EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: Tracking and handling in SIAMED of SDA post-authorisation measures for centrally authorised products		
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1. Purpose

To describe the process of tracking and handling in SIAMED SDA Post-Authorisation Measures (PAMs) for Centrally Authorised medicinal Products (CAPs) for human use. In the context of the evaluation of safety signals, the Pharmacovigilance Risk Assessment Committee (PRAC) may recommend that supplementary information is submitted by relevant Marketing Authorisation Holders (MAHs). These submissions constitute SDA PAMs. Upon adoption of such a PRAC recommendation on a signal, SDA PAM(s) are entered in SIAMED, thus allowing tracking the request to the MAH(s), the scientific grounds, the applicable timelines, as well as the final conclusion.

The purpose of this SOP is to ensure that these activities are handled in an efficient and consistent way, and by doing so support pharmacovigilance at EU level.

This SOP does not cover the tracking and handling of PRAC requests for supplementary information concerning Nationally Authorised Products (NAPs).

2. Scope

This SOP applies to the Signal and Incident Management Service (P-PE-SIM) and the Product Application Business Support Team (I-BD-BUS).

3. Responsibilities

It is the responsibility of the Heads of Service to ensure that this procedure is adhered to within their Service. The responsibility for the execution of each step of this procedure is identified in the right-hand column of section 9.

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4. Changes since last revision

New SOP.

5. Documents needed for this SOP

- Email template - PAM Submission – Timetable (TT) of signal assessment (EMA/71054/2017)

  (Cabinets/06.Corporate governance/06.02 Integrate management system/2. IMS Manual/2. Corporate control documents/4. SOPs and WINs/*3000-3999 H (human)/3441 SOP-Update of SIAMED with signal management data)

6. Related documents

- Questions & Answers on signal management

  (Home / Human regulatory / Post authorisation / Pharmacovigilance / Signal management / Questions and answers on signal management)
  http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/09/WC500150743.pdf

- Post-authorisation measures: questions and answers

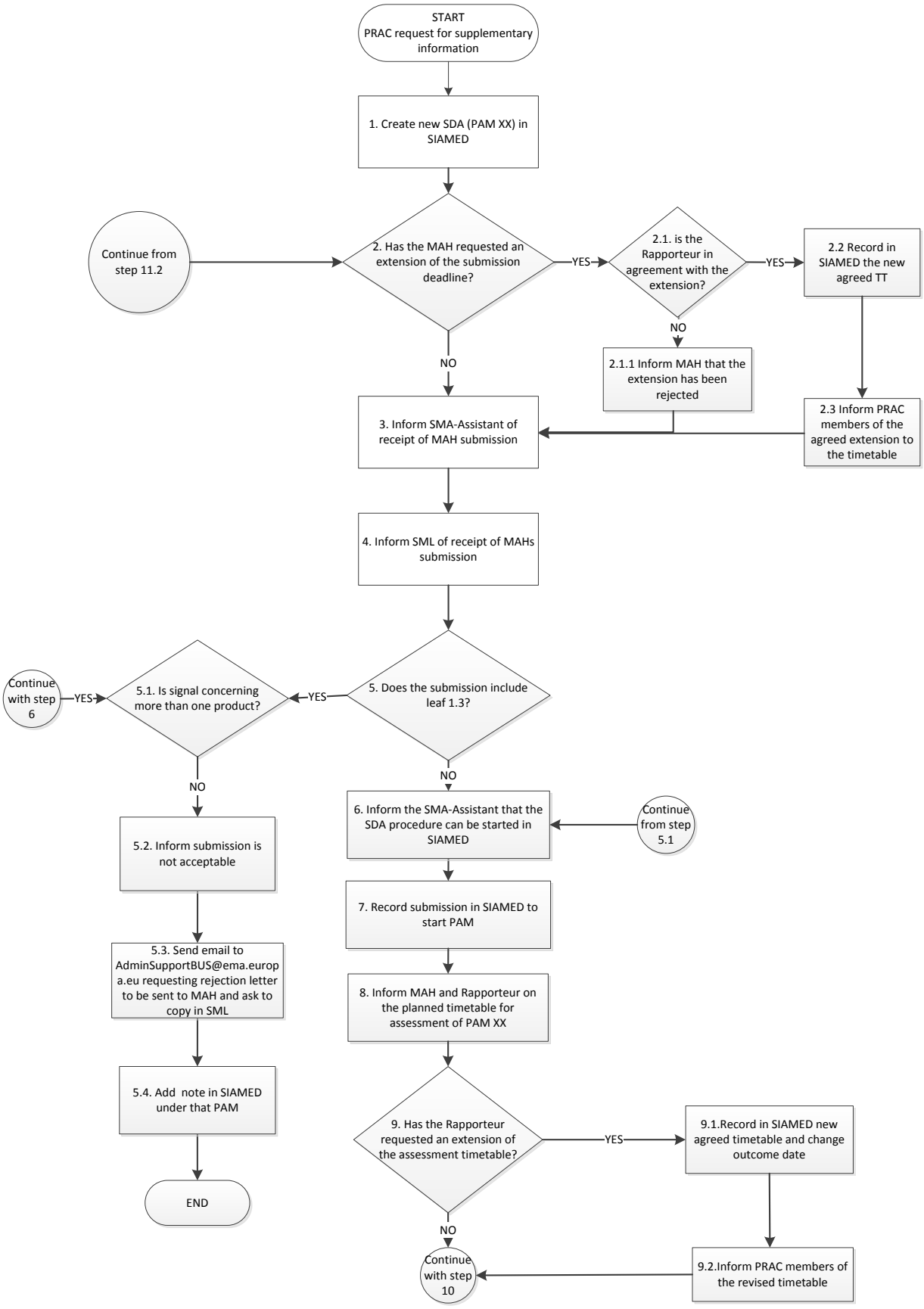
  (Home / Human regulatory / Post authorisation / Post authorisation procedural Q&A / Post authorisation measures)
  http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/q_and_a/q_and_a_detail_000037.jsp&mid=WC0b01ac0580023e7a

