EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: Handling of safety information from non-EEA regulatory authorities		
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1. Purpose

This SOP describes the current process followed in the Pharmacovigilance and Epidemiology Department (P-PE) in order to distribute, evaluate and track safety information emerging from pre- and post-authorisation surveillance conducted by other regulatory authorities for Centrally Authorised Products (CAPs) and substances.

The safety information considered in this SOP is received in the framework of the Confidentiality Arrangements signed between the European Medicines Agency/European Commission and non-EEA regulatory authorities, such as the Food and Drug Administration (USA) or the Ministry of Health Labour and Welfare and the Pharmaceuticals and Medical Devices Agency (Japan).

Safety issues from non-EEA regulatory authorities which concern nationally authorised products (NAPs) are included in an Excel file circulated to the network every month.

2. Scope

The SOP applies to the Signal and Incident Management Service of the Pharmacovigilance and Epidemiology Department.

3. Responsibilities

It is the responsibility of the Head of Department to ensure that this procedure is adhered to within his/her Department. The responsibilities for the execution of the particular steps of this procedure are identified in Section 9 (Procedure) of this SOP.

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4. Changes since last revision

- Organisational names have been aligned with the new Agency structure.

5. Documents needed for this SOP

- SOP/H/3065 – Signal management for centrally authorised products
- WIN/H/3268 - Maintenance of Signal Detection tracking table.

6. Related documents

- Scientific Group table: located in DREAM under Cabinets/14. Working areas/14.03 P-Division/03. P-PE Activities/P-PE-SIM/Templates and guidance documents

7. Definitions

AF-IA: International Affairs Division

CAP: Centrally Authorised Product. Medicinal product which has been authorised in Europe via the centralised procedure.

EEA: European Economic Area

EPITT: European Pharmacovigilance Issues Tracking Tool

H-SD: Human – Signal Detection. Electronic mailbox where all e-mails related to signal detection and signal management which require archiving are sent and recorded.

NAP: Nationally Authorised Product. Medicinal product which has been authorised in Europe via a national, mutual recognition or decentralised procedure.

P-PE: Pharmacovigilance and Epidemiology Department of the Inspections, Human Medicines Pharmacovigilance and Committees Division

P-PE-SIM: Signal and Incident Management Service of the Pharmacovigilance and Epidemiology Department

P-PE-SIM International coordinator: P-PE-SIM team member responsible for distributing the safety information from non-EEA regulatory authorities to the Signal Management Leads

