CASE AUTH/3887/4/24

COMPLAINANT v CIPLA

Allegations regarding company processes

CASE SUMMARY

This case was in relation to the alleged failure of Cipla to keep any records of company interactions with health professionals for a number of years, including no record of 1:1 calls, meetings or conferences that health professionals had attended.

The outcome under the 2021 Code was:

Breach of Clause 5.1	**Failing to maintain high standards**

No Breach of Clause 2	**Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**

This summary is not intended to be read in isolation.
For full details, please see the full case report below.

FULL CASE REPORT

A complaint about Cipla (EU) Limited was received from an anonymous, non-contactable complainant, who described themselves as a pharmaceutical company employee.

COMPLAINT

The complaint wording is reproduced below:

> "No records of company interaction with HCPs for over a few years. The evidence to support this is if a subject access from a HCP went to the organisation they could not tell you when and what was discussed with healthcare professionals. No record of 1:1 calls, meetings or conferences HCPs attended. If the company was asked for these records they would not be able to present them. That's the evidence. This puts the employees at risk if a HCP makes a complaint or there is an adverse event, how would they investigate. I have been made aware as employees themselves told me, the company was too laid back, easy going, don't even keep records and management are fully aware of this but say they will bring in a system but no system ever comes."

When writing to Cipla, the PMCPA asked it to consider the requirements of Clause 5.1 and Clause 2 of the 2021 Code.

CIPLA'S RESPONSE

The response from Cipla is reproduced below with some typographical errors corrected:

> "Thank you for your email of 2nd April 2024 regarding the allegation regarding company processes within Cipla (EU) Ltd in the UK, made to the PMCPA by an anonymous complainant.
>
> We pride ourselves on maintaining high standards and abiding by the ABPI Code of Practice 2021 (CoP) and believe that the information in this response and attachments will demonstrate the breadth and depth of the processes in place. These help us to meet the requirement to maintain high standards at all times (Clause 5.1) and thus avoid failing in our duty to uphold confidence in the industry (Clause 2).
>
> We understand that the complainant has not provided any evidence which would establish a basis for the allegation.
>
> In our response summary we seek to provide:
>
> 1. Reassurance that Cipla (EU) Ltd in the UK has ensured that it has broad processes to meet requirements and other obligations as a pharmaceutical company operating within the CoP. This has changed over time as the company's activities have changed.
> 2. Examples and supporting information covering relevant representative activities as requested by the PMCPA, including standard operating procedures (SOPs) and guidance documents for representative activities, meetings and relating to record keeping and document retention which we are happy to enclose.
> 3. Confirmation we have a clear understanding of the importance of pharmacovigilance (PV) being a separate process as specifically mentioned by the complainant. We outline other guidance around similarly important communications including product quality complaints and medical information requests, noted by representatives following their contact with healthcare professionals (HCPs) and other relevant decision makers (ORDMs) as appropriate.
>
> **Standard operating procedures and guidance documents**
> To summarise and put into context the company's considered approach and undertakings, related to the CoP, we should explain that we have reviewed and adapted our processes as the nature of the business has evolved. This has ensured that our processes remain current and fit for purpose.
>
> Cipla commenced activities in 2018 which fall under the scope of the CoP. The early promotion to healthcare professionals (HCPs) and other relevant decision makers was initiated in 2019 and conducted through [named contract sales team] and also a [named remote working contract team]. Certified items used by representatives include the provision of briefing documentation as detailed in Clause 17.9. Two examples from early 2019 attached demonstrate the content of these, which are provided appropriate to the focus and nature of the representative activity. Representatives then, and now, receive training in the CoP (Clauses 9 & 17 in particular), including expectations for

interactions with HCPs, average call contact rates of not normally more than 3 times per year, remote working considerations, handling PV reports within 24 hours and appropriately directing other enquiries (e.g. medical information, product quality, questions on other Cipla products), in a timely manner via identified and appropriate UK head office personnel.

