EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

# Standard operating procedure

| Title: Notifications from MAHs on PhV non-compliance issues | | |
|---|---|---|
| Status: PUBLIC | | Document no.: SOP/INS/2061 |
| Lead author | Approver | Effective date: 11-APR-17 |
| Name: Camelia Mihaescu | Name: Ana Rodriguez Sanchez Beato | Review date: 11-APR-20 |
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## 1. Purpose

The purpose of this standard operating procedure is to describe the process for receiving and assessing pharmacovigilance related non-compliance notifications sent to the EMA by Marketing Authorisation Holders.

## 2. Scope

This SOP applies to EMA staff in: P-CI-CNC, P-PE, I-BD-DSA and V-VM.

## 3. Responsibilities

It is the responsibility of each Head of Service to ensure that this procedure is adhered to within their own sector. The responsibility for the execution of a particular part of this procedure is identified in the right-hand column of section 9.

## 4. Changes since last revision

New SOP.

## 5. Documents needed for this SOP

- Notification log (located in DREAM *Cabinets/04. Inspections/ 2. PHV/ PHV Inspections/ Notifications from MAHs on PhV non-compliance issues)*

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
**Telephone** +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
**Send a question via our website** www.ema.europa.eu/contact

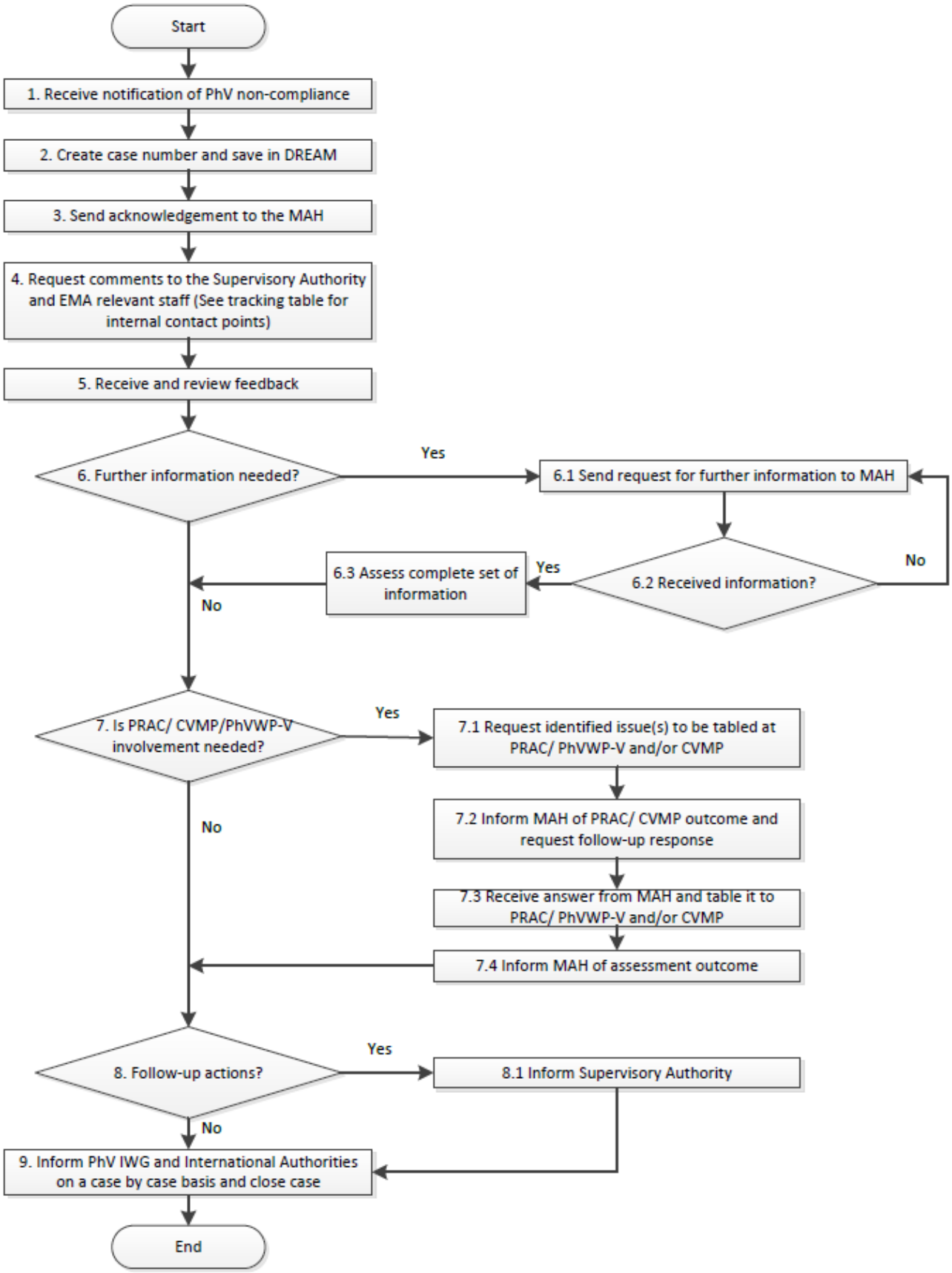
## 6. Related documents

N/A

## 7. Definitions

| | |
|---|---|
| AST | Assistant |
| CVMP | Committee for Medicinal Products for Veterinary Use |
| DREAM | Document Records Electronic Archive Management |
| EMA | European Medicines Agency |
| EV | EudraVigilance |
| I-BD-DSA | I-Division - Business Data and Analytics Department- Data Standardisation and Analytics Service |
| MAH | Marketing Authorisation Holder |
| MS | Member State |
| P-CI-CNC | P-Division- Compliance and Inspections Department– Clinical and Non-Clinical Compliance Service |
| PhV | Pharmacovigilance |
| PhV IWG | Pharmacovigilance Inspectors Working Group |
| PhVWP-V | CVMP Pharmacovigilance Working Party |
| P-PE | P-Division- Pharmacovigilance and Epidemiology Department |
| PRAC | Pharmacovigilance Risk Assessment Committee |
| RFI | Request for Further Information |
| SA | Scientific Administrator |
| SOP | Standard Operating Procedure |
| V-VM APH | V-Division- Veterinary Medicines Department - Animal and Public Health Service |

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



# 9. Procedure

| Step | Action | Responsibility |
|---|---|---|
| **1.0** | **Receive notification of PhV non-compliance** | AST/SA receiving the notification |
| **2.0** | **Create case number and save in DREAM** | |
