Medicines & Healthcare products
Regulatory Agency

PHARMACOVIGILANCE
INSPECTION REPORT

Pharmacovigilance System Name: Pfizer Group of Companies

MHRA Inspection Number: Insp GPvP 57-6709-0021

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ABBREVIATIONS

ADR	Adverse Drug Reaction
AE	Adverse Event
CAPA	Corrective and Preventative Action
EMA	European Medicines Agency
EU	European Union
GVP	Good Vigilance Practice
HCP	Healthcare Professional
ICSR	Individual Case Safety Report
MAH	Marketing Authorisation Holder
PBRER	Periodic Benefit Risk Evaluation Report
PIL	Patient Information Leaflet
PRAC	Pharmacovigilance Risk Assessment Committee
PSMF	Pharmacovigilance System Master File
PSUR	Periodic Safety Update Report
PV	Pharmacovigilance
QPPV	Qualified Person responsible for Pharmacovigilance
RMP	Risk Management Plan
SmPC	EU Summary of Product Characteristics
SOP	Standard Operating Procedure
UK	United Kingdom

SECTION A: INSPECTION REPORT SUMMARY

Inspection type:	Statutory National Inspection
System(s) inspected:	Pfizer group of companies and [redacted]
Site(s) of inspection:	Pfizer Canada 17300 Trans-Canada Highway Kirkland Quebec Canada H9J 2M5
Main site contact:	[redacted]
Date(s) of inspection:	16 - 19 September 2025
Lead Inspector:	[redacted]
Accompanying Inspector(s):	[redacted]
Previous inspection date(s):	Previous MHRA GPvP inspections of Pfizer were conducted on the following dates: 21 -24 June 2021 15-18 December 2020 22-26 August 2016 7-11 February 2011 & 15-17 March 2011 13-16 November 2007 5-7 January 2005 18-22 October 2004
Purpose of inspection:	Inspection of pharmacovigilance systems to review compliance with UK requirements.
Products selected to provide system examples:	As part of the general systems review, specific ADR reports were reviewed for [redacted] Specific signal reports were looked at for [redacted] and PSURs were examined for [redacted]
Name and location of UK QPPV:	[redacted]
Global PV database (in use at the time of the inspection):	[redacted] (Commercially available)
Key service provider(s):	Quinesca Solutions were used to support with ICSR management
Inspection finding summary:	0 Critical findings 0 Major findings

	5 Minor findings
Date of first issue of report to MAH:	15 October 2025
Deadline for submission of responses by MAH:	19 November 2025 15 January 2026
Date(s) of receipt of responses from MAH:	18 November 2025 13 January 2026
Date of final version of report:	20 January 2026
Report author:	[redacted]

SECTION B: BACKGROUND AND SCOPE

B.1 Background information

The Pfizer group of companies (hereby to be referred to as Pfizer) was selected for joint inspection by the MHRA and Health Canada as part of a pilot GPvP joint inspections programme. The inspection planning, preparation and conduct was performed jointly with Health Canada inspectors. However, the inspection findings issued by Health Canada have been reported within a separate Health Canada Inspection Report.

The purpose of the inspection was to review compliance with currently applicable UK and Canadian pharmacovigilance regulations and guidelines. In particular, 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'. In addition, reference was made to the Canadian pharmacovigilance regulations which will be described in the Health Canada Inspection Report.

A list of reference texts is provided at Appendix I.

Pfizer is a multinational pharmaceutical company, with global corporate headquarters in New York, USA. Multiple legal entities of the Pfizer group of companies hold marketing authorisations within the UK and were covered as part of this inspection. They include Pfizer Limited, Hospira UK Limited and Seagen UK Limited. BioNTech manufacturing GmbH (BNT) is the MAH for the [redacted] however, PV processes for this product were not looked at in detail by the MHRA at this inspection. Pfizer's product portfolio comprises innovative and generic small molecules, biological therapies and vaccines which are present globally. In the UK, Pfizer has products which are authorised by both the Category 1 and Category 2 route.

