CASE/0216/06/24

ROCHE v BAYER

Allegations about promotion ahead of marketing authorisation

CASE SUMMARY

This intercompany complaint related to a meeting at which a US-based named speaker, whose attendance was sponsored by Bayer, delivered two presentations on age-related macular degeneration (AMD). Roche alleged that Bayer's sponsorship was not strictly arm's length as it had prior knowledge of the likely content of the presentations, which included discussion of Eylea (aflibercept 8mg), an unlicensed product in the UK at that time and that the circumstances, including the presence of representatives at the event, amounted to pre-licence and/or disguised promotion.

There was an appeal by Bayer of the Panel's three breach rulings.

The outcome under the 2021 Code was:

Breach of Clause 2 [Panel's breach ruling upheld at appeal]	**Bringing discredit upon, and reducing confidence in, the pharmaceutical industry**
Breach of Clause 3.1 [Panel's breach ruling upheld at appeal]	**Promoting a medicine prior to the grant of its marketing authorisation**
Breach of Clause 5.1 [Panel's breach ruling upheld at appeal]	**Failing to maintain high standards**

No Breach of Clause 3.6	**Requirement that materials and activities must not be disguised promotion**
No Breach of Clause 17.2	**Requirement that representatives must maintain high standards of ethical conduct in the discharge of their duties and comply with all relevant requirements of the Code**

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 Roche Products Ltd about Bayer plc.

COMPLAINT

The complaint wording is reproduced below:

> "Following unsuccessful ICD between companies, Roche is seeking PMCPA adjudication to ensure appropriate resolution of the above. A copy of correspondence exchanged between Roche and Bayer during ICD is attached for your reference in addition to Roche's summary below
>
> **Background**
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> On [date] 2023, Roche and Bayer were both in attendance at the [named event]. Both companies had received requests for sponsorship from [named professor], the HCP organising the event, and as part of Bayer's sponsorship financial provisions had been made specifically to support a speaker from the USA, [named speaker], to provide two presentations on the following topics:
>
> 'Is 16 weeks dosing the new expectation in AMD? Experience with emerging therapies. [Named speaker], [US organisation] – with sponsorship from Bayer.'
>
> 'Managing side effects of emerging therapies for AMD. [name speaker]'
>
> At the time of the presentation, Bayer had UK marketing authorisation for 2mg aflibercept (received in 2012) and Roche had UK marketing authorisation for faricimab (received 2022), both of which are licensed for the treatment of AMD. Bayer had a higher dose (8mg) formulation of aflibercept, with a 16-week dosing regime, licensed in the US for the treatment of AMD, with marketing authorisation expected imminently in the UK. Dosing schedules for all three therapies are outlined in the respective SPCs, with extracts provided in the Appendix of this letter.
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> It is worth noting the relevance of the speaker being from the USA is that the difference between the UK and USA AMD treatment landscapes at the time of the presentation was the 8mg aflibercept formulation had a marketing authorisation in the USA but not in the UK.
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> The first presentation at [named event] by the Bayer sponsored speaker included detailed study results from the pivotal unlicensed 8mg aflibercept clinical trial. The second presentation also referenced the unlicensed 8mg aflibercept formulation and contained comparative claims about the unlicensed 8mg aflibercept formulation in relation to other licensed anti-VEGF medicines and the licensed 2mg aflibercept formulation.
>
> In both these presentations, the only emerging therapy mentioned was aflibercept 8mg, since the other therapies were licensed. The following disclaimer '[named speaker's] attendance has been supported through Bayer sponsorship of the [named event]. Bayer has had no input to the content of [named speaker's] presentation' was present adjacent to each of the two topics on the agenda.
>
> Photographic evidence of the slides in question are included for the panel's information.
>
> For further context, please note that, during the sponsored speaker's presentations, promotional representatives from Bayer were present in the room.

Bayer subsequently received UK marketing authorisation for 8mg aflibercept in January 2024.

Roche complaint

As part of ICD Roche requested copies of correspondence between Bayer and [named professor] as well as any associated representatives briefing materials.

On review of the documentation, it became apparent that both Roche and Bayer had received requests for sponsorship from the meeting organiser, which included a copy of the draft [named event] agenda. Within this programme, the presentation titles for [named speaker] were included, 'Is 16 weeks dosing the new expectation in AMD? Experience with emerging therapies. [Named speaker], [US organisation] – with sponsorship from Bayer.' and 'Managing side effects of emerging therapies for AMD. [named speaker]'.

Roche considers it implausible that Bayer would not have reviewed this programme as part of their due diligence process for provision of sponsorship and therefore had clear visibility of these presentation titles. Roche notes once again that at the time the only **emerging** therapy with a standard 16w dosing interval was the unlicensed 8mg aflibercept formulation. Given this, Roche considers the following statement (made in Bayer's response letter 16th Feb) disingenuous:

'….we now repeat a clear and unequivocal denial that Bayer had prior knowledge of the content of either of [named speaker's] presentations at the [named event] last December'

Roche's fundamental concern is that Bayer considers it appropriate to provide sponsorship specifically for a speaker session, of which they had clear visibility of the presentation titles that would no doubt contain information about their product that did not have marketing authorisation in the UK, irrespective of an arm's length arrangement and appropriate disclaimers in place. In addition to this, they had a promotional presence at the meeting in the form of representatives being in the room during the sponsored sessions. This coincides with anticipated marketing authorisation of the 8mg formulation being expected imminently.

Considering the above, Roche believes this activity is pre-license and/or disguised promotion of the 8mg formulation of aflibercept and as such, Roche would consider Clauses 3.1, 3.6, 17.2, 5.1 and 2 of the Code to be in breach. Given the seriousness of the allegations, and that we have failed to resolve the issues successfully through inter-company dialogue, Roche welcomes the PMCPA's consideration of this matter.

