Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

PHARMACOVIGILANCE INSPECTION REPORT

Pharmacovigilance System Name: Cipla Ltd.

MHRA Inspection Number: Insp GPvP 36390/18209568-0001

10 South Colonnade, Canary Wharf, London E14 4PU **T** 020 3080 6000 **E** gpvpinspectors@mhra.gov.uk
www.gov.uk/mhra

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ABBREVIATIONS

ADR	Adverse Drug Reaction
AE	Adverse Event
CAPA	Corrective and Preventative Action
CHMP	Committee for Medicinal Products for Human Use
DCP	Decentralised Procedure
EMA	European Medicines Agency
EU	European Union
GVP	Good Vigilance Practice
HCP	Healthcare Professional
ICH	International Conference on Harmonisation
ICSR	Individual Case Safety Report
KPI	Key Performance Indicator
MAH	Marketing Authorisation Holder
MRP	Mutual Recognition Procedure
NAP	Nationally Authorised Product
NCA	National Competent Authority
PSMF	Pharmacovigilance System Master File
PSUR	Periodic Safety Update Report
PV	Pharmacovigilance
PVA	Pharmacovigilance Agreements
QA	Quality Assurance
QMS	Quality Management System
QPPV	Qualified Person responsible for Pharmacovigilance
RMM	Risk Minimisation Measures
RMP	Risk Management Plan
SDEA	Safety Data Exchange Agreement
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:	Cipla Europe NV, Cipla (EU) Ltd. and Cipla (UK) Ltd., PSMF [redacted]
Site(s) of inspection:	**06 – 09 August 2019:** Cipla Ltd. R&D centre, Building No. 14, West Block, 2nd Floor, LBS Marg, Vikhroli (W), Mumbai, Maharashtra 400083, India **12-13 August 2019:** Vigi Medsafe Private Limited 8-2-293/82/A, Plot No. 226, Road no 17, Jubilee Hills Checkpost, Andhra Bank Building, Jubilee Hills, Hyderabad – 500033, Telangana, India
Main site contact:	[redacted]
Date(s) of inspection:	06-09 August 2019 inspection at offices of Cipla with remote inspection support from UK 12-13 August 2019 inspection at offices of service provider Vigi Medsafe
Lead Inspector:	[redacted]
Accompanying Inspector(s):	
Previous inspection date(s):	02-03 and 08-12 May 2017 08 – 10 December 2015 24 – 26 June 2014
Purpose of inspection:	Inspection of pharmacovigilance systems to review compliance with UK and EU requirements.
Name and location of EU QPPV:	[redacted]
Global PV database (in use at the time of the inspection):	Argus 8.1.1 (commercially available)
Key service provider(s):	Pharmacovigilance services provided by Vigi Medsafe for ICSR management and by Sciformix for signal detection and aggregate report writing. Global medical information services provided by Bioclinica
Inspection finding summary:	02 Major findings 02 Minor findings
Date of first issue of report to MAH:	12 September 2019
Deadline for submission of responses by MAH:	16 October 2019
Date(s) of receipt of	16 October 2019, 06 November 2019

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responses from MAH:	
Date of final version of report:	07 November 2019
Report author:	[redacted]

SECTION B: BACKGROUND AND SCOPE

B.1 Background information

Cipla Ltd. was selected for routine inspection as part of the MHRA's statutory, national pharmacovigilance inspection programme. The purpose of the inspection was to review compliance with currently applicable EU and UK pharmacovigilance regulations and guidelines. In particular, reference was made to Directive 2001/83/EC as amended, Commission Implementing Regulation (EU) No 520/2012 and the adopted good pharmacovigilance practices (GVP) Modules. A list of reference texts is provided in Appendix I.

Cipla Ltd. is a global pharmaceutical organisation, with origins in the manufacture of active pharmaceutical ingredients and generics, developing into a marketing authorisation holder for generic products in multiple countries, with national licences in EU countries (UK, Germany, Spain and Norway) as well as some non-EU countries, where it provides product 'direct to market' (DTM). In other territories, Cipla operates a 'business to business' (B2B) model, supplying product through third party business partners who hold the licences in those territories, which include EU and non-EU countries.