Pfizer's global PV activities are centralised under the umbrella of the Chief Marketing Office (CMO) with many PV activities including operation and strategic aspects of PV, such as collection, assessment, reporting and monitoring the safety profile of all Pfizer products, being undertaken by departments within Worldwide Safety (WWS). WWS activities are undertaken at multiple locations globally including Walton Oaks in the UK, and various sites within the USA, India, Philippines, Europe and China. In addition, Pfizer had 56 country-based Drug Safety Units (DSUs) which collect safety information and report to local authorities.

B.2 Scope of the inspection

The inspection included a review of the global pharmacovigilance systems and was performed at Pfizer Canada offices in Kirkland, Quebec, Canada. Personnel from Pfizer Canada, Pfizer UK and WWS attended the Kirkland site to participate in the inspection. Where personnel were not available in person, teleconferences were held. The inspection did not cover processes specific to BioNTech and [redacted]

The inspection was performed using interviews and document review (including outputs from the global safety database and listings of medical information enquiries and product complaints). The systems reviewed during the inspection are highlighted in the Pharmacovigilance Inspection Plan (attached as Appendix II).

B.3 Documents submitted prior to the inspection

The company submitted a PSMF ([redacted] version [redacted] June 2025) to assist with inspection planning and preparation. Specific additional documents were also requested by the inspection team and provided by the company prior to the inspection.

B.4 Conduct of the inspection

In general, the inspection was performed in accordance with the Inspection Plan. However, the following interview sessions were not conducted: computer systems validation, qualifications of personnel and job descriptions/training program and records, quality systems surrounding pharmacovigilance activities including deviations, change controls, simulation exercises and self-inspection program and maintenance of records.

A wrap up meeting was held to review the inspection findings at Pfizer Canada, Kirkland on 19 September 2025 and an exit meeting is due to be on 10 October 2025. This is in line with Health Canada procedures.

A list of the personnel who attended the exit meeting will be 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.

SECTION C: INSPECTION FINDINGS

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

Since the previous inspection in 2021, the company had made the following changes to the pharmacovigilance system:

- The EU QPPV [redacted] assumed the role of the UK QPPV as of 01 April 2024.
- At this time a UK National Contact Person (NCP), [redacted] was nominated.
- Pfizer has made several acquisitions, which include;
  - [redacted]
  - [redacted]
  - [redacted]
  - [redacted]
- Pfizer divested [redacted] in October 2022.

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

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

C.4.3 Minor findings

MI.1 Management of Biological Medicinal Products

Finding MI.1 a)
The MAH did not have processes or procedures in place to fully comply with the expectations set out within GVP module P.II for biological medicinal products, examples include: a) There was no procedure to ensure that, where appropriate, signals for biological products were evaluated in the context of batch-specific exposure data, including numbers/codes of delivered or sold batches, their size and the regions or countries where the respective batches have been delivered to support the requirements within GVP module P.II.B.4. It was identified that validated signals of [redacted] – 30 May 2023 and [redacted] – 05 May 2025 for [redacted] a biological product, had not had any batch specific evaluation conducted. However, for both signals it is acknowledged that batch specific evaluation may not have been appropriate as both signals were identified via the PSUSA /PRAC. b) There was no procedure which described when the safety team would be informed of significant changes to the manufacturing process for biological products. It is acknowledged that [redacted] version [redacted] effective date 23 June 2023, does state that safety will be notified if a quality review has identified an issue which poses a potential risk to patient safety. However, there was no procedure which dictated routine alerts to safety regarding changes in the manufacturing processes so they could proactively look for signals resulting from that change as per requirements within GVP module P. II. No significant manufacturing changes were identified for [redacted] c) There was no process which describes what would constitute a significant change to the manufacturing process of biological products which might warrant an update to the risk management plan as per GVP module P.II.B.1.2. This has been reported as a minor finding as it is acknowledged that the company were using batch specific data to conduct signal detection.
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**
[redacted]	

MI.2 Signal Management

Finding MI.2 a)
In accordance with [redacted] version [redacted] TMEs (targeted medical events) and DMEs (Designated medical events) should be reviewed for all products as part of the product surveillance signal detection. However, during the inspection an example was seen during a live demonstration where there were no written comments to document the review of the present TMEs. Only the received DME had been commented on in [redacted] to evidence the review and decision made on this event.
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)

There were examples of validated signals which did not appear to have undergone a full signal evaluation in accordance with GVP module IX or internal procedure [redacted]. For instance [redacted], a signal identified of [redacted], had no documented literature search conducted. It was stated that a literature search was not done as it had been conducted as a routine search on 26 November 2024 (which is the date before the signal was validated on 27th November 2024); however, a specific literature search in the context of this signal did not appear to have been conducted, and the signal evaluation report did not refer to the routine search either.

