Medicines & Healthcare products
Regulatory Agency

PHARMACOVIGILANCE
INSPECTION REPORT

Pharmacovigilance System Name: Bristol-Myers Squibb

MHRA Inspection Number: Insp GPvP 11184/108564-0009

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ABBREVIATIONS

CAPA	Corrective and Preventative Action
CD	Controlled Distribution
CSV	Computer System Validation
[redacted]	
eRMP	electronic Risk Management Programme
EU	European Union
GVP	Good Vigilance Practice
HCP	Healthcare Professional
ICH	International Conference on Harmonisation
[redacted]	
LMPS	Local Market Patient Safety
MA	Marketing Authorisation
MAH	Marketing Authorisation Holder
PAF	Prescription Authorisation Form
PPP	Pregnancy Prevention Plan
PSMF	Pharmacovigilance System Master File
PV	Pharmacovigilance
QC	Quality Control
QMS	Quality Management System
QPPV	Qualified Person responsible for Pharmacovigilance
RMM	Risk Minimisation Measures
RMP	Risk Management Plan
UAT	User Acceptance Testing
UK	United Kingdom

SECTION A: INSPECTION REPORT SUMMARY

Inspection type:	Statutory National Inspection
System(s) inspected:	Bristol-Myers Squibb [redacted]
Site(s) of inspection:	ARC Uxbridge, Sanderson Road, United Kingdom, UB8 1DH
Main site contact:	[redacted] Associate Director, Pharmacovigilance Strategy Lead ARC Uxbridge, Sanderson Road, United Kingdom, UB8 1DH [redacted]
Date(s) of inspection:	27 – 30 June 2023 Day 1: Remote Days 2 – 4: Onsite
Lead Inspector:	[redacted]
Accompanying Inspector(s):	
Previous inspection date(s):	Previous inspections of Bristol Myers Squibb: 29 – 01 December 2022 (Investigator site inspection) 25 – 25 August 2022 02 – 05 March 2020 08 – 11 February 2010 22 – 25 January 2007 12 – 15 December 2005 and 06 – 07 February 2006 Previous inspections of [redacted] 16 – 17 and 21 – 22 July 2020 22 – 24 January 2019 04 – 08 December 2017 08 – 11 July 2013 21 – 24 April 2009 (UK) & 14 – 17 December 2009 (US) 11 – 13 March 2008 (UK) & 31 March – 04 April 2008 (US)
Purpose of inspection:	Inspection of pharmacovigilance systems to review compliance with UK and EU requirements, focusing on the [redacted] risk management system
Products selected to provide system examples:	[redacted]
Name and location of UK QPPV:	[redacted] Bristol Myers Squibb GesmbH, Rivergate, Gate 1, Handelskai 921200, Vienna,

	Austria [redacted]
Global PV database (in use at the time of the inspection):	[redacted]
Key service provider(s):	The following services relating to the risk management system were outsourced as follows; • Qinecsa Solutions: [redacted] processing activities including mailbox management, receipt, triage, data entry, quality control and follow-up • Promotional Mailing Services Group: Storage and distribution of [redacted] and [redacted] Additional Risk Minimisation Materials to HCPs. Distribution of pregnancy prevention programme (PPP) correspondence to HCPs. • Insight Medical Writing Limited/Certara USA, INC: Medical writing services for the [redacted] Annual Audit Reports • Syneos: Publishing services for [redacted] Annual Audit Reports • [redacted] Order management, warehousing, supply and distribution of the [redacted] to UK PPP registered pharmacies. • IT Vendors: o Accenture: PPP eRMP-UK application implementation and IT support o Salesforce: Platform host provider for the PPP eRMP-UK application. o Ownbackup: Backup capability provider for Salesforce hosted systems.
Inspection finding summary:	0 Critical findings 0 Major findings 2 Minor findings
Date of first issue of report to MAH:	22 August 2023
Deadline for submission of responses by MAH:	28 September 2023
Date(s) of receipt of responses from MAH:	26 September 2023
Date of final version of report:	18 January 2024
Report author:	[redacted] Pharmacovigilance Inspector

SECTION B: BACKGROUND AND SCOPE

B.1 Background information

Bristol-Myers Squibb (BMS) was selected for a post-launch inspection as part of the MHRA's statutory, national pharmacovigilance inspection programme. The purpose of the inspection was to review the procedures, processes and electronic systems in place to manage the controlled distribution system and pregnancy prevention programme (PPP) for [redacted] (herein referred to collectively as [redacted] in accordance with the approved risk management plan (RMP) and risk management system agreed with the MHRA. Reference was made to The Human Medicines Regulations 2012 as amended, Commission Implementing Regulation (EU) No 520/2012, Regulation (EC) No 726/2004, 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, reference was made to the 'Detailed Description of the Implementation of Additional Risk Minimisation Measures for [redacted] version [redacted] approved by the MHRA on 06 October 2022.

