EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Work instructions

Title: Training for signal management leads		
Applies to: Signal Management Leads in the Signal Management service (P-PH-SMA) and personnel in the Learning and Development service (A-HR-LAD).		
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1. Changes since last revision

- Revision of the training topics in line with the new EU signal management process.
- Revision of the training records to reflect the new functionalities provided by SAP-HR
- Process alignment with the Memorandum IAP-A13003-4-03 – Management of scientific and regulatory training within the P-division.

2. Records

- Training records created according to this WIN are recorded in the SAP-HR under the staff training history.
- Certificates of attendance (or copies) of external courses may also be sent to A-HR-LAD.
- Records of the signal validation, ORGAM and department meeting minutes are saved in DREAM (3. Pharmacovigilance/PhV-Human/Signal detection activities).
- Checklist (Doc ref: EMA/757763/2015) listing relevant SOPs/WINs and guidelines together with the training topics that should be covered during the Signal Detection and Management Basic Training Programme is saved in DREAM (3. Pharmacovigilance/PhV-Human/Training activities and information events).

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3. Instructions

This WIN consists of 2 Sections:

3.1 Signal Detection and Management Basic Training Programme.

3.2 Continuing Development Training Program for Signal Management Leads.

3.1. Signal Detection and Management basic training programme

Objectives

The Signal Detection and Management basic training programme is equivalent to a training curriculum in SAP-HR. It is formed by training courses entered in SAP-HR for which a training certificate will be delivered upon completion of all the courses.

The objective of this training curriculum is to provide the new Signal Management Leads (including trainees and National experts on secondments) in the Signal Management service with the knowledge, guidance and methods to perform signal detection and management activities in line with their job descriptions, the relevant SOPs and WINs and the objectives in their annual appraisals. This training curriculum is not provided to other EMA staff.

General principles

New Signal Management Leads (including trainees and National experts on secondments as relevant), refer in this WIN as “the trainee” will be assigned a mentor appointed by the head of the Signal Management service (P-PH-SMA). The role of the mentor is to oversee the entire training process and ensure that the trainee completes the whole training programme accordingly. Training on specific topics may be provided by other members of the Signal Management service than the mentor; these sessions should be agreed and coordinated by the mentor.

Before the training activities start, the mentor/Head of Service should contact A-HR-LAD requesting allocation of the training curriculum to the trainee.

The minimum training topics to be covered during this training curriculum together with the compulsory SOPs, WINs and guidelines are listed in the Training for signal management leads – Checklist. This checklist aims to provide an overview of the training curriculum and could be used to monitor the progress during the training period. Once all the courses are completed successfully, an email should be sent to A-HR-LAD by the mentor or the Head of Service informing on the completion of the training curriculum by the trainee. A-HR-LAD should update the training records in SAP-HR.

The training duration and extent of the specific topics covered during this basic training programme should be determined by the Head of Service and the mentor according to the experience, knowledge and expertise of the trainee. Exemptions for training topics already covered during previous positions and/or courses should be communicated to A-HR-LAD in order to document the exception in the training curriculum.

Training on SOPs, WINs and Guidelines

Before signal detection and management activities are performed, the trainee should read and understand the relevant SOPs and WINs which are allocated in SAP-HR under “career and job” “access your learning”. Training completion and acknowledgment of those SOPs and WINs is recorded by the trainee as per general process for recording training of SOPs and WINs in SAP-HR.

The SOPs and WINs considered most relevant for signal detection and management are listed in the *Training for signal management leads – Checklist*. The most updated version of the documents should always apply.

A thorough and detailed training on signal detection and management guidelines is not expected during the basic training programme, but the trainee should be made aware of the most relevant guidelines (e.g. Report of CIOMS Working Group VIII, guideline on the use of statistical signal detection methods, EU SmPC guideline, EMA pharmacovigilance system manual). Only the GVP Module IX on Signal Management and the EMA Questions and Answers on signal management are considered needed for the basic programme and therefore included in the *Training for signal management leads – Checklist*.

The SOPs, WINs and GVP Module IX should be used as guidance for training on the specific topics relevant to the signal detection and management process and therefore it would be appropriate to set up different sessions with the mentor in order to discuss and clarify the procedures described in the SOPs, WINs and GVP Module IX.

Training topics

The following training topics should be covered during the signal detection and management basic training.

MedDRA

The trainee should attend the MedDRA training course organised by MSSO. The sessions will cover coding with MedDRA and Safety Data Analysis and SMQs. MSSO training materials may be also used when relevant.