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.3 Deviation Management

Finding MI.3 a)
Gaps were identified with the documentation and management of deviations (quality events, or QEs) which were raised against the pharmacovigilance system. As per GVP module I expectations, it is recommended that the MAH's quality system includes: "records to demonstrate that deficiencies and deviations from the established quality system are monitored, that corrective and preventive actions have been taken, that solutions have been applied to deviations or deficiencies and that the effectiveness of the actions taken has been verified." [redacted] designated as major, with submission date 19 March 2025, was opened following the identification of errors and omissions by two [redacted] staff impacting UK and Ireland. Whils[redacted] documented CAPA for the identified deficiencies, the QE lacked granularity and failed to further assess certain areas, some of which impacted communications to the MHRA, examples included: I. No consideration was documented of the impact of the lack of availability of up-to-date product information (SmPC or PIL) on emc or on the UK MHRA Product information website https://products.mhra.gov.uk/. II. The number of UK issues noted in[redacted] ("Seventy-seven activities with at least one issue were identified across[redacted] products … [redacted] had impact to product on the market") did not match the numbers listed in the linked [redacted] (see below). III. The QE did not consider the end-to-end labelling quality system[redacted], or other systems and trackers e.g. why the systems did not detect some of the missed milestones and actions, whether information in[redacted] or other trackers may be inaccurate. IV. No effectiveness check was considered necessary for this deficiency and hence the preventative measure would not be evaluated for effectiveness: "Preventative action: Regulatory Sciences to work with digital partners to develop automation of the UK/IRE mailbox to help colleagues and managers to have oversight of work in progress (Due date 17-Jan-2026)" V. There was no assessment of impact of the QE deficiencies (if any) on the UK PSMF e.g. metrics in Annex F. [redacted] Separately, [redacted] was opened on 19 January 2025 by the [redacted] organisation to investigate the product quality impacts of the deviation. Deficiencies in the QE record were identified. Deficiencies observed included: I. [redacted] was opened on 16 Jan 2025, an issue escalation report [redacted] was opened on 19 March 2025 and closed on 20 March 2025, but DMRC was not notified of PIL non-conformances until after the inspection on 30 September 2025 ([redacted]), a delay of over six months. Per A Guide to Defective Medicinal Products (published August 2021, A guide to defective medicinal products - GOV.UK) Section 4, notification should be immediate: "These conditions place a statutory duty on the holder of a manufacturer's licence to inform the licensing authority immediately when they become aware of any defect which could result in a recall."