A list of reference texts is provided at Appendix I.

Bristol Myers Squibb (BMS) is a global biopharmaceutical company headquartered in New York, USA, with sites in more than 50 countries worldwide. On 20 November 2019, BMS acquired Celgene, which included [redacted]) within the acquisition portfolio. The [redacted] products are authorised via the EU centralised procedure in Northern Ireland and via national marketing authorisations (PLGB) in Great Britain.

At the time of acquisition, Celgene operated a dual paper and electronic controlled distribution and PPP system as part of their risk management commitments for the [redacted] products in the UK. These systems were reviewed as part of an MHRA inspection in 2017, which resulted in a critical finding (ref: Insp GPvP 21752/2907930-0007). Due to the critical finding, the risk management system was re-inspected in 2019, which again resulted in a critical finding (ref: Insp GPvP 21752/2907930-0014). A further re-inspection was conducted in 2020 which determined that critical deficiencies relating to risk management identified during the previous inspection had been addressed and no further deficiencies associated with the risk management system were identified.

In September 2022, BMS submitted version [redacted] of the 'Detailed Description of the Implementation of Additional Risk Minimisation Measures for [redacted]. This detailed the planned updates to the system, including implementation of the new electronic PPP system - electronic Risk Management Programme (eRMP) (refer to section C.1 for further detail of the changes). This was approved by the MHRA on [redacted]. The new system when live on [redacted]

At the time of inspection BMS outsourced the following services related to the risk management system:

- Qinecsa Solutions: Prescription Authorisation Form (PAF) processing activities including mailbox management, receipt, triage, data entry, quality control and follow-up.
- Promotional Mailing Services Group: Storage and distribution of [redacted] Additional Risk Minimisation Materials to HCPs; distribution of pregnancy prevention programme (PPP) correspondence to HCPs.

- Insight Medical Writing Limited/Certara USA, INC: Medical writing services for the [redacted] Annual Audit Reports.
- Syneos: Publishing services for [redacted] Annual Audit Reports.
- [redacted]: Order management, warehousing, supply and distribution of the [redacted] to UK PPP registered pharmacies.
- IT Vendors:
    - Accenture: PPP eRMP-UK application implementation and IT support
    - Salesforce: Platform host provider for the PPP eRMP-UK application.
    - Ownbackup: Backup capability provider for Salesforce hosted systems.

B.2 Scope of the inspection

The inspection focussed on the compliance of the risk management system for [redacted] BMS in line with version [redacted] of the 'Detailed Description of the Implementation of Additional Risk Minimisation Measures for [redacted]' and the updates made to the system within this version. The inspection was performed at the BMS offices in Uxbridge. Personnel from the UK affiliate attended the site in order to participate in the inspection and personnel located abroad participated via videoconferences.

The inspection was performed using interviews and document review, and included view-only access to the eRMP system by the inspectors. The scope of the inspection is highlighted in the Pharmacovigilance Inspection Plan (attached as Appendix II).

B.3 Documents submitted prior to the inspection

The company submitted a PSMF (version [redacted] effective 21 April 2023 and version [redacted] effective 22 May 2023) 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. The company also submitted a number of document requests in advance of the inspection, details of which are contained within document request sheet A and B.

B.4 Conduct of the inspection

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

A closing meeting was held to review the inspection findings at the BMS office in Uxbridge on 30 June 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.

SECTION C: INSPECTION FINDINGS

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

Since the previous inspection in July 2020 the company had made the following changes to the [redacted] risk management system:

On [redacted]:

- The process was changed to allow all UK Prescription Authorisation Forms (PAFs), including paper forms (previously managed separately offline) to be managed in the electronic Risk Management Programme (eRMP) platform.
- The [redacted] BMS Self-Audit process, which was only in effect for this product, was retired in the UK. This annual process, which is still in effect in Ireland, was used to identify non-adherence with the PPP for pharmacies not utilising the legacy eRMP system. As paper PAFs were completed at the time of dispensing and retained in the pharmacies for a minimum of 2 years, follow-up on non-adherence occurred as part of the Self-Audit process. The annual Self-Audits were also used to collect data required for the Audit report.