In the early period a limited number of meetings were supported by or organised by Cipla (EU) Ltd. and these were coordinated centrally, utilising a meetings approval process to confirm these meet requirements under Clause 10 and gain appropriate signatory approval of these prior to committing to undertaking.

From the start of commercial operations in the UK the approval process for materials has been set out and adhered to with qualified signatories conducting reviews, certification / examination processes as necessary (Clause 8). Two signatories are both registered pharmacists, one has been in place continuously since 2018.

Compliance Guidance Documents	**Identifier & Date**
Review and approval process for promotional and non-promotional materials inc archiving	[version number] February 2024
Guidance document for distribution of promotional and non-promotional materials to the sales team	[version number] Jan 2023
Procedure for withdrawal of promotional and non-promotional materials	[version number] Jan 2023
UK Social Media Policy	[version number] Jan 2023

In addition, we develop and certify information on our promoted product portfolio for provision to patients prescribed these respiratory medicines. We also undertake some disease awareness and corporate communications for the general public. Our approval process ensures that these comply with the relevant CoP requirements (primarily Clause 26).

We have transitioned from remote working contract representatives to employed representatives and have extended the meetings approval process to KAMs [Key Account Managers]. The most recent guidance and process documents for this are noted below.

Meetings Guidance Documents (relevant to KAMs)	**Identifier & Date**
Guidance document UK company supported third party organised events in the UK	[version number] January 2023
Use of consultants guidance document	[version number] Jan 2023
Transfer of value guidance document	[version number] Jan 2023

Meeting Approvals Process Documents (relevant to KAMs)	Identifier & Date
Cipla meeting approval process briefing slides	[version number] Nov 2023
KAM meeting approval process briefing	[version number] Nov 2023
Meeting approval form (MAF) - Company Initiated Organised Events Template A	November 2023
Meeting approval form (MAF) - Third Party Organised Events Template B	November 2023
Meeting Attendance Form	[version number] March 2023
FMV rates	November 2023

Record keeping/document retention
A list of active materials and withdrawals is maintained and updated weekly on an electronic system accessed by both compliance personnel and senior staff at Cipla (EU) Ltd. Retention of certificates is undertaken as noted in Clause 8.6 and this is reiterated in the review and approval process documentation.
Approvals for meetings are similarly documented on a shared database and transfer of value recorded in the meeting approval forms and confirmed on meeting completion for subsequent disclosure (Clause 10.10).
Contacts made by individual representatives are noted to assess frequency of calls made on HCPs and ORDMs (Clause 17.4). For representative organised meetings, the collation of attendee list is noted within the briefing documentation enclosed. In addition, the different meeting approval forms collate information on sponsorship costs and fees for services. This information is essential with regard to collection and recording of Transfer of Value (ToV) disclosure information for the different recipient groups for submission as required under Clauses 28-31.

Disclosure
Cipla (EU) Ltd has provided an annual submission via ABPI ToV portal for the last 4 years, as payments for declaration were made.

Given we can demonstrate that processes are in place for representative activities, meetings and record keeping and document retention we would therefore refute the allegation of a lack of processes being established and undertaken, for which no evidence has been provided by the anonymous complainant.

Pharmacovigilance
The complainant raised the question that if there was an adverse event reported during a contact with an HCP how would the company know and investigate this without their contact details having been logged.

Any adverse event reported to an employee or contracted third party representing Cipla needs to be handled in a specific and appropriate manner. This is separate to any recording of promotional contact with an HCP and is covered as part of the mandatory annual PV training undertaken with all Cipla (EU) Ltd colleagues. The latest PV training was undertaken on 23rd October 2023 with digital log recording completion of all

associates. New starters complete this as part of their onboarding training. As part of this training the important nature of collecting and reporting essential details within the 24-hour period, via the dedicated PV email, is emphasised.

We trust we have satisfactorily demonstrated a range of processes designed to ensure the CoP requirements are met, are well established, consistently undertaken and have been since Cipla (EU) Ltd commenced direct contact with HCPs and other decision makers in the UK.