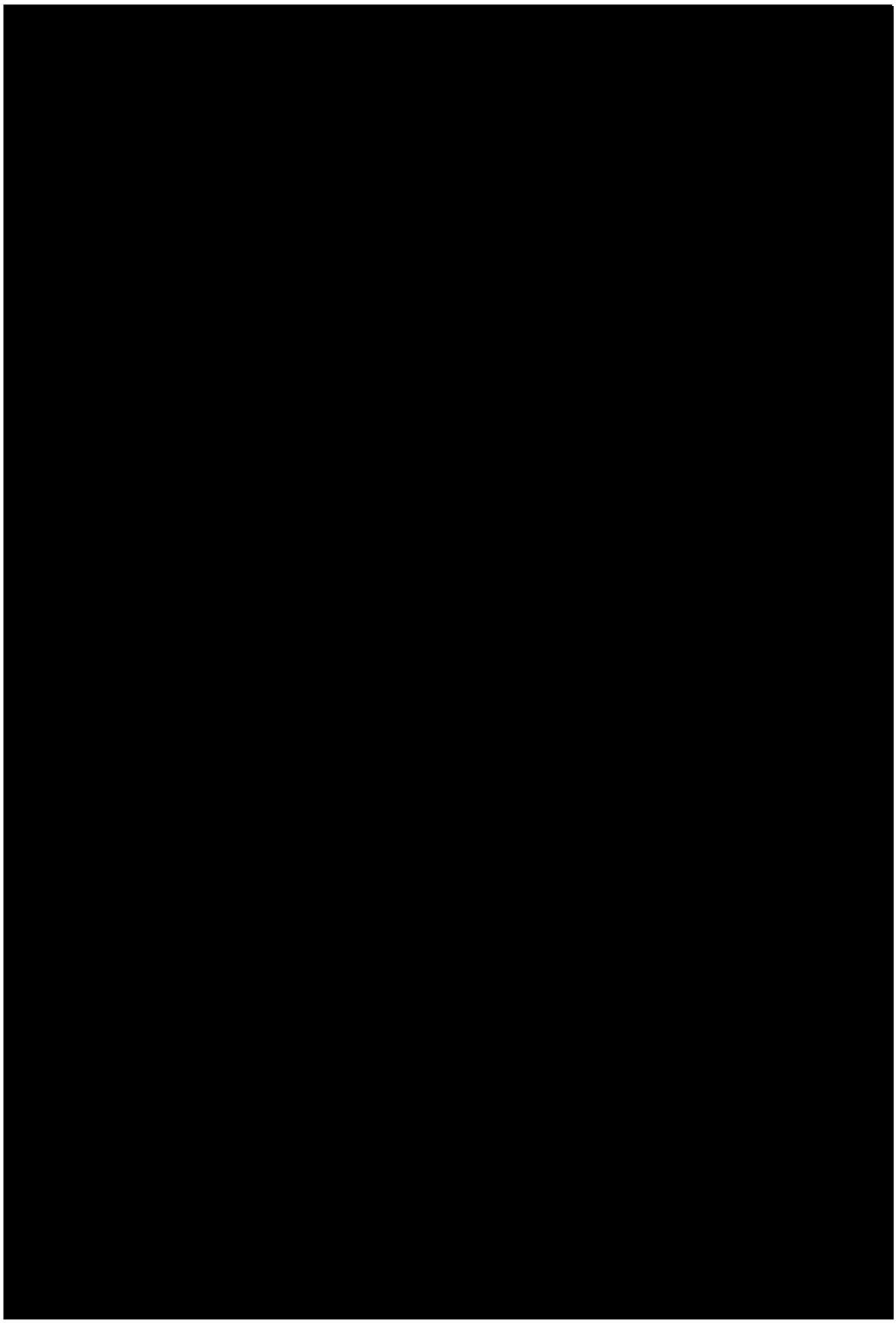
II. The overall impact assessment within [redacted] stated: "No impact to supply, No market action identified at this point." However, this did not align with the message in the linked deviation [redacted] which stated: [redacted] meeting and Health Hazard assessments for [redacted] products, prior to notifying the Defective Medicines Report Centre (DMRC)".