In the UK, licences are held by the MAH Cipla (EU) Ltd. Other licences in Europe are held by Cipla (EU) Ltd. and Cipla Europe NV, Belgium. All products are covered by the Cipla Ltd. pharmacovigilance system described in PSMF [redacted]

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Pharmacovigilance activities for ICSR management and literature surveillance are outsourced to service provider Vigi Medsafe, whilst aggregate report writing and some activities relating to signal detection is outsourced to Sciformix, and medical information services are conducted by service provider Bioclinica. The QPPV and backup are inhouse at Cipla. All other pharmacovigilance activities including the preparation, maintenance and implementation of RMPs, the management of signals, and regulatory submissions including of aggregate reports, ICSRs and safety variations, are conducted inhouse by Cipla.

B.2 Scope of the inspection

The inspection included a review of the global pharmacovigilance system and was performed at Cipla's offices in Mumbai, India and at the offices of service provider Vigi Medsafe in Hyderabad, India. Personnel from Cipla attended the Vigi Medsafe site in person and via teleconference in order to participate in the inspection.

The inspection was performed using interviews and document review (including outputs from the global safety database). 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] effective 04 July 2019) 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. Minor amendments to the inspection plan that occurred during the inspection are highlighted using italic text in Appendix II.

The inspection onsite at the offices of Cipla was supported by an inspector working remotely from the UK.

Closing meetings were held at the end of each site visit at the offices of Cipla in Mumbai on 09 August 2019 and of Vigi Medsafe in Hyderabad on 13 August 2019 to give feedback regarding inspection findings and observations.

Lists of the personnel who attended the interim closing meetings are contained in the Closing Meeting Attendance Records, 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 MHRA inspection in 2017, in addition to the implementation of systems in accordance with the 2017 inspection CAPA, the company had made extensive changes to the pharmacovigilance system, including:

- All UK licences were transferred to be held by MAH Cipla (EU) Ltd. All EU licences that were held by Cipla (UK) Ltd., and Cipla (EU) Ltd. were in the process of being transferred to Cipla Europe NV, Belgium.
- Cipla Croatia d.o.o. was divested from the Cipla company group.
- Pharmacovigilance activities were in the process of transfer from the previous service provider APCER at the time of the last MHRA GPvP inspection in 2017.
    - ICSR management activities were transferred to service provider SciFormix on 07 August 2017 and then to service provider Vigi MedSafe on 17 January 2018.
    - Aggregate report management was transferred from APCER to Sciformix on 01 June 2017.
    - Signal detection activities were transferred from Cipla to Sciformix on 01 June 2017.
    - Literature surveillance was transferred from APCER to Sciformix on 07 August 2017 and then to Vigi Medsafe on 08 October 2018.
    - Medical information activities for the EU were transferred from APCER to Bioclinica on 10 November 2017.

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- The QPPV changed from [redacted] to [redacted] on 11 September 2017.
- The pharmacovigilance department inhouse at Cipla had been restructured and re-mapped to reside under the corporate Quality Department with a new Head of pharmacovigilance. The team had increased headcount from 33 to 52.
- The Argus global safety database was upgraded to version 8 in January 2019.

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 which are graded as critical or major will be shared with the EMA, other 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 Collection and collation of safety reports

Requirements:

GVP Module VI, Collection, management and submission of reports of suspected adverse reactions to medicinal products (Rev 2)
VI.C.2.2. Responsibilities of the marketing authorisation holder in the EU
"The marketing authorisation holder shall ensure that any information on adverse reactions, suspected to be related to at least one of the active substances of its medicinal products authorised in the EU, is brought to its attention by any company outside the EU belonging to the same mother company (or group of companies). The same applies to the marketing authorisation holder when having concluded a commercial agreement with a company outside the EU for one of its medicinal products authorised in the EU. Pursuant to Article 107(1) of Directive 2001/83/EC, the marketing authorisation holder shall record those reports of suspected adverse reactions and shall ensure that they are accessible at a single point within the EU." [emphasis added]

Cipla had a commercial model of both direct to market supply (DTM) and business to business supply (B2B) of its products globally. Since the MHRA GPvP inspection in 2017, extensive work was undertaken by Cipla to strengthen the global pharmacovigilance system with regards to the collection of relevant safety information. Cipla had set up the Global Products List (GPL) in the SAP enterprise resource planning system, which allowed for the use of a block in SAP to prevent product supply to territories where no SDEA was signed. Cipla also revised the Master Business Partner List, which provided the drug safety department with oversight of which business partners had SDEAs in place, and those that were pending. These approaches afforded appropriate oversight and control for partners, such as distributors, in territories where Cipla held the marketing authorisations (DTM).

