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 2019 to August 2021

1. INTRODUCTION

This report provides an overview of the audit activities conducted from September 2019 to August 2021 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 period[1]

- 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 is based on the PAFG/PRAC recommendation “Guidance on Network Risk Ratings of Pharmacovigilance Process Areas” and reflected in the audit strategy in force since March 3rd 2017.
The audit strategy was reviewed by management involved in pharmacovigilance activities, including experts and communication professionals, and adapted in order to improve clarity and practical applicability, but no major changes were introduced. This revised audit strategy was approved by Head of Agency on October 2nd 2020.

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
86	Crisis management	19.02.2020
87	DCP RMS (part: RMP assessment)	03.01.2020
88	Implementation of PhV measures (CSP-implementation, DHPC, educational material)	19.02.2020
89	Non-interventional studies	19.12.2019

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

90	Quality system	18.06.2020
100	PASS assessment	17.02.2021
109	Quality system	18.08.2021

3.2.2 AUDIT 86 - Crisis management

3.2.2.1 Objective and scope

Objective: to check effectiveness of the process for management of quality defects and compliance with GVP modules I and XV
Scope:

- Communication professional
- Good Manufacturing Practice department

3.2.2.2 Audit body

Quality Management department & internal auditors

3.2.2.3 Opinion

SOPs are in place, sufficiently detailed, regularly updated and followed. A significant deviation from procedures were issues registered directly by the communication professional (e.g. from EMAs' communication e-mails) that were processed to "issue monitoring reports" (press statements for standby) without involvement of responsible departments.
While all steps in the management of quality defects are well documented and traceable, the documentation of external communication was partially not filed appropriately.

3.2.3 AUDIT 87 - DCP RMS

3.2.3.1 Objective and scope

Objective: to check effectiveness of the process for decentralised procedures with Austria as RMS and compliance with ISO 9001 (for RMP-assessment with GVP modules V + XVI)
Scope (departments):

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

3.2.3.2 Audit body

Quality Management department & internal auditors

3.2.3.3 Opinion

Cross-organisational cooperation is very effective. Both within departments as well as across internal interfaces there is evidence of structured communication on process and ongoing procedures.
Process control and process support is appropriate. SOPs are partially not fully up to date.
Process surveillance focuses on national implementation phase, as the rest of the process is fully regulated by European guidelines.
As example for ongoing process improvement, the recent implementation of IT support for the presubmission phase is highlighted.

3.2.4 AUDIT 88 - Implementation of PhV measures

3.2.4.1 Objective and scope

Objective: to check effectiveness of the processes for implementation of pharmacovigilance measures (implementation of CSP, DHPC and educational material) and compliance with GVP modules I, XV + XVI

Scope (departments):

- Regulatory Affairs

3.2.4.2 Audit body

Quality Management department & internal auditors

3.2.4.3 Opinion

The process for implementation is well established and documented, but formal communication to PRAC member and PhV assessors should be improved. SOPs are outdated and the process for assessment of educational material is not described in the quality system. Access to current information on medicines sales should be established to be available for impact assessment.

3.2.5 AUDIT 89 - Non-interventional studies

3.2.5.1 Objective and scope

Objective: to check effectiveness of the process for registration of non-interventional studies and compliance with GVP modules I + VIII

Scope (departments):

- Clinical Trials (incl. internal interfaces)

3.2.5.2 Audit body

Quality Management department & internal auditors

3.2.5.3 Opinion

Most steps in the process for registration of non-interventional studies are automated. Assessment is only required in cases of missing or negative opinion of the ethics committee. Spot checks foreseen by SOPs are currently not regularly performed, and SOPs and guidance provided on the website are not up to date.

IT supports routine registration well, but reports, queries and data provision to external stakeholders are not supported.

The main observation of the audit was that the national legislation (NIS ordinance) should be revised as for several requirements the wording is not precise, which leads to misinterpretations or requests for clarification.

3.2.6 AUDIT 90 - QMS

3.2.6.1 Objective and scope

Objective: to check effectiveness of the quality system and compliance with GVP modules I and IV

Scope (departments):

- Quality Management

3.2.6.2 Audit body

Internal auditors from mother organisation of medicines agency

3.2.6.3 Opinion

The stability of the quality management system was checked based management of nonconformities from previous audits and the management review for 2019. QMS documentation is clearly structured and essential documents are up to date. The quality system is well implemented and stable. QMS staff work in compliance and are competent.

3.2.7 AUDIT 100 - PASS assessment

3.2.7.1 Objective and scope

Objective: to check effectiveness of the process for PASS assessment and compliance with GVP modules I + VIII
Scope (departments):

- Assessment Pharmacovigilance

3.2.7.2 Audit body

Quality Management department & internal auditors

3.2.7.3 Opinion

The process is well managed both from the scientific/regulatory and the operational perspective. The audited procedure was (though rather complex) well traceable. The auditor recommended to define how to file information available before start of procedure and to establish formal communication to other concerned departments. The SOP on RMP assessment should be amended to include aspects of PASS assessment.

3.2.8 AUDIT 109 - QMS

3.2.8.1 Objective and scope

Objective: to check effectiveness of the quality management system and compliance with ISO 17020
Scope (departments):

- Quality Management

3.2.8.2 Audit body

Internal auditor from mother organisation of medicines agency

3.2.8.3 Opinion

There were no significant changes of the quality system since the last internal system audit in 2019, except that the pharmaceutical laboratory of the OMCL renounced national accreditation (but continues to hold a MJA certificate from EDQM).
I order to include several normative/legal requirements, the QMS is very extensive regarding documented internal requirements and corresponding records. Requirements regarding the QMS are well integrated and there is evidence that the system is continuously improved. Observations from this audit are minor. The process for adoption of QMS documents from the mother organisation's QMS should be reconsidered.

3.2.9 Audit outcomes and actions

Actions based on an audit outcome that was 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
90	KSTE-BQPGZK	SOP A39 on risk communication is not updated and is referencing to other documents that were declared invalid	Major	SOP A39 updated	17.09.2021	complete	follow-up by line management and internal auditors (pending)

3.2.9.1 Summary of action plan for current reporting period

The following table provides an overview of audit outcomes and their implementation.

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

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 deprtment and their implementation by BASG at September 2021.

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

4.2 OUTSTANDING ISSUES FROM PRIOR BIENNIAL REPORTS

There were no outstanding issues from prior reports.

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 **Date**

Wirthumer-Hoche Christa
am 16.9.2021

Dieses Dokument wurde amtssigniert.

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