? If yes, go to step 2.10 If no, go step 2.11	
2.10	Send standard email of suspension of validation (see Annex A) to: applicant contact point, cc to product shared mailbox, sender of the letter (if different to contact point), PM/ProcM, AST and rapporteurs. Update SIAMED with suspended validation outcome. Proceed to 3.0	VO
2.11	Send standard email of rejection of submission (see Annex A) to: applicant contact point, cc to product shared mailbox, sender of the letter (if different to contact point), PM/ProcM, AST and	VO/ProcM

[2] Information on the currently valid version of the VNeeS Guideline and tools is found on the Veterinary eSubmissions website.

Step	Action	Responsibility
	rapporteurs. Update SIAMED with invalid outcome. Proceed to 3.0	
3.0	**Post technical validation**	
3.1	Archive CD/DVD in “CD submission” folders, as applicable.	AA
3.2	Follow the relevant SOP/WIN for the type of procedure to be processed.	PM/VO/ProcM
4.0	**End of procedure**	

Annex A – Standard e-mail of rejection of submission

Dear <name of responsible person>,

Please be informed that your electronic application received by EMA on <date of receipt>, reference <reference of the application>, is technically invalid. This means that the application cannot be processed further at this stage.

Please find attached the verification report issued by the VNeeS checker tool listing all deficiencies to be addressed.

For Initial MA Application/Extension:

You will receive a validation suspension letter shortly.

Please note that in order to demonstrate your continued intention to submit the application you should submit a revised application dossier in accordance with the next recommended submission date <date> published on the EMA's website.

Kind regards,

<Signature of Administrative Assistant>

For all procedures other than Initial MAA/Extension:

You will receive a <negative validation> <negative review outcome> letter shortly.

Please note that you may submit a new application dossier in accordance with the recommended submission dates published on the EMA's website where applicable.

Kind regards,

<Signature of Administrative Assistant>