Report to the European Commission/Management Board on Pharmacovigilance audits carried out in the Agency for Medicinal Products and Medical Devices (HALMED), Croatia

from 21/09/2015 to 19/09/2017

1. INTRODUCTION

The report is prepared in the context of the obligation under Article 101 (2) of the Directive 2001/83/EC that states: "The 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 from 21/09/2015 to 19/09/2017 conducted 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 to perform 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. BRIEF DESCRIPTION OF THE PHARMACOVIGILANCE SYSTEM

Developments in the pharmacovigilance system since the last report
Since the last report the changes that were implemented were in a connection with:

- Quality system for Pharmacovigilance Activities –revision of corresponding SOPs connected to GVP Modules that had been revised;
- The Head of Inspection Unit comprising PV inspection has been changed
- The upgrade to the existing databases.

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 13/01/2016.

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
8-16	Internal audit 8-16	18/04/2016
12-16	Internal audit 12-16	22/12/2016
17-16	Internal audit 17-16	20/12/2016
9-17	Internal audit 9-17	25/07/2017

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 8-16

- Module I
- Module VI
- Module XV

Internal audit 12-16

- Module III

Internal audit 17-16

- Module II
- Module VII
- Module X

Internal audit 9-17

- Module VIII
- Module IV
- Module IX
- Module V
- Module XVI

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 or major 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.

The overall opinion for the reported period on the HALMED Pharmacovigilance quality system is that system has been very well organised and can assure the high quality of pharmacovigilance activities.

3.2.2.4 Audit outcomes and actions

There were no nonconformities based on four audit outcomes which were reported and rated as 'Critical' and or 'Major', in line with the guidance provided in the GVP Module IV Pharmacovigilance 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* 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	2	2	0	0
Total	2	2	0	0

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 /Regulation (EC) No.726/2004.

Siniša Tomić, PhD, Associate Professor

Head of Agency

Date 19/09/2017