Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

PHARMACOVIGILANCE INSPECTION REPORT

Pharmacovigilance System Name:	Glenmark Pharmaceuticals Europe Ltd.
MHRA Inspection Number:	Insp GPvP 25258/310505-0004

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Table of Contents

ABBREVIATIONS

aRMM	Additional Risk Minimisation Measures
BCP	Business Continuity Plan
CAPA	Corrective and Preventative Action
DPLT	Demand Planning & Logistics Team
EMA	European Medicines Agency
ERP	Enterprise Resource Planning
EU	European Union
FDA	Food and Drug Administration
GDP	Good Distribution Practice
GPhC	General Pharmaceutical Council
GMC	General Medical Council
GVP	Good Vigilance Practice
ICH	International Conference on Harmonisation
ICSR	Individual Case Safety Report
KPI	Key Performance Indicator
LP	Licensing Partner
LPVRP	Local Pharmacovigilance Responsible Person
MAH	Marketing Authorisation Holder
MHRA	Medicines and Healthcare Products Regulatory Agency
PADER	Periodic Adverse Drug Experience Report
PAF	Prescription Authorisation Form
PPP	Pregnancy Prevention Programme
PRF	Pharmacy Registration Form
PSMF	Pharmacovigilance System Master File
PSNI	Pharmaceutical Society of Northern Ireland
PV	Pharmacovigilance
QA	Quality Assurance
QMS	Quality Management System
QPPV	Qualified Person responsible for Pharmacovigilance
RMP	Risk Management Plan
SDEA	Safety Data Exchange Agreements

SOP	Standard Operating Procedure
UK	United Kingdom
USA	United States of America

SECTION A: INSPECTION REPORT SUMMARY

Inspection type:	Statutory National Inspection, including a pre-launch inspection of the [redacted] risk management system
System(s) inspected:	Glenmark Pharmaceuticals Europe Ltd. [redacted]
Site(s) of inspection:	Remote
Main site contact:	[redacted] UK QPPV Address: Glenmark Arzneimittel GmbH, Industriestr. 31, Groebenzell 82194, Germany Mobile: [redacted] Email: [redacted]
Date(s) of inspection:	30 January – 01 February 2023 (a half day office-based review of the [redacted] inspectorate risk assessment questionnaire was conducted on 20 December 2022)
Lead Inspector:	[redacted]
Accompanying Inspector(s):	[redacted]
Previous inspection date(s):	09 – 12 February 2016 29 September – 02 October 2014 03 – 05 May 2011
Purpose of inspection:	Inspection of pharmacovigilance systems to review compliance with UK and EU requirements. This included a pre-launch inspection of the [redacted] risk management system to assess whether it met the requirements set out by the MHRA and was operating in accordance with the quality management system
Products selected to provide system examples:	Risk management system for [redacted]
Name and location of UK QPPV:	[redacted] UK QPPV Address: Glenmark Arzneimittel GmbH, Industriestr. 31, Groebenzell 82194, Germany Mobile: [redacted] Email: [redacted]
Global PV database (in use at the time of the inspection):	[redacted]
Key service provider(s):	Key pharmacovigilance activities associated with the [redacted] risk management system were conducted in-house Other key pharmacovigilance activities outsourced to service providers included ICSR management (LabCorp Scientific Services & Solutions) and auditing services (Symogen Ltd.)
Inspection finding summary:	4 Major findings 3 Minor findings
Date of first issue of report to MAH:	07 March 2023
Deadline for submission of responses by MAH:	Initial: 13 April 2023 Follow-up 1: 31 May 2023
Date(s) of receipt of responses from MAH:	Initial: 06 April 2023 Follow-up: 19 May 2023
Date of final version of report:	06 July 2023

Report author:	[redacted] Pharmacovigilance Inspector Responses reviewed and finalised by [redacted] Pharmacovigilance Inspector

SECTION B: BACKGROUND AND SCOPE

B.1 Background information

Glenmark Pharmaceuticals Europe Ltd. (hereafter referred to as Glenmark) was selected for inspection as part of the MHRA's statutory, national pharmacovigilance inspection programme. The purpose of the inspection was to review compliance with currently applicable UK and EU pharmacovigilance regulations and guidelines. Reference was made to The Human Medicines Regulations 2012 as amended, Commission Implementing Regulation (EU) No 520/2012 and the EU good pharmacovigilance practices (GVP) Modules as modified by the guidance note 'Exceptions and modifications to the EU GVP that apply to UK MAHs and the licensing authority'. Additionally, part of the inspection was a pre-launch inspection of the [redacted] risk management system, to review the procedures and processes in place to manage the controlled access programme and pregnancy prevention programme (PPP) for generic [redacted] in accordance with the approved risk management plan (RMP) and risk management system agreed with the MHRA. Reference was made to the 'Detailed Description of the Implementation of Additional Risk Minimisation Measures for Generic [redacted] approved by the MHRA in November 2022.

A list of reference texts is provided at Appendix I.

Glenmark is a generics pharmaceutical company, headquartered in Mumbai, India, with regional offices in the USA, Germany and UK. The global pharmacovigilance department, based in Mumbai, is responsible for core pharmacovigilance activities, while regional pharmacovigilance functions are required to coordinate and support local pharmacovigilance activities. The local pharmacovigilance responsible person (LPVRP) in the UK and their deputy are responsible for the majority of key activities involved in the [redacted] risk management system, whilst the UK QPPV is responsible for maintaining oversight of the system.

The company has a large number of products licensed in the UK that comprise a mix of national, decentralised, mutual recognition and centralised authorisations. The product portfolio focuses on dermatology, respiratory and oncology therapeutic areas.

Information on the [redacted] risk management system

Glenmark was granted a marketing authorisation with conditions for [redacted] in the UK on [redacted] is a known teratogenic product. The conditions of the licence were as follows:

- To agree the details of a controlled distribution system with the MHRA and implement such programme to ensure that prior to prescribing (and where appropriate, and in agreement with the MHRA, prior to dispensing) all healthcare professionals who intend to prescribe or dispense [redacted] are provided with a physician information pack containing the following:
    - Educational health care professionals kit
    - Educational brochures for patients
    - Patient cards (prescription authorisation forms in the UK)
    - Summary of product characteristics and package leaflet and labelling
- To implement a PPP. Details of the PPP should be agreed with the MHRA and put in place prior to the launch of the product
- To agree the final text of the physician information pack contents with the MHRA
- To agree the implementation of the patient card system with the MHRA

A pre-launch inspection was triggered to ensure the quality management systems supporting the controlled access system and PPP were appropriate. Prior to the inspection, risk minimisation materials had been approved by the MHRA assessment team in Safety and Surveillance.

B.2 Scope of the inspection

The scope of the inspection was focused on two areas: the [redacted] UK risk management system and the wider quality management system. The inspection took place remotely and primarily took the form of document review. Personnel from Glenmark UK and headquarter offices were available throughout the inspection and participated in planned interview sessions and ad hoc discussions held via videoconference. The systems reviewed during the inspection are highlighted in the Pharmacovigilance Inspection Plan (attached as Appendix III).

B.3 Documents submitted prior to the inspection

The company submitted a UK PSMF (version [redacted] dated 15 September 2022) to assist with inspection planning and preparation. Specifically, for the pre-launch inspection of the [redacted] risk management system, Glenmark provided the completed risk assessment questionnaire and supporting documentation prior to the inspection to confirm inspection readiness. The company also submitted a number of document requests in advance of the inspection, details of which are contained within document request sheet A.

B.4 Conduct of the inspection

In general, the inspection was performed in accordance with the Inspection Plan.

The inspection included a half-day office-based risk assessment, which was held on 20 December 2022, to review the answers and documents provided in response to the [redacted] inspectorate risk assessment questionnaire.

A closing meeting was held remotely via videoconference to review the inspection findings on 01 February 2023. A list of the personnel who attended the closing meeting is contained in the Closing Meeting Attendance Record, which will be archived together with the inspection notes, a list of the documents requested during the inspection and the inspection report.

A post-inspection letter was sent on 09 February 2023 to outline the major findings identified in relation to the [redacted] risk management system (also documented in this report as MA.1 and MA.2), in order to support Glenmark to promptly address those deficiencies. The post-inspection letter can be found in Appendix II. Glenmark were asked to provide a written update on the remediation activities and relevant supporting documentation. These amendments were provided to the Lead Inspector on 28 February 2023 and reviewed on 06 March 2023; all amendments were deemed to be acceptable.

