EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: Handling and validation of EU-RMP annex 1		
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1. Purpose

This SOP describes the procedure followed by the Data Collection and Management (P-PV-DCM) and Risk Management Sections (P-PV-RM) in the Pharmacovigilance and Risk Management Sector (P-PV) regarding the European Risk Management Plan Annex 1 (EU-RMP Annex 1) submissions for Centrally Authorised Medicinal Products. This procedure covers the activities related to the EU-RMP Annex 1 from administrative handling to validation. It begins with the provision of the EU-RMP Annex 1 file by a Marketing Authorisation Holder (MAH) and ends with the validation of its record in the EPITT RMPs module ("EPITT RMP record"). The validation either determines the EPITT RMP record as valid or leads to a request for a corrected file to the MAH.

2. Scope

This SOP applies to the staff members of P-PV-DCM and P-PV-RM involved in the EU-RMP Annex 1 activities.

3. Responsibilities

It is the responsibility of the Head of Sector to ensure that this procedure is adhered to within his Sector. The responsibility for the execution of each step of this procedure is identified in the right-hand column of section **9. Procedure**.

4. Changes since last revision

Updated to reflect the new organisational structure of the Agency and the extended purpose of the EU-RMP Annex 1 to support the monitoring of pharmacovigilance and risk management activities by

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means of the European Pharmacovigilance Issues Tracking Tool (EPITT). As a consequence, all sections were modified.

5. Documents needed for this SOP

- **The EU-RMP Annex 1 file** is emailed by the MAH to the H-EURMP-EVINTERFACE mailbox (for the definitions see section **7 Definitions**).
- **The EPITT RMP record** is the EU-RMP Annex 1 file loaded into the EPITT RMPs module.
- **The EU-RMP PDF** is saved in a dedicated DREAM folder and linked with the corresponding EPITT RMP record.

6. Related documents

- **Guideline on Risk Management systems for Medicinal Products for Human Use**
  Doc Ref.: EMEA/CHMP/96268/2005

  Cabinets/13. Projects/2001 review/EMEA consequences/Public implementation/Risk Management/Risk Management guideline
- **Annex C: Template for EU Risk Management Plan**
  Doc. Ref. EMEA/192632/2006

  Cabinets/13. Projects/2001 review/EMEA consequences/Public implementation/Risk Management/Risk Management guideline/Template
- **WIN/H/3312 on 'EU-RMP Annex 1: Administration'**
- **WIN/H/3292 on 'EU-RMP Annex 1: Validation'**