Appendix (Extracts from SPCs)

a. Extract from aflibercept 2mg SPC for the treatment of AMD

wet AMD

The recommended dose for Eylea is 2 mg aflibercept, equivalent to 0.05 mL.

Eylea treatment is initiated with one injection per month for three consecutive doses. The treatment interval is then extended to two months.

Based on the physician's judgement of visual and/or anatomic outcomes, the treatment interval may be maintained at two months or further extended using a treat-and-extend dosing regimen, where injection intervals are increased in 2- or 4-weekly increments to maintain stable visual and/or anatomic outcomes. If visual and/or anatomic outcomes deteriorate, the treatment interval should be shortened accordingly.

There is no requirement for monitoring between injections. Based on the physician's judgement the schedule of monitoring visits may be more frequent than the injection visits.

Treatment intervals greater than four months or shorter than 4 weeks between injections have not been studied (see section 5.1).

b. Extract from faricimab SPC for the treatment for AMD

The recommended dose for Vabysmo is 6 mg (0.05 mL solution) administered by intravitreal injection every 4 weeks for the first 4 doses.

Thereafter, treatment may be individualised using a treat-and-extend approach following an assessment of the individual patient's anatomic and visual outcomes. The dosing interval may be extended up to every 16 weeks, and extensions in increments of up to 4 weeks should be considered, based on the physician's judgement of the individual patient's anatomic and/or visual outcomes. If anatomic and/or visual outcomes change, the treatment interval should be adjusted accordingly, and interval reductions of up to 8 weeks may be implemented if deemed necessary (see section 5.1). Treatment intervals shorter than 21 days between injections have not been studied.

Monitoring between the dosing visits should be scheduled based on the patient's status and at the physician's discretion, but there is no requirement for monthly monitoring between injections.

c. Extract from now licensed 8mg aflibercept SPC for the treatment of AMD

The recommended dose is 8 mg aflibercept, equivalent to 0.07 ml solution. The posology is the same for the nAMD and DMO indications. The 8 mg dose requires use of the Eylea 114.3 mg/ml vial.

Eylea treatment is initiated with 1 injection per month for 3 consecutive doses. Injection intervals may then be extended up to every 4 months based on the physician's judgement of visual and/or anatomic outcomes. Subsequently, the treatment intervals may be further extended up to 5 months, such as with a treat-and-extend dosing regimen, while maintaining stable visual and/or anatomic outcomes (see section 5.1).

If visual and/or anatomic outcomes deteriorate, the treatment interval should be shortened accordingly based on the physician's discretion. The shortest interval between 2 injections is 2 months in the maintenance phase.

Eylea at monthly doses of 8 mg has not been studied for more than 3 consecutive doses."

When writing to Bayer, the PMCPA asked it to consider the requirements of Clauses 17.2, 5.1, 3.6, 3.1 and 2 of the 2021 Code.

BAYER'S RESPONSE

The response from Bayer is reproduced below:

> "Thank you for your email dated 24 June 2024, in which you notify us of a complaint to the PMCPA ('Complaint') from Roche, alleging breaches of Clauses 3.1, 3.6, 17.2, 5.1 and 2 the 2021 UK APBI Code of Practice ('the Code').
>
> Bayer takes its responsibility to comply with the Code and to maintain high standards extremely seriously. Bayer does not accept the allegations from Roche that the arrangements for arm's length sponsorship of [named speaker's] talk at the [named event] on [date] 2023 were in breach of Clauses 3.1, 3.6, 17.2, 5.1 or 2 of the Code.
>
> Before addressing the complaint, Bayer would like to raise the issue of Roche's repeated failure to comply with normal conventions and standards of ICD in this case, including PMCPA guidance on ICD and Paragraph 5.3 of the PMCPA Constitution and Procedure. Transparency, fairness and consistency in ICD are the cornerstones of pharmaceutical industry self-regulation. It is also a long-established principle that, during ICD, companies should treat each other with respect and without disparagement.
>
> It is the view of Bayer that any failure to adhere to these principles is a failure to meet the high standards required by the Code. Failure to maintain high standards in ICD may serve to discredit and reduce confidence in the pharmaceutical industry and its ability to self-regulate.
>
> **Conduct of Intercompany dialogue by Roche**
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> Guidance provided by the PMPCA on conduct of inter-company complaints states that it is important to comply with both the letter and the spirit of Paragraph 5.3 of the PMCPA Constitution and Procedure in this regard. It further states that if these requirements are not satisfied, the Director will so advise the complainant company and the complaint will not proceed.
>
> Roche has requested arbitration of this matter from the PMCPA following what it perceives as a failure of intercompany dialogue (ICD) to reach resolution. However, it is Bayer's position that **Roche offered a verbal resolution of this complaint to Bayer** at the face-to-face meeting of senior company personnel held at [location] on 2 May 2024, which was subsequently withdrawn without adequate explanation.
>
> Roche has also failed to comply with the requirements of Paragraph 5.3 of the PMCPA Constitution and Procedure, and related guidance, through its **failure to provide a complete record of ICD to the PMCPA**.
>
> [Enclosure provided] summarises the progress of ICD in this case over a 6 month period from 19 December 2023 to 17 June 2024. Bayer has a number of significant concerns

regarding the way in which Roche has conducted ICD and does not believe that the requirements of Paragraph 5.3 have been met. To summarise:

1. **Withdrawn offer of resolution:** Roche offered a verbal resolution of this complaint to Bayer at a face-to-face meeting of senior company personnel held at [location] on 2 May 2024, which was subsequently withdrawn by Roche without adequate explanation.
2. **Failure to provide a complete record of ICD to the PMCPA:** the record of ICD provided by Roche does not contain *'all ICD letters between Roche and Bayer'* as stated in the title of the merged pdf file provided by Roche. Two important documents are missing . As far as Bayer is aware, Roche has not provided these documents to the PMCPA subsequent to their letter to the PMCPA of 6 June 2024.
3. **Disparagement of Bayer during ICD:** during the ICD process, Roche made false and disparaging allegations against Bayer in its letter to Bayer dated 28 March 2024 (of deliberate document falsification), of such gravity that a formal apology was offered by Roche and accepted by Bayer at the meeting on 2 May.
4. **Repeated failure to comply with normal conventions and standards of ICD, including PMCPA guidance on ICD.** Specifically:
    a. Roche submitted its complaint to the PMCPA on 6 June, after Roche had indicated to Bayer on 3 June its probable intention to request 'adjudication' from the PMCPA, but before notifying Bayer (on 17 June) that ICD had been formally concluded and confirming that a complaint had been submitted. Escalation to PMCPA took place on 6 June without Bayer being offered the opportunity to respond to Roche's comments on the draft minutes of the 2 May meeting.
    b. Repeated introduction of new complaints, unrelated to the original complaint and unsupported by evidence, into ICD . This was also a feature of ICD with Roche in the ongoing Case AUTH/3764/4/23 Bayer vs Roche, as described in the Bayer letter to PMCPA, 25 April 2023.
    c. Making multiple and constantly evolving allegations against Bayer, often with lack of clarity as to the basis for the alleged breaches of specific Code clauses and whether or not individual allegations raised had been satisfactorily resolved. The importance of consistency in Code allegations is highlighted in PMCPA guidance on ICD
    d. In the course of this ICD, Roche has repeatedly demanded access to materials going above and beyond the requirements of ICD, some of which have been provided by Bayer in an effort to reassure Roche.

Points (1) and (2) above are of particular gravity and merit further detail.

1. Withdrawn offer of resolution in ICD

Over a 6 month period, Bayer has made every effort to bring this matter to an amicable conclusion within ICD, including organisation of a 2-hour face-to-face meeting attended by [employees] from Bayer, and [employees] from Roche. This meeting was held at [location] in London on 2 May 2024.

Bayer had left the meeting with Roche on 2 May in the genuine belief the complaint had been resolved following lengthy discussion between senior members of both companies,

and that the meeting had been constructive and helpful to improve the mutual understanding between our companies.

However, in an email dated 7 May, Roche implied indirectly that the offer of resolution made on 2 May at the meeting had been rescinded, stating that *'all options'* remained open. This U-turn was confirmed in a telephone conversation between Roche and Bayer UK Medical Directors on 10 May. During this telephone conversation it was explained to Bayer that Roche had changed its position on resolution due to *'internal realignment'* following the meeting with Bayer; no further justification was provided.

We reiterate our sentiment that this sudden and unexpected change in Roche's position, without clear explanation and followed by rapid escalation of the complaint to the PMPCA, before ICD was completed , is not in the spirit of constructive ICD and does not meet the requirements of Paragraph 5.3 of the Constitution and Procedure. Accordingly, the previous verbal statement of settlement by Roche made on 2 May should be considered to stand and the complaint should be rejected.

2. Failure to provide a complete record of ICD to the PMCPA

We would refer you to [copy provided] as this provides a summary of the ICD timeline, all relevant exchanges between Bayer and Roche and a table summarising how allegations of specific breaches evolved during ICD. As far as Bayer is aware from the documents provided in 0216/06/24, Roche has apparently failed to share with the PMCPA two critical documents, namely:

1. **A letter from Bayer to Roche dated 12 June 2024** , written in response to Roche's letter to Bayer of 3 June. In its letter of 3 June, Roche made amendments to the draft minutes of the meeting between Bayer and Roche held on 2 May and detailed new allegations against Bayer unrelated to the current complaint and unsupported by evidence. Bayer refutes that these amendments are accurate and that they provide a complete record of the discussions on 2 May. It appears that Roche has sent the PMCPA their letter of 3 June with amendments to the draft meeting minutes, including these disputed additions, but not Bayer's letter of 12 June containing important corrections to and concerns with Roche's version of the minutes.
2. **An email from Roche to Bayer dated 17 June 2024**, responding to our letter of 12 June and stating formally that ICD between our companies is now closed. This email also confirms escalation of the complaint to the PMCPA. ICD was therefore formally closed between our companies 11 days after Roche had escalated the complaint.

Bayer now includes these documents to complete the ICD record.

It is the view of Bayer that Roche should have provided the PMCPA with the further correspondence between Bayer and Roche, even if these occurred after their letter to the PMCPA of 6 June, in order to ensure the record of ICD was fair, transparent and complete in accordance with PMCPA Guidance on ICD and the complaints procedure. There was sufficient time for Roche to do so between Roche's receipt of Bayer's letter on 12 June and the PMCPA contacting Bayer on 24 June.

Given all the above, in particular the verbal offer of settlement of the complaint that was freely offered by Roche at the in-person meeting with Bayer on 2 May, but subsequently withdrawn by Roche, Bayer contends that the requirements of Paragraph 5.3 of the PMCPA Constitution and Procedure have not been met. Bayer therefore respectfully asks the PMCPA to consider that this complaint does not merit escalation to the Panel.

Bayer response to the complaint Case 0216/06/24

Notwithstanding that the complaint raised by Roche in Case 0216/06/24 had been settled at an intercompany level and therefore Bayer asserts it does not merit escalation to the PMCPA and consideration by the Panel, Bayer would like to provide its response to the allegations made by Roche.

Background to Bayer sponsorship of the [named event] Winter Meeting, [date] 2023.

