

**Report to the European Commission on  
Pharmacovigilance audits carried out in  
BASG/AGES (Austrian Federal Office for Safety in  
Health Care / Austrian Medicines and Medical  
Devices Agency), Austria**

**Period of time from September 2015 to August 2017**

## 1. INTRODUCTION

This report provides an overview of the audit activities conducted from September 2015 to August 2017 by the internal auditors of the Austrian Federal Office for Safety in Health Care / Austrian Medicines & Medical Devices Agency (BASG/AGES), coordinated by BASG/AGES quality management.

## 2. Developments in the pharmacovigilance system since the last report

Significant changes during the reporting period

### Legislation and regulatory

No changes since the last report.

### Standards and Procedures

Apart from regular updates of internal quality documentation no changes since the last report.

### Quality system for Pharmacovigilance Activities

No changes since the last report.

### Critical Pharmacovigilance Processes

No changes since the last report. In the context of risk assessment for internal audits, the criticality of PV processes was reviewed, considering the PAFG/PRAC recommendation "Guidance on Network Risk Ratings of Pharmacovigilance Process Areas", see 3.1.

### Other changes

No changes since the last report.

## 3. INTERNAL AUDIT ACTIVITY FOR THE PERIOD UNDER REVIEW

### 3.1 RISK ASSESSMENT

The risk assessment of PV processes (based on the PAFG/PRAC recommendation "Guidance on Network Risk Ratings of Pharmacovigilance Process Areas") was reviewed in a joint meeting of all managers of departments involved in PV activities, resulting in minor adaptations. The only major change was the suggestion to enhance audit activities of processes that run across organisational interfaces. The final audit strategy was prepared based on this risk assessment and was approved by Head of Agency on March 3<sup>rd</sup> 2017.

### 3.2 SUMMARY OF THE AUDITS FOR THE PERIOD UNDER REVIEW

#### 3.2.1 AUDIT ASSIGNMENTS FOR THE PERIOD UNDER REVIEW

All audits listed were performed in line with the guidance provided in the GVP Module IV Pharmacovigilance audits.

Audit No	Audit title	Date of audit report
35	single assessment PSUR	05.01.2016
36	renewal RMS human	05.10.2015
42/PQO01	communication in crisis management	13.11.2015
49	DHPC	14.07.2016
50	PV inspection	23.01.2017

60	Quality Management System	09.08.2017
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### 3.2.3 Audit 35 - single assessment PSUR

#### 3.2.3.1 Objective and scope

Objective: check recently implemented process and compliance with GVP modules I+VII)

Scope:

- CMDh member (application for rapporteurship)
- Administrators for CP (administrative reception)
- Pharmacovigilance Assessment dept. (assessment, PRAC discussion)
- Invoicing dept.

#### 3.2.3.2 Audit body

Quality Management department & internal auditors

#### 3.2.3.3 Opinion

The audited procedure was (for AT as well as on EU level) one of the first PSUSAs and at the beginning of the procedure it was for all actively involved not completely clear how the new legal requirements should be implemented in practice. This applies also to the IT support foreseen, as the central repository of EMA was still in the pilot phase at start of procedure. Traceability was overall very good, though the auditors had to access individual personal mailboxes in several cases. At the time of finalisation of the audit report the process was already fully supported by an electronic workflow, so this issue could be considered obsolete.

Lessons learned from the first experiences feed continuously back to process optimisation, but are not yet completely reflected in SOPs. This applies e.g. to the process steps of application for rapporteurship at CMDh and the administrative reception and capturing in the IT system. Apart from work time spent there is currently no systematic collection of KPIs, but the CMDh ranking of PSUSA rapporteurships is discussed as possible quality indicator.

### 3.2.4 Audit 36 - RMS renewal human

#### 3.2.4.1 Objective and scope

Objective: to check effectiveness of the process and compliance with ISO 9001

Scope:

- Medical Assessment department
- PV assessment department

#### 3.2.4.2 Audit body

Quality Management department & internal auditors

#### 3.2.4.3 Opinion

The business process “renewal DCP with AT=RMS” follows without any deviations the Best practice guide on the processing of renewals in the MRP/DCP as well as the internal SOP L\_Z126. The auditors observed some minor opportunities for improvement, that are easy to implement, including the improvement of the interface between the in-house IT application and CTS in order to improve the efficiency of data transfers.

### 3.2.5 Audit 42/PQO01/2015 - communication in crisis management

#### 3.2.5.1 Objective and scope

Objectives:

- To check effectiveness of crisis management (with focus on external communication)
- To check compliance with GVP modules I + XV
- To establish a gap analysis of the QMS of the mother organisations communications department (9001 certified, but not part of the medicines agency division) to GVP modules I + XV

Scope:

- risk communication coordinator
- crisis team (deputy head of medicines agency, head of marketing authorisation department, CMDh alternate, risk communication coordinator, liaison officer to COM department)
- communications department (part of mother organisation; this part of the audit was performed as audit PQO01 on behalf of the mother organisation's quality unit)

#### 3.2.5.2 Audit body

- Quality Management department & internal auditor from mother organisation (for audit 42 in the medicines agency)
- Staff Unit for AGES Quality Management, performed by internal auditors from the QM dept. of the medicines agency + the mother organisation (for audit PQO01 in the COM dept.)

#### 3.2.5.3 Opinion

Medicines Agency:

An upcoming "media crisis" (enhanced media coverage without any safety concerns) could be managed well though the circumstances were suboptimal (prolonged weekend and absence of key staff). Traceability was overall very good, though the auditors had to access the individual personal mailbox of the risk communication coordinator. Currently there is no effective deputy regulation for this key function.

