CASES AUTH/3779/6/23 and AUTH/3780/6/23

EX-EMPLOYEE v BOEHRINGER INGELHEIM AND ELI LILLY

Concerns about the promotional material approval process

CASE SUMMARY

This case was in relation to the promotional material approval process used within the alliance of Boehringer Ingelheim (Case AUTH/3779/6/23) and Eli Lilly (Case AUTH/3780/6/23). The complainant made allegations around the accessibility of the most up-to-date approved version of the standard operating procedure and the accessibility and documentation of training.

In both cases, the outcome under the 2021 Code was:

No Breach of Clause 5.1	**Requirement to maintain high standards at all times**
No Breach of Clause 9.1	**Requirement that all relevant personnel concerned with the preparation or approval of material or activities covered by the Code must be fully conversant with the Code and the relevant laws and regulations**

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 was received from an anonymous, non-contactable complainant, who described themselves as a former employee, about the Boehringer Ingelheim and Eli Lilly alliance.

COMPLAINT

The complaint wording is reproduced below:

> "I have concerns about the PMAP (promotional material approval process) used within the Alliance of Boehringer Ingelheim and Lilly. My specific concern is about the accessibility of the most up to date, current, approved procedure and the relevant training that employees are required to obtain, including onboarding of new starters and periodic refresher training to existing employees. I have seen examples of agreements outside of the PMAP between individual job originators and certifiers – if this is because there's been an update to the official PMAP that's not clear; if it is because a new best practice has been identified then the PMAP has not been amended to include that - or at least, to the best of my knowledge, it is not shared with the rest of the team. The PMAP procedure available to the team is a word document with track changes and comments, it certainly does not look like an official document. I have asked for a proper document and for training to be documented in the learning

plan but had not received satisfactory answers. While jobs might be approved to high standards thanks to each member of the team doing their best and being extra cautious, I am concerned that the Alliance is not following a standard procedure and not everyone in the team, from BI or from Lilly, has the same understanding of the PMAP requirements and confidence in acting accordingly."

When writing to Boehringer Ingelheim and Eli Lilly, the PMCPA asked them to consider the requirements of Clauses 5.1 and 9.1 of the 2021 Code.

BOEHRINGER INGELHEIM'S RESPONSE (Case AUTH/3779/6/23)

The response from Boehringer Ingelheim is reproduced below:

"We understand that this complaint was made by an anonymous complainant who describes him/herself as a former employee of the Boehringer Ingelheim and Eli Lilly Alliance (the Alliance).

I would like to begin by stating that Boehringer Ingelheim Ltd (BI) is committed to operating in a professional, ethical and transparent manner and we keep patients at the heart of all that we do. We take compliance with the ABPI Code of Practice (the Code) very seriously and have steps in place to ensure robust procedures continue to underpin all our activities and we embrace a compliance culture that is fully embedded into the business with the support of senior leadership and the Ethics & Compliance Department. We were therefore surprised to receive the complaint which broadly alleged inadequacies in our training and procedural practices. We were also disappointed that the alleged 'former employee', should they be a former BI employee, did not use our internal 'Speak up procedure' to air their concern. We strongly disagree with the assertions made by the complainant and do not recognise the description they have provided. The following paragraphs provide further detail and address the concerns raised by the complainant.

1. <u>Accessibility of the most up to date, current, approved procedure</u>

The complainant alleges that they are concerned about the accessibility of the most up-to-date, current and approved PMAP procedure. The complainant states: *"The PMAP procedure available to the team is a word document with track changes and comments, it certainly does not look like an official document".*

The Standing Operation Procedure (SOP) for the Promotional Materials Approval Process (PMAP) is formally approved by the Country Managing Directors of both Lilly and BI, and for BI employees is located within the BI Quality Management System (Vault Quality Docs, VQD). This SOP can be accessed by BI employees either directly via VQD or indirectly from the internal Legal and Compliance SharePoint site (which links through to VQD). This ensures that BI employees have reference access to the version made effective in the approved Quality Management System and employees are trained as such through individualised trainings allocated in their role-specific training plans. Please see Figure 1:

[Figure 1: Screenshot of the Boehringer Ingelheim SharePoint compliance page. Image showing a page within the Legal & Compliance section of the Boehringer Ingelheim

SharePoint site, titled “Alliance”, with a link to SOP [number] (Promotional Materials Approval Process) and the following text: “BI and Lilly have an agreement as an Alliance who together promote the Jardiance product family. The Alliance have a common SOP called the Promotional Materials Approval Process (PMAP) which deals with materials approvals, but for all other processes each company follows its own internal SOPs. The Promotional Materials Approval Process (PMAP) SOP covers the approval of materials within the BI-Lilly Alliance. For non-Alliance materials, refer to the Materials Approval SOP.”]