Bayer received a letter from [named professor] on 26 October 2023 , an eminent UK specialist in ophthalmology of both national and international repute, enquiring whether Bayer UK would support attendance of a specific expert speaker, [named speaker], at the [named event] , which was to be held at the [name of venue] on [date] 2023. We confirm the request was unsolicited.

Bayer considered the request from [named event] for [named speaker's] attendance as speaker to be well-justified on educational grounds. [Named speaker] [US organisation] is a world-renowned Medical and Surgical Retina Specialist, an advisor to [organisation] and an eminent clinical trial specialist with over 300 publications and many awards to [their] name. [Named speaker]and [their] colleagues at [US organisation] have between them led, participated in and co-authored the vast majority of pivotal studies of all available intravitreal anti-VEGF therapies and it was therefore unsurprising that the [named event] considered [them] to be ideally placed to give a balanced and authoritative overview of current expert opinion to their attendees.

The letter contained a provisional copy of the [named event] agenda, which Bayer reviewed to determine that the overall meeting content was of significant educational value to a health professional audience and thus suitable for Bayer sponsorship. Presentation titles included in the provisional agenda, including [named speaker's], were not considered to be final.

In [their] letter, [named professor] writes the following:

'I would be most grateful if Bayer would consider sponsoring the event at a platinum level by offering [£ amount] to the organisation. Bayer would have exhibitor stand at the meeting.

We would use this support in part to bring a USA speaker, [*named speaker], to the meeting to share [their] experience. Bayer would have no input or control to the content of [their] presentations, however. Sharing of such education and experience by world leaders is invaluable to our community who look to such thought leaders to enable advancement of patient care in the UK.'*

The PMCPA explicitly allows for 'arm's length' arrangements whereby, for example, a pharmaceutical company can sponsor *'material produced by an independent organisation which mentions its own products and not be liable under the Code for its contents, but only if, inter alia, there has been a strictly arm's length arrangement between the parties'*

Bayer is confident that the arrangement with [named event] met the terms of this PMCPA guidance. Such arm's length sponsorship must be declared in a transparent manner, but the sponsoring company does not carry responsibility for the contents of the meeting unless there has been company influence upon it. The intended independence of [named speaker's] presentation content is made clear in the request from [named professor] to Bayer, by the terms of the Declaration of Transparency of Sponsorship accepted by [named professor] on behalf of [named event] as a condition of Bayer sponsorship and was acknowledged plainly for all meeting attendees via display of the declaration agreed between Bayer and [named event], as Roche accepted in ICD, stating in their letter to Bayer of 19 December 2023 that *'There is a clear disclosure statement….'* regarding the sponsorship arrangements between Bayer and [named event] visible at the meeting.

[Paragraphs removed due to confidentiality]

Roche has stated that it believes Bayer had prior knowledge of the content of [named speaker's] presentations, but provides no evidence to support this allegation beyond its opinion of the provisional [named event] agenda, specifically the terms *'emerging therapies'* and *'16-week intervals'*, which Roche interprets as relating solely to aflibercept 8mg.

In response to this, Bayer would like to point out that aflibercept 2mg (EYLEA 40mg/mL, Bayer) and faricimab (Vabysmo, Roche) are both anti-vascular endothelial growth factor drugs (anti-VEGFs), licensed for a maximum 16 week (4 month) extension of therapy intervals as part of a treat-and-extend regimen in neovascular age-related macular degeneration (nAMD) and vision impairment due to diabetic macular oedema (DMO), and were so licensed in the UK at the time of the meeting. Other licensed drug therapies, namely ranbizimab (Lucentis, Novartis and a number of newly available branded ranibizumab biosimilars) and brolucizumab (Beovu, Novartis) can also be used on-label at 16 week intervals in nAMD and DMO.

It is also relevant that Bayer in the UK does not consider aflibercept 8mg (EYLEA 114.3mg/mL) to be a '16 week' therapy in either nAMD or DMO, as whilst it can be used on-label at any interval from 8 weeks up to 20 weeks after the initial monthly loading period, it is unique amongst anti-VEGF therapies in being licensed to extend up to 20 weeks (5 months) as part of a treat-and-extend regimen . Bayer considers the capability to extend to 20 weeks on-label to be a critical differentiator of aflibercept 8mg from other anti-VEGF treatments in the UK, all of which have licensed posologies and clinical trial experience limited to extensions of 16 weeks, such as aflibercept 2mg or faricimab.

The term 'emerging therapies' is ill-defined, and may include investigational products, newly launched products and/or products such as Roche's faricimab which at the time of the [named event] meeting in December 2023 had been available in the US for less than 2 years, hence real world data on longer treatment intervals up to 16 weeks were still emerging. Other long-acting anti-VEGF therapies (such as port delivery systems or conbercept, a recombinant fusion protein expected to have a posology similar to

aflibercept 2mg) are also either already licensed and available in some countries or undergoing late stage clinical trials.

The detailed content of [named speaker's] presentations therefore could not reasonably be determined by terms such as *'16 weeks'* and *'emerging'* in the presentation titles in the provisional agenda alone. Furthermore, as the sponsorship from Bayer was 'arm's length', [named speaker] and the [named event] would have had complete freedom to change the provisional titles and contents of [their] talks, without reference to Bayer, at any point. Roche's assertion that Bayer could have had *'no doubt'* of the talks' content is therefore false and without evidence to support it. Indeed, had Bayer insisted that sponsorship of [named speaker's] presence at the [named event] was contingent on delivery of presentations with specific agreed titles, the sponsorship would not have met the requirements of the PMCPA guidance on arms' length arrangements.