On [redacted]:

- Following approval of version [redacted] of the 'Detailed Description of the Implementation of Additional Risk Minimisation Measures for [redacted] by the MHRA on [redacted], BMS went live with a new eRMP – the [redacted] Activities surrounding this included data migration of electronic PAFs (but not paper PAFs), healthcare professionals and patient data from the legacy RMP-UK to the [redacted] platform, and migration of pharmacy registration data from the legacy [redacted]
- Significant changes to the controlled distribution process and PPP were made including:
    - Streamlined Quality Management System (QMS) for all products.
    - Pharmacy registrations were managed in the eRMP, which included the new function for automated email notifications and the [redacted] was retired.
    - All PAFs were quality control (QC) checked within the eRMP within 5 business days (previously managed in [redacted] on a monthly basis).
    - All PAFs were entered into the [redacted] platform utilising a standard workflow, regardless of any missing information (previously in the legacy RMP-UK there was a separate Incomplete PAF workflow).
    - PAFs that were non-adherent or missing information were flagged in the platform automatically and had associated follow-up tasks generated by the [redacted] platform based on pre-defined criteria (previously follow-up was managed using an [redacted] tracker).
    - A new set of reports were created in the [redacted] to enable data extraction. These included: 'All PAF report', 'Pharmacy/Product Registration report' and the 'Non-adherence report'.
    - The reconciliation process of PAFs vs product supply was changed so that data was reviewed at the pharmacy level (previously at the trust/group level).
    - A more comprehensive follow up process was created and reconciliation outcomes, whereby non-response resulted in an assessment of unconfirmed non-adherence, were introduced.
- Management of product orders was reassigned to the BMS Order Management team from [redacted] (previously managed by the distributor [redacted].

The controlled distribution process was updated to include the daily provision of [redacted] pharmacy registration status by the Local Market Patient Safety (LMPS) team (note: pharmacies needed to complete individual registrations for each product separately).

At the time of inspection:

- [redacted] was in the process of being updated to detail how paper and electronic PAF data should be retrieved from the new [redacted] platform, manipulated and analysed for the purposes of authoring the annual audit reports for [redacted]. The next annual audit report, which would include data from the new [redacted] system, was due for submission by 26 December 2023 ([redacted] DLP 26 June 2023).

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 Quality Management System

At BMS, the process of reconciling units (packs) of [redacted] supplied to registered UK pharmacies against received PAF data was conducted every quarter for the 12-months prior. The Q1 2023 reconciliation was reviewed on inspection, which included data from April 2022 to March 2023.

In order to generate the reconciliation data, sales/order data for the required period was downloaded using a customised report in [redacted] for data from 1 October 2022 and onwards; and for data prior to this date the [redacted] from [redacted] was used. This data was then combined to create the 'Orders (combined)' spreadsheet. As this data only contained customer sales information at the Trust/Private Group/Health Board level, mapping activities had to be carried out to map the trust orders with the associated pharmacy.

For the PAF data the 'All PAFs Report' from the [redacted] platform was generated for the required period and filtered to identify all PAFs with a status of 'dispensed'. For PAF data pertaining to the period prior to go-live of the [redacted] (27 March 2023), the 'All PAF report' from the legacy [redacted] platform was also used to review the PAF data.

The combined order data and PAF data was further combined into the final reconciliation spreadsheet to calculate the variance between total units (packs) supplied and total PAFs with a status of 'dispensed' over the 12-month period.

This high-level information was covered in the single PPP manual [redacted] (version [redacted] effective 27 March 2023). However, there were some deficiencies in the procedural documentation observed during inspection.