The PMAP is the only SOP that is jointly approved by both BI and Lilly, and each company is responsible for ensuring training and access for their employees to the effective version of the SOP. Access for BI employees is as described above. To allow access for Lilly employees, who are unable to access the BI Quality Management System, the PMAP SOP is also housed in the *Jardiance Brand Team* MS Teams folder to which all BI and Lilly colleagues working in the Alliance have access. Of relevance to the complaint, it was noted that a working draft Word version of the PMAP SOP has, at times, also been housed in the MS Teams folder. To avoid any confusion between the PDF final approved version and the working Word draft, we have taken steps to remove the draft from the MS Teams site and house it only in the Alliance Compliance Committee working folder.

2. Learning plan documentation

The complainant further alleges that: *‘I have asked for a proper document and for training to be documented in the learning plan but had not received satisfactory answers’.*

This statement implies that the PMAP is not documented on learning plans and that employees to not have access to effective versions of the SOP via our quality management system (VQD). We refute this. When a new employee (or contractor third party working on behalf of BI) joins BI, their line manager ensures that the new joiner is allocated a role-specific training curriculum within the BI Learning One Source (LOS) system which tracks allocation and completion of mandated trainings against deadlines for completion. Learning assignments are assigned to new joiners and periodic learning assignments, (which may, for example, be triggered by updates to SOPs) are allocated to existing employees throughout the year.

The attached curricula report for [promotional materials approval process SOP number] shows the BI employee groups who are allocated PMAP training. All BI employees working on the Alliance are formally allocated PMAP-related trainings in LOS.

BI is not responsible for allocating PMAP training to Lilly employees or tracking such completion, this is the responsibility of Lilly.

In addition to receiving the PMAP in Alliance-related training curriculae [sic], all Alliance members receive regular face-to-face/virtual training sessions on the PMAP procedure and the LPAD, (the Local Policy Alignment Document which describes the working arrangements between BI and Lilly). The training sessions are delivered by the Ethics and Compliance (E&C) departments of both companies. The objective of the training is for attendees to understand the key principles of the Alliance LPAD and PMAP, to

recognise which document to refer to when carrying out an Alliance activity and to understand how to access BI policies and procedures. The completion of the PMAP SOP training as well as the face-to-face /virtual training sessions are documented within BI's LOS and separately by Lilly according to their procedures. For reference, please find the training presentation attached as well as a sample report which shows the BI employee completion of these training sessions 2021 to date.

Based on the explanations and evidence provide, BI refutes the allegations made by the Complainant.

3. Raised concerns not addressed

The complainant has also claimed to have raised their concern internally but: *"had not received satisfactory answers".*

BI have no record of any such concern being raised. We take our 'Speak Up' process very seriously and all employees have training on how to speak up, either in person or anonymously via a Speak Up portal. The Speak Up process is encouraged across the organisation and any reports are managed by the E&C department. We can confirm that we have received no such reports raised either directly via the portal or notified indirectly via another employee. We have other platforms which allow for the sharing of concerns. These include the Alliance Meeting forums, the weekly Job Bag prioritisation meetings, the bi-weekly Alliance Medical Meeting and the monthly Alliance Compliance Committee meeting. There is no record of any such concern being raised in any of these platforms, as such we refute this allegation.

4. Training

The complainant raised concerns about training in association with the PMAP specifically: *"the relevant training that employees are required to obtain, including onboarding of new starters and periodic refresher training to existing employees".*

As we have illustrated earlier in this response, all BI Alliance employees are formally allocated training on the PMAP[1] in their LOS curriculae [sic], completion of which is formally tracked in LOS. Training is provided during the onboarding period and whenever there is an update to the PMAP for all BI Alliance members. To illustrate this I have attached the timeline of training for a BI new starter to the Alliance team (this member started in their post in January 2022). As such we refute the complainant's allegation that training is not provided either as a new starter or on update of the PMAP itself.