As already stated to Roche in ICD, Bayer agreed to the terms set out in [named professor's] letter of 26 October and, in line with Clause 10.9 of the Code, a Declaration of Transparency of Sponsorship was agreed between Bayer and on behalf of the [named event]. [Named professor] accepted the sponsorship under the terms that Bayer would have no input to the content of [named speaker's] presentation, and on condition that the following statement appears at the meeting *'[named speaker's] attendance has been supported through Bayer sponsorship of the [named event]. Bayer has had no input to the content of [named speaker's] presentation.'*

Bayer had no part in organising [named speaker's] travel to the meeting nor any other aspects of their stay in the UK for this purpose. The total sponsorship was paid to [named event] via a single invoice for the full amount, and it was [named event] that made all the arrangements. The invoice simply states this was a meeting sponsorship, there were no further requirements placed upon [named event] by Bayer other than agreeing to the Declaration of Transparency of Sponsorship.

All arrangements with [named speaker] relating to [their] presence at [named event], the title of [their] presentation and any discussions regarding the content of [their] talk, were handled by [named professor] and [named event] wholly independently of Bayer. Bayer had no contact whatsoever with [named speaker] on this matter. Furthermore, at no time did Bayer enter into any agreement with [named professor], nor any other person involved in organising the meeting, either formally or informally, to ensure aflibercept (either 2mg or 8mg) was mentioned in [named speaker's] talk.

[Named professor] formally accepted the sponsorship from Bayer on this basis and the conditions of the sponsorship were made clear to all attendees. Bayer was supporting attendance by a particular expert speaker, [named speaker], at the [named event], on a strictly arms' length basis, not supporting the delivery by [named speaker] of any specific content.

Presence of Bayer sales personnel at the [named event]

Roche states that Bayer had *'a promotional presence at the meeting in the form of representatives being in the room during the sponsored sessions'.* Bayer can confirm that two Bayer sales representatives were present in the room during the sponsored sessions, together with one other member of Bayer staff. It should be noted that at the time of the

[named event], Bayer already had a formulation of aflibercept (aflibercept 2mg, Eylea 40 mg/mL) licensed and available in the UK in two presentations (vial and pre-filled syringe) for use in a number of indications in medical retina.

It is common practice for company personnel (commercial and medical) to attend educational sessions at third-party events where there are sponsorship arrangements with pharmaceutical companies in place. Indeed, at the [named event] on [date] 2023, all three Roche [named event] attendees, including the Roche promotional representative, also attended all the educational sessions.

Bayer had no prior knowledge that references to aflibercept 8mg would be included in [named speaker's] presentations at [named event]. To provide relevant context to Roche's comment concerning the presence of Bayer staff when [named speaker] was speaking, the staff in question were sitting in a room with around 150 other people and it would have caused considerable disturbance and disrespect to the speaker and the audience to have stood up and left the room in the middle of a presentation as soon as aflibercept 8mg was mentioned. Bayer therefore do not accept Roche's allegation that the actions of the Bayer sales representative at [named event] were in breach of Clause 17.2 of the Code.

Like all Bayer staff, Bayer sales representatives are fully trained on the Code, including the importance of promoting Bayer products only within the terms of their marketing authorisations. All sales representative training and briefing on aflibercept 8mg has been appropriately certified and includes clear and prominent instructions not to discuss aflibercept 8mg proactively with customers outside the terms of its marketing authorisation, and to refer any unsolicited off-label customer enquiries (including any enquiries prior to grant of marketing authorisation in the UK) to Bayer medical for response. Bayer refutes any suggestion by Roche that Bayer sales representatives have promoted or discussed aflibercept 8mg prior to its marketing authorisation, at the [named event] or elsewhere, and Roche has failed to provide any evidence that this has occurred.

Bayer notes the PMCPA request for a copy of any briefing provided by Bayer to sales personnel attending [named event]. For the [named event], Bayer did not believe that a specific sales briefing document was required for this meeting and thus we do not have one to share. Bayer's understanding is that it is not a Code requirement for all sales representatives to have a specific certified briefing for every meeting they attend in a promotional capacity.

We note that despite making an allegation of a breach of clause 17.2 of the Code, Roche has not made any specific allegation of off label promotion or other wrongdoing by the Bayer sales representatives at [named event], other than Roche's belief that their physical presence in the meeting room during [named speaker's] presentations was improper. Roche has not made any accusation to the PMCPA that Bayer staff were engaged in off-label discussions with health professionals at [named event], nor provided any evidence of off-label promotion by Bayer sales representatives at [named event] or elsewhere. Bayer therefore denies that any breach of clause 17.2 has occurred.

Bayer also notes the PMCPA request for a copy of the presentations/material at issue together with details as to how the material was used, and a copy of the certificate approving the material in question. Bayer does not and has never had copies of [named

speaker's] presentations at [named event]. This material has never been reviewed by Bayer and has not been certified by Bayer.

A copy of the Bayer UK Standard Operating Procedure relating to provision of sponsorship is attached as requested.

Conclusion

Conduct of ICD and appropriateness of PMCPA escalation

- Bayer has made significant efforts to resolve Roche's complaint via ICD over a 6 month period, during an ICD process which Bayer contends did not adhere to the requirements of the PMCPA in several respects. Indeed, at a meeting of senior Roche and Bayer personnel on 2 May, both parties had agreed that the complaint was satisfactorily resolved.
- Subsequently, Roche informed Bayer that an *'internal realignment'* had occurred and the complaint would consequently be passed to the PMCPA. This escalation occurred on 6 June, before Bayer had been given the opportunity to respond to significant amendments, including new and unsubstantiated allegations, made by Roche on 3 June to the draft minutes of the 2 May meeting between our companies. Escalation also occured before ICD was formally closed by Roche on 17 June. Copies of **all** relevant ICD documents have not, as far as Bayer is aware, been provided to the PMCPA by Roche.
- Bayer therefore contends that the requirements of Paragraph 5.3 of the PMCPA Constitution and Procedure have not been met. Accordingly, the previous verbal statement of settlement by Roche made on 2 May should stand and we respectfully request that the complaint should be rejected.