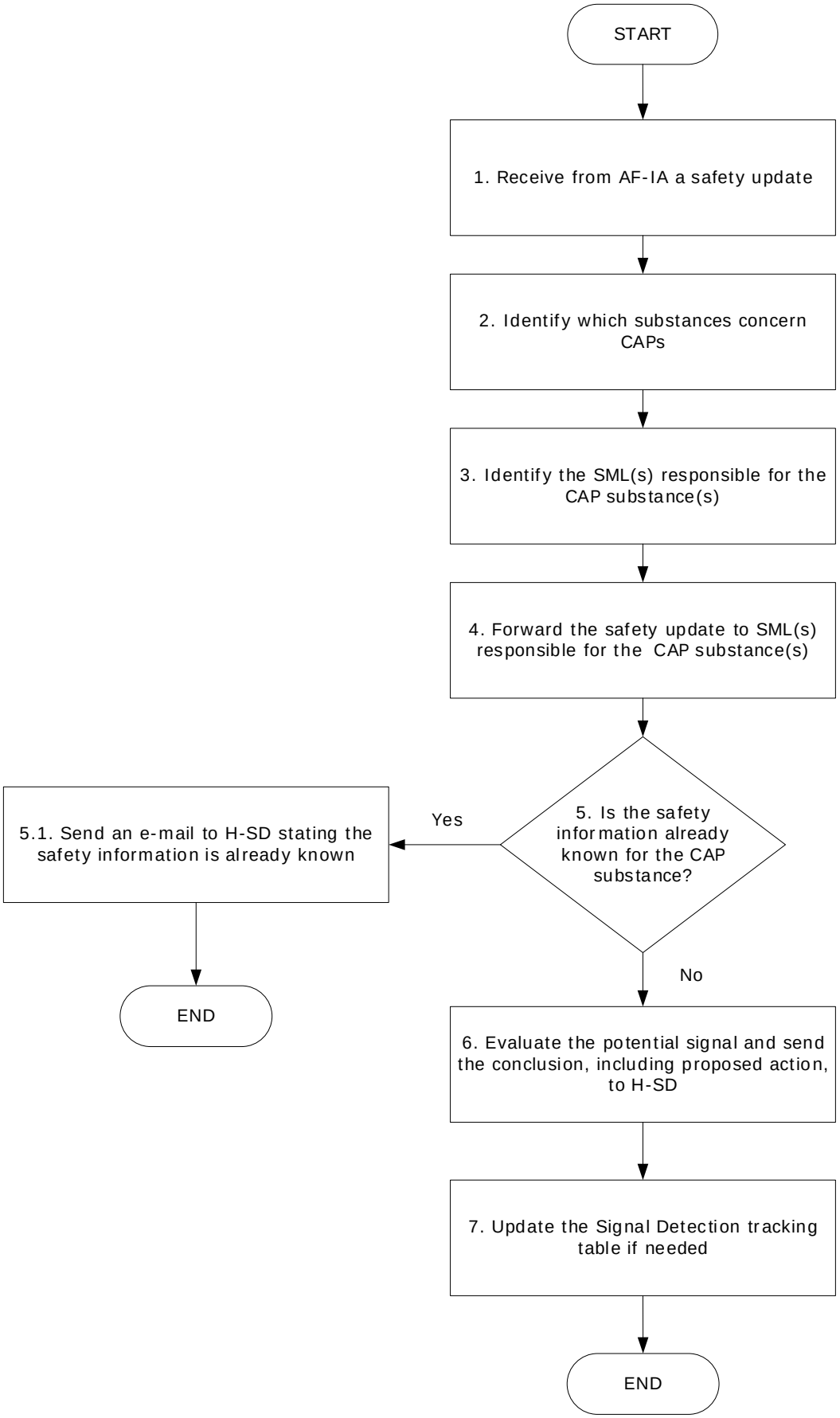
PSUR: Periodic Safety Update Report

RMP: Risk Management Plan

SML: Signal Management Lead (staff member responsible for signal management in the P-PE Department)

SmPC: Summary of Product Characteristics

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



9. Procedure

Step	Action	Responsibility
1	Receive from AF-IA a safety update Receive a safety update from the EMA International Team within the Office of the Executive Director.	P-PE-SIM International coordinator
2	Identify which substances mentioned in the safety update concern CAPs This information can be found in the Scientific Group table (column 'Authorisation procedure').	P-P E-SIM International coordinator
3	Identify the SML(s) responsible for the CAP substance(s) This information can also be found in the Scientific Group table (column 'ASSESSOR_EMA').	P-P E-SIM International Coordinator
4	Forward the safety update to the SML(s) responsible for the CAP substance(s) mentioned in the safety update The P-PE-SIM International coordinator forwards the safety update by e-mail to the relevant validator(s) and to the H-SD mailbox.	P-P E-SIM International Coordinator
5	Is the safety information already known for the CAP substance? A safety information is known when it is already communicated to the Rapporteur, monitored in the PSUR and/or RMP, or included in the SmPC. If Yes, continue with step 5.1. If No, continue with step 6.	SML
5.1	Send an e-mail to the H-SD mailbox stating the safety information is already known When a SML receives several safety concerns which are already known within one safety update, there is no need to send separate e-mails to H-SD confirming the status. It is sufficient to send just one e-mail to H-SD with all the known concerns coming from the same safety update. No further action is required.	SML
6	Evaluate the potential signal and send the conclusion, including proposed action, to the H-SD mailbox As described in SOP/H/3065 *Signal management for centrally authorised products*.	SML
7	Update the Signal Detection Tracking Table In case the SML has sent an e-mail to H-SD stating that no action was necessary, the P-PE-SIM Secretary does not need to open a potential signal in the Signal Detection Tracking Table. In case the SML has sent an e-mail to H-SD proposing further action, the P-PE-SIM Secretary updates the Signal Detection Tracking Table, as described in WIN/H/3268 *Maintenance of Signal Detection tracking table*.	P-PE-SIM Secretary

10. Records

- The possible safety signals are listed in the Signal Detection Tracking table. This table is named ‘SDMDB-IM_RM 2.xls’ and is located in DREAM under Cabinets/03. Pharmacovigilance/PhV - Human/3.3 Signal detection activities/01 Signal detection tracking tools/IM RM CAP list.
- All P-PE-SIM correspondence is sent by e-mail and recorded in the H-SD mailbox located in Outlook under Public folders/All Public folders/Chrono In/EMAILS/H-SD.
- Incoming emails to the International Affairs Division are located in Outlook under Public Folders\All Public Folders\Chrono In\WORKFLOW\WF International.
- All safety signals sent to the Rapporteur are recorded in EPITT.
- NAP safety issues are included in a table named ‘NAP safety issues from non-EU regulators’, which is located in DREAM under Cabinets/03. Pharmacovigilance/PhV - Human/3.3 Signal detection activities/02 Signals exchanged with non-EU regulatory Authorities/NAPs. This table is updated regularly and sent to LIST-H-PHARMACOVIGILANCE@EUDRA.ORG once a month.