SECTION C: INSPECTION FINDINGS

C.1 Summary of significant changes and action taken since the last inspection

Since the previous inspection in 2016, the company had made the following changes to the pharmacovigilance system:

- [redacted] was appointed EU QPPV on 31 December 2020, he also assumed the role of UK QPPV from 19 April 2021
- [redacted] was appointed LPVRP for the UK in January 2019 and since May 2021 she has also acted as the National Contact Person for PV in the UK

C.2 Definitions of inspection finding gradings

Critical (CR): a deficiency in pharmacovigilance systems, practices or processes that adversely affects the rights, safety or well-being of patients or that poses a potential risk to public health or that represents a serious violation of applicable legislation and guidelines.

Major (MA): a deficiency in pharmacovigilance systems, practices or processes that could potentially adversely affect the rights, safety or well-being of patients or that could potentially pose a risk to public health or that represents a violation of applicable legislation and guidelines.

Minor (MI): a deficiency in pharmacovigilance systems, practices or processes that would not be expected to adversely affect the rights, safety or well-being of patients.

Comment: the observations might lead to suggestions on how to improve quality or reduce the potential for a deviation to occur in the future.

The factual matter contained in the Inspection Report relates only to those things that the inspection team saw and heard during the inspection process. The inspection report is not to be taken as implying a satisfactory state of affairs in documentation, premises, equipment, personnel or procedures not examined during the inspection.

Findings from any inspection that covers products authorised in respect of Northern Ireland which are graded as critical or major will be shared with the EMA, EU competent authorities and the European Commission.

C.3 Guidance for responding to inspection findings

Responses to inspection findings should be clear, concise and include proposed actions to address both the identified deficiency and the root cause of the deficiency. Consideration should also be given to identifying and preventing other potential similar deficiencies within the pharmacovigilance system.

Responses should be entered directly into the table(s) in section C.4. The following text is intended as guidance when considering the information that should be entered into each of the fields within the table(s). 'Not applicable' should be entered into the relevant field if the requested information is not appropriate for the finding in question.

Root Cause Analysis Identify the root cause(s) which, if adequately addressed, will prevent recurrence of the deficiency. There may be more than one root cause for any given deficiency.
Further Assessment Assess the extent to which the deficiency exists within the pharmacovigilance system and what impact it may have for all products. Where applicable, describe what further assessment has been performed or may be required to fully evaluate the impact of the deficiency e.g. retrospective analysis of data may be required to fully assess the impact.
Corrective Action(s) Detail the action(s) taken / proposed to correct the identified deficiency.
Preventative Action(s) Detail the action(s) taken / proposed to eliminate the root cause of the deficiency, in order to prevent recurrence. Action(s) to identify and prevent other potential similar deficiencies should also be considered.
Deliverable(s) Detail the specific outputs from the proposed / completed corrective and preventative action(s). For example, updated procedure/work instruction, record of re-training, IT solution.
Due Date(s) Specify the actual / proposed date(s) for completion of each action. Indicate when an action is completed.

Further information relating to inspection responses can be found under 'Inspection outcomes' at: https://www.gov.uk/guidance/good-pharmacovigilance-practice-gpvp

C.4 Inspection findings

C.4.1 Critical findings

No critical findings were identified from the review of pharmacovigilance processes, procedures and documents performed during this inspection.

C.4.2 Major findings

MA.1 Management of non-compliance with the [redacted] PPP

Requirements:

The Human Medicines Regulations 2012 (Statutory Instrument 2012 No. 1916) as amended
Part 11, Regulation 182
"(2) The holder must (as part of its pharmacovigilance system) —
[…]
(c) operate a risk management system for the product in accordance with the risk management plan (if any) for the product (subject to regulation 183);
(d) monitor the outcome of the risk minimisation measures which are contained in the risk management plan (if any) for the product or which are laid down as conditions of the authorisation of the product under regulations 59 to 61 (conditions of UK marketing authorisation);"

Detailed Description of the Implementation of Additional Risk Minimisation Measures for Generic [redacted] approved by MHRA on 07 November 2022

Finding MA.1 a)

Issues were identified with the Prescription Authorisation Form (PAF) tracker [redacted] that had the potential to prevent the identification and recording of non-compliance to the [redacted] PPP.

i. The need to counsel male patients on the teratogenic risk of [redacted] was not included as a critical error in the PAF tracker. This is a data field critical to assessing compliance to the PPP requirements. As such, there was potential that PAFs missing this information would not be identified as non-compliant and would not be followed-up.
ii. The PAF tracker did not include a field to record the date the PAF was received by Glenmark. This date enabled the review of whether PAFs had been submitted by the pharmacist on the same day as dispensing, which is one of the requirements of the PPP.
iii. The formatting of the PAF tracker prevented the input of non-compliant information regarding the number of [redacted] cycles a patient had been prescribed. Column O 'Number of cycle(s) prescribed' had a drop-down option with available answers 1 – 3. Although it is unlikely that more than three cycles would be prescribed, and this would represent non-compliance to the requirements of the PPP, there should be an option to record more than three cycles on the PAF tracker should it occur.

Root Cause Analysis

[redacted]

[redacted]

Further Assessment

[redacted]

Corrective Action(s)

[redacted]

Deliverable(s)	Due Date(s)
[redacted]	

Preventative Action(s)

[redacted]

Deliverable(s)	Due Date(s)
[redacted]	

Finding MA.1 b)

There was no process to identify, track, and manage pharmacies that were persistently non-compliant, either in respect of submitting non-compliant PAFs or failing to submit PAFs with every prescription.

As per section [redacted] and [redacted] of SOP [redacted] (effective 23 February 2023), Glenmark had a process to identify non-compliant PAFs and conduct quarterly reconciliations to identify pharmacies that were not submitting PAFs and perform follow-up where necessary to obtain the relevant information.

There were clear criteria for deregistration of pharmacies based on non-response or poor response to follow-up (pharmacies would be deregistered if no satisfactory response was received within one business day from the last follow-up attempt for critical errors, or one month from the last follow-up attempt for non-critical errors).

However, the processes in place and the information to be recorded did not enable any trending of repeated non-compliance. As such, the MAH could not ensure that pharmacies that had been deregistered multiple times for persistent non-compliance would be identified and prevented from reregistering without having implemented effective CAPA and remedial actions.

Root Cause Analysis

[redacted]

Further Assessment

[redacted]

Corrective Action(s)

[redacted]

[redacted]

Deliverable(s)	Due Date(s)
[redacted]	

Preventative Action(s)

[redacted]

Deliverable(s)	Due Date(s)
[redacted]	

Finding MA.1 c)

There was no process to formally record the outcome of the quarterly reconciliations, including any follow-up attempts associated with non-compliance identified, or any subsequent actions taken.

Section [redacted] of SOP [redacted] (effective 23 February 2023) described Glenmark's reconciliation process and stated, *"If any discrepancies are identified, the pharmacy will be contacted to find out the reason for the non-compliance. Any missing PAFs will also be requested. The same timelines for follow up of pharmacies for incomplete or non-compliant PAFs will be followed. If there is any evidence of wholesaling of [redacted] the MHRA will be notified by the UK QPPV within two business days of identification and the pharmacy will be de-registered from the PPP."* It was confirmed verbally by Glenmark that reconciliation was to be conducted via email with the Demand, Planning and Logistics team (DPLT), whereby an [redacted] sheet documenting how much [redacted] had been distributed was to be provided by DPLT. There was no other system to record the activities conducted.