Allegations re: Bayer activities at [named event], [date] 2023

- Bayer fundamentally disagrees with Roche's assertion that it had prior knowledge of the content of [named speaker's]presentation, and specifically that it would contain information on aflibercept 8mg, which at the time was unlicensed.
- Bayer's support of the [named event] was provided on an arm's length basis in line with PMCPA guidance and the Code, based on a provisional agenda provided by the meeting organiser. Bayer had no prior knowledge or control over the content of [named speaker's] presentations. Indeed, Roche has not provided any evidence in support of its assertion that Bayer had such prior knowledge.
- Bayer refutes any suggestion by Roche that Bayer sales representatives have promoted or discussed aflibercept 8mg prior to its marketing authorisation, at the [named event]or elsewhere and, again, Roche has failed to provide any evidence that this has occurred.

Bayer therefore denies any breach of clauses 3.1, 3.6, 5.1, 17.2 or clause 2 of the Code.

Bayer PLC is committed to upholding the requirements of the ABPI Code of Practice. We hope our response addresses your concerns accordingly and look forward to your response in due course."

FURTHER RESPONSE FROM BAYER

Further information from Bayer was received on 30 June 2025 as follows:

> "Thank you for your email of 23 June 2025 requesting further information from Bayer in relation to the complaint in Case 0216 concerning a presentation which occurred at the [named event] held in [location] on [date]. We are pleased to provide the information you requested, together with some additional explanatory context. Some materials have been redacted to remove email addresses and telephone numbers, and also to remove names of individuals not already shared with the PMCPA. We would be grateful if the internal communications are treated in confidence and are not shared with Roche.
>
> 1. *A dated copy of the email and enclosed draft agenda that was initially received by Bayer*:
>   - Enclosure 1a is the initial email to Bayer with attached sponsorship request and draft agenda, sent by [named professor] jointly to a member of the Bayer ophthalmology sales team and the Bayer [Senior employee] on 23 October 2023. You will note that this email has been forwarded from the sales representative concerned to their line manager on 23 June 2025 following the PMCPA request for further information from Bayer. The [Senior employee] in copy to the original is no longer with Bayer.
>   - Enclosure 1b was an attachment to enclosure 1a and is the original sponsorship request to Bayer, dated 23 October 2023. This document was not provided to the PMCPA in our original response of 9 July 2024 as it contained a typographical error which [named professor] subsequently corrected during correspondence with the Bayer medical department (see below and enclosures 2a and 2b for details of this). Enclosure 2b is considered by Bayer to be the sponsorship request on the basis of which the sponsorship was approved and has previously been provided to the PMCPA.
>   - Enclosure 1c is the draft agenda originally attached to the email of 1a alongside enclosure 1b.
>
> 2. *Any other relevant email correspondence between Bayer and [named event] relating to the meeting at issue*;
>   - Enclosure 2a is an email thread between [named professor] and a senior member of the Bayer medical department, occurring between 25 and 30 October 2023. Enclosure 1b was attached to the first email in the thread (dated 25 October) but not the draft agenda [1c]. You will note that a typographical error in the original letter [1b], which changed the meaning of the sentence, was spotted by Bayer and corrected by [named professor]; the declaration of sponsorship wording was also agreed during this exchange.
>   - Enclosue [sic] 2b is the revised letter requesting sponsorship, dated 26 October 2023, with the typographical error corrected. This was sent to Bayer on 27 October 2023 as part of this email thread [2a]. This document was previously provided to the PMCPA in Bayer's original response of 9 July 2024.
>   - To the best of our knowledge, there was no other email correspondence on this topic between Bayer and [named professor] or Bayer and other [named event] organisers, other than presumably cover emails for sending the sponsorship agreement etc. These latter were probably sent by Bayer

administration functions and would not have touched upon details of meeting content.

3. *A copy of the certified concept document and sponsorship agreement*

    - Enclosure 3a (sponsorship agreement) has already been provided in our original response to the PMCPA of 9 July 2024. This agreement acted as the concept document in this case. There is no other concept document.

    - The arrangements for this meeting were approved as a sales force sponsorship meeting in line with the requirements of Clause 10.1 of the Code. The Veeva CRM system process flow is started by the sales representative (key account manager), who will create and submit an event, with information including, name, timings, sub-type and product. They will include a summary of the meeting, including Bayer's proposed involvement, and estimated associated expenses with a breakdown of the expense type. The details of the event and proposed expenses are reviewed by a manager, who will accept or reject the meeting. For a sponsored meeting such as this one, there are additional requirements of the 3rd party sponsorship request, a declaration and transparency of sponsorship letter must be attached once sponsorship is agreed, and the 3rd party materials, such as the agenda with appropriate Bayer declaration of involvement, submitted no less than 2 weeks before the event. Subsequent to the event, an actual attendance report must be submitted into the same event, which is why the last edit is after the occurrence of the event. This is to capture the cost per head for each meeting to ensure compliance with SOPs and ABPI code.

4. *Confirmation of whether and how health professionals had been directed to the session at issue by Bayer*;
    - I am pleased to confirm that Bayer did not request any of its staff to invite any delegates to [named event], as invitations to this meeting were wholly the responsibility of the meeting organisers. Nor did Bayer or its sales representatives or other staff, whether in attendance at the [named event] or not, suggest or advise delegates attending the [named event] to attend to [named speaker's] session.