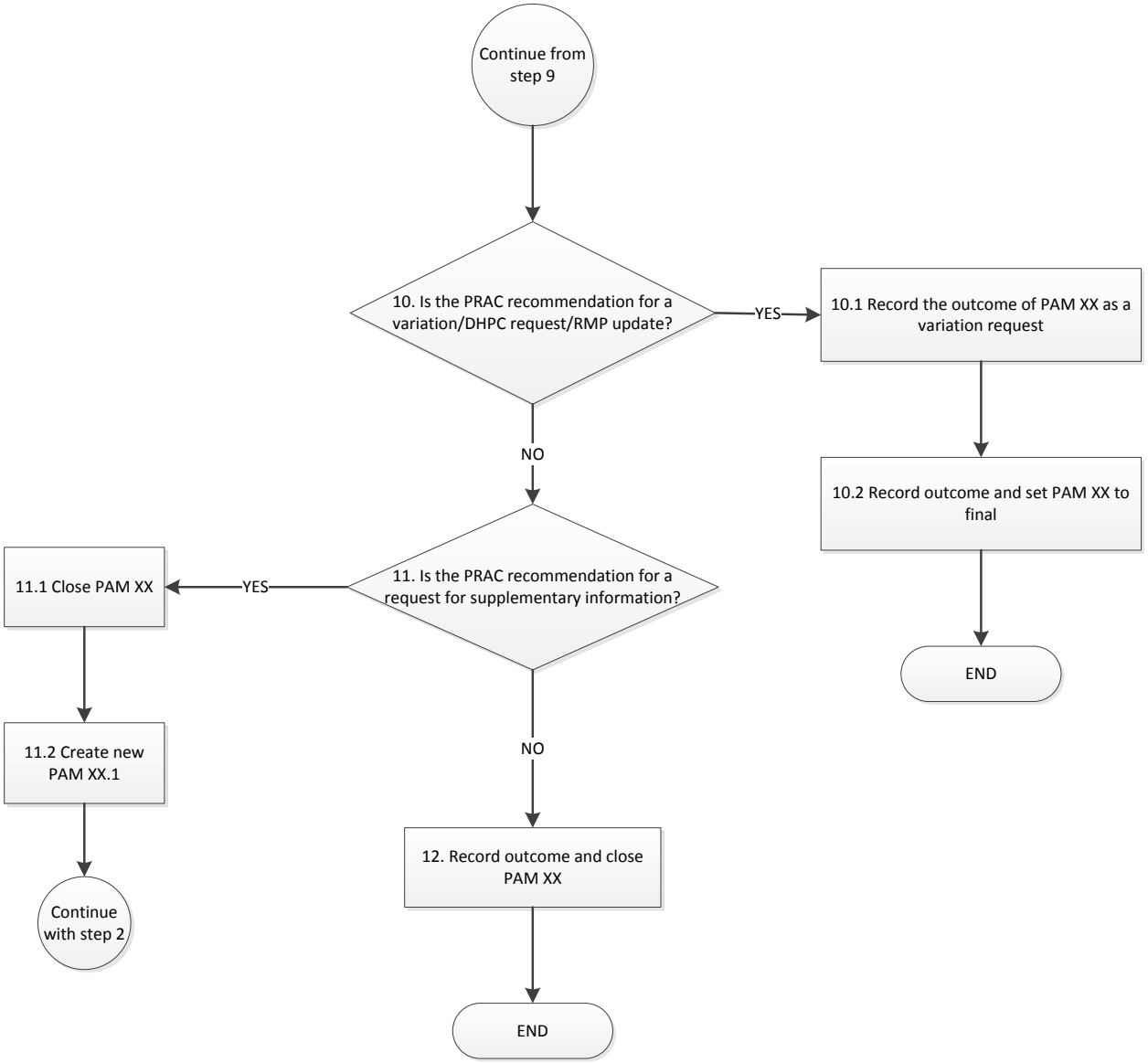
7. Definitions

AdminSupportBUS@ema.europa.eu	Functional mailbox to request that a PAM (SDA) rejection letter is sent
CAP	Centrally Authorised medicinal Product
DREAM	Documents Records and e-Archive Management
eCTD	electronic Common Technical Document
EURS	European Review System for eCTDs
I-BD-BUS	Product and Application Business Support
MAH	Marketing Authorisation Holder
NAP	Nationally Authorised Medicinal Product
PAM	Post-Authorisation Measure
PAMs-Help	Post-Authorisation Measure assistants
P-PE-SIM	Signal and Incident Management Service
PRAC	Pharmacovigilance Risk Assessment Committee
PSM	Product mailbox
SDA-PAMsubmissions	Functional mailbox to track and manage SDA-PAM submissions

SIAMED	EMA's product information and application tracking system
Signal	Information that arises from one or multiple sources (including observation and experiments), which suggests a new potentially causal association or a new aspect of a known association, between an intervention and an event or set of related events, either adverse or beneficial, that is judged to be of sufficient likelihood to justify verificatory action.
SMA-Assistant	Signal and Incident Management Service Assistant ** The Assistant mentioned within this SOP is the one usually in charge of PRAC support activities.*
SML	Signal Management Lead (PL in SIAMED)
TOD	Table of decisions section in SIAMED
TT	Timetable

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




Continue from step 9
10. Is the PRAC recommendation for a variation/DHPC request/RMP update?
YES
10.1 Record the outcome of PAM XX as a variation request
10.2 Record outcome and set PAM XX to final
END
NO
11. Is the PRAC recommendation for a request for supplementary information?