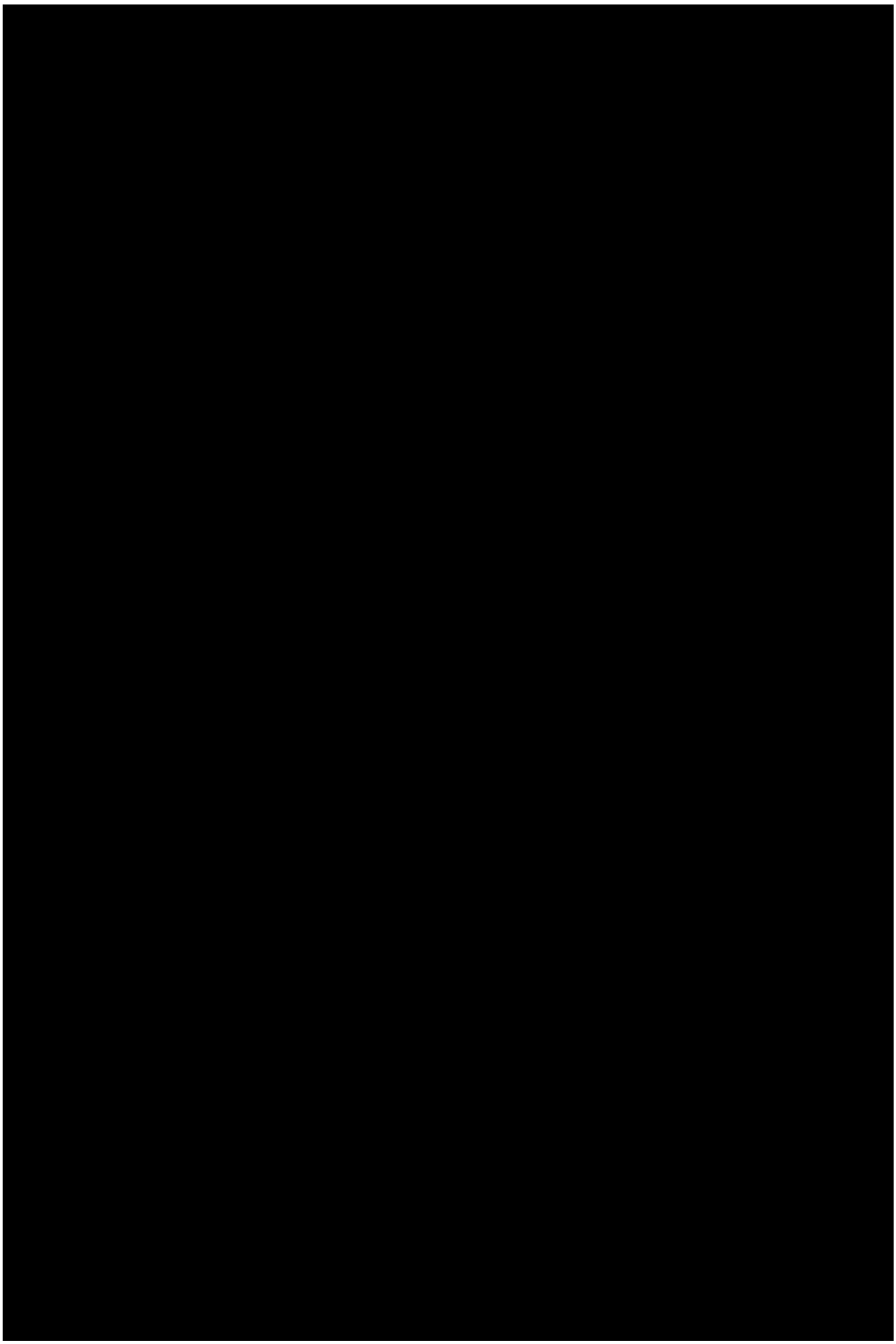
III. No CAPA had been recorded for this significant deviation. Under the section "CAPA Required?", the QE record stated "No".

IV. [redacted] noted [redacted] regulatory issues were identified, [redacted] of those issues had impact to products in the UK market". This differed to the number reported in [redacted] (see above).

Root Cause Analysis

[redacted]





[redacted]

Further Assessment

[redacted]

Corrective Action(s)

[redacted]

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

Preventative Action(s)

[redacted]

[redacted]

Deliverable(s)	Due Date
[redacted]	

MI.4 Management and Reporting of Adverse Reactions

Finding MI.4 a)
AEs and ADRs received from organised data collection programmes/ Company Sponsored programmes (CSP) were inconsistently captured in the safety database as spontaneous despite the CSP being evaluated by the MAH as a solicited reporting programme. Cross divisional procedure [redacted] Company sponsored programs' version [redacted] effective date 05 January 2023, states that 'As part of Consultation, Safety reviews programs to categorize them for safety report handling. Based on the program's design, Safety determines whether any Product Safety Information from the program will be processed as spontaneous or solicited for purposes of regulatory reporting." The programme [redacted] e was evaluated as being a solicited programme for the purposes of safety reporting; however, there were two reports identified within the safety database which were given the case type of spontaneous. [redacted] The MAH stated during the inspection that these adverse reactions were reported in a spontaneous manner, as even though the patient was part of the PSP these specific reports were reported through the pharmacy rather than through the PSP itself. However, regardless of how the safety information was provided, the fact that this information was received from consumers enrolled in the PSP, the information should be evaluated as solicited.
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 MI.4 b)

An isolated example was identified where a targeted follow-up questionnaire / data capture aid (DCA) for [redacted] was sent late per company procedures.