5. *Any communications, such as by email, to stand personnel and sales representatives that were to be present at the [named event] at issue*.
    - I can confirm that there were no specific instructions to Bayer staff attending the [named event] at issue, whether sent by email or otherwise. As already demonstrated, Bayer provided "hands off" sponsorship towards conduct of this UK academic meeting, including the cost of [named speaker] attending as speaker. The sponsorship included the benefit to Bayer of having a promotional stand at the meeting and allowed the presence of some Bayer personnel, including sales personnel, at the meeting. There was no other Bayer input to meeting conduct or content. As such, no meeting-specific briefing document was provided for Bayer attendees but, as with any external meeting attended by our sales team, Bayer expects all its sales representatives to deport themselves at all times according to the requirements of the ABPI Code of Practice"

PANEL RULING

This case was escalated to the PMCPA by Roche as a result of alleged unsuccessful intercompany dialogue (ICD) with Bayer who responded that ICD had been prematurely escalated by Roche. Consideration was given by the case preparation manager and a decision was made that there was fundamental disagreement between the parties which could not be resolved, and that ICD had been unsuccessful in relation to the allegations at issue; the case was referred to the Panel to rule on these matters.

The allegations, made by Roche, related to a meeting at which a US-based named speaker, whose attendance was sponsored by Bayer, delivered two presentations on age-related macular degeneration (AMD). Roche alleged that Bayer's sponsorship was not strictly arm's length as it had prior knowledge of the likely content of the presentations, which included discussion of aflibercept 8mg, an unlicensed product in the UK at that time and that the circumstances, including the presence of representatives at the event, amounted to pre-licence and/or disguised promotion.

Bayer submitted that it had received an unsolicited request from a named healthcare organisation in October 2023 to sponsor a meeting. The sponsorship package included an exhibition stand and sponsorship of two presentations delivered by a US-based named speaker. The request specified Bayer would have no input or control of the content of the presentations and the accompanying draft agenda listed the speaker as presenting two sessions titled: 'Is 16 weeks dosing the new expectation in AMD? Experience with emerging therapies' and 'Managing side effects of emerging therapies for AMD'.

Bayer submitted that the sponsorship was provided on an arm's length basis and that all arrangements with the speaker were handled by the named healthcare organisation independently of Bayer. Bayer submitted it had no contact with the speaker, nor did it enter into any agreement with the named healthcare organisation, either formally or informally, to ensure aflibercept (either 2mg or 8mg) was mentioned in the presentation.

The Panel noted Roche's concern that at the time of the presentation, Bayer had UK marketing authorisation for aflibercept 2mg (received in 2012) and Roche had UK marketing authorisation for faricimab 6mg (received 2022), both of which were licensed for the treatment of AMD. Bayer had a higher dose formulation, aflibercept 8mg, with a 16-week dosing regime, licensed in the US, with marketing authorisation expected imminently in the UK.

Roche was concerned that Bayer would have had visibility of the presentation titles in advance of the meeting which should have indicated that there would have been information about aflibercept 8mg in the presentations. Roche also raised concerns that there was promotional presence in the form of representatives during the sponsored sessions.

The sponsorship request

Roche submitted that it had also received a request for sponsorship from the named professor organising the event for the healthcare organisation.

The Panel noted from the original letters provided by the parties that aspects of the request letter were identical with the differing aspect of Roche's letter reading as follows:

"The sponsorship would include the following request:

- Event hire,
- Audio visual and technical assistance hire
- Event catering
- Administration support

I would also be very grateful if you would consider sponsoring an in-person speaker from the USA to attend. We would be delighted if [different named speaker] would attend and give two talks titled:

1. Anatomical Endpoints with Vabysmo®▼ (faricimab); how important are they'? 25 minutes with 15 minutes panel discussion"

In lieu of the above, the corresponding section of Bayer's original request letter, also dated 23 October, stated:

"We would use this support to bringing a USA speaker, [named speaker] to the meeting to share [their] experience. Bayer would now control over the content of [their] presentations". [sic]

The Panel noted that the request and agenda had initially been sent to two Bayer commercial employees on 23 October and that a senior medical employee received the same email request from the named professor of the healthcare organisation two days later, on 25 October, following some form of verbal interaction, which the Panel had no information about. In this regard, the Panel observed the return email sent by the medical employee on 26 October started with "Thank you [named professor] for your prompt response – and it was lovely to speak with you yesterday" and went on to highlight an inaccuracy. The email included reference to the request letter being corrected to "Bayer would have no input or control over the content of [their] presentations" which was followed by a suggested declaration of sponsorship statement and reference to a planned call in November 2023 to discuss the SPECTRUM study.

The Panel observed that unlike Roche's request, Bayer's request letter included reference to having no input or control over the presentations. In this regard, the Panel noted the named professor's response of 27 October stated "The relationship is slightly different with Roche. They are bringing a speaker and are sponsoring the talk. I have given the title but they will have control over the content. It will however, be made very clear to the audience and in the final agenda that is the case".

The Speaker and Presentations

The Panel noted the named speaker was a US-based retinal specialist and appeared to be an international key opinion leader in their field. Roche highlighted they were also a leading investigator on Bayer's PULSAR study (high dose 8mg aflibercept study) and that the only meaningful difference between UK and US practice at the time of the [named event] meeting was the 8mg aflibercept formulation was licensed in the US but not in the UK.

Roche submitted the first presentation, titled "Is 16 weeks dosing the new expectation in AMD? Experience with emerging therapies", included detailed study results from the pivotal unlicensed 8mg aflibercept clinical trial. The second presentation, titled "Managing side effects of emerging

therapies for AMD", also referenced the unlicensed 8mg aflibercept formulation and contained comparative claims about the unlicensed 8mg aflibercept formulation in relation to other licensed anti-VEGF medicines and the licensed 2mg aflibercept formulation.

