Medicines & Healthcare products Regulatory Agency

Pharmacovigilance Office Based Risk-Assessment (OBRA) Form

Section 1: OBRA plan (completed before OBRA is conducted)	
MHRA Inspection Number:	Insp GPvP 8553/19889136-0004
Company/MAH name	Dr. Reddy's Laboratories (UK) Ltd.
Parent inspection number and dates	Insp GPvP 8553/22742163-0001 25 – 28 May 2021 Insp GPvP 8553/18014-0021 16, 21-23 October 2019
OBRA team	[redacted]
Objective of OBRA	To determine whether actions taken to address and prevent the critical deficiency (identified at Insp GPvP 8553/22742163-0001, CR.1 a)), where PSURs for four active substances had not been submitted to NCAs, have been effectively implemented and are robust.
Estimated number of OBRA days required	3 days
Suggested dates for OBRA	11 – 14 September 2023
MS Team for OBRA	MHRA-GPVP-DrReddys_Sept2023-EXT
Scope of OBRA	• Corrective actions to include a review of those committed to within the inspection report for CR.1 a) (Insp GPvP 8553/22742163-0001). Review deliverables and associated deviation report and any further documents around handling of this process. • Preventative actions to include a review of those committed to within the inspection for MA.2 a) (Insp GPvP 8553/18014-0021): ○ Revision of [redacted] ○ Effectiveness of the preventative actions The scope will not just be limited to the above and will be decided upon by the lead inspector as the OBRA is conducted. The above is to provide the MAH with an outline of what to expect for provision of documents and SME availability if necessary.
Section 2: OBRA summary (completed after OBRA is conducted)	
Number of actual inspector days for OBRA	3 days

Further critical or major findings identified*	No critical or major findings identified
Further minor findings identified (including comments or recommendations)	**MI.1 Quality Management System** A minor finding was issued for the following deficiencies: a) No records were available to demonstrate to the Inspector that Dr Reddy's had defined the method and due date for the effectiveness check of the remediation activities conducted for CR.1 a) from the 2021 MHRA inspection (Insp GPvP 8553/22742163-0001) at the time of CAPA closure. It is acknowledged that the MAH provided evidence to show that an effectiveness check was undertaken and prepared on 8 September 2023; however, the documentation did not demonstrate that the MAH had agreed the time period and strategy for the effectiveness check at the time of CAPA closure (17 August 2021). This finding is graded as minor as there was no downstream impact to the timeliness of PSUR submissions. The MAH is reminded of *GVP module II, II.B.11. Documentation of the quality system:* "In order to have a systematic approach, the organisation should define in advance: • methods for monitoring the effectiveness of the pharmacovigilance system (see I.B.12.). […] It is recommended that the documentation of the quality system also 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." b) The PSMF and annexes ([redacted] date effective: 31 August 2023) contained a discrepancy in the named vendor responsible for medical writing of PSURs. The information in the main body of the PSMF attributed the responsibility of PSUR writing to ProPharma, whereas Annex A and Annex C listed iSafety as the responsible vendor. The discrepancy was present because iSafety was acquired by ProPharma group in 2021, however the MAH did not transparently convey this in the PSMF.

	c) Minor data entry errors in the PSUR tracker were identified for the fields 'EURD List' and 'Month due' for some products. Examples are as follows: i. The 'EURD List' column in the PSUR tracker was filled in incorrectly for 10 products, deviating from [redacted] 8 September 2023). The work instruction stated that the 'EURD List' should have "Y if listed in the EURD list as requiring generic/hybrid PSURs, N if generic PSURs not required". However, "N" was incorrectly indicated for the following products: • With a hybrid application (Article 10(3) of Directive No 2001/83/EC) legal basis: [redacted] • With an informed consent application (Article 10c of Directive No 2001/83/EC) legal basis: [redacted] ii. The [redacted] entries for 'Month due' in the PSUR tracker did not correspond to the correct month of the submission due date in the EURD list as follows: • [redacted] 'Month due' entry was March 2022 but submission due date was 31/03/2023 • [redacted] 'Month due' entry was December 2022 but submission due date was 24/02/2024 The MAH confirmed that these fields were not used downstream to drive PSUR submissions and timelines. Furthermore, no occurrences of late PSUR submission since 2021 were identified during this OBRA. The MAH confirmed on inspection that there was no quality control check step every time the PSUR tracker is updated in the current process.
Final outcome of OBRA	*This section of the form will be completed when the final version containing the QPPV's acknowledgement and signature is issued by the Inspector.*
Closing meeting date and attendees	14 September 2023 12:30 – 12:45 Attendees: [redacted]

	[redacted]
Signed by lead inspector	Signature: [redacted] Name: [redacted] Date: 28/09/2023
Signed and acknowledged by UK QPPV	Statement of acknowledgement: Acknowledge the recipt. Signature: [redacted] Date: 29-Sep-2023 | 4:25 PM IST

*For critical or major findings identified from OBRA, the company must provide a written response which includes:

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.