With regards to partners in territories where Cipla employed the B2B model, the following deficiencies were observed:

Finding MA.1

Cipla did not have mechanisms in place to receive reports of suspected adverse reactions from business partners outside the EU for medicinal products for which Cipla held a marketing authorisation in the EU. As Cipla was not receiving any potential cases, it could not ensure that its regulatory obligations as EU MAH, to collect and record these cases and report to EudraVigilance where applicable, were being met.

For example:

- Cipla had a supply agreement dated 19 July 2019 with partner Rex in New Zealand and Australia, for products that Cipla held licences for in the EU. This agreement

outlined that Rex would act as Cipla's representative in the territory (Article 2.1). The SDEA in place between Cipla and Rex, signed 04 June 2015, stated that Cipla would send all safety reports for these products to Rex, however for products which Cipla had EU reporting obligations, there was no reciprocal agreement included within the SDEA.

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The agreement template 'SDEA/PVA Template: Partner as MAH (For US & ROW)' in Annexure A2 of [redacted] 'Safety data exchange agreements/pharmacovigilance agreements' [redacted] effective 11 July 2019), only included reporting obligations for the partner in the territory. There were no clauses or instructions for the MAH in the non-EU territory to share ICSRs with Cipla as to allow Cipla to meet its reporting responsibilities within the EU (for instances where Cipla held EU authorisations for products included within the agreement).

The 'PV obligations tracker' (provided in response to document request L5) indicated that [redacted] of the [redacted] entries where a business partner was MAH had listed "N/A" or "not required" for the partner to send Cipla cases (it is acknowledged not all of these partners would be supplying products that were authorised to Cipla in the EU).

This approach towards these partners resulted in the omission of relevant information within the PSMF (please refer to finding MA.2b), and Cipla confirmed verbally that this would impact on the inclusion of these partners in the pharmacovigilance audit programme.

Based on the text quoted from GVP Module VI.C.2.2., it is the MHRA's expectation that, for the third party commercial partners outside the EU to whom Cipla supplies medicinal products for which Cipla holds a licence in the EU, Cipla has mechanisms to ensure that any information on adverse reactions, suspected to be related to these medicinal products, is brought to its attention.

MHRA post inspection request: In the responses, the MAH should consider the approach and appropriate mechanism(s) to employ to ensure the above, including the type of agreement/or addition of text in existing agreements that is required, based on the nature of the business partner, the nature of the commercial arrangement in place and the likelihood of each partner to receive safety relevant information.

Root Cause Analysis

[redacted]

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[redacted]

Further Assessment

[redacted]

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[redacted]

Corrective Action(s)
[redacted]

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

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[redacted]

Preventative Action(s)
[redacted]

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

MA.2 Pharmacovigilance system master file

Requirements:

GVP Module II, Pharmacovigilance system master file (Rev 2)
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 […]
Information about third parties (licence partners or local distribution/marketing arrangements) should also be included in the section describing contracts and agreements (see II.B.4.2. and II.B.4.8.)."

II.B.4.8. Annex to the PSMF
"The list of medicinal products authorised in the EU should also include the authorisation number(s) including, per authorisation: […] *- the presence on the market in the EU [DIR Art 23(a), REG Art 13(4)]"*

Finding MA.2 a)

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Annex B of the PSMF, 'List of business partner' [redacted] contained business partners which marketed Cipla products, where Cipla was the MAH in territories outside of the EU. However, as Cipla had not regarded business partners who were the MAH in non-EU territories (for example Rex, as referred to in finding MA.1) as a source of safety data, they had not been included within Annex B or Annex C, 'Sources of safety data' v16.2.

Root Cause Analysis

[redacted]

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[redacted]

Further Assessment

[redacted]

Corrective Action(s)

[redacted]

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

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[redacted]

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

Finding MA.2 b)
Annex H contained incorrect marketing status for some products authorised in the UK. It was identified that licences for the following products were listed in Annex H as 'not-marketed' in the UK, however the data in the 'current UK authorised list' compiled as per [redacted] 'Process for preparation and circulation of product lust and process for

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confirmation of commercialisation status [redacted] effective 28 September 2018), confirmed that these were in fact marketed in the UK at the time of the inspection:

[redacted]

Additionally, the annex stated that topiramate was marketed, however information from the commercial function confirmed that it was not.