YES
11.1 Close PAM XX
11.2 Create new PAM XX.1
Continue with step 2
NO
12. Record outcome and close PAM XX
END

9. Procedure

Step	Action	Responsibility
	PRAC REQUESTS SUPPLEMENTARY INFORMATION	
1.	Create in SIAMED an SDA PAM (PAM XX) for each CAP for which an MAHs has/have been requested by the PRAC to submit supplementary information. *Note 1: This is done following adoption of PRAC recommendations on signals.* *Note 2: SDA PAMs need to include the EPITT ref. no. of the signal procedure, the wording of the PRAC recommendation and the planned TT of assessment.*	SMA-Assistant
2.	Has an MAH requested an extension of the submission deadline? If yes, go to step 2.1 If no, go to step 3	SML
2.1	Are the PRAC Rapporteur(s) in agreement with the request for extension of the submission deadline? If yes, go to step 2.2 If no, go to step 2.1.1 *Note: SML liases with the PRAC Rapporteur(s) for agreement to the MAH's request for extension of the submission deadline.*	SML
2.1.1	Inform the MAH that the extension has been rejected. Go to step 3.	SML
2.2	Record in SIAMED the new agreed TT for submission and assessment and inform the MAH(s). Go to step 3. *Note: Enter in SIAMED the new agreed TT under the section "Description" as, once the PAM has been created in SIAMED, the due date (as entered in step 1) cannot be changed until the submission of data is received by the MAH.*	SMA-Assistant
2.3	Inform the PRAC of the agreed extension to the submission deadline	SML
	MAH SUBMISSION RECEIVED	
3.	Send the workflow email to the SDA-PAMsubmissions mailbox, cc: PSM, to inform that an MAH submission has been received.	I-BD-BUS
4.	Inform the SML that the submission from the MAH(s) has been received.	SMA-Assistant