Glenmark are reminded of the requirements of the annual audit report to provide information on pharmacies that have not been compliant with the requirement to submit PAFs for each prescription of [redacted] ncluding the total number of packs supplied,

the number (%) of packs accounted for by PAFs received initially, the number (%) of packs accounted for by PAFs received after follow-up, and any remedial action. In order to collate this information, Glenmark should have a robust process for recording the outcomes and associated actions of quarterly reconciliations.
Root Cause Analysis
[redacted]
Further Assessment
[redacted]
Corrective Actions
[redacted]

Deliverable(s)	Due Date(s)
[redacted]	

[redacted]

Preventative Action(s)	
[redacted]	
Deliverable(s)	Due Date(s)
[redacted]	

MA.2 Written procedures

Requirements:

Commission Implementing Regulation (EU) No. 520/2012
Article 11(1)(a)
"Specific quality system procedures and processes shall be in place in order to ensure the following:
(a) the continuous monitoring of pharmacovigilance data, the examination of options for risk minimisation and prevention and appropriate measures are taken by the marketing authorisation holder;"

Detailed Description of the Implementation of Additional Risk Minimisation Measures for Generic [redacted] approved by MHRA on 07 November 2022

Finding MA.2 a)

The SOPs governing the [redacted] PPP and controlled distribution system lacked sufficient detail across a number of processes. The following issues were identified:

[redacted] effective 23 February 2023)

i. Section [redacted] included a list of critical errors for PAFs. The need to counsel male patients on the teratogenic risk o[redacted] was not included as a critical error, despite this data field being critical to assessing compliance to the PPP requirements.
ii. The SOP did not describe the process of manually generating a Pharmacy Registration Number. This was an internal tracking number with a defined format that was used to link the pharmacy with their respective PAFs. Additionally, this number was to be entered into the Enterprise Resource Planning (ERP) system by the Responsible Person to be used as a search term when identifying pharmacies as part of the controlled distribution process. The SOP did not include the

requirement to forward this number to the relevant members of staff for entry into the ERP system.

iii. Section [redacted] described the pharmacy registration process and stated, "*Upon receipt of a PRF from the Pharmacist (…)*"; however, there was no further information detailing how pharmacy registration forms (PRFs) were to be received by Glenmark.

iv. Section [redacted] stated, "*The Pharmacy will be considered registered once their details have been entered into the Pharmacy Registration Tracker*". However, in the Pharmacy Registration Tracker ([redacted]), there was the option for the 'Pharmacy Registration Status' to be entered as 'Registration pending'. It was described by Glenmark that if a PRF is received that is non-compliant or incomplete, the pharmacy will be contacted to correct the form and their registration status will be entered as pending until the PRF is complete. This was not reflected in the SOP.

v. Section [redacted] described the process of checking PAFs and stated, "*The UK LPVRP / designee must also check that the PAF is sent by the Pharmacist on the same day as dispensing*"; however, there was no further instruction in the SOP as to actions required should the PAF not be received on the same day as dispensing.

vi. The SOP did not describe the process for a duplicate check to distinguish between initial and follow-up PAFs, which was a process described by Glenmark during the inspection. The SOP also did not sufficiently detail how follow-up PAFs should be entered on the PAF tracker [redacted]

[redacted] (effective 24 January 2023)

vii. Section [redacted] stated, "*The BCP should be tested as per the PPP Business Continuity Plan Testing (found at the end of this document). (…) This test should also include a detailed test of functioning of the (…) fax line*". However, in the Business Continuity Plan Testing described in the SOP, there was no reference to a test of the fax line. The fax line was one of the routes for PRFs and PAFs to be received by Glenmark.

This finding has been graded as major as deficiencies were identified across numerous processes. Glenmark are reminded that prior to the launch of [redacted] on the UK market, there should be an effective SOP in place for which all relevant members of staff have received training.

Root Cause Analysis

[redacted]

Further Assessment

[redacted]

[redacted]

Corrective Action(s)
[redacted]

Deliverable(s)	Due Date(s)
[redacted]	

Preventative Action(s)
[redacted]

Deliverable(s)	Due Date(s)
[redacted]	

MA.3 Pharmacovigilance audit

Requirements:

GVP Module IV – Pharmacovigilance audits (Rev 1)
IV.B.2 The risk-based approach to pharmacovigilance audits
"Risk assessment should be documented appropriately for the strategic, tactical and operational planning of pharmacovigilance audit activity in the organisation"

IV.B.2.1. Strategic level audit planning

IV.B.2.2. Tactical level audit planning

Glenmark' s pharmacovigilance audit strategy was outlined in section [redacted] of the UK PSMF [redacted] dated 13 January 2023). Their audits were categorised into full pharmacovigilance system, affiliates, licensing partners and service providers. Global systems were subject to a routine full pharmacovigilance system audit every two years, affiliates and licensing partners were subject to a 2 – 3-year audit cycle in accordance with the outcome of annual risk assessments, and service providers were selected for audit according to contracted activities on a 2 – 3-year audit cycle.

GVP audit risk assessment questionnaires [redacted] were sent annually by Glenmark to affiliates, licensing partners and some service providers. Subsequently, an annual GPvP [redacted] was created, which documented the scores from the risk assessment questionnaires for those entities and was used to determine the audit schedule for the year.

The following issues were identified with Glenmark' s pharmacovigilance audit strategy and application of risk assessment:

Finding **MA.3 a)**

Deficiencies in the risk assessment and risk score calculation were identified that had an impact on the creation of the annual audit schedule and had the potential to result in the exclusion of high-risk affiliates and licensing partners.

i. Missing distributors: [redacted] distributors were included in PSMF Annex [redacted] however, only three distributors were listed in the GPvP [redacted] which was used to determine the audit schedule.

ii. Missing licensing partners: Five examples were identified where licensing partners had not been entered on the GPvP [redacted] and as such were not considered for audit. For four of these licensing partners, the company had not completed a risk assessment questionnaire [redacted] whilst in the fifth example [redacted] the company had completed a risk assessment questionnaire. According to [redacted] effective 29 July 2022), for licensing partners or service providers "*If the questionnaire is still not received, then the highest risk score will be allocated to that organization.*"

iii. Issues with the total risk score calculation:
   a. Examples of absent risk score values in the GPvP [redacted] were identified that, if completed, may have increased the total risk score above the minimum threshold (a score of [redacted] to trigger an audit:
      i. [redacted] a licensing partner, did not provide a response to the question 'number of products covered in the PSMF' within the risk

assessment questionnaire [redacted] This field was left blank in the GPvP [redacted] however, if it had been correctly completed it would have resulted in a total risk score between [redacted] and [redacted]

ii. [redacted] a licensing partner, did not provide a response to two questions in the risk assessment questionnaire. These fields were left blank in the GPvP [redacted] however, if they had been completed correctly it would have resulted in a total risk score between [redacted] and [redacted]

iii. The [redacted] affiliate provided a response to all the questions in the risk assessment questionnaire; however, the field for 'number of products covered in the PSMF' was left blank in the GPvP [redacted] Had this field been completed correctly, it would have resulted in a total risk score between [redacted] and [redacted]

b. Answers to the risk assessment questionnaire provided by [redacted] a licensing partner, were not accurately translated into risk scores in the GPvP [redacted]. Question [redacted] relating to the existence of additional risk minimisation measures (aRMMs), was not answered by the partner; however, a risk score of one had been assigned. [redacted] effective 29 July 2022) stipulated that if not all information was provided in the questionnaire, the PVQA Lead was to "*write back to the stakeholder for getting missing/unclear information*"; however, there was no further guidance on the score to assign if no subsequent response was received from the partner. It is acknowledged that the total risk score for the company would not have met the threshold for inclusion in the audit schedule.

c. The total risk score calculation for [redacted] a licensing partner, failed to calculate due to an error on the GPvP [redacted] spreadsheet. As such, the company were not considered in the risk calculation. It is acknowledged that the total risk score for the company did not meet the threshold for inclusion in the audit schedule.

iv. Errors in the GPvP [redacted]

a. [redacted] a licensing partner, had been assigned a total risk score of [redacted] but had not been added to the GPvP [redacted] despite meeting the threshold. It was confirmed by Glenmark that the company had been incorrectly risk assessed due to an error in the SDEA tracker; however, this had not been corrected in the GPvP [redacted]

b. The GPvP [redacted] stated that the licensing partner, [redacted] would be audited in 2023; however, it was confirmed by Glenmark that the company were to be audited in 2024.

c. The licensing partner, [redacted] was incorrectly included in the GPvP [redacted] Glenmark was acting as the manufacturer for the products in scope of the agreement, and as such there was no requirement for Glenmark to conduct a pharmacovigilance audit of the company.