5. Agreements outside of the PMAP

The complainant claims to have seen: *"examples of agreements outside of the PMAP between individual job originators and certifiers – if this is because there's been an update to the official PMAP that's not clear; if it is because a new best practice has been identified then the PMAP has not been amended to include that – or at least, to the best of my knowledge, it is not shared with the rest of the team."*

BI is not aware of any 'agreements outside of the PMAP'. This is an unsupported assertion as the complainant has provided no evidence of this. The PMAP is the agreed and approved process followed by all members of The Alliance. There are no other "agreements".

The complainant alludes to these agreements potentially being "new best practice" and appears to expect the PMAP to be amended to include the "best practice". The Oxford dictionary defines 'best practice' as: *'a way of doing something that is seen as a very good example of how it should be done and can be copied by other companies or organizations'*. The complainant appears to have confused 'best practice' with 'standard operating procedure'. The Alliance shares best practise amongst its members in a number of ways, however the PMAP is the approved procedure that all members follow. One example of a way in which The Alliance shares best practice is the "Alliance Compliance hot Topics" section of the monthly Alliance brand team meeting. Another example is the UKIE Alliance Compliance Committee (ACC). This is a forum for discussion between Alliance Medical and the E&C functions for topics related to the execution of activities under the scope of the Compliance Agreement between Lilly and BI. The purpose of ACC is to establish and manage a compliance framework and ensure that both partners in Alliance are supportive of planned actions and responses. Please find attached the ACC charter.

6. Concerns that Boehringer and Eli Lilly members do not have the same understanding

The complainant concludes their complaint by stating: "*While jobs might be approved to high standards thanks to each member of the team doing their best and being extra cautious, I am concerned that the Alliance is not following a standard procedure and not everyone in the team, from BI or from Lilly, has the same understanding of the PMAP requirements and confidence in acting accordingly*".

As we have demonstrated earlier in our response: there is a BI and Lilly approved PMAP SOP which is accessible to all members of the Alliance.

I have also noted how we share best practice across the Alliance- in this regard we consider the complainant's comments on this matter unsubstantiated, and we refute these allegations. Furthermore, the complainant's own thoughts on the 'high standards' of our work appears to contradict their own claims regarding understanding of the PMAP. It would not be possible for the Alliance to produce 'high standards of work' without a consistent understanding of procedures facilitated by our PMAP and training processes.

Summary

We would like to conclude by reviewing the clauses you noted in your correspondence:

5.1 (9.1) High standards must be maintained at all times.

9.1 (16.1) All relevant personnel, including representatives, and members of staff, and others retained by way of contract, concerned in any way with the preparation or approval of material or activities covered by the Code must be fully conversant with the Code and the relevant laws and regulations.

We strongly refute the complainant's unsupported allegations. Throughout this response I have provided evidence of BI's robust approaches to training and access to procedures. I therefore believe that BI has maintained high standards (Clause 5.1) and ensured that BI Alliance members have adhered to the requirements of clause 9.1. We maintain that we have not breached the Code of Practice in this respect."

ELI LILLY'S RESPONSE (Case AUTH/3780/6/23)

The response from Eli Lilly is reproduced below:

"The complaint concerns the PMAP (promotional material approval process) used within the Alliance of Boehringer Ingelheim and Lilly (the Alliance). Under the Alliance agreement between Boehringer Ingelheim and Lilly the PMAP procedure is a Boehringer Ingelheim-owned procedure signed off by Alliance representatives from both Lilly and Boehringer-Ingelheim entitled 'Circulation, Review, Approval and Certification of Promotional/Non-Promotional Materials'. The complainant has raised concerns about the accessibility of the most up to date, current, approved procedure, and the relevant training that employees are required to obtain, including onboarding of new starters and periodic refresher training to existing employees.

Lilly takes compliance very seriously and understands and fully respects the ABPI Code of Practice. Lilly strives to ensure that all its procedures are up-to-date and accessible, and all Lilly existing and new employees are regularly trained on the relevant procedures, including the PMAP process as it relates to the Alliance. We attach the PMAP procedure training slide deck, which is developed, maintained, and approved by Lilly and Boehringer Ingelheim, and the training record of Lilly employees and contractors (past and present) working in the Alliance, to this letter as evidence to our commitment to deliver robust and up-to-date training. As outlined above, the PMAP procedure is a Boehringer Ingelheim owned document and the training slide deck which includes the PMAP procedure training is based on the effective version of that procedure. The up-to-date PMAP procedure is made accessible to the relevant Lilly associates who work in the Alliance via an Alliance MS Teams channel and this is outlined to individuals during their training (slide 29) using the Boehringer Ingelheim and Lilly approved training deck. Boehringer Ingelheim, as owner of the SOP, will be providing a copy of the SOP with their response to this complaint.