Finding MI.1 a)
For the Q1 2023 reconciliation of PAFs vs product packs, there was no detailed procedural guidance in effect at the time to support the several steps of data manipulation required to create the numerous spreadsheets used for reconciliation. The Q1 2023 reconciliation activities were initiated on 30 April 2023 and whilst it is acknowledged that a [redacted] job aid was provided during the inspection, this was an initial draft (with no version or dates available), and the overarching single PPP manual that was in effect at the time did not provide adequate detail to enable the production of the combined data in the final 'Reconciliation' spreadsheet. Specifically, detail was missing as to which date fields were used to include raw data from the PAF reports to obtain the data for the 12-month period. For the new [redacted] platform report, the prescription date, dispensing date, as well as 'PAF Dispensed Status Date' could be used. For the old eRMP report, ordered date, approval date and dispensing date could be used. It was confirmed verbally on inspection that the data would be filtered using the dispensing date, and for the new [redacted] platform report if this date was not available the prescription date would be used, but this was not detailed in the procedural document. Additionally, to map pharmacies to a Trust/Private Group/Health Board for the sales data, pivot tables and duplicate checks were used. However, the single PPP manual did not cover this process in adequate detail to describe the steps needed to conduct this essential data

manipulation to create the 'Orders (combined)' spreadsheet. There was also no detail as to which steps of data manipulation would be subject to QC and how this QC would be conducted, and by whom.

The MAH is reminded of HMR Schedule 12A, Part 3, paragraph 11(1)(a) and Commission Implementing Regulation (EU) No 520/2012, Section 2, Article 11 (1)(a) which state:
"(1) Specific quality system procedures and processes must 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 that appropriate measures are taken by the holder;"

Whilst no downstream impact was observed, quality systems should include procedures detailed enough to enable staff to consistently perform the activities surrounding PAF vs pack reconciliation which was a significant aspect of measuring compliance with and effectiveness of the [redacted] PPP.

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 Computer System Validation

Development, validation and functionality of the new [redacted] platform was reviewed on inspection.

The following deficiencies were identified:

Finding MI.2 a)

Within the [redacted] platform, the expiry date of a pharmacy registration (linked to a particular product) for the fields 'Product Registration End Date' and 'De-registration date' were calculated as 2 years plus 1 day from Product Registration Date instead of exactly 2 years. This defect was identified by the MAH through User Acceptance Testing (UAT) on 20 October 2022 and had not been resolved prior to [redacted] system deployment on 27 March 2023 (release version [redacted] The defect remained open during the inspection, with no action date identified for correcting the defect.

The expiry date was inaccurate by one additional day compared to the conditions of the MHRA marketing authorisation for [redacted] which stated in [redacted]. In the MHRA-approved 'Detailed Description of the Implementation of Additional Risk Minimisation Measures for [redacted] (version [redacted] approved by the MHRA on 06 October 2022), the MAH stated that 'The expiry date of the pharmacy product registration will be automatically set at 2-years.'

Per [redacted] (version [redacted] effective 06 January 2023) section 3 Test Defect Management 'c. Any defects related to business critical or regulatory requirements identified during testing must be resolved either with a technical solution or a procedural control prior to the release. They cannot be deferred to a later release.' Per Appendix [redacted], the definition of Low criticality was 'Defect does not significantly impact the user's ability to perform business operations and processes.' Subsequently, the defect was assigned criticality of 'Low' and was a 'CSV Deferred Action' to be actioned at a future release, even though the defect related to a regulatory requirement.

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.2 b)

A deviation from the [redacted] had not been documented in the Validation Summary Report.

[redacted] (version [redacted] decision date 28 April 2022) section 8.3.1 stated 'the System Test Summary Report is to be completed prior to start of UAT execution.' However, UAT and System Testing for release 1.2 of the [redacted] system occurred in parallel due to BMS using an 'agile' approach to the design and development of the system. This change to the CSV plan was not reflected in the [redacted] (version [redacted] decision date 20 March 2023) in the section designed to capture deviations.

Root Cause Analysis	
[redacted]	
Further Assessment	
[redacted]	
Corrective Action(s)	
[redacted]	
Deliverable(s)	**Due Date(s)**
[redacted]	
Preventative Action #1	
[redacted]	
Deliverable(s)	**Due Date(s)**
[redacted]	
Preventative Action #2	
[redacted]	
Deliverable(s)	**Due Date(s)**
[redacted]	