Due to the numbers of attendees of this training course, whenever possible the mentor and/or Service Head will reserve in advance a place so that the trainee will be able to attend the training as early as possible. The EU network training centre (http://euntc.eudra.org/index.html) should be consulted to arrange this training.

This topic should also cover the installation and use of the MedDRA browser.

SIAMED

A basic training on SIAMED should be provided; this training should cover an overview of the information recorded in SIAMED, the tracking of signal follow-up PAMs (SDA) and generation of annexes for the Committees' procedures.

Training on relevant documents

The trainee will be introduced to the most relevant documents used for signal detection and management such as CHMP assessment report of the original opinion, Periodic Safety Updates Reports (PSURs), Risk Management Plans (RMPs), marketing authorisations applications, renewals, referrals, extensions of indications, variations as well as the corresponding Assessment Reports.

This session will also cover the structure of the electronic repositories EURS (eCTDs), DREAM, product Outlook folders, EURD list, PSUR repository and their search functionalities in order to facilitate retrieval of pertinent documents and information.

EPITT

The trainee should attend the EPITT training provided by the Monitoring and Incident Management (P-PH-MIM) service. The EPITT – User Guide and Question and Answers on EPITT should be used to support the training.

The EU network training centre (http://euntc.eudra.org/index.html) should be consulted to arrange this training.

Literature search in signal detection

The trainee will be introduced on how to perform literature searches and set up alerts in order to support the signal detection and validation activities.

In addition, the trainee should attend the "Introductory session" organised by the EMA Information Centre.

Signal detection

This training topic should cover the signal detection process using the electronic reaction monitoring reports (eRMRs) from EudraVigilance, the literature alerts and communications from other pharmacovigilance entities. This should also cover the notification of signals and the records in the signal validation tracking table.

Signal validation

This training topic should cover the validation process for opened signals including the review of individual cases, literature, source documents and the creation of signal validation reports and signal descriptions.

The trainee should perform screening of the eRMRs and signal validation. These activities should be checked as relevant by the mentor and feedback to the trainee should be provided. The duration of this training exercise will be determined by the trainee's performance, experience and expertise. The duration of the period will be discussed and agreed by the trainee, the mentor and Service Head.

Signal Management process

This training topic should cover all the aspects relating to the different steps in the signal management process at the EU level which include the following main areas:

- Signal Management procedure for signal assessment (SDA-PAMs)
- Signal assessment in PSURs
- PRAC agendas and minutes
- PRAC timetables
- PRAC assessment reports and recommendation for actions including published PRAC recommendations and translations
- CHMP related activities
- Guidance for writing PRAC recommendations
- Managing Meeting Document System (MMD)
- Assessment report redaction guideline
- PRAC Annex C

EVDAS

The trainee should attend the EVDAS training organised by Signal Management (P-PH-SMA) service for experts of national competent authorities, when places are available. This training is not considered compulsory for the performance of signal management activities. Basic principles on EVDAS may be provided by the mentor during the training programme.

3.2. Continuing Development Training Program for Signal Management Leads

After completion of the Signal Detection and Management basic training programme, the Signal Management leads will undertake the continuous training activities in line with the Memorandum IAP-A13003-4-03 – Management of scientific and regulatory training within the P-division. Training areas and specific courses should be identified and discussed during the yearly staff appraisal. All the training courses attended should be recorded.

EMA training catalogue and EU network training centre

In order to identify relevant training courses, Signal Management Leads are encouraged to consult the EMA general training catalogue and the courses offered by the EU network training centre (EU NTC). Of special interest would be the courses related to Pharmacovigilance and EudraVigilance.

SOPs and WINs

Signal Management Leads should read and understand any new or updated SOPs and WINs related to Signal Detection and Management activities. Acknowledgement of reading and understanding will be recorded in SAP-HR under “career and job” “access your learning”.

Training received during signal validation, ORGAM and department meetings

Technical tools, signal detection methods, specific drug safety issues and targeted ADR topics are covered during the signal validation, ORGAM and department meetings. These meetings are intended to share knowledge and expertise and therefore are considered an integral part of the continuing development programme.

P-PH-SMA assistants record in the meeting minutes the list of attendees as well as the topics covered during the meeting. These records are stored electronically in DREAM.

External training courses in therapeutic areas and in other topics of interest

In view of the need to maintain and expand the knowledge regarding pertinent topics (therapeutic areas, epidemiology, statistics, pharmacovigilance, etc.), Signal Management Leads should be encouraged to attend external courses, conferences and congresses in order to build their expertise and keep up to date with new developments.

The external training courses are subject to budget and staff availability. Management at Service, Department and Division level would endeavour to facilitate these training participations.