Root Cause Analysis

[redacted]

[redacted]

Further Assessment

[redacted]

[redacted]

Corrective Action(s)

[redacted]

[redacted]

Deliverable(s)	Due Date(s)
[redacted]	
Preventative Action(s)	
[redacted]	

[redacted]

Deliverable(s)	Due Date(s)
[redacted]	

Finding MA.3 b)

The procedural documentation relating to and supporting the Glenmark pharmacovigilance audit strategy was not sufficiently detailed. The following issues were identified:

i. The audit strategy, as defined in PSMF section [redacted] dated 13 January 2023) and [redacted], effective 31 January 2023), lacked sufficient detail on the pharmacovigilance systems and processes that would be considered for audit. Section [redacted] of the PSMF referred to 'full pharmacovigilance system' audits and [redacted] listed 'System / Process' as a type of audit; however, these entities were not further defined. As such, there was no assurance that all areas of the pharmacovigilance system, including critical pharmacovigilance processes (as outlined in GVP Module I.B.11.3.), were appropriately considered for audit.

ii. The risk assessment and prioritisation methodology for inclusion of local pharmacovigilance service providers in the audit strategy and tactical audit plan was undefined in procedural documentation. [redacted] effective 29 July 2022) required PVQA to "*Send out GVP Audit Risk Assessment Questionnaire* [redacted] *to either affiliate / License Partner (LP) / Service Provider (SP) within Q3 of the year*"; however, this was not the process followed for local service providers listed in PSMF Annex [redacted] 'PV service providers for UK'. Glenmark described verbally during the inspection that local service providers would be risk assessed by the PVQA function and the LPVRP by loosely following the criteria listed in the risk assessment questionnaire [redacted] As an example, for the UK marketing research organisation, [redacted] an informal risk assessment between the PVQA function and the UK LPVRP was carried out via email taking into consideration the date since the last audit and the scope of services provided.

iii. The audit strategy was not sufficiently detailed to outline which entities could be reasonably audited over a 2-5-year period. The audit strategy, as defined in section [redacted] of the PSMF, stated that "*Affiliates and LPs will be on a 2 to 3-year audit cycle in accordance with the outcome of the annual risk assessments*" and "*Service providers will be selected according to contracted activities on a 2 to 3-year audit cycle*". However, there was no further information on the specific affiliates, licensing partners and service providers that would be prioritised during the 2-5-year period. In addition, it was not clear if all affiliates, licensing partners and service providers

would be audited at least once in the 2-3-year audit cycle, or whether specific entities would be selected for audit every 2-3 years based on risk assessments. It is acknowledged that the GPvP [redacted] included planned dates (i.e., 2023, 2024, 2025 or 2026) for the assessed affiliates and business partners for which an audit was necessary; however, how these audits had been assigned was not clearly described in the audit strategy.

Root Cause Analysis

[redacted]

Further Assessment

[redacted]

[redacted]

Corrective Action(s)

[redacted]

Deliverable(s)	Due Date(s)
[redacted]	

Preventative Action(s)
[redacted]

Deliverable(s)	Due Date(s)
[redacted]	

Finding MA.3 c)
The documented pharmacovigilance audit risk assessment for the following pharmacovigilance service providers was unclear and inadequate: i. [redacted] provided the services of distributing Direct Healthcare Professional Communication letters and materials associated with aRMMs in the UK. The communication of changes to a product's benefit-risk balance to patients and healthcare professionals is a critical pharmacovigilance process; however, the vendor had been identified as "*not directly involved in any PV process*" within email communication, without further supporting rationale or any documentation of risk factors. ii. [redacted] provided record management services in the UK, including archiving of clinical trial documentation, pharmacovigilance QA audit documentation, decommissioned third party agreements and related documents. The MAH indicated in emails that the vendor was "*not directly involved in any PV processes and would not report safety information and therefore a PV audit would*

not be required." However, the vendor was involved in a pharmacovigilance process, as defined by GVP I.B.10. Record management, and as such the rationale was not accurate.

iii. Service provider [redacted] was involved in the translation of literature publications. The MAH indicated in the rationale that "*as per our risk assessment process* [redacted] *does not possess any of the risk factors that could be considered for the purposes of a risk assessment. They are therefore low risk with regards to auditing*". As the risk assessment process did not define the risk factors for service providers (please refer to finding MA.3b point ii), the basis for the decision not to audit this party was unclear.

Root Cause Analysis

[redacted]

Further Assessment

[redacted]

Corrective Action(s)

[redacted]

Deliverable(s)	Due Date(s)
[redacted]	

Preventative Action(s)

[redacted]

Deliverable(s)	Due Date(s)
[redacted]	

MA.4 ICSR management

Requirements:

The Human Medicines Regulations 2012 (Statutory Instrument 2012 No. 1916) as amended
Regulation 188(1)(a)
"[The holder of a UK marketing authorisation, traditional herbal registration or Article 126a authorisation] must in relation to the product [(including listed NIMAR products in Northern Ireland)]—
(a) submit electronically to the [licensing authority] a report on all serious suspected adverse reactions that occur in the [United Kingdom] and [countries other than the United Kingdom] before the end of the period of 15 days beginning on the day following the day on which the holder gained knowledge of the reaction;"

GVP Module VI – Collection, management and submission of reports of suspected adverse reactions to medicinal products (Rev 2)
IV.B.2. Validation of reports
"If information on the reporter's country is not available, the country where the notification was received or where the review took place should be used in the ICSR."

Finding MA.4 a)

Serious case [redacted] was reported to the MHRA outside of the 15-day timeframe required for serious ICSRs. The case was initially received by Glenmark from the Canadian regulatory agency on 09 November 2022 and reported a number of adverse events that were associated with patient hospitalisation. However, the case was not expedited to the MHRA until 23 December 2022, 44 days after the initial serious report was received.

Additionally, this case was not captured as a late submission within KPIs in PSMF Annex F1 'Expedited Reporting' (version 10, effective 20 January 2023), which showed that no late cases were reported for December 2022.

The line listing provided for the purposes of the inspection indicated that between October and December 2022, a further 20[‡] serious reports were initially submitted to the MHRA more than 15 days after the initial case was received, but only one report (submitted in October 2022) was identified as late within the metrics presented in PSMF Annex F1. In response to this finding, the company should conduct an impact assessment to validate whether other late cases have been incorrectly reported within metrics as submitted on-time.

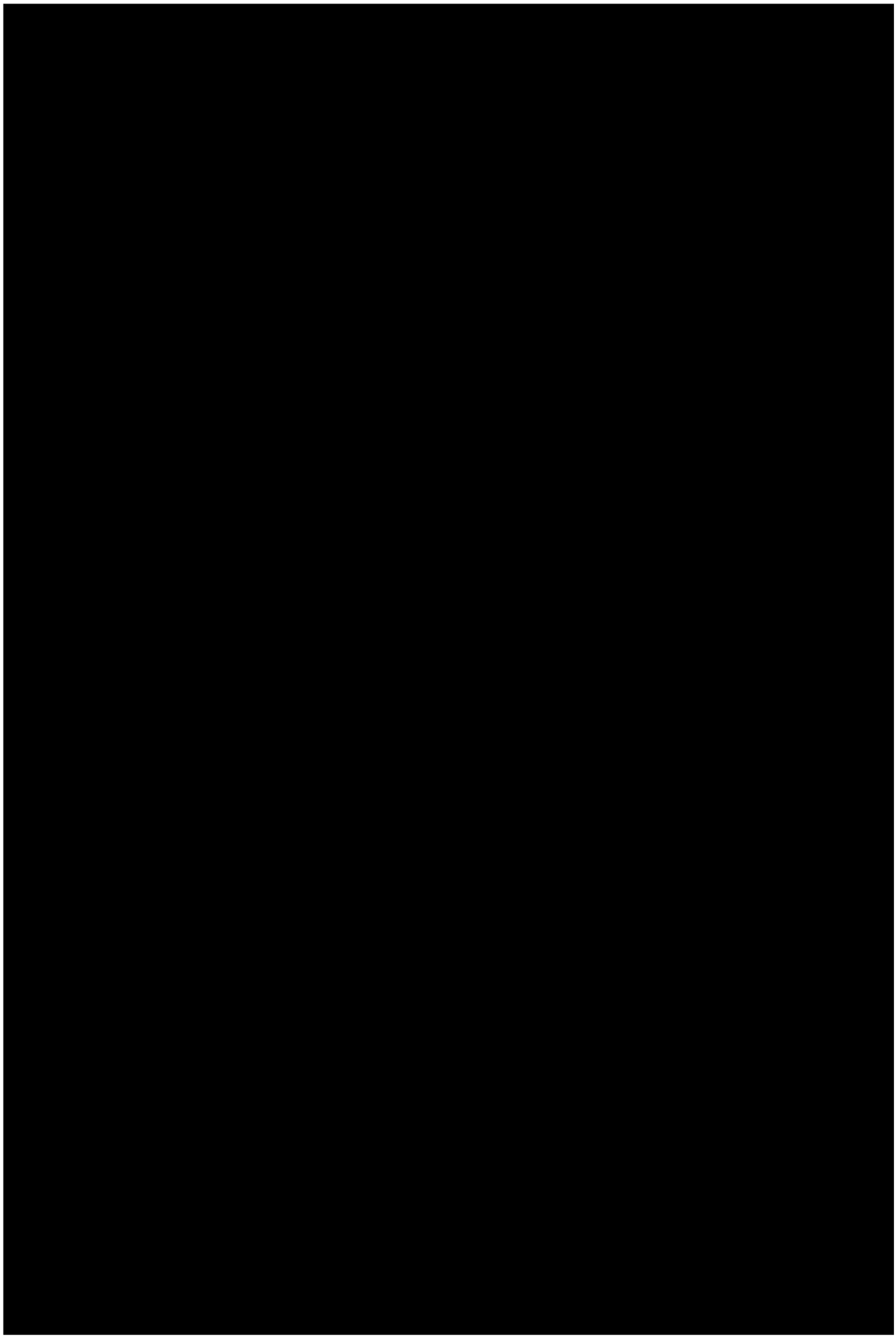
[redacted]