Step	Action	Responsibility
5.	Does the EURS submission include eCTD leaf 1.3? If yes, go to step 5.1 If no, go to step 6	SML
5.1	Does the signal for which the submission was received concern more than 1 product? If yes go to step 6 If no, go to step 5.2 *Note: The number of products concerned by a signal can be appraised by using article 57 database.*	SML
5.2	Send an email to the SMA-Assistant to inform that the submission is not acceptable.	SML
5.3	Send an email to AdminSupportBUS@ema.europa.eu to request to send a rejection letter to the relevant MAH and ask SML and PSM to be copied in the correspondence.	SMA-Assistant
5.4	Add a note in SIAMED under PAM XX to clarify that PAM XX can be re-used for any other PAM for that particular product. End of the procedure.	SMA-Assistant
6.	Inform SMA-Assistant that the submission is acceptable and that PAM XX can be started in SIAMED.	SML
7.	Record in SIAMED submission of PAM XX with the e-CTD sequence number and date of receipt. Allocate resources and record predicted outcome date. *Note: The recording of the predicted outcome is needed to ensure that the outcome date will be shown in Annex C circulated by PAMs-Help.*	SMA-Assistant
8	Send an email to the concerned MAH(s) copying the SML, PRAC Rapporteur and PSM to acknowledge the submission and indicate the planned timetable for the assessment of PAM XX.	SMA-Assistant
9.	Has the PRAC Rapporteur requested an extension of the assessment timetable? If yes go to step 9.1 If no, go to step 10	SML
9.1	Enter in SIAMED the new assessment TT agreed with the PRAC Rapporteur and inform the MAH(s).	SMA-Assistant

Step	Action	Responsibility
	Note: A comment should be added to the description of the signal to reflect in Annex C the Rapporteur's request and the consequent change in the TT.	
9.2	Inform PRAC of the revised timetable	SML
	PRAC FOLLOW UP DISCUSSION	
10.	Is the PRAC recommendation for a variation / DHPC request / RMP update? If yes go to step 10.1 If no, go to step 11	SMA-Assistant
10.1	Record in SIAMED the outcome of PAM XX as a variation request and enter the full PRAC recommendation under section TOD. *Note: This starts the CHMP adoption phase in SIAMED.*	SMA-Assistant
10.2	Record in SIAMED the final outcome as "CHMP in agreement" and set PAM XX as final, once the PRAC recommendation for a variation/DHPC request/RMP update has been endorsed by the CHMP. End of procedure.	SMA-Assistant
11	Is the PRAC recommendation for a request for supplementary information / LoQ to MAH? If yes go to step 12.1 If no, go to step 13	SMA-Assistant
11.1	Record in SIAMED the outcome of PAM XX as closed and enter the full PRAC recommendation under section TOD.	SMA-Assistant
11.2	Create a new subordinate PAM procedure for this signal as PAM XX.1. Go to step 2 of the procedure. *Note: What is indicated as PAM XX in the flowchart, is now to be intended as PAM XX.1*	SMA-Assistant
12.	Record in SIAMED the outcome of PAM XX as closed and enter the full PRAC recommendation under section TOD. End of procedure. *Note: This applies when the PRAC recommends no action/routine*	SMA-Assistant

Step	Action	Responsibility
	pharmacovigilance activities for a signal.	

10. Records

- The email mentioned in step 3 is stored in electronic format in the functional mailbox All Public Folders/Chrono In/WORKFLOW/SDA-PAMsubmissions.
- The emails reflecting the decision of the Rapporteur(s) regarding and PRAC regarding the extension of the submission timeline or the assessment timeline are stored in electronic format in the relevant PSM(s) All Public Folders/Human Products/1 – Centralised procedure/relevant invented name(s).