With regards to clause 9.1, any signatories working in the Alliance are fully trained and notified as final signatories with respect to the ABPI Code of Practice and slides 18 onwards of the training materials clearly address specific code requirements as they pertain to the activities of the Alliance including certification requirements, hard copy sign off and disclosures. We believe this demonstrates that we strive always to ensure that individuals working within the Alliance are conversant with the Code and the relevant laws and regulations.

With regards to clause 5.1, we take our commitment to maintaining high standards with respect to the PMAP process seriously. As outlined above, we have a robust training and governance processes in place to ensure employees are trained on the PMAP process, keep record of said training, and make content accessible to all employees to ensure understanding and compliance. We believe these actions make clear our desire to always maintain high standards with our PMAP process.

Finally, we can confirm that we have no record of a concern being raised by a Lilly employee or contractor with regards to documentation of PMAP training or access to the PMAP SOP. Lilly encourages a speak up culture, and has internal processes in place for reporting concerns, including the facility to report anonymously via a third-party managed system, the Ethics and Compliance Hotline. We attach a copy of our procedure 'Speaking Up: No retaliation' which includes direction on how to report concerns."

PANEL RULING

The complainant, a former employee, made allegations about the promotional material approval process (PMAP) used within the alliance of Boehringer Ingelheim (BI) and Eli Lilly. The complainant stated that they were "concerned that the Alliance [was] not following a standard procedure and not everyone in the team, from BI or from Lilly, has the same understanding of the PMAP requirements and confidence in acting accordingly." Specifically, the complainant made allegations around the accessibility of the most up-to-date approved version of the standard operating procedure (SOP), accessibility and documentation of training, and that they had seen "examples of agreements outside of the PMAP between individual job originators and certifiers".

The Panel noted that the case preparation manager had asked the two companies to consider the requirements of Clause 5.1 (the requirement to maintain high standards) and Clause 9.1 when responding to this complaint. Clause 9.1 stated, among other things, that all relevant personnel concerned in any way with the preparation or approval of material or activities covered by the Code must be fully conversant with the Code and the relevant laws and regulations.

The Panel noted from Boehringer Ingelheim's and Eli Lilly's submissions that the relevant SOP was owned by Boehringer Ingelheim and jointly approved by both companies but that each company was responsible for ensuring training and access to the effective version for their employees.

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The Panel noted Boehringer Ingelheim's submission that the PMAP SOP was held in its Quality Management System and that Boehringer Ingelheim employees could access it either directly or via a link from its internal Legal and Compliance SharePoint site. The Panel noted Boehringer Ingelheim's submission that this would ensure that employees had reference access to the version made effective in the approved Quality Management System and employees were trained as such through individualised trainings allocated in their role-specific training plans.

Regarding the complainant's general allegation that not everyone in the team from Boehringer Ingelheim or Lilly had the same understanding of the PMAP requirements and confidence in acting accordingly, the Panel considered that the complainant bore the burden of proof and did not consider that they had provided evidence to establish their allegation on the balance of probabilities in relation to this point. It was not for the Panel to infer detailed reasons to support a complainant's allegations, therefore the Panel made no ruling in this regard.

The Panel noted the complainant's allegation that the PMAP procedure did not look like an official document and was a Word document with tracked changes and comments. The

complainant did not provide this file as part of their complaint. The Panel noted that the SOP document pdf provided as part of Boehringer Ingelheim's submission was clearly marked with an "effective date" and a watermark stating "working copy". In the Panel's view, it was clear that the SOP file was an "official document" and was clearly marked to indicate the date on which it became effective. The Panel noted Boehringer Ingelheim's submission that a working draft of the SOP had, at times, been housed in the Jardiance Brand Team Microsoft Teams folder that was also used to share the effective version of the SOP with Eli Lilly employees. The Panel noted that the complainant had the burden of proving their complaint on the balance of probabilities. All complaints were judged on the evidence provided by the parties. In the Panel's view, there was no evidence before it that the presence of the working draft Word document in the Microsoft Teams folder in addition to the current working copy of the SOP had meant that employees were not following the standard procedure.

The complainant alleged that they had "seen examples of agreements outside of the PMAP between individual job originators and certifiers" but the Panel noted that they had not provided any evidence in this regard.