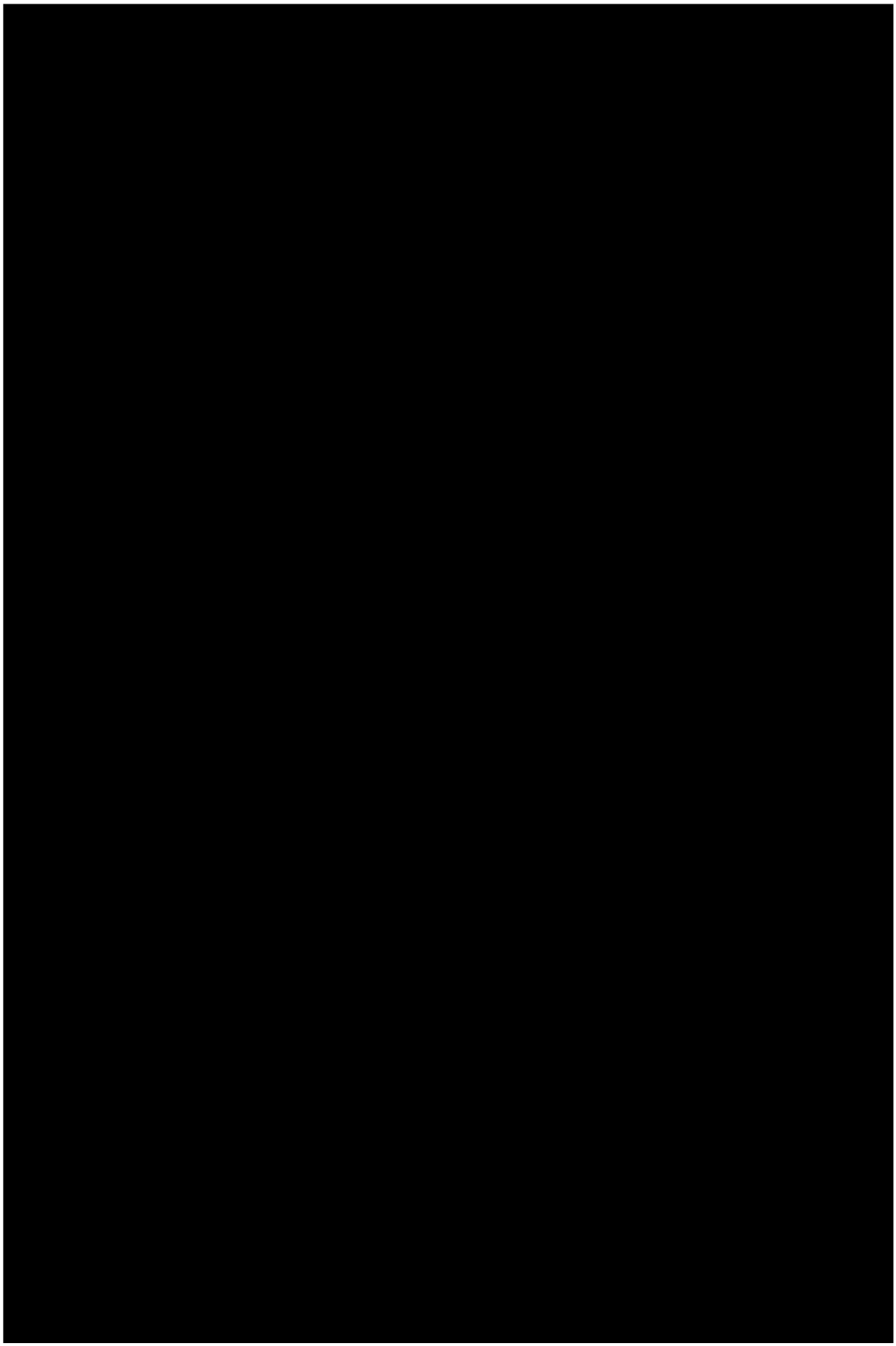
Lead inspector note (10 May 2023): This finding was withdrawn based on the supporting records provided by Glenmark in response to the inspection report.

Root Cause Analysis

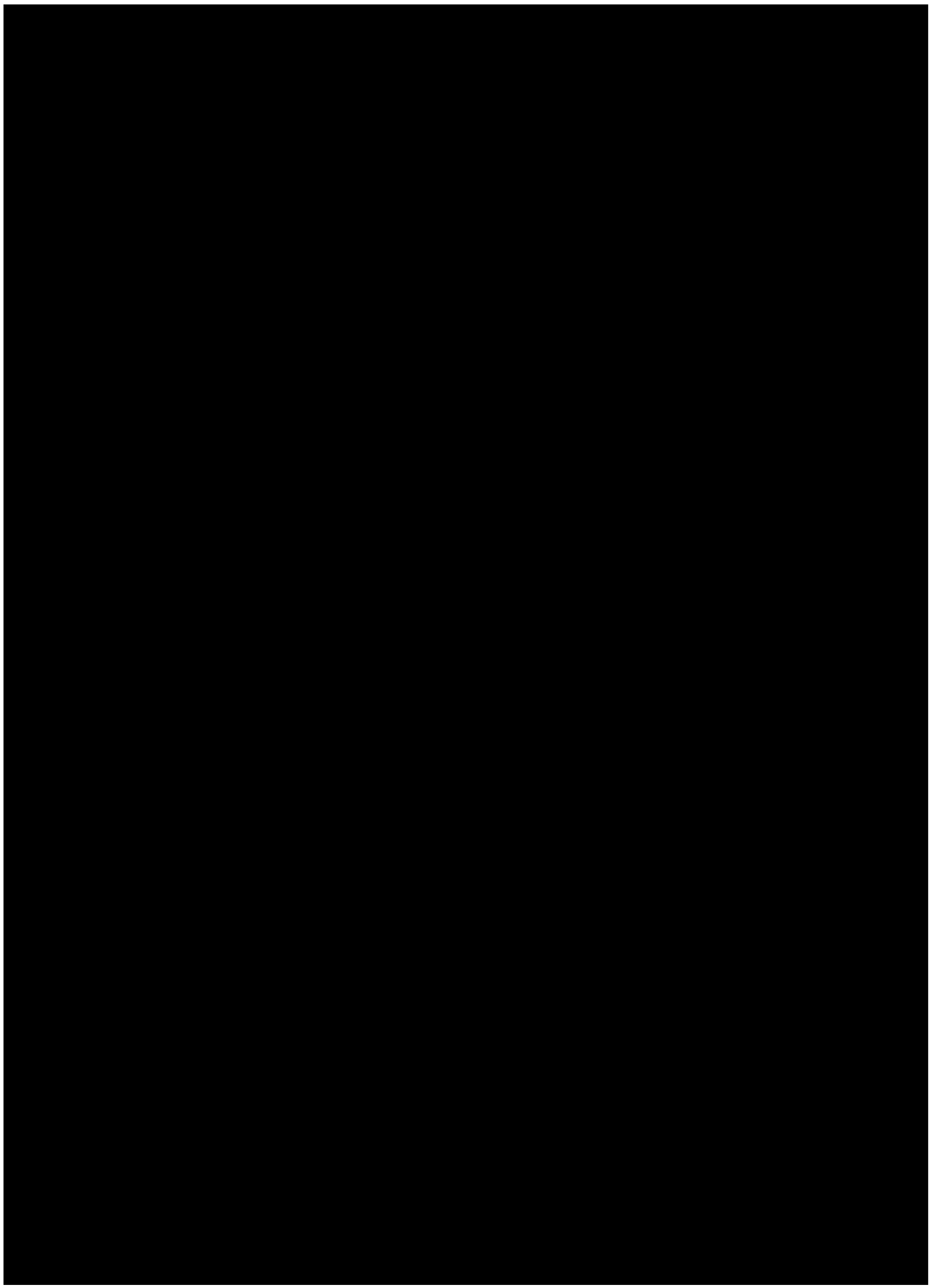
[redacted]