Spontaneous case [redacted] for [redacted] with the adverse reaction of [redacted] was received on 23 July 2024. A follow-up letter sent by the MAH on 01 August 2024 did not contain the [redacted] data capture aid. The data capture aid was subsequently sent with follow ups on 19 August 2024 and 9 September 2024, 19 days after the initial follow-up was sent.

Per Pfizer procedure [redacted] Follow-up Activities, Specific Requirements (effective 15-May-2024), the first follow up attempt using a data capture aid (DCA) should be sent within 7 calendar days from the time case processing is completed, and at the same time as other follow up activities.
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.4 c)
There were isolated examples of incorrect case processing for two adverse reaction reports, these were: 1) Case [redacted], a serious case of [redacted] with three Pfizer products, [redacted]) was received from the MHRA in relation to a [redacted] sponsored study. This was transmitted to Pfizer as a spontaneous case however it was reclassified within the Pfizer safety database to 'non-Pfizer sponsored interventional study'. This is not aligned with GVP module VI.C.1.1 which states these cases should be

processed as spontaneous. The change in case type would have also impacted the PSUR inclusion with this case appearing within the solicited column of the post marketing data summary tabulation rather than the spontaneous column.

2) Case [redacted] with event of [redacted]' for the [redacted] contained an inaccurate case narrative, which stated "A possible contributory role of the suspect products cannot be excluded for the reported event based on the known safety profile". The company confirmed that company causality was assessed as unrelated, which was correctly captured within the safety database causality field, and that the narrative will be amended to reflect the unrelated company causality.

3) Case [redacted] was initially received by Medical Information (MedInfo) [redacted] on 10 June 2024, where it was reported by a pharmacist that a female patient experienced bruises at the injection site with the product [redacted] On 20 June 2024, significant additional information was received by MedInfo [redacted] However this information was not identified as being significant until the time of the inspection and therefore the additional information had not been captured within [redacted]

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]	

[redacted]

MI.5 Requests from Health Authorities

Finding MI.5 a)	
The PRAC assessment report date 28 November 2024 for [redacted] PSUR DLP 15 May 2024 requested the MAH to review the classification of all cases originating from US patient support programmes; however, there was no evidence that the MAH had undertaken this until August 2025, when a decision was taken to make all PSP programmes solicited. In addition, there was no evidence provided that any assessment had been conducted to identify whether received cases from the programme should be reclassified.	
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.5 b)

Pfizer was unable to provide the information requested regarding the last batch released with the superseded component code for the products below until Day 3 of the inspection, even though this information had been requested as a pre-inspection request submitted to the MAH on 29 July 2025.

[redacted]

Pfizer indicated that in the above cases, the information was provided by contract manufacturing organisations (CMOs).

Root Cause Analysis

[redacted]

Further Assessment

[redacted]

Corrective Action(s)

[redacted]

Deliverable(s) N/A	**Due Date(s)** N/A

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

C.4.4 Comments

1. A delay was identified in the submission of a Type IA variation relating to [redacted] and [redacted] which subsequently impacted the implementation date to the emc.

Regarding [redacted], a Type IA variation to section 4.4 with a general warning regarding [redacted] and an update to section 4.8 to add the adverse reaction [redacted] with a frequency 'Not known', and consequentially an update to the PIL was submitted to the MHRA on 22 January 2024. This was 25 days after the CMDh deadline. The CMDh scientific conclusions for [redacted] were published on 25 October 2023 and required the submission of the variation by the MAH by 28 December 2023.

The MAH appears to have submitted the update incorrectly as part of Type IB variation on 19 December 2023. Validation queries from the RMS relating to the CMDh recommendation requested: "This change should be submitted as a standalone Type IA (C.I.3.a) variation. According to the CMDh grouping guidance, safety-relevant changes must not be grouped with IB or II variations that could delay implementation." The MAH submitted the standalone Type IA variation for the CMDh PSUSA recommendations on 22 January 2024.

