EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: SIAMED-related data validation of new veterinary centralised procedures		
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1. Purpose

The purpose of this SOP is to describe the process of SIAMED-related data validation and data exchange between the PMs in the Veterinary Unit and the SIAMED Administrator for new centralised procedures; throughout evaluation until Commission Decision. The data entry and validation process is outlined in its entirety to promote an understanding of PM involvement.

2. Scope

This SOP applies only to the procedures mentioned above and only to the data flow associated with SIAMED; between the SIAMED administrators and the PMs. The SOP applies to the Veterinary Unit and SIAMED Administrator only.

3. Responsibilities

It is the responsibility of the Head of Section (VROS) to ensure that this procedure between PMs and the SIAMED Administrator is adhered to. The responsibility for the execution of a particular part of this procedure is identified in the right-hand column of 9. Procedure.

4. Changes since last revision

Re-naming of responsible Section

5. Documents needed for this SOP

Sign-off page for internal data validation after opinion (SIAMED template 194-S)

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Sign-off page for internal data validation after withdrawal (SIAMED template – to be created when needed)

Validation letter to MAH (SIAMED template 195-S)

SIAMED data validation sheet (195a-S)

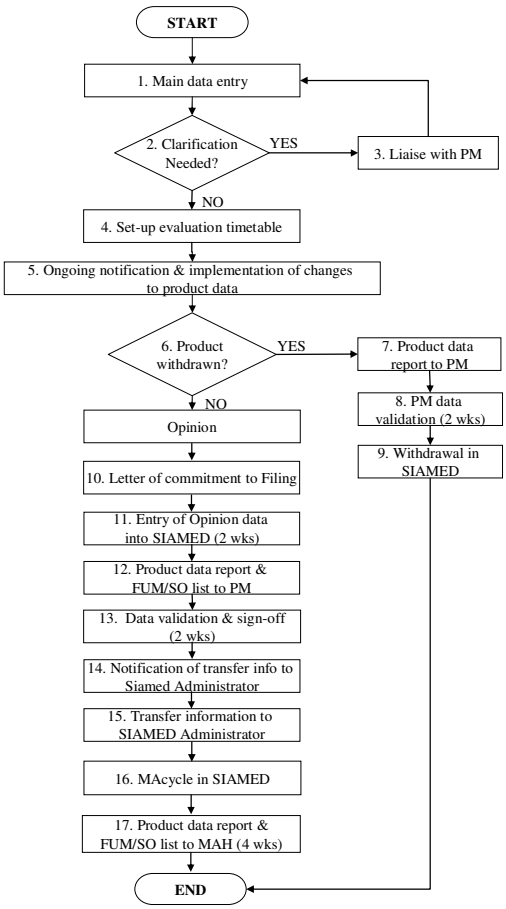
6. Related documents

Annex 1 - Overview of product data in SIAMED (terminology as in SIAMED)

7. Definitions

FUM	Follow-up measure
MAH	Marketing Authorisation Holder
Product data report	SIAMED printout of product data on a particular product
PM	Project Manager
SIAMED administrator	Person responsible for SIAMED updates
SO	Specific obligation

8. Process map(s)/ flow chart(s)



9. Procedure

Step	Action	Responsibility
1	Enter main product data into SIAMED from Application form.	SIAMED administrator
2	If problems and questions arise during initial data entry, go to Step 3. If not, go to Step 4.	SIAMED administrator
3	Liaise with PM. Go to Step 1.	SIAMED administrator
4	Set-up of evaluation timetable in SIAMED.	SIAMED Administrator
5	Ongoing notification of changes to product data during and after evaluation phase	PM
6	If the application is withdrawn, go to Step 7. If not, there will be either a positive or negative opinion. Go to Step 10.	SIAMED administrator
	WITHDRAWAL OF APPLICATION:	
7	Send product data report to PM with request for validation (paper version).	SIAMED administrator
8	Validate data / provide information on grounds for withdrawal, within 2 weeks.	PM
9	Incorporate withdrawal information in SIAMED.	SIAMED administrator
	POSITIVE/ NEGATIVE OPINION:	
10	Copy letter of Commitment to SIAMED Administrator (at time of Opinion)	PM
11	Enter Letter of Commitment data in SIAMED within 2 weeks. Enter opinion date and any modifications to previous product in SIAMED within 2 weeks.	SIAMED Administrator
12	After opinion, send Product Information Report and FUM / SO list to PM for validation with sign-off (paper version).	SIAMED administrator
13	Send data validation / information on changes, if applicable, to SIAMED administrator, with sign-off (paper version), within 2 weeks.	PM
14	Update of data in SIAMED	SIAMED Administrator
15	Enter Marketing Authorisation date in SIAMED	SIAMED administrator
16	After Marketing Authorisation send product data report, and FUM / SO list to MAH for validation, within 4 weeks. Paper version into Master File.	SIAMED administrator

10. Records

Backup copies of SIAMED (routine IT data back-up)

Annex 1

Overview of product data in SIAMED (terminology as in SIAMED)

GENERAL	Invented name Product number (EMA number) PM Overall number of presentations Submission date Validation date Start date
PRODUCT INFORMATION	Applicant / MAH (SME tick box) Generic/Brand INN INN not available (y/n) Eligibility basis Eligibility date Legal basis of application Resubmission (y/n) Scientific advice provided (y/n) Scientific advice date (latest date) Accelerated procedure (y/n) Full or Partial Exceptional circumstances (y/n) Vaccine (y/n)
ANNEX A DATA	Pharmaceutical form Strength Route of administration Primary container Package size Packaging Full description of packaging Content Species Wihdrawal period
PRESENTATION DATA	
Administrative information	Country of origin (as per Applicant address) Availability restrictions Legal status Contains GMO (y/n)
Manufacturers	Manufacturer responsible for batch release Manufacturer of the active substance Manufacturer of the finished product Manufacturer of semi-finished product Manufacturer responsible for QC / batch control / testing Manufacturer responsible for packaging / labelling Manufacturer responsible for storage
Ingredients	Active substance / amount / reference monograph / additional comments Excipients / amount / reference monograph / additional comments Overages / amount / reference monograph / additional comments Other excipients / amount / reference monograph / additional comments Ingredients of animal origin (as per TSE table)
Therapeutic groups (ATC)	Main therapeutic group (first level of ATC Vet code) Additional therapeutic groups (first level of additional ATC Vet code)

Indications	Indications – summary (i.e. "treatment of … / prevention of … / immunisation against …") Indications – full (as per SPC) General appearance ATC code Shelf life
Source material	Species Tissue Country of origin Substance
Contacts	Contact person for MAH Contact person during the procedure Contact person responsible for pharmacovigilance Contact person responsible for batch release
Rapporteur/Co-Rapporteur	Name of Rapporteur Name of Co-Rapporteur
Experts	Name(s) of experts Role of Experts
Withdrawal period	Species/Tissue/Remarks
POST-APPROVAL FOLLOW-UP (PSURs/FUMs/SOBs/ Sunset clause	Type Area Due date Description