[redacted]





[redacted]



Further Assessment	
[redacted]	
Corrective Action(s)	
[redacted]	
Deliverable(s)	**Due Date(s)**
[redacted]	
Preventative Action(s)	
[redacted]	
Deliverable(s)	**Due Date(s)**
[redacted]	

Lead inspector note (10 May 2023): Finding MA.4 b) was downgraded to minor and can be found in MI.3 a).

MA.5 Pharmacovigilance system master file

Requirements:

The Human Medicines Regulations 2012 (Statutory Instrument 2012 No. 1916) as amended
Regulation 184(1)(b)
"The holder must—
(b)place a note concerning the main findings of each audit on the pharmacovigilance system master file on completion of each audit;"

Commission Implementing Regulation (EU) No. 520/2012
Article 2
"The pharmacovigilance system master file shall contain at least all of the following elements:
(2) a description of the organisational structure of the marketing authorisation holder, including the list of the site(s) where the following pharmacovigilance activities are undertaken: individual case safety report collection, evaluation, safety database case entry, periodic safety update report production, signal detection and analysis, risk management plan management, pre- and post-authorisation study management, and management of safety variations to the terms of a marketing authorisation;"

Article 3

"The pharmacovigilance system master file shall have an Annex containing the following documents:
(3) the list of subcontracts referred to in Article 6(2);
(5) a list of all scheduled and completed audits; (c, e, and f) and
(6) where applicable, a list of the performance indicators referred to in Article 9;"

Article 6(2)
"The marketing authorisation holder shall draw up a list of its existing subcontracts between it and the third parties referred to in paragraph 1, specifying the product(s) and territory(ies) concerned."

GVP Module II – Pharmacovigilance system master file (Rev 2)
II.B.4.7. PSMF section on quality system
Subsection: 'Auditing'
"A description of the approach used to plan audits of the pharmacovigilance system and the reporting mechanism and timelines should be provided, with a current list of the scheduled and completed audits concerning the pharmacovigilance system maintained in the annex referred to II.B.4.8. [IR Art 3(5)]. This list should describe the date(s) (of conduct and of report), scope and completion status of audits of service providers, specific pharmacovigilance activities or sites undertaking pharmacovigilance"

II.B.4.3. PSMF section on the sources of safety data
"The description of the main units for safety data collection should include all parties responsible, on a global basis, for solicited and spontaneous case collection for products authorised in the EU. This should include medical information sites as well as affiliate offices and may take the form of a list describing the country, nature of the activity and the product(s)"

II.B.4.6. PSMF section on pharmacovigilance system performance
"*In the annex, figures/graphs should be provided to show the timeliness of 15-day and 90-day reporting over the past year*"

Finding MA.5 a)

The following issues were identified with the annexes of the UK PSMF (version [redacted] dated 13 January 2023):

Annex [redacted]

i. Information was missing from PSMF Annex [redacted]
   a. Glenmark affiliate audits conducted in [redacted] and the [redacted] n 2022 were not listed, even though UK authorised active substances were also marketed in these territories.
   b. The audit of the [redacted] service provider, [redacted] conducted in 2019, was not included, despite UK authorised active substances being marketed in these territories.
   c. The annex did not include the dates individual audit reports were issued.

ii. PSMF Annex [redacted] was incomplete as it did not include CAPA relating to critical and major findings from audits [redacted] and [redacted]

Annex [redacted]

iii. The service provider PharmaLex was not included in PSMF Annex [redacted] or Annex [redacted] even though they provided the role of the LPVRP in several European countries, such as Romania, Croatia, Slovenia and Belgium, where UK authorised active substances were marketed. It is acknowledged that PharmaLex and the territories it was operating in was referred to in PSMF Annex [redacted] however, no information regarding the concerned medicinal products was included.

iv. PSMF Annex [redacted] included the vendor, [redacted] despite the agreement having terminated in December 2021.

Annex [redacted]

v. Annex [redacted] did not include a clear list of affiliates and medical information sites. It is acknowledged that Annex [redacted] contained the names of countries and the name of the contact person in each country; however, it was not clear within the organisation chart which of these were affiliates, and as such this information was insufficient to satisfy the requirements outlined in GVP Module II.B.4.3.

Annex [redacted]

vi. The tables showing ICSR reporting compliance to the MHRA and EMA, which were presented in PSMF Annex [redacted] dated 20 January 2023) were cut-off and did not show the percentages for 90-day-reporting compliance.

Root Cause Analysis

[redacted]

[redacted]

Further Assessment

[redacted]

[redacted]

Corrective Action(s)
[redacted]

Deliverable(s)	Due Date(s)

[redacted]

Preventative Action(s)
[redacted]

Deliverable(s)	Due Date(s)
[redacted]	

C.4.3 Minor findings

MI.1 Management of the [redacted] PPP

Finding MI.1 a)

The following issues were identified with the trackers used to record information on registered pharmacies and submitted PAFs, as per the requirements of the [redacted] PPP.

PRF tracker [redacted]

i. The PRF tracker did not include a field to record the pharmacist GPhC/PSNI registration under part 2. Part 2 of the tracker was used to record details of additional pharmacy sites associated with the registration of the pharmacy submitting the form.

PAF tracker [redacted]

ii. Inappropriate drop-down answers had been included for two indications of [redacted]. Under the columns [redacted] and [redacted] there was a drop-down option to select 'Low- or intermediate-1 risk'. There was no corresponding question for these indications in the PAF and it was confirmed that they were irrelevant for these two indications.

iii. Inappropriate drop-down options had been included for sections relating to follow-ups 3, 4 and 5. Options of 'Yes', 'No' or 'NA' were given for fields to be completed with the name of the individual conducting the follow-up, the time and the date of the follow-up.

Root Cause Analysis

[redacted]

Further Assessment

[redacted]

Corrective Action(s)

[redacted]

[redacted]

Deliverable(s)	Due Date(s)
[redacted]	
Preventative Action(s)	
[redacted]	
Deliverable(s)	**Due Date(s)**
[redacted]	

Finding MI.1 b)

The process to check for pharmacies that required reregistration to the [redacted] PPP was not sufficient to ensure that all pharmacies would be contacted prior to the registration expiry date.

In section [redacted] of SOP [redacted] (effective 23 February 2023), it stated, "*The UK LPVRP / designee will check the registration status of pharmacies on a quarterly basis. Pharmacists will be notified of the need to re-register one month prior to their registration expiry date via letter or email.*" When asked about the practicalities of identifying pharmacies during the quarterly review, Glenmark stated that conditional formatting would be present in the [redacted] PRF tracker [redacted] that would flag pharmacies whose registration was to expire in five weeks and seven days (the conditional formatting was not present on the PRF tracker at the time of the inspection). However, as the check was to be conducted quarterly and pharmacies were to be contacted one month prior to registration expiry, this conditional formatting would not identify all pharmacies that needed to be contacted in the quarter (i.e., if the registration expiry date was greater than five weeks but less than 12 weeks).