The Panel noted the complainant's allegations regarding training on the PMAP SOP for new starters, periodic refresher training for existing employees, and their request for "a proper document" and this training to be documented. The Panel noted Boehringer Ingelheim's submission that new starters were allocated a role-specific training curriculum within the company's learning system and that these learning assignments and periodic learning assignments (that might be triggered, for example, by updates to SOPs) were assigned to employees via the system throughout the year. The Panel noted the report provided by Boehringer Ingelheim that showed employees who had completed the training relating to the PMAP SOP and Boehringer Ingelheim's submission that all their employees working in the alliance were allocated PMAP-related training. The Panel noted the non-specific nature of the complainant's allegation regarding the accessibility of training. It was not for the Panel to infer reasons on behalf of the complainant.

There was no evidence before the Panel that the complainant had raised their concerns about either the SOP document or the recording of training directly with Boehringer Ingelheim.

The Panel noted its comments above relating to each element of the complaint. The Panel did not consider that the complainant had established their case on the balance of probabilities. The Panel did not consider that Boehringer Ingelheim had failed to ensure that all relevant personnel were fully conversant with the Code, and the Panel ruled **no breach of Clause 9.1**. Having noted Boehringer Ingelheim's submission that the up-to-date SOP was made available to employees through its Quality Management System and that all relevant employees were trained on the SOP upon joining the company and received periodic training where relevant, the Panel did not consider that Boehringer Ingelheim had failed to maintain high standards in this regard. The Panel ruled **no breach of Clause 5.1**.

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The Panel noted Eli Lilly's submission that the PMAP procedure used within the alliance was owned by Boehringer Ingelheim and signed off by representatives from both companies. Eli Lilly submitted that the up-to-date procedure was made available to relevant Eli Lilly employees via a relevant Microsoft Teams channel.

Regarding the complainant's general allegation that not everyone in the team from Boehringer Ingelheim or Lilly had the same understanding of the PMAP requirements and confidence in acting accordingly, the Panel considered that the complainant bore the burden of proof and did not consider that they had provided evidence to establish their allegation on the balance of probabilities in relation to this point. It was not for the Panel to infer detailed reasons to support a complainant's allegations, therefore the Panel made no ruling in this regard.

The Panel noted the complainant's allegation that the PMAP procedure did not look like an official document and was a Word document with tracked changes and comments. The complainant did not provide this file as part of their complaint. The Panel noted its comments on this matter in relation to Case AUTH/3779/6/23. There was no additional evidence before the Panel on this matter.

The complainant alleged that they had "seen examples of agreements outside of the PMAP between individual job originators and certifiers" but the Panel noted that they had not provided any evidence in this regard.

The Panel noted the complainant's allegations regarding training on the PMAP SOP for new starters, periodic refresher training for existing employees, and their request for "a proper document" and this training to be documented. The Panel noted the training slides, which included information about the PMAP and stated that the Alliance Microsoft Teams channels were used to share Boehringer Ingelheim policies and procedures with Eli Lilly staff working within the alliance and that the PMAP document was in the Jardiance Brand Team folder, provided as part of Eli Lilly's submission. The Panel noted that Eli Lilly had provided a list of staff who had completed this training. The Panel also noted Eli Lilly's submission that any signatories working in the alliance were fully trained with respect to the Code. The Panel noted the non-specific nature of the complainant's allegation regarding the accessibility of training. It was not for the Panel to infer reasons on behalf of the complainant.

There was no evidence before the Panel that the complainant had raised their concerns about either the SOP document or the recording of training directly with Eli Lilly.

The Panel noted its comments above relating to each element of the complaint. The Panel did not consider that the complainant had established their case on the balance of probabilities. The Panel queried what procedures were in place to ensure that the most up-to-date version of the PMAP SOP was made available to Eli Lilly employees, in the Jardiance Brand Team folder in MS Teams, following updates to the SOP in the Boehringer Ingelheim quality management system, however Eli Lilly made no submission in this regard. Nonetheless, the Panel noted Eli Lilly's submission that the up-to-date PMAP SOP was made accessible to relevant Eli Lilly employees who worked in the Alliance through an Alliance Microsoft Teams channel and that Eli Lilly provided relevant training on the procedure and related Code requirements. Based on the information before it, the Panel did not consider that Eli Lilly had failed to maintain high standards in this regard or that it had failed to ensure that all relevant personnel were fully conversant with the Code, and the Panel ruled **no breaches of Clauses 5.1 and 9.1**, accordingly.

Complaint received **19 June 2023**

Case completed **21 August 2024**