C.4.4 Comments

i. BMS conducted a suite of proactive notifications to HCPs prescribing and dispensing [redacted] to inform them of the planned launch of the new [redacted] system. One such communication was sent to registered pharmacies that were using the paper PAF process to invite them to a demonstration the new electronic platform. One instance (out of two sampled examples) was identified where a pharmacy [redacted] registered with the paper PAF process was missed off the distribution list of this communication. Evidence was however seen, to show that the chief pharmacist was sent the initial letter on 26 October 2022 notifying HCPs of the implementation of the new [redacted] system.

ii. [redacted] (version [redacted] effective 27 March 2023) did not include any details on the timings of when pharmacies should be contacted if PAFs are submitted on superseded paper PAF versions. The job aid stated in section 3.2.1 that for initial outreach a new row should be added to the [redacted] During the inspection five paper PAFs were identified which were dispensed on superseded versions of the [redacted] and [redacted] PAF (dated March 2022) between 29 March 2023 and 21 June 2023. BMS explained in writing that these PAFs had not been added to the tracker as "there is a 3-month grace period/implementation period applied following the distribution of updated educational materials to HCPs before the previous version of the PAF meets the criteria as retired. This allows the integration of updated materials into prescribing and dispensing processes within the hospitals and pharmacies". The updated PAF became effective in March 2023 with go-live of the new [redacted] system.

iii. There was a minor discrepancy in the [redacted] (version [redacted] date created June 2023) regarding the creation of new eRMP system trackers for business continuity purposes. The plan stated that the trackers should be created within four weeks of new system implementation [redacted]); however, the deadline for completion date was stated as [redacted], 12 weeks after go-live of the new system.

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) as amended.
- Commission Implementing Regulation (EU) No 520/2012.
- Regulation (EC) No 726/2004
- Directive 2001/83/EC
- 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.
- 'Detailed Description of the Implementation of Additional Risk Minimisation Measures for [redacted] approved by MHRA on [redacted]'

APPENDIX II PHARMACOVIGILANCE INSPECTION PLAN

MHRA INSPECTION NUMBER	TBC	**INSPECTION TEAM**	[redacted] (Lead Inspector), [redacted]
PHARMACOVIGILANCE INSPECTION OF	Bristol-Myers Squibb: [redacted] UK Risk Management System	**DATES**	27 – 30 June 2023
LOCATION	Day 1 (27 June): Remote Days 2 – 4: Onsite (ARC Uxbridge, Sanderson Road, United Kingdom, UB8 1DH)	**START TIME**	09:00 BST

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

This inspection will focus on the BMS controlled distribution and pregnancy prevention programme (PPP) and new [redacted] platform for all [redacted] products. Topics to be covered (but are not limited to):

- [redacted] platform development, validation and functionality
- controlled distribution and adherence to the PPP
- management of non-compliance
- quality management (training, business continuity and oversight mechanisms, including that of vendors)

The inspection plan below outlines the topics for which specific sessions are requested to orientate inspectors around the systems and processes in place. Additional ad hoc discussions with company personnel may also be required. Please ensure that subject matters experts are available and indicate any times personnel may be unavailable in the below. The inspectors will liaise with the designated inspection host to arrange ad hoc discussions as required.

The remainder of the inspection will consist of document review and document requests will be submitted throughout the course of the inspection.

The inspection is anticipated to take four days to complete. A closing meeting will be held on Friday 30 June 2023 (timing to be confirmed) during which feedback on the inspection will be provided to the company.

Tuesday, 27 June 2023

Opening Meeting 09:00 BST, held by videoconference, led by the lead inspector. The agenda will be: • Review of the scope and arrangements for the inspection • Company presentation by BMS to provide an overview of the [redacted] risk management system, the supporting quality system and the key parties implementing and running the system. Changes made to the system since the previous inspection should be highlighted, along with corresponding timelines. BMS should also provide an overview of how the changes to the system were managed and how this was communicated with vendors. The presentation should last no longer than 20 minutes.	**Opening meeting attendees:** • [redacted] Director, Head of Patient Safety, UK & Ireland • [redacted] Associate Director, Patient Safety • [redacted] Associate Director, Patient Safety
Demonstration - *10:00 BST* Held by videoconference, led by company • A live interactive demonstration is requested of the risk management system for [redacted] and the [redacted] platform. This should include how prescribers and pharmacies are registered, enter data and submit PAFs, and how information from PAFs is databased and stored. In addition, newly updated functions of the system should be demonstrated, for example the template reports which have replaced various trackers. If any supporting platforms or back-end sites are in place for admin activities and reporting tools, please ensure these are available to view.	**Demonstration attendees:** • [redacted] Associate Director, Patient Safety • [redacted] Senior Manager, Patient Safety, Risk Management Operations • [redacted] IT Service Delivery Lead
Interview 1 - 14:00 BST, held by videoconference **Computer system validation of the [redacted] platform:**	*Please list personnel who will be available for interview/ad hoc questions regarding the specified topics; including job title and*