Additionally, Glenmark stated that the outcome of this quarterly check would be recorded in the tracker using the following columns: 'Date of last registration check', 'Outcome of

registration status check' and 'Reminder email sent'. These were not present on the tracker at the time of the inspection.
Root Cause Analysis
[redacted]
Further Assessment
[redacted]
Corrective Action(s)
[redacted]

Deliverable(s)	Due Date(s)
[redacted]	

Preventative Action(s)
[redacted]

Deliverable(s)	Due Date(s)
[redacted]	

MI.2 Deviation management

Finding MI.2 a)

There were significant delays in agreeing a CAPA plan for deviations identified in the Glenmark pharmacovigilance system. PSMF Annex [redacted] dated 13 January 2023), section 'Self-reported CAPA' listed four CAPA items which had been under investigation for up to seven months without any agreed CAPA plans being implemented:

i. Three of the affected CAPA related to delays in the training of new staff (general pharmacovigilance awareness training and training pertinent to their role)
   a. [redacted] opened on 03 June 2022
   b. [redacted] opened on 28 July 2022
   c. [redacted] opened on 21 September 2022

ii. [redacted] opened on 30 November 2022, related to a late PADER submission to the FDA. In the PSMF annex the field 'Details of Non-compliance' stated "*Under investigation*" for this CAPA.

iii. Supporting procedure, [redacted] effective 30 November 2021), did not state any timelines for the development and agreement of CAPA plans associated with deviations.

Root Cause Analysis

[redacted]

Further Assessment

[redacted]

Corrective Action(s)
[redacted]

Deliverable(s)	Due Date(s)
[redacted]	

Preventative Action(s)
[redacted]

Deliverable(s)	Due Date(s)
[redacted]	

Finding MI.2 b)

Delays of up to nine months in formally closing deviations were identified:

i. [redacted] All remediation actions were completed as per the target due date of 15 April 2022; however, the deviation remained open for a further nine months until 25 January 2023. As a result, this deviation was included in PSMF Annex [redacted] dated 13 January 2023), section [redacted]

ii. [redacted] All remediation actions had been completed by 31 August 2022; however, the deviation was closed over four months later on 06 January 2023. As a result, this deviation was included in PSMF Annex [redacted] dated 15 September 2022), section [redacted]

[redacted] effective 30 November 2021) stated under section [redacted] that a "*Deviation shall be closed within 15 calendar days after completion of last remedial action.*"

Root Cause Analysis

[redacted]

Further Assessment

[redacted]

Corrective Action(s)

[redacted]

Deliverable(s)	Due Date(s)
[redacted]	

Preventative Action(s)

[redacted]

Deliverable(s)	Due Date(s)
[redacted]	

Finding MI.2 c)

Deficiencies were identified with the handling of [redacted] which related to delays in the dissemination of regulatory intelligence to functional leads:

i. An inappropriately long timeframe of two years was assigned to complete the remediation action, which was to retrain the regulatory intelligence coordinator. The reason given for this timeframe was that the supporting procedural documentation was due to be updated by 28 February 2023 to clarify the escalation route to request extensions to the dissemination of regulatory intelligence. The updated SOP was made effective on 31 August 2022 but in the meantime no other mitigating actions, such as retraining of the regulatory intelligence coordinator, were completed until the updated SOP was available.

ii. The deviation request date on the deviation form was incorrectly stated as 08 January 2020 when it should have been 08 January 2021.

Root Cause Analysis

[redacted]

Further Assessment

[redacted]

Corrective Action(s)

[redacted]

Deliverable(s)	Due Date(s)
[redacted]	

Preventative Action(s)

[redacted]

[redacted]

Deliverable(s)	Due Date(s)
[redacted]	

MI.3 ICSR management

Finding MI.3 a)

Spontaneous serious case [redacted] was incorrectly assessed as invalid and hence not reported to the MHRA.

Case [redacted] was received on 05 July 2022 via Glenmark Global Customer Services reporting that a patient frequently sliced fingers on the packaging of [redacted] Despite information indicating the presence of an identifiable reporter (e.g., email address), the case was assessed as invalid because the reporter country was unknown. Glenmark are reminded that if the reporter's country is not available, the country where the notification was received or where the review took place should be used in the ICSR, as per the guidance in GVP Module VI.B.2.

Root Cause Analysis

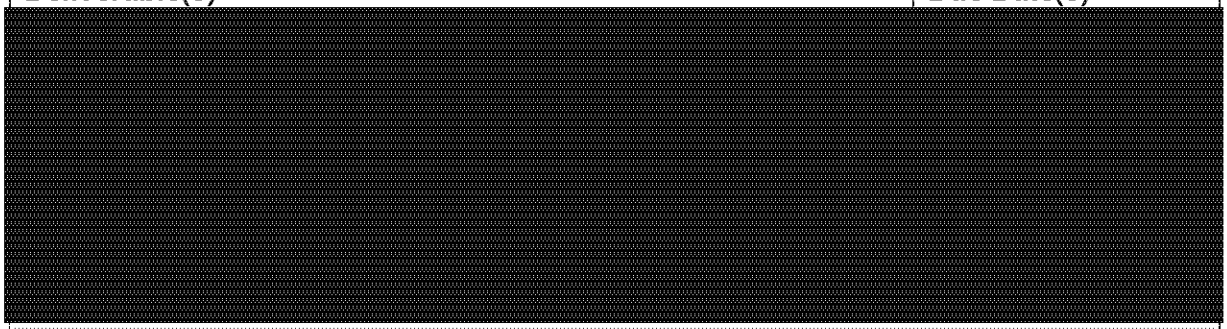
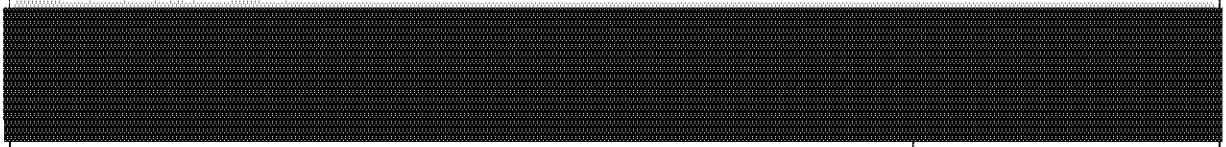
[redacted]

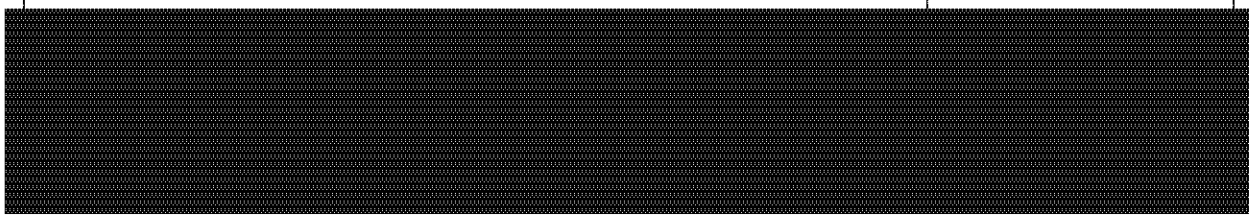
Further Assessment

[redacted]

Corrective Action(s)

[redacted]

Deliverable(s)	Due Date(s)
	
Preventative Action(s)	
	



C.4.4 Comments

1. Training materials for the [redacted] risk management system

- The [redacted] PPP training slide deck for Glenmark and service provider employees (version [redacted] effective 23 January 2023) included misleading statements regarding the use of [redacted] in women of child-bearing potential. References taken from the slide deck included "*How can Glenmark ensure* [redacted] *is not prescribed to and is not used by Pregnant women & women of child-bearing potential??*" and "*This means* [redacted] *must never be taken by (…) women who can become pregnant, even if they are not planning to become pregnant*". These statements are false, as it is the purpose of the PPP to allow these women to take [redacted] safely. Glenmark are recommended to update their training materials to correct this misleading information.

2. Procedural documentation governing the [redacted] risk management system

- Section [redacted] of SOP [redacted] (effective 23 February 2023) included the statement "*check that the pharmacy is registered / blocked in the ERP system*". The term 'blocked' is explained later in section [redacted] with the description *"(exclusion removed)";* however, Glenmark are encouraged to provide the explanation at the first mention of the term.