GVP Module II.B.6. states that the information in the PSMF shall be "accurate and reflect the current system in place". Inaccurate information on whether products are marketed in the UK, particularly those that are subject to additional risk minimisation measures in the UK, has potential to impact on the ability of inspectors to fulfil their supervisory duties when scheduling and planning an inspection.

Root Cause Analysis

[redacted]

Further Assessment

[redacted]

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[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 Case processing

Finding MI.1
During case processing, Vigi Medsafe used the 'Compiled Products List' (CPL) (dated 04 July 2019) which listed the products Cipla were marketing in different territories, to determine the validity of case reports based on the suspect product. When compared with the list of UK products which were commercialised, provided to the inspectors in response to request H5 'Confirm which UK licensed products are currently marketed', inaccuracies were identified in the CPL. For example: Products that were confirmed to be on the market in the UK but were listed in the CPL either as not commercialised or with no information on commercialisation status: [redacted] There were also products which did not include a marketing status in the CPL: [redacted]
Root Cause Analysis
[redacted]

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Further Assessment
[redacted]

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[redacted]

Corrective Action(s)

[redacted]

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

Preventative Action(s)

[redacted]

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

MI.2 Periodic safety update reports

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Finding MI.2
It was stated by the MAH in response to document requests [redacted] that adverse events from spontaneous sources and serious adverse events from post-marketing solicited sources that were not related to company products were not being excluded from PSUR post-marketing summary tabulations. Cipla are reminded that GVP Module VII.B.5.6.3. PSUR sub-section "Cumulative and interval summary tabulations from post-marketing data sources" describes the inclusion of adverse reactions in these tabulations, and adverse events should not be presented. In response to this finding, Cipla should ensure that the data in future PSUR tabulations is correct and changes to cumulative counts of post marketing ADRs in these tabulations in sequential PSURs are explained for the assessor.
Root Cause Analysis
[redacted]
Further Assessment
[redacted]
Corrective Action(s)
[redacted]
Deliverable(s) / **Due Date(s)**
[redacted]
Preventative Action(s)
[redacted]

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[redacted]

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

SECTION D: CONCLUSIONS AND RECOMMENDATIONS

D.1 Conclusions

The extensive remedial work at Cipla over the past two years was reviewed during the inspection and is acknowledged by the inspection team. The inhouse team and expertise that has been put in place since the previous MHRA GPvP inspections provide confidence that on satisfactory remediation of the reported findings and with continued stability within the organisation, the system will be considered to be in compliance with EU regulations.

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 MAH is encouraged to share this inspection report with relevant service providers to whom it has sub-contracted pharmacovigilance activities. Service providers are reminded that deficiencies that are more broadly applicable to MAHs not subject to this inspection may need to be shared with those affected, such that appropriate CAPA can be derived. The service provider and MAH(s) affected should be able to demonstrate effective assessment and resolution of deficiencies that have been reported during any inspection.

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

- Regulation (EC) No. 726/2004 (Title II, Chapter 3), as amended.
- Directive 2001/83/EC, as amended.
- Commission Implementing Regulation (EU) No 520/2012.
- Guideline on good pharmacovigilance practices (GVP).
- The Human Medicines Regulations 2012 (Statutory Instrument 2012 No. 1916).
- EMA/CHMP/ICH/287/1995: ICH guideline E2B (R3) on electronic transmission of individual case safety reports (ICSRs) - data elements and message specification - implementation guide.
- CPMP/ICH/3945/03: E2D "Post-Approval Safety Data Management: Definitions and Standards for Expedited Reporting".

APPENDIX II PHARMACOVIGILANCE INSPECTION PLAN

MHRA INSPECTION NUMBER	TBC	**DAY**	1
PHARMACOVIGILANCE INSPECTION OF	Cipla	**DATE**	06 August 2019
LOCATION	Cipla Ltd., R&D, West Block, 2nd Floor, L.B.S. Marg, Vikhroli (West), Mumbai-400083, India	**START TIME**	9.00am arrival for 9.30am start

Purpose of Interview	**Session Lead**	**Staff to be interviewed**
Opening Meeting Review of scope of inspection and inspection plan **Company Presentation** Overview of the company, the pharmacovigilance system, the quality system and areas undergoing remedial activities *(approx. 20 minutes)*	[redacted]	[redacted]
Document review	-	Inspectors only
LUNCH	-	-