Subsequently, the emc was updated in a timely manner per internal procedures on 25 January 2024. However, per CMDh deadlines and MHRA expected timeframes, the emc should have been updated no later than 12 January 2024 i.e. ten working days after the deadline date for submission of the Type IA variation. However, because of the delay to the Type IA submission, the MAH implemented onto emc a few days after this, on 25 January 2024.

2. Errors were identified on the Pfizer variation tracking spreadsheet shared during the inspection in relation to the [redacted] variation to update the safety information for [redacted]

   A. The type of variation was IAIN with a Date of Submission of '19-Dec-23'; however, 19-Dec-23 was the date of the incorrect Type IB submission. The date of submission of the correct Type IA submission was 22 January 2024.
   B. The MHRA Variation Reference Number for the safety variation was incorrect on the spreadsheet. Instead of [redacted] the variation tracker displayed [redacted]

3. Per Pfizer procedures, Data Capture Aids (DCAs) were not routinely applicable to reports originating from literature, and DCAs were manually scheduled on an as needed basis. As the case reviewer must proactively schedule a DCA for a literature article, the MAH is advised to consider if current practice may result in non-compliance with the RMP in situations where extra information is needed that could change the clinical case assessment. Furthermore, as there is no requirement to document in the case file that the DCA has been considered and rejected, there may be instances where DCAs were not sent but should have been.

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, do 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).
- 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.
- EMA/CHMP/ICH/544553/1998: ICH guideline E2C (R2) on periodic benefit-risk evaluation report (PBRER).
- CPMP/ICH/3945/03: ICH guideline E2D "Post-Approval Safety Data Management: Definitions and Standards for Expedited Reporting".

APPENDIX II PHARMACOVIGILANCE INSPECTION PLAN

Market Authorization Holder Name (MAH):	PFIZER CANADA ULC BioNTech Manufacturing GMBH GenMed A Division of Pfizer Canada ULC Seagen Inc
Address:	17300 Trans-Canada Highway Kirkland QUÉBEC CANADA H9J 2M5
Contact Person:	[redacted]
Importer Name (If applicable) :	Pfizer Canada ULC
Inspector Name(s) from Health Canada:	[redacted]
Inspector Name(s) from MHRA:	[redacted]
Inspection Date:	2025-09-16 to 2025-09-19
Inspection Type:	Onsite regular GVP Inspection

Day 1 Tuesday 16Sept2025

Time	Session	Pfizer
9H00	Opening Meeting • Objectives and scope of the inspection, logistics • MAH presentation • Organizational chart • Changes since the last GVP inspection	[redacted]
10H15-11H45	Quality Complaints, medical information requests and other sources involving ADRs	
	Phase IV clinical trials & Patient support programs/Patient reimbursement / Patient assistance programs (if applicable)	
13H30 – 15h15	Processes and procedures for the receipt, handling, evaluation, and reporting of ADRs and unusual	

Time	Session	Pfizer
	failures in efficacy of new drugs to Health Canada - Invalid cases	[redacted]
15h30 – 16h30	Literature Review	

Day 2 Wednesday 17Sept2025

Time	Session	Pfizer
9H00 – 10H30	• Updates to routine safety information including Core information Label (inc SmPC) and PILs/product monographs update	[redacted]
10H45 – 11H45	• Periodic Safety Update Reports / Issue-related summary reports	
13H30- 14H30	• Computer systems validation	

Day 3 Thursday 18Sept2025

Time	Session	Pfizer
9H00 – 10H00	• Signal detection	[redacted]
	• Notifying Health Canada of foreign actions	
10H15 – 11H45	• Qualifications of personnel and job descriptions / Training program and records	
	• Quality systems surrounding pharmacovigilance activities including deviations, change controls, simulation exercises, self-inspection program	
13H30-14H30	• Maintenance of records	

Day 4 Friday 19Sept2025

Time	Session	Pfizer
TBD	• Inspection wrap-up	[redacted]