- The following issues with [redacted] (effective 23 February 2023) were self-identified by Glenmark in the lead-up to the MHRA inspection. Requests were made by Glenmark personnel to update the SOP during the next planned update; however, reference to these updates are being included as a comment in the inspection report for record purposes and to ensure that the updates are correctly implemented.
    - Section [redacted] referred to the UK PV BCP and Watford (UK) Office IT Continuity Plan [redacted] however, there was no reference to procedure [redacted] (effective 24 January 2023), the Business Continuity Plan for [redacted] Pregnancy Prevention Programme United Kingdom.
    - The reference numbers for the pharmacy registration tracker, PAF tracker, registration letter, and de-registration letter were erroneously recorded [redacted] respectively).

3. Pharmacovigilance audit

- The risk assessment questionnaire [redacted] included questions that were not directly inputted into the total risk score calculation:
    - *Question 7.1: Do you have a document describing your Pharmacovigilance system? (e.g., Pharmacovigilance System Master File)*
    - *Question 8.1: Do you have a system in place to archive all documents?*

  As these questions are relevant to critical pharmacovigilance processes, Glenmark should consider whether answers to these questions should be incorporated into the total risk score calculation to ensure a robust risk assessment for the audit of third parties.

4. PSMF

- PSMF Annex [redacted] dated 15 September 2022) contained audits that were not conducted in accordance with GVP Module IV, as they reviewed product quality and GDP topics unrelated to pharmacovigilance:
    - Self-inspection (internal audit) schedule Glenmark QA Europe [redacted]
    - [redacted] Glenmark Arzneimittel GmbH

  It is acknowledged that these were removed by Glenmark in PSMF version [redacted] (effective 13 January 2023), and as such this has been included as a comment in the inspection report for awareness.

SECTION D: CONCLUSIONS AND RECOMMENDATIONS

D.1 Conclusions

The factual matter contained in the Inspection Report relates only to those things that the inspection team saw and heard during the inspection process. The Inspection Report is not to be taken as implying a satisfactory state of affairs in documentation, premises, equipment, personnel or procedures not examined during the inspection. It is recommended that you review whether the inspection findings also apply to areas not examined during the inspection and take appropriate action, as necessary.

The responses to the inspection findings, which include proposed corrective and preventative actions, appear to adequately address the issues identified. No additional responses are required at this time. When the company has adequately implemented the proposed corrective and preventative actions, the pharmacovigilance system will be considered to be in general compliance with applicable legislation.

D.2 Recommendations

The Lead Inspector has recommended that the next MHRA inspection is performed as part of the routine risk-based national inspection programme.

APPENDIX I REFERENCE TEXTS

- The Human Medicines Regulations 2012 (Statutory Instrument 2012 No. 1916) as amended
- Commission Implementing Regulation (EU) No 520/2012
- Guideline on good pharmacovigilance practices (GVP)
- Exceptions and modifications to the EU guidance on good pharmacovigilance practices that apply to UK marketing authorisation holders and the licensing authority
- CPMP/ICH/5716/03: ICH guideline E2E "Pharmacovigilance Planning"
- 'Detailed Description of the Implementation of Additional Risk Minimisation Measures for Generic [redacted] approved by MHRA on 07 November 2022

APPENDIX II POST-INSPECTION LETTER

Sent 09 February 2023:

Glenmark GPvP post-inspection letter

APPENDIX III PHARMACOVIGILANCE INSPECTION PLAN

MHRA INSPECTION NUMBER	Insp GPvP 25258/310505-0004	**INSPECTION TEAM**	[redacted]
PHARMACOVIGILANCE INSPECTION OF	Glenmark Pharma	**DATES**	30 January – 01 February 2023
LOCATION	Remote inspection	**START TIME**	09:00am GMT

Inspection plan (N.B. the plan may be subject to change in the lead-up to, or during, the inspection)

The scope of the inspection will include the following topics:

Glenmark [redacted] UK risk management system:

- Controlled distribution and adherence to the pregnancy prevention programme (PPP)
- SOPs, controlled documents and associated PPP materials
- Quality management of the system (training, resource management and audit)

Quality management system:

- Management of deviations and CAPA
- Pharmacovigilance audit
- Compliance monitoring
- Training

An opening meeting will be held by videoconference on Monday 30 January at 9.00am (UK time), which will be led by the lead inspector. The agenda will be as follows:

- Review of the scope and arrangements for the inspection
- Company presentation by Glenmark to provide an overview of the company and pharmacovigilance system. The presentation should focus on the risk management system and quality system which supports the aRMM requirements for [redacted] as well as the wider quality management system in place as part of Glenmark's pharmacovigilance system. The presentation should last no longer than 20 minutes.

In relation to Glenmark's [redacted] UK risk management system, a demonstration will be required to show how pharmacies are registered, how PAFs are reported, how information from PAFs is databased and stored, how follow-up is tracked and how trending is performed to identify non-compliance issues. This is requested for 10am on Day 1 of the inspection.

The remainder of the inspection will consist of remote document review, written requests for documentation and ad hoc video/telephone clarifications with subject matter experts as required. Please provide details of the primary contact point who can assist with any ad hoc questions from the inspectors or arrange calls between inspectors and subject matter experts if required.

The inspection is anticipated to take three days to complete. A closing meeting will be held via videoconference on Wednesday 01 February (timing to be confirmed) during which feedback on the inspection will be provided to the company.

Glenmark are requested to complete the below with the names and job titles of the primary contact point, relevant subject matter experts and those staff who will be dialling in to the opening meeting.

Designated contact point:

Name	Job Title	Email	Telephone
[redacted]	EU & UK QPPV	[redacted]	
	UK MHRA National Point of Contact / UK Local Pharmacovigilance Responsible Person (LPVRP)		

Subject matter experts (by topic):

Name	Job Title	Email	Telephone
Glenmark [redacted] UK risk management system: Controlled distribution and adherence to the pregnancy prevention programme (PPP)			
[redacted]	UK MHRA National Point of Contact / UK LPVRP	[redacted]	
	Deputy UK LPVRP		
Glenmark UK risk management system: SOPs, co			
[redacted]	Quality Assurance Officer	[redacted]	
	Manager, QMS		
Quality management of the system (training, resource management and audit)			
[redacted]	Manager, QMS	[redacted]	

[redacted]	Senior Auditor & Lead - PV QA	[redacted]
	PV Compliance and Training Manager	
Quality management system: Management of deviations and C		
[redacted]	EU QMS Manager & UK QP	[redacted]
	Manager, QMS	
	Senior Auditor & Lead - PV QA	
Quality management system: Pharmacovigilance audit		
[redacted]	Senior Auditor & Lead - PV QA	[redacted]
	Vice President - Clinical & PV QA	
Quality management system: Compliance monitoring		
SMEs responsible for [redacted] PPP compliance:		
[redacted]	UK MHRA National Point of Contact / UK LPVRP	[redacted]
	Deputy UK LPVRP	
Departmental SMEs responsible for compliance:		
[redacted]	Senior Manager - Pharmacovigilance	[redacted]
	Senior Manager, Head Safety Evaluation & Risk Management - Pharmacovigilance	
	Senior Manager - Pharmacovigilance	
	Manager - Pharmacovigilance	

[redacted]	Sr. Manager	[redacted]

Quality management system: Training

[redacted]	Quality Assurance Officer	[redacted]
	Manager, QMS	
	Assistant Manager - Pharmacovigilance	

Opening meeting attendees:

Name	Job Title	Email	Telephone
[redacted]	EU & UK QPPV	[redacted]	
	Senior Vice President and Global Head - PV and MA		
	UK MHRA National Point of Contact / UK LPVRP		
	Deputy UK LPVRP		
	Senior Auditor & Lead - PV QA		
	Country Manager - United Kingdom		
	PV Compliance and Training Manager		
	Director of Demand Planning and Logistics Europe		
	Senior Financial Controller		

[redacted]	Senior Director - IT Europe & LATAM	[redacted]
	Vice President - Regulatory Affairs	
	Associate Director In licensing Head - Regulatory Affairs and Centre of Excellence for Europe and Americas	
	Vice President - Clinical & PV QA	
	EU QMS Manager & UK QP	
	Senior Manager - Pharmacovigilance	
	Senior Manager, Head Safety Evaluation & Risk Management - Pharmacovigilance	