Report to the European Commission on Pharmacovigilance audits carried out in The Medicines and Healthcare products Regulatory Agency of the United Kingdom: September 2017 to September 2019

1. INTRODUCTION

This report provides an overview of the audit activities conducted from September 2017 to September 2019 by the internal auditors of the Medicines and Healthcare products Regulatory Agency (MHRA) and the Quality Standards Manager of the MHRA's Vigilance and Risk Management of Medicines Division.

2. DEVELOPMENTS IN THE PHARMACOVIGILANCE SYSTEM SINCE THE LAST REPORT

The MHRA relocated offices during 2018.

Transition of the MHRA to certification against ISO 9001:2015 in 2018. There are no other significant changes during the reporting period.

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 quality audit priorities for the period under review. The final audit strategy was prepared based on this risk assessment and was approved by the Director of the MHRA's Vigilance and Risk Management of Medicines Division on 30th April 2019.

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
IES1718_04	Assessing non-compliance, determining and applying sanction	7th December 2017
VRMM 06 2017	Process of signal management review	9th January 2018
VRMM 01 2018	Collection, management and reporting of suspected adverse reactions	23rd May 2018
VRMM 02 2018	Safety communication	7th June 2018
IES1819_01	Monitoring and enforcing compliance with relevant good practices through regulatory inspections	4th July 2018
VRMM 03 2018	Procedure for additional monitoring	5th November 2018
VRMM 01 2019	Process of signal management review	8th April 2019
VRMM 04 2019	Management, reporting and communicating information on suspected adverse reactions	2nd July 2019
VRMM 05 2019	Risk management systems combined with tools, educational materials and effectiveness measurement for risk minimisation	22nd July 2019

3.2.2 ASSESSING NON-COMPLIANCE, DETERMINING AND APPLYING SANCTION IES1718 04

3.2.2.1 Objective and scope

To determine if the processes for assessing non-compliance, determining and applying sanction are compliant with ISO 9001:2008 and relevant processes.

The scope of the audit covers referrals to the MHRA's Inspection Action Group.

3.2.2.2 Audit body

The audit was conducted by an internal auditor in the Inspection, Enforcement and Standards Division.

3.2.2.3 Opinion

Process conforms to internal audit procedures and ISO 9001:2008. There were no non-conformities or improvement actions.

3.2.3 PROCESS OF SIGNAL MANAGEMENT REVIEW VRMM 06 2017

3.2.3.1 Objective and scope

To assess compliance with the documented pharmacovigilance system, applicable legislation and GVP guidelines, the MHRA quality management system and ISO 9001:2008.

The scope of the audit is to ensure that signal management activities operate in accordance with procedures.

3.2.3.2 Audit body

The audit was conducted by an internal auditor in the Devices Division with the support of the Quality Standards Manager for the Vigilance and Risk Management of Medicines Division.

3.2.3.3 Opinion

Processes and activities were compliant with applicable legislation and GVP guidelines, the MHRA's quality management system and the requirements of ISO 9001:2008. There was one minor non-conformity. A few observations were recorded and presented as opportunities for improvement. Corrective action has been satisfactorily completed.

3.2.4 COLLECTION, MANAGEMENT AND REPORTING OF SUSPECTED ADVERSE REACTIONS VRMM 01 2018

3.2.4.1 Objective and scope

To assess compliance with the documented pharmacovigilance system, applicable legislation and GVP guidelines, the MHRA quality management system and ISO 9001:2015.

The scope of the audit is to ensure that the collection, management and reporting of suspected adverse reactions operate in accordance with procedures.

3.2.4.2 Audit body

The audit was conducted by an internal auditor in the Inspection, Enforcement and Standards Division with the support of the Quality Standards Manager for the Vigilance and Risk Management of Medicines Division.

3.2.4.3 Opinion

Processes and activities were compliant with applicable legislation and GVP guidelines, the MHRA's quality management system and the requirements of ISO 9001:2005. There was one minor non-conformity. Corrective action has been satisfactorily completed.

3.2.5 SAFETY COMMUNICATION VRMM 02 2018

3.2.5.1 Objective and scope

To assess compliance with the documented pharmacovigilance system, applicable legislation and GVP guidelines, the MHRA quality management system and ISO 9001:2015.

The scope of the audit is to ensure that safety communication activities operate in accordance with procedures.

3.2.5.2 Audit body

The audit was conducted by an internal auditor in the Inspection, Enforcement and Standards Division with the support of the Quality Standards Manager for the Vigilance and Risk Management of Medicines Division.

3.2.5.3 Opinion

Processes for safety communications conform to procedures which reflect the GVP guidelines, the MHRA quality management system and ISO 9001:2015. There were no non-conformities and one improvement suggestion.