• An overview of the validation strategy and activities conducted is to be provided by the company	*subject matter expertise. Please indicate any time zone differences. Notes may also be added for individuals to indicate any periods of unavailability during the inspection.* Interviewee(s): • [redacted] Senior Manager, IT Quality Management, CSV Operations • [redacted] Associate Director, IT Business Partnering (US Time zone) • [redacted] Associate Director, Digital Capability Management, IT GRM EMEA & AsiaPac BAU • [redacted] IT Service Delivery Lead
Wednesday, 28 June 2023	

Interview 2 - 09:30 BST **Compliance and QMS of the [redacted] risk management system**, including but not limited to: • Annual audit report activities • Training • Business continuity • Governance • Oversight of the service providers	*Please list personnel who will be available for interview/ad hoc questions regarding the specified topics; including job title and subject matter expertise. Please indicate any time zone differences. Notes may also be added for individuals to indicate any periods of unavailability during the inspection.* Interviewee(s): • [redacted] Associate Director, Patient Safety • [redacted] Associate Director, Patient Safety • [redacted] IT Service Delivery Lead • [redacted] Senior Manager, IT Quality Management, CSV Operations

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

Designated contact point:

[redacted] Pharmacovigilance Strategy Lead

[redacted] **(back up):** Director, Head of Patient Safety, UK & Ireland

Opening meeting attendees:

[redacted] Director, Head of Patient Safety, UK & Ireland (UK Time zone) [redacted]

[redacted] Associate Director, Pharmacovigilance Strategy Lead (UK Time zone) [redacted]

[redacted]: Associate Director, Patient Safety (UK Time zone) [redacted]

[redacted] Head, Pharmacovigilance & Lifecycle Management Quality, (UK Time zone) [redacted]

[redacted] Executive Director, EEA & UK QPPV (UK Time zone) [redacted]

[redacted] Senior Vice-president Worldwide Patient Safety (US Time zone) [redacted]

[redacted] Associate Director, Patient Safety (UK Time zone) [redacted]

[redacted] Senior Manager, IT Quality Management, CSV Operations (UK Time zone) [redacted]

[redacted] Global Risk Management (GRM) Lead, Publishing and Support, (UK Time zone) [redacted]

[redacted] Associate Director, Medical Lead, Myeloma/Myeloid, (UK Time zone) [redacted]

[redacted] General Manager, UK & Ireland (UK Time zone) [redacted]

[redacted] Associate Director, Global Regulatory Science (GRS) Lead, UK & Ireland, (UK Time zone) [redacted]

[redacted] Executive Director Europe | International Patient Safety (EU Time zone) [redacted]

[redacted] Associate Director, Global Safety Systems, Local Market Operations (UK Time zone) [redacted]

Subject matter experts (by topic):

PPP:

[redacted] Director, Head of Patient Safety, UK & Ireland (UK Time zone)

[redacted] Associate Director, Patient Safety (UK Time zone)

[redacted] Associate Director, Patient Safety (UK Time zone)

[redacted] Senior Manager, Patient Safety, Risk Management Operations (UK Time zone)

Validation/IT:

[redacted] Senior Manager, IT Quality Management, CSV Operations (UK Time zone)

[redacted] BMS IT Service Delivery Lead (UK Time zone)

[redacted] Associate Director, IT Business Partnering (US Time zone)

[redacted] Associate Director, Digital Capability Management, IT GRM EMEA & AsiaPac BAU (UK Time zone)

[redacted] Senior Manager, GxP IT Quality Assurance & E-compliance (US Time zone)

RMP:

[redacted] GRM Lead, Publishing and Support, (UK Time zone)

[redacted] Director: Risk Management Local Support, (UK Time zone)

Regulatory:

[redacted] Associate Director, Global Regulatory Science (GRS) Lead, UK & Ireland, (UK Time zone)

Quality Assurance:

[redacted] Associate Director, PV Auditing (UK Time Zone)