We hope that this clarifies the situation and that no further action will be required. However, should you have any questions please do not hesitate to contact me."

FURTHER RESPONSE FROM CIPLA – PART 1

The Panel required further information from Cipla in order to complete its consideration of this case. The Panel wrote to Cipla and asked it to:

"Please submit the following, noting that the complainant's allegation is regarding "*no records of company interaction with HCPs for over a few years*":

1. Details of records of interactions between representatives and health professionals: what is recorded, and where?
2. Cipla's response letter states "*Contacts made by individual representatives are **noted** to assess frequency of calls made on HCPs and ORDMs*": where and how are such contacts/interactions between representatives and health professionals noted?
3. A copy of the standard operating procedure which covers the activities of representatives
4. A copy of the mandatory annual PV training undertaken by all Cipla (EU) Ltd colleagues"

The response from Cipla is reproduced below:

"We pride ourselves on maintaining high standards and abiding by the ABPI Code of Practice 2021 (CoP) at the time of the complaint and believe that the information in this response and attachments will demonstrate the breadth and depth of the processes in place. These help us to meet the requirement to maintain high standards at all times (Clause 5.1) and thus avoid failing in our duty to uphold confidence in the industry (Clause 2).

We understand that the complainant has not provided any evidence which would establish a basis for the allegation.

In response to these questions that seek additional clarification please see below:

Point 1: Details of records and interactions between representatives and health professionals: what was recorded, and where?

Cipla had been in discussions with [named Customer Relationship Management (CRM) company] since September 2023 and this system was implemented in July 2024. Each KAM as part of their on-boarding is trained on how to use this system.

Previously the KAM kept excel records.

Point 2: Cipla's response letter states *"Contacts made by individual representatives are **noted** to assess frequency of calls made on HCPs and ORDMs"*: where and how are such contacts/interactions between representatives and health professionals noted?

As noted in Point 1 a formal CRM system was implemented in July 2024. Before this time records were collected in excel and sales management policed call frequency and this was reiterated as per the briefs produced in initial e-mail to PMCPA regarding this complaint.

Contacts made by individual representatives are noted to assess frequency of calls made on HCPs and ORDMs (Clause 17.4). For representative organised meetings, the collation of attendee list is noted within the briefing documentation enclosed. In addition, the different meeting approval forms collate information on sponsorship costs and fees for services. From previous email dated 15th April 2024 to PMCPA.

Point 3: A copy of the standard operating procedure which covers the activities of representatives.

This complaint was made under the **2021 CoP** and Cipla did not have a specific SOP that covered the activities of representatives. The KAM team are very experienced and hence on-boarding, regular team meetings and interactions with sales manager and marketing plus briefing documents and briefing calls (e.g. re meetings process) provided the framework for them to work within.

Point 4: A copy of the mandatory annual PV training undertaken by all Cipla (EU) Ltd colleagues

Annual PV training is completed on an internal portal and reminders are sent to the team member and their manager to ensure all of the UK team are trained annually. The training is not downloadable.

We trust we have satisfactorily demonstrated a range of processes designed to ensure the 2021 CoP requirements were met, are well established, consistently undertaken and have been since Cipla (EU) Ltd commenced direct contact with HCPs and other decision makers in the UK."

FURTHER RESPONSE FROM CIPLA – PART 2

The Panel had not been provided with a copy of the excel spreadsheet referred to in Cipla's further information. The Panel requested a copy of it and the response from Cipla is reproduced below:

"Please find attached information from [named contract sales team].

We can confirm the following:

- The team used a CRM system provided by [named CRM system company] to record all of their engagement activities with HCPs
- The customer database which sat behind this system was the [named system] provided by [named company]
- Our representatives were tasked with updating and submitting all of their contact information into the CRM, and this was reported back weekly
- We have all the data for the interactions we delivered between 2018 and 2021
- We have provided the basic information you have requested in the excel file above, which is comprised of:
    - The customer unique identifier
    - The date a contact was made
    - The products that were discussed

- The attached is a sub-set of the data we hold specifically filtered to meet your current request. Further information including details of each representative activity, customer adoption ladder status and call notes is in the raw data but we have not extracted that as yet."