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Sources of safety information Including but not limited to: - Management of SDEAs - Maintenance of the Master Business Partner List and PSMF Annexes B and C - Audit of business partners	[redacted]	[redacted]
[redacted]		

MHRA INSPECTION NUMBER	TBC	**DAY**	2
PHARMACOVIGILANCE INSPECTION OF	Cipla	**DATE**	07 August 2019
LOCATION	Cipla Ltd., R&D, West Block, 2nd Floor, L.B.S. Marg, Vikhroli (West), Mumbai-400083, India	**START TIME**	9.00am

Purpose of Interview	**Session Lead**	**Staff to be interviewed**
Document review	-	Inspectors only
Data management Including but not limited to: - Data clean up activities - Data extraction for signal detection, PSUR production and ad hoc searches as required	[redacted]	[redacted]
LUNCH	-	-
Risk management Including but not limited to: - Implementation of UK additional risk minimisation measures - Oversight and compliance management of risk management plan commitments	[redacted]	[redacted]
Document review	-	Inspectors only

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MHRA INSPECTION NUMBER	TBC	**DAY**	3
PHARMACOVIGILANCE INSPECTION OF	Cipla	**DATE**	08 August 2019
LOCATION	Cipla Ltd., R&D, West Block, 2nd Floor, L.B.S. Marg, Vikhroli (West), Mumbai-400083, India	**START TIME**	9.00am

Purpose of Interview	**Session Lead**	**Staff to be interviewed**
Document review	-	Inspectors only
Maintenance of reference safety information - Identification of required updates from various sources - Submission of safety variations - Implementation of approved updates to product information including SmPC, patient information leaflets and online sources of information	[redacted]	[redacted]
LUNCH	-	-
Document review and ad hoc interview sessions as required	-	Inspectors only

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MHRA INSPECTION NUMBER	TBC	**DAY**	4
PHARMACOVIGILANCE INSPECTION OF	Cipla	**DATE**	09 August 2019
LOCATION	Cipla Ltd., R&D, West Block, 2nd Floor, L.B.S. Marg, Vikhroli (West), Mumbai-400083, India	**START TIME**	9.00am

Purpose of Interview	**Session Lead**	**Staff to be interviewed**
Oversight and supervision of the pharmacovigilance system by the MAH and by the QPPV	[redacted]	[redacted]
LUNCH	-	-
Document review and ad hoc interview sessions as required	-	Inspectors only
Inspectors meeting	-	Inspectors only
Interim closing meeting*	-	All welcome

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MHRA INSPECTION NUMBER	TBC	**DAY**	5
PHARMACOVIGILANCE INSPECTION OF	Cipla	**DATE**	12 August 2019
LOCATION	Vigi Medsafe Private Limited 8-2-293/82/A, Plot No. 226, Road no 17, Jubilee Hills Checkpost, Andhra Bank Building, Jubilee Hills, Hyderabad – 500033, Telangana, India	**START TIME**	9.00am for 9.30am start

Purpose of Interview	**Session Lead**	**Staff to be interviewed**
ICSR management - Case check-in and processing - Reporting to EudraVigilance - Follow-up activities	[redacted]	[redacted]
LUNCH	-	-

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Data migration Data migrated to the Cipla database by Vigi Medsafe	[redacted]	[redacted]
~~***Maintenance of EU labels***~~ ~~*Activities conducted by Vigi Medsafe in relation to the maintenance and update of EU summaries of product characteristics and patient information leaflets*~~	[redacted]	[redacted]

MHRA INSPECTION NUMBER	TBC	**DAY**	6
PHARMACOVIGILANCE INSPECTION OF	Cipla	**DATE**	13 August 2019
LOCATION	Vigi Medsafe Private Limited 8-2-293/82/A, Plot No. 226, Road no 17, Jubilee Hills Checkpost, Andhra Bank Building, Jubilee Hills, Hyderabad – 500033, Telangana, India	**START TIME**	9.00am

Purpose of Interview	**Session Lead**	**Staff to be interviewed**
Oversight and supervision of the service provider by Cipla Including but not limited to: - Compliance metrics - Management of non-compliance in the quality management system	[redacted]	[redacted]
LUNCH	-	-

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Document review and ad hoc interview sessions as required	-	Inspectors only
Inspectors meeting	-	Inspectors only
Interim closing meeting*	-	All welcome