Report to the European Commission[1] on Pharmacovigilance audits Carried out in the Agency for Medicinal Products and Medical Devices (HALMED), Croatia

from 19/09/2017 to 12/09/2019

[1] Delete as necessary – National Competent Authorities are required to report to the European Commission (Directive 2001/83/EC Art.101(2), European Medicines Agency is required to report to its Management Board (Regulation (EC) No.726/2004 Art 28f)

1. INTRODUCTION

The report is prepared in the context of the obligation under Article 101 (2) of the Directive 2001/83/EC states: "Member States shall perform a regular audit of their Pharmacovigilance system and report the results to the Commission on 21 September 2013 at the latest and then every 2 years thereafter."

This report provides an overview of the audit activities conducted from 19/09/2017 to 21/09/2019 by the Agency for Medicinal Products and Medical Devices (hereinafter referred as "HALMED"), Croatia, based on the internal audit which are planned to fulfil the Union legal requirements in the field of pharmacovigilance.

For this purpose, HALMED has planned and performed 4 internal audits to check the compatibility of all requirements set in Good pharmacovigilance practices guidelines within HALMED's units responsible for pharmacovigilance activities.

The realisation of achieved goals has been examined during the internal audit whose details are given in the report below.

2. DEVELOPMENTS IN THE PHARMACOVIGILANCE SYSTEM SINCE THE LAST REPORT

Significant changes during the reporting period

- Legislation and regulatory
  - No change
- Standards and Procedures
  - No change
- Quality system for Pharmacovigilance Activities
  - Revision of corresponding SOPs connected to GVP Modules that had been revised;
- Critical Pharmacovigilance Processes
  - The upgrade to the existing databases.
- Other changes
  - The Head of Inspectorate has been changed.

3. INTERNAL AUDIT ACTIVITY FOR THE PERIOD UNDER REVIEW

3.1 RISK ASSESSMENT

A risk assessment exercise was conducted in order to determine the pharmacovigilance system audit priorities for the period under review. The final audit strategy was prepared based on this risk assessment and was approved by the quality manager of HALMED on 21/12/2017.

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
4-18	Internal audit 4-18	17.09.2018.
11-18	Internal audit 11-18	24.09.2018.
3-19	Internal audit 3-19	27.03.2019.
9-19	Internal audit 9-19	18.07.2019.

3.2.2 AUDIT REPORT

3.2.2.1 Objective and scope

The objective of the audits was to determine the compliance of HALMED pharmacovigilance system with the Guideline on good pharmacovigilance practices.
The scope of the audit included compliance with stated Modules of the Guideline on good pharmacovigilance practices.

Internal audit 4-18
- Module III

Internal audit 11-18
- Module V
- Module VIII
- Module IX
- Module XVI

Internal audit 3-19
- Module I
- Module IV
- Module VI
- Module X
- Module XV

Internal audit 9-19
- Module II
- Module VII

3.2.2.2 Audit body
The Office for quality management of HALMED

3.2.2.3 Opinion
Sufficient and appropriate audit procedure has been conducted and evidence gathered to support the accuracy of the conclusions reached and contained in this report. The conclusions were based on a comparison of the situations as they existed at the time of audit against the audit criteria defined in the Quality manual and corresponding standard operating procedures.
The internal auditing team concluded that no critical nonconformities were noted as defined by GVP Module IV (see 3.2.2.4).
Evaluated pharmacovigilance processes are adequate, appropriate, and effective to provide reasonable assurance that potential risks for public health are being properly managed and that the objectives are met.

Despite some difficulties noted, the overall opinion for the reported period on the HALMED Pharmacovigilance quality system is that system functioned very well and can assure the high quality of pharmacovigilance activities.

3.2.2.4 Audit outcomes and actions

Actions based on 4 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
11-18	1	Due to insufficient human resources signal detection process for three active substances has not been regularly carried out in the period from 11/2018 until 03/2019.	**Major**	A backlog resolving plan has been agreed and is underway.	Dec 2019	ongoing	Internal audit
3-19	2	The traceability of follow-up process for ICSR cases has not been fully implemented in HALMED's new adverse reaction monitoring system (OPeN).	**Major**	System upgrades are ongoing and a substitute monitoring process has been established during the upgrade period.	Nov 2019	ongoing	Internal audit

3.2.2.5 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	2	0	0	2
Total	2	0	0	2

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 HALMED and their implementation by the HALMED at 19/09/2017.

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

There were no ongoing issues from prior biennial reports.

4.2 OUTSTANDING ISSUES FROM PRIOR BIENNIAL REPORTS

No outstanding issues from prior biennial reports were recorded.

5. DECLARATION

The Agency for Medicinal Products and Medical Devices (HALMED) 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 our organisation under Directive 2001/83/EC[2].

Siniša Tomić, PhD, Associate Professor

Head of Agency

Date 12/09/2019

2 Delete as necessary – National Competent Authorities are required to perform a regular audit of their Pharmacovigilance system and report the results to the Commission on 21 September 2013 at the latest and then every 2 years thereafter. (Directive 2001/83/EC Art.101(2),
The European Medicines Agency is required regular independent audits of its pharmacovigilance tasks and report the results to its Management Board on a 2-yearly basis. (Regulation (EC) No.726/2004 Art 28f)