FURTHER RESPONSE FROM CIPLA – PART 3

The Panel wrote to Cipla again:

> "I note that you have provided a report from [named contract sales team] that covers interactions between September 2018 and March 2021.
>
> In a previous communication, you advised that Cipla implemented a CRM system in July 2024 and prior to that KAM kept excel records of their interactions with health professionals.
>
> We previously requested excel records covering 2020-2023. You have not provided any evidence for 2021-2023. Please can you urgently provide these excel records covering the period 2021-2023."

The response from Cipla is reproduced below:

> "We have attached information from [named contract sales team]
>
> The [named CRM system] was used from February 2019- Aug 2022 as Cipla used a contract KAM team."

PANEL RULING

This complaint about Cipla EU Ltd ("Cipla") was received from a complainant who described themselves as a pharmaceutical company employee. The complainant alleged that Cipla had failed to keep any records of company interactions with health professionals for a number of years, including no records of 1:1 calls, meetings or conferences that health professionals had attended.

The Panel noted that the complainant was anonymous and non-contactable and had provided limited information. As with any complaint, the complainant had the burden of proving their complaint on the balance of probabilities; the matter would be judged on the evidence provided by the parties.

The Panel noted that the complainant had not provided any evidence to support their complaint but had stated "*If the company was asked for these records they would not be able to present them. That's the evidence*". The Panel appreciated the difficulty in providing evidence to support the absence of something.

The Panel considered that whilst the Code did not stipulate how organisations should record interactions with health professionals, to not record interactions at all would make complying with certain aspects of the Code extremely difficult, for example the need to ensure the frequency of calls made to health professionals is not inconvenient.

The Panel noted Cipla's submission that it had commenced promoting to health professionals and other relevant decision makers in 2019, which had been conducted through a contract sales team and a remote working contract team. The contract sales team had used a Customer Relationship Management (CRM) system to record all of their engagements with health professionals and Cipla had provided a report, sourced from the contract sales team company, documenting all contacts made with health professionals between 2018 and 2021. In addition, the remote working contract team confirmed they had used a CRM system between February 2019 and when the contract was completed, in August 2022.

Cipla submitted that it had implemented a CRM system in July 2024, which was after this complaint had been received. Prior to this, Key Account Managers (KAMs) had kept excel records. Based on this information, the Panel was under the impression that between August 2022 and July 2024, representative interactions were captured using excel. However, Cipla failed to provide any example of this, despite repeated requests from the Panel.

As part of its submission, Cipla provided a briefing presentation for KAMs which outlined the "Cipla KAM Meeting Approval Process". The Panel noted that these slides referred to a "Meeting Attendance form" being available and that "collation of attendee list" appeared on a slide titled "Meeting information capture". In the Panel's view, this indicated that KAMs were instructed to specifically record health professional attendance at meetings to some degree.

Whilst it was clear to the Panel that prior to August 2022 representative interactions were captured by contract sales team companies utilised by Cipla, the Panel had been provided with no evidence to support the presence of records during the period August 2022 to July 2024. The small mention of an attendance form within the KAM Meeting Approval process did not negate this impression. The Panel considered representative records of interactions with health professionals as something Cipla should have had easy access to and been readily available to provide (with any sensitive information redacted). Taking all the above into account, the Panel considered that the failure of Cipla to evidence that it captured representative interactions with health professionals over a period of nearly two years meant that Cipla had failed to maintain high standards. The Panel therefore ruled **a breach of Clause 5.1** of the 2021 Code.

The Panel noted that Clause 2 was a sign of particular censure and reserved for such use. The Panel considered that the matters raised by the complainant were adequately covered by its

ruling above and did not consider that a breach of Clause 2 was warranted. The Panel therefore ruled **no breach of Clause 2.**

Complaint received **02 April 2024**

Case completed **16 July 2025**