

**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 2017 to August 2019

1. INTRODUCTION

This report provides an overview of the audit activities conducted from September 2017 to August 2019 by the internal auditors of the Austrian Federal Office for Safety in Health (BASG), coordinated by the dept. Quality Management.

2. DEVELOPMENTS IN THE PHARMACOVIGILANCE SYSTEM SINCE THE LAST REPORT

Significant changes during the reporting period¹

- Legislation and regulatory
No changes since the last report.
- Standards and Procedures
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.
- 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”), which resulted in the audit strategy approved by Head of Agency on March 3rd 2017 was escalated via WGQM to PRAC and HMA and was confirmed. Therefore, it was not considered necessary to revise the audit strategy.

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
59	ICSR, signal detection, evaluation and assessment	18.01.2018
61	Rapid alerts and non-urgent information	20.12.2017
68	Additional Monitoring	27.03.2019
75	DSURs	04.02.2019
79	Quality System	12.09.2019

¹ Strengths and improvements in the pharmacovigilance system may be included under this heading

3.2.2 AUDIT 59 – ICSR, SIGNAL DETECTION, EVALUATION AND ASSESSMENT

3.2.2.1 Objective and scope

Objective: to check effectiveness of the process and compliance with GVP modules I, VI + IX

Scope:

- Dept. Blood Tissues & Vigilance
- Interface to PRAC member & Dept. Assessment Pharmacovigilance

3.2.2.2 Audit body

Quality Management department & internal auditors

3.2.2.3 Opinion

Management of ICSRs follows an established process, but the corresponding SOPs were not yet updated in order to reflect direct reporting to EudraVigilance by industry stakeholders.

Signal detection and evaluation was audited for a substance for which AT is lead member state (currently 50 substances) and was fully traceable. On national level, signal detection is performed only in exceptional cases due to limited human resources.

3.2.3 AUDIT 61 – RAPID ALERTS AND NON-URGENT INFORMATION

3.2.3.1 Objective and scope

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

Scope:

- Dept. Regulatory Affairs (human RA/NUIs)
- Dept. Herbal, Homoeopathic & Veterinary Medicinal Products (vet. RA/NUIs)

3.2.3.2 Audit body

Quality Management department & internal auditors

3.2.3.3 Opinion

Human RA/NUIs: Management of passive RA/NUIs was well traceable. Actively, a single case of a NUI was issued in 2011. For such cases, internal interactions between assessors, PRAC- and CMDh-members, decision procedures and the link to crisis management should be regulated in more detail.

Veterinary RA/NUIs: Management of passive RA/NUIs was well traceable. No active case was available for audit.

3.2.4 AUDIT 68 – ADDITIONAL MONITORING

3.2.4.1 Objective and scope

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

Scope:

- Dept. Regulatory Affairs
- Medical Assessment
- Quality Assessment Medicinal Products
- Assessment Pharmacovigilance

3.2.4.2 Audit body

Quality Management department & internal auditors

3.2.4.3 Opinion

As internal responsibilities were not fully clarified until summer 2017, systematic implementation of additional monitoring was not ensured and no feedback process to EMA regarding implementation and termination of additional monitoring was established. The auditor considered the process as currently defined as suitable, however noted opportunities for improvement to be managed by training, e.g. for alignment of the authorisations of generics with the reference product, and the management of the interface between regulators and the PRAC member regarding PASS. Existing SOPs should be updated in this respect. Furthermore, it was noted that the IT service for management of marketing authorisations currently does not allow queries by users of the additional monitoring status.

3.2.5 AUDIT 75 – DSURS

3.2.5.1 Objective and scope

Objective: to check effectiveness of the process and compliance with ICH EF2, GVP modules I + VI (as applicable)

Scope:

- Dept. Clinical Trials
- Interface to Dept. Blood Tissues & Vigilance

3.2.5.2 Audit body

Quality Management department & internal auditors

3.2.5.3 Opinion

Due to limited resources, DSUR assessment is performed according to documented risk-based criteria. Considerations for process optimisation focus on these external restrictions of capacity, as is documented in internal reports and reports to the Ministry. SOPs are up-to-date, the audited business cases followed the procedures and were fully traceable.

3.2.6 AUDIT 79 – QUALITY SYSTEM

3.2.6.1 Objective and scope

Objective: to check system compliance to ISO 9001

Scope:

- Procedural member of BASG (i.e. head of agency): context of the organisation, management review
- Dept. Quality Management: management of CAPA, control of documents, internal audits

3.2.6.2 Audit body

Internal auditors from medicines agency and mother organisation

3.2.6.3 Opinion

The process description reviewed as part of the internal audit are up-to-date, consistent and sufficiently detailed to ensure the functioning of the quality management system.

Requirements are communicated and largely complied. In a specific case, it was not possible to present the approval for a consulting service during the audit. The audited processes are traceable, adequately monitored and controlled. No systematic or repeated deviations were detected. In the interests of continuous improvement, possibilities for increasing customer feedback and patient reporting should be evaluated. The measures taken as part of the continuous improvement process appear effective in preventing the recurrence of errors.

3.2.6 Audit outcomes and actions

In the reporting period, no major or critical deficiencies of the pharmacovigilance system were identified by internal audits.

3.2.7 Summary of action plan for current reporting period

In the reporting period, no major or critical deficiencies of the pharmacovigilance system were identified by internal audits.

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 their implementation by BASG at September 2019.

For action from audit outcome graded as:	Total	Number implemented	Number not implemented	
			Not started	In progress
Critical	0	0	0	0
Major	2	2	0	0
Total	2	2	0	0

4.2 OUTSTANDING ISSUES FROM PRIOR BIENNIAL REPORTS

- A structured business continuity plan (finding KSTE-9QLJUX from audit 29, major) was implemented in January 2019.
- Insufficient human resources for PV inspections (finding KSTE-AHSH9X from audit 50, major) were effectively addressed by recruitment and training.

5. DECLARATION


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

Christa Wirthumer-Hoche

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Head of the National Competent Authority

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Date

Wirthumer-Hoche Christa
 am 13.9.2019

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