| 2.1 | Create case number and fill in columns A to H in the Notification log saved in DREAM. | AST/SA receiving the notification |
| 2.2 | Save notification (scanned copy of the notification letter/ e-mail) in DREAM<br><br>Document naming convention: *Document name to start with the date, in the format: 'YY-MM-DD'.* | AST/SA receiving the notification |
| 2.3 | Inform P-CI-CNC about the receipt of a PhV-non-compliance notification, by forwarding the information to the email address: gcp@ema.europa.eu and copy sma-assistants@ema.europa.eu, who will alert the relevant Signal Management Lead, should the notification be related to a signal. | AST/SA receiving the notification |
| **3.0** | **Send acknowledgement of receipt to the MAH** | AST/SA receiving the notification |
| **4.0** | **Request comments from the Supervisory Authority and EMA staff in I-BD-DSA, including assessment of a potential impact to public and/or animal health. Depending on the topic of the notification, EMA staff in P-PE and V-VM could be involved in the assessment of the notification.**<br>(see tracking table for internal contact points in the notification log) | SA in P-CI-CNC |
| **5.0** | **Receive and review feedback** | SA in P-CI-CNC |
| **6.0** | **Further information** | |
| 6.1 | If additional information is needed from the MAH for the assessment of the notification, send RFI to MAH and save correspondence in DREAM. | SA in P-CI-CNC |
| 6.2 | Receive response to the RFI from MAH and save correspondence in DREAM. | SA in P-CI-CNC |
| 6.3 | Assess the notification including the additional information provided in the RFI. | SA in P-CI-CNC |
| **7.0** | **PRAC/CVMP/ PhVWP-V involvement** | |
| 7.1 | Request identified issues in the PhV non-compliance notification to be tabled at PRAC/ PhVWP-V and/or CVMP for discussion | SA in P-CI-CNC |
| 7.2 | Once a conclusion has been reached at PRAC/ CVMP level, inform MAH of PRAC/ CVMP discussions outcome and request a follow-up response, if applicable. | SA in P-CI-CNC |
| 7.3 | Receive response from MAH and table it to PRAC/ PhVWP-V and/or CVMP for further discussion. | SA in P-CI-CNC |
| 7.4 | Inform the MAH of the PRAC/ V-PhVWP final assessment outcome | SA in P-CI-CNC |
| **8.0** | **Follow-up actions** | |
| 8.1 | If follow-up is required, inform the Supervisory Authority | SA in P-CI-CNC |
| **9.0** | **Inform PhV IWG and International Authorities on a case by** | |

| Step | Action | Responsibility |
|---|---|---|
| | **case basis and close the case** | |
| 9.1 | For the case closure, fill in the columns I to Q in the notification log | SA in P-CI-CNC |

# 10. Records

Electronic copies of notifications received from MAHs and all related correspondence are saved in DREAM under: *Cabinets /04. Inspections / 2. PHV/ PHV Inspections/ Notifications from MAHs on PhV non-compliance issues.*