7. Definitions

Abbreviations

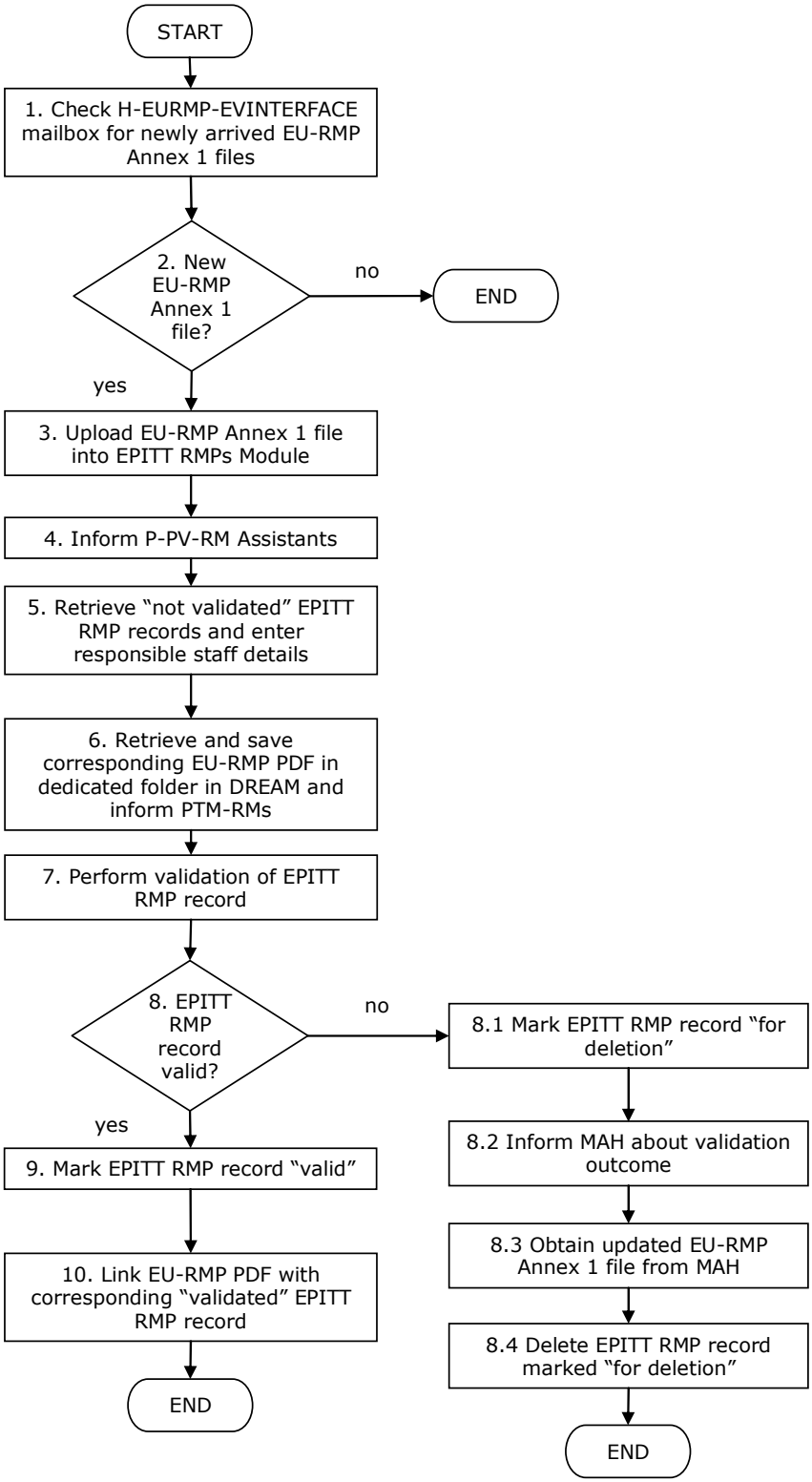
CAP	Centrally Authorised Product
DREAM	Document Records Electronic Archive Management
EMA	European Medicines Agency
EPITT	European Pharmacovigilance Issues Tracking Tool
EU	European Union
EV	EudraVigilance
MAH	Marketing Authorisation Holder
P-PV-DCM	Data Collection and Management Section
P-PV-RM	Risk Management Section
PTM-RM	Project Team Member Risk Management
RM	Risk Management
RMP	Risk Management Plan

Definitions

- **Centrally Authorised medicinal Product (CAP)** is a product authorised through the centralised Community procedure, for which there is a single application, a single evaluation and a single authorisation allowing direct access to the single market of the Community. A marketing authorisation granted under the centralised procedure is valid for the entire Community market, which means the medicinal product may be put on the market in all Member States.
- **EPITT RMP record:** The record of the EU-RMP Annex 1 file in the EPITT RMPs module.
- **EudraVigilance (EV)** is the European data-processing network and management system as established in accordance with Regulation (EC) No 726/2004 and Directive 2001/83/EC as amended. It allows the Agency to manage the electronic data exchange of Individual Case Safety Reports (ICSRs) and to support the EU pharmacovigilance and risk management activities at Community level.
- **EU-RMP Annex 1** is the structured electronic representation of the EU Risk Management Plan in order to allow for the monitoring of
  - identified and potential risks,
  - identified and potential interactions,
  - important missing information,