3.2.6 MONITORING AND ENFORCING COMPLIANCE WITH RELEVANT GOOD PRACTICES THROUGH REGULATORY INSPECTIONS IES1819 01

3.2.6.1 Objective and scope

To understand why inspection planning is carried out in the way it is currently done and look for ways to improve this part of the inspection process.

The scope of the audit is the scheduling of inspections across all GXPs. Processes involved in determining the duration of audits are not within scope of the audit.

3.2.6.2 Audit body

The audit was conducted by an internal auditor in the Inspection, Enforcement and Standards Division.

3.2.6.3 Opinion

Process conforms to internal procedures and ISO 9001:2015. No non-conformities were reported. Two improvement opportunities were addressed.

3.2.7 PROCEDURE FOR ADDITIONAL MONITORING VRMM 03 2018

3.2.7.1 Objective and scope

To assess compliance with the documented pharmacovigilance system, applicable legislation and GVP guidelines, the MHRA quality management system and ISO 9001:2015.

The scope of the audit is to ensure that additional monitoring activities operate in accordance with procedures.

3.2.7.2 Audit body

The audit was conducted by an internal auditor in the Transformation Division with the support of the Quality Standards Manager for the Vigilance and Risk Management of Medicines Division.

3.2.7.3 Opinion

Processes and activities were compliant with applicable legislation and GVP guidelines, the MHRA's quality management system and the requirements of ISO 9001:2005. No non-conformities were reported. A few observations were noted and addressed as improvement opportunities.

3.2.8 PROCESS OF SIGNAL MANAGEMENT REVIEW VRMM 01 2019

3.2.8.1 Objective and scope

To assess compliance with the documented pharmacovigilance system, applicable legislation and GVP guidelines, the MHRA quality management system and ISO 9001:2015.

The scope of the audit is to ensure that signal management activities operate in accordance with procedures.

3.2.8.2 Audit body

The audit was conducted by an internal auditor in the Transformation Division with the support of the Quality Standards Manager for the Vigilance and Risk Management of Medicines Division.

3.2.8.3 Opinion

No non-conformities were reported. Case folder records were not reviewed during the audit. A few observations were noted and addressed as improvement opportunities.

3.2.9 MANAGEMENT, REPORTING AND COMMUNICATING INFORMATION ON SUSPECTED ADVERSE REACTIONS VRMM 04 2019

3.2.9.1 Objective and scope

To assess compliance with the documented pharmacovigilance system, applicable legislation and GVP guidelines, the MHRA quality management system and ISO 9001:2015.

The scope of the audit is to ensure that management, reporting and communicating information on suspected adverse reactions operate in accordance with procedures.

3.2.9.2 Audit body

The audit was conducted by an internal auditor in the Transformation Division with the support of the Quality Standards Manager for the Vigilance and Risk Management of Medicines Division.

3.2.9.3 Opinion

One minor non-conformity was recorded in the internal audit and is subject to appropriate corrective action. A few observations were noted as improvement opportunities.

3.2.10 RISK MANAGEMENT SYSTEMS COMBINED WITH TOOLS, EDUCATIONAL MATERIALS AND EFFECTIVENESS MEASUREMENT FOR RISK MINIMISATION VRMM 05 2019

3.2.10.1 Objective and scope

To assess compliance with the documented pharmacovigilance system, applicable legislation and GVP guidelines, the MHRA quality management system and ISO 9001:2015.

The scope of the audit is to evaluate risk management systems combined with tools, educational materials and effectiveness measurement for risk minimisation.

3.2.10.2 Audit body

The audit was conducted by an internal auditor in the Transformation Division with the support of the Quality Standards Manager for the Vigilance and Risk Management of Medicines Division.

3.2.10.3 Opinion

Processes and activities were compliant with applicable legislation and GVP guidelines, the MHRA's quality management system and the requirements of ISO 9001:2005. No non-conformities were reported. A few observations were noted as improvement opportunities.

3.2.2.4 Audit outcomes and actions

No actions relating to critical and major non-conformities are prescribed.

Audit No	Find No	Audit outcomes description	Grading	Action short description	Action end date	Comments on status of actions	Type of follow-up required

3.2.2.5 Summary of action plan for current reporting period

Not applicable.

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

4. FOLLOW-UP

4.1 SUMMARY OF ACTION PLANS FROM PRIOR BIENNIAL REPORTS

Not applicable.

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

4.2 OUTSTANDING ISSUES FROM PRIOR BIENNIAL REPORTS

Not applicable.

5. DECLARATION

The MHRA Chief Executive 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[1].

19/08/2019

…….. **…….**

Head of the National Competent Authority **Date**

1 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)