SOPs for crisis management, issues management reporting and press relations are in place and followed. The auditors identified some opportunities for improvement that were openly discussed with auditees.

COM department:

Processes and responsibilities are clearly regulated. Traceability is ensured and no systematic deviations were observed. SOPs are updated and improved.

Gap analysis to GVP: The quality system in place is structured acc. to ISO 9001, but fulfils all relevant requirements of GVP I. The observation of archiving times defined by GVP I is in the responsibility of the medicines agency. The only step relevant to GVP XV that is actively performed by the COM department is the check of information provided by the medicines agency for press suitability and readability by laypersons.

### 3.2.6 Audit 49 - DHPC

#### 3.2.6.1 Objective and scope

Objective: to check effectiveness of the process and compliance with GVP modules I + XV

Scope: Regulatory affairs dept.

#### 3.2.6.2 Audit body

Quality Management department & internal auditors

### 3.2.6.3 Opinion

Direct Health Care Professional Communication (DHPC) regarding a changed risk profile of medicinal products is currently focussing on the check of implementation of PRAC recommendations by the MAH. Due to lack of defined internal communication channels, a robust check for completeness of applications is currently not possible. Purely national DHPC were never performed up to now and are not expected for the future. The process is optimised regarding resources, but does not include internal peer review or measurement of effectiveness. The SOP is outdated, and the process is not supported by IT workflow or document management system. Good traceability was given regarding documents on the shared server and the individual mailbox of the assessor. Currently, no effective deputy regulation for the assessor is in place.

## 3.2.7 Audit 50 – PV inspection

### 3.2.7.1 Objective and scope

Objectives:

- to check effectiveness of the process
- compliance with GVP modules I + III
- follow-up of change of key staff

Scope: Blood, tissues and vigilance department

### 3.2.7.2 Audit body

Quality Management department & internal auditors

### 3.2.7.3 Opinion

SOPs are in place and updated. KPIs are in place for controlling the process and as basis for reporting. According to national legislation, all MAHs have to be inspected in regular intervals. Due to restricted resources, this is currently not possible in the intervals proposed by GVP III (4 years). All authorised companies were subjected to a risk rating in order to support the selection of inspections to be performed. The reporting obligations to the European network are fulfilled. The exceptional situation, that the process was temporarily “orphaned” as the only fully trained PV inspector left the agency in July 2016 will be ended by the completion of training by her replacement scheduled for Q1/2017.

## 3.2.8 Audit 60 - Quality System

### 3.2.8.1 Objective and scope

Objective: to check compliance of the quality system with ISO DIS 17025:2017 (including specific aspects required by GVP I and IV)

Scope: Quality Management department

### 3.2.8.2 Audit body

Internal auditor from mother organisation

### 3.2.8.3 Opinion

The QMS was audited against the draft ISO DIS 17025:2017 without detecting of non-conformities according to the current standard. Deviations to the draft standard were classified as opportunities for improvement. Corresponding actions shall be implemented until 12 months after publication of the definitive version. The management system is considered excellent. All processes and records are traceable. The management system is subject to ongoing improvement and can be considered pronouncedly stable, based on results of KPIs.

### 3.2.2.4 Audit outcomes and actions

Actions based on 3 audit outcomes which are reported and rated as 'Critical' and as 'Major', in line with the guidance provided in the GVP Module IV Pharmacovigilance audits.

Audit No	Find No	Audit outcomes description	Grading	Action short description	Action end date	Comments on status of actions	Type of follow-up required
49	KSTE-ABSDY2	no effective deputy regulation for safety communication assessor	major	implementation and training of deputy	22.03.2017	2 deputies were appointed, trained, granted relevant access rights and sign-off responsibility	follow-up by line management and internal auditors (done)
50	KSTE-AHSH9X	insufficient human resources for PV inspections	major	recruitment and training	pending	1 inspector completed training in Q1/2017. Recruitment process for 1 additional inspector is currently ongoing	follow-up by line management and internal auditors (pending)

## 4. FOLLOW-UP

### 4.1 SUMMARY OF ACTION PLANS FROM PRIOR BIENNIAL REPORTS

The following table provides an overview of earlier audit outcomes issued by the Quality management department and internal auditors and their implementation by the BASG/AGES at September 2017.

For action from audit outcome graded as:	Total	Number implemented	Number not implemented	
			Not started	In progress
Critical	0	0	0	0
Major	1	0	0	1
Total	1	0	0	1

### 4.2 OUTSTANDING ISSUES FROM PRIOR BIENNIAL REPORTS

Implementation of a structured business continuity plan (finding KSTE-9QLJUX from audit 29, major) is still outstanding. A project for implementation is planned to start in Q3/2017 at level of the mother organisation. Meanwhile, the disaster recovery plan of the IT department was tested and audited internally (audit PQO/05/2016, not part of this report) as well as externally with satisfactory results. At level of the Medicines Agency, time-critical processes were identified and reviewed regarding resources required for continuous service (including an audit focus on deputy regulations).

The follow-up of the redesigned process for crisis management (finding No. 1751 from audit 01/2012, major) was performed as internal audit 42/PQO01 (see 3.2.5) with satisfactory results.

## 5. DECLARATION

The Austrian Federal Office for Safety in Health Care confirms that this report contains a complete account of all pharmacovigilance system audit activity performed in the period under review to fulfil the obligations of this organisation under Directive 2001/83/EC.

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**Head of the National Competent Authority**

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**Date**

Wirthumer-Hoche Christa  
am 10.8.2017



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Bundesamt für Sicherheit im Gesundheitswesen  
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