  in relation to suspected adverse reactions reported to EudraVigilance for centrally authorised medicinal products in line with Regulation (EC) No 726/2004, Directive 2001/83/EC as amended and Volume 9A of 'The Rules Governing Medicinal Products in the European Union' of the Notice to Marketing Authorisation Holders. The EU-RMP Annex 1 also supports the monitoring of additional EU risk management activities by means of EPITT.
- **European Pharmacovigilance Issues Tracking Tool (EPITT)** is a web-based system that facilitates the safety information exchange and communication between the Member States and the tracking of the substances safety information and related documents. EPITT is accessible via EudraNet under: *fmp7://fmapps.eudra.org/PhVWP+Tracking*.
- **H-EURMP-EVINTERFACE mailbox** is the EudraVigilance e-mailbox for EU-RMP Annex 1 submissions. It is located in Outlook under Public Folders/All Public Folders/Chrono In/Emails. P-PV-DCM and P-PV-RM have access to it.
- **Marketing Authorisation Holder (MAH)** is an organisation that is holding a valid marketing authorisation for a medicinal product independent of the authorisation procedure of this medicinal product.
- **Product Short Name** is defined as the given name to a medicinal product, which may be either an invented, common or scientific name without a trademark or the name of the manufacturer.

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



9. Procedure

Step	Action	Responsibility
1.	**Check H-EURMP-EVINTERFACE mailbox for newly arrived EU-RMP Annex 1 files** Follow WIN/H/3312 on *'EU-RMP Annex 1: Administration'* to perform this task.	P-PV-DCM
2.	**Is there a newly arrived EU-RMP Annex 1 file in the mailbox?** Follow WIN/H/3312 on *'EU-RMP Annex 1: Administration'* to perform this task. No, End. Yes, continue with Step 3.	P-PV-DCM
3.	**Upload EU-RMP Annex 1 file into EPITT RMPs Module** Follow WIN/H/3312 on *'EU-RMP Annex 1: Administration'* to perform this task. This includes marking of the EPITT RMP record "not validated."	P-PV-DCM
4.	**Inform P-PV-RM Assistants** Follow WIN/H/3312 on *'EU-RMP Annex 1: Administration'* to perform this task'.	P-PV-DCM
5.	**Retrieve "not validated" EPITT RMP records and enter responsible staff details** Follow WIN/H/3292 on *'EU-RMP Annex 1: Validation'* to perform this task.	P-PV-RM Assistants
6.	**Retrieve and save corresponding EU-RMP PDF in dedicated folder in DREAM and inform PTM-RMs** Follow WIN/H/3292 on *'EU-RMP Annex 1: Validation'* to perform this task. This task includes labeling the files according to the convention defined in this WIN.	P-PV-RM Assistants
7.	**Perform validation of EPITT RMP record** Follow WIN/H/3292 on *'EU-RMP Annex 1: Validation'* to perform this task.	PTM-RM

Step	Action	Responsibility
8.	**Is EPITT RMP record valid?** Follow WIN/H/3292 on *'EU-RMP Annex 1: Validation'* to perform this task. No, continue with Step 8.1. Yes, continue with Step 9.	PTM-RM
8.1	**Mark EPITT RMP record „for deletion"** Follow WIN/H/3292 on *'EU-RMP Annex 1: Validation'* to perform this task.	PTM-RM
8.2	**Inform MAH about validation outcome** Follow WIN/H/3292 on *'EU-RMP Annex 1: Validation'* to perform this task. This task includes copying the H-EURMP-EVINTERFACE mailbox.	PTM-RM
8.3	**Obtain updated EU-RMP Annex 1 file from MAH** Follow WIN/H/3312 on *"EU-RMP Annex 1: Validation"* to perform this task.	P-PV-DCM
8.4	**Delete EPITT RMP record marked "for deletion"** Follow WIN/H/3312 on *'EU-RMP Annex 1: Administration'* to perform this task. End.	P-PV-DCM
9.	**Mark EPITT RMP record "valid"** Follow WIN/H/3292 on *'EU-RMP Annex 1: Validation'* to perform this task.	PTM-RM
10.	**Link EU-RMP PDF with corresponding "validated" EPITT RMP record** Follow WIN/H/3312 on *'EU-RMP Annex 1: Administration'* to perform this task. End.	P-PV-DCM

10. Records

The EU-RMP Annex 1 files are stored in DREAM as defined in WIN/H/3312 on *'EU-RMP Annex 1: Administration'*, the EU-RMP PDF files likewise in DREAM as defined in WIN/H/3292 on *'EU-RMP Annex 1: Validation'*, and the correspondence with the MAH in the H-EURMP-EVINTERFACE mailbox.