As part of its ICD, Bayer submitted both presentations were balanced, with neither focussed on aflibercept 8mg. Bayer stated the first presentation had no particular emphasis on aflibercept 2mg or 8mg and the second presentation contained only one passing reference to aflibercept 8mg. Roche's submission contradicted this, stating at least fifteen slides discussed aflibercept 8mg in a presentation of approximately thirty slides in the first presentation.

The Panel noted Roche provided photographs taken of both presentations although it was unclear whether images of all slides had been included.

The image of what appeared to be the opening slide of the first presentation was titled "Extended Duration and Higher Dose Anti-VEGF agents 'Is 12 Weeks the New Norm?'". The first half of the slides provided referred to various anti-VEGF therapies with particular focus on faricimab. The remaining fifteen slides then focussed on aflibercept 8mg, after being introduced by a slide titled "High-Dose Aflibercept – Rationale & Clinical Studies". The first slide of the section was titled "Duration of Aflibercept Activity is Directly [illegible] to Dose", which described the characteristics of aflibercept 8mg, which was followed by a table comparing the molar equivalency of four anti-VEGF therapies (aflibercept 2mg, ranibizumab 0.5mg, faricimab 6mg, aflibercept 8mg and brolucizumab 6mg). Of the fifteen slides on aflibercept 8mg before the Panel, six slides referenced or discussed the PULSAR clinical trial, presenting treatment outcomes with the 8mg formulation in patients with nAMD. The slides then went on to focus on the PHOTON trial, with the opening slide titled "Aflibercept 8mg for Diabetic Macular Edema – 2-Year Results of the Phase 2/3 PHOTON Trial", with what appeared to be the speaker's name as [an] author.

The Panel noted from the images provided by Roche that the second presentation focussed on complications with intravitreal injections. The Panel observed various slides included references to aflibercept. For example, aspects of the PHOTON and PULSAR trials were provided in the context of a slide titled "What About Increased Volume" and there was also a table that listed the molar equivalency of the anti-VEGF therapies aflibercept 2mg, ranibizumab 0.5mg, faricimab 6mg, aflibercept 8mg 50ml and aflibercept 8mg 70ml. The presentation went on to display post-marketing data on retinal vasculitis and anti-drug antibody rates for brolucizumab, faricimab and aflibercept, the latter of which had favourable data, and another slide titled "Why Less Anti-Drug Antibodies with Aflibercept" included illustrations of its mode of action.

Sixteen-week dosing

In response to Roche's allegation that aflibercept 8mg was the only emerging therapy with a standard 16-week dosing interval, Bayer submitted that the term "emerging therapies" was ill-defined and may include investigational products or newly launched products, with various other anti-VEGF therapies having recently been licensed in other countries or undergoing late-stage clinical trials. Bayer submitted that aflibercept 2mg and faricimab were both licensed for a maximum sixteen-week extension of therapy intervals as part of a treat-and-extend regimen in nAMD and vision impairment due to DMO; ranibizumab and brolucizumab could also be used on-label at sixteen-week intervals. Bayer further submitted it did not consider aflibercept 8mg to be a sixteen-week dosing formulation, as whilst it could be used on-label at any interval from

eight weeks up to twenty weeks after the initial monthly loading period, it considered the capability to extend to twenty weeks on-label to be a critical differentiator of aflibercept 8mg from other anti-VEGF treatments in the UK, all of which had licensed posologies and clinical trial experience limited to extensions of sixteen weeks.

The Panel noted according to Section 4.2 of the summary of product characteristics (SPC) for aflibercept 8mg (Eylea 114.3mg/mL), after an initial monthly loading dose for the first three months, injection intervals could be extended up to every four months; treatment intervals could be further extended up to five months, such as with a treat-and-extend dosing regimen. The aflibercept 2mg (Eylea 40mg/mL) SPC, by contrast, stated the treatment interval following the monthly loading dose could be extended to and maintained at two months, or further extended to up to four months using a treat-and-extend dosing regimen in nAMD and DMO. The SPC for faricimab 6mg (Vabysmo 120mg/L) similarly, referred to dosing intervals of up to sixteen weeks for nAMD and DMO.

Aflibercept 2mg and faricimab 6mg both had limited evidence above four months, with clinical trial experience limited to extensions of sixteen weeks according to Bayer.

Section 5.1 of the aflibercept 8mg (Eylea 114.3mg/mL) SPC detailed the PULSAR trial for nAMD and the PHOTON trial for DMO which each had three treatment arms with patients assigned in a 2:1:1 ratio: aflibercept 8mg every twelve weeks, aflibercept 8mg every sixteen weeks and aflibercept 2mg every eight weeks. At week 60 in the PULSAR trial, for the aflibercept 8mg arms, the Panel noted 43.1% of the patients in the twelve weekly group were extended to a dosing interval of sixteen weeks and 38.5% of patients in the sixteen weekly group were extended to an interval of twenty weeks. At week 60 in the PHOTON trial, 42.6% of the 8mg twelve weekly group were extended to a dosing interval of sixteen weeks and 34.2% of the 8mg sixteen weekly group were extended to an interval of twenty weeks.

Ruling

The Panel considered it was possible for a company to sponsor materials and activities in which its own products were mentioned and not be liable under the Code for its contents, but only if there had been a strictly arm's length arrangement with no input by the company and no use by the company. It had previously been decided, in relation to material/activities aimed at health professionals, that the content would be subject to the Code if it was promotional in nature or if the company had used the material for a promotional purpose. Even if neither of these applied, the company would be liable if it had been able to influence the content of the material in a manner favourable to its own interests.

In practical terms, the Panel considered that the arrangements must be such that there can be no possibility that the pharmaceutical company has been able to exert any influence or control over the final content of the material.

Factors which might mean there had not been a strictly arm's length arrangement would include, but not be restricted to:

- Initiation of the material, or the concept for it, by the pharmaceutical company.
- Influence from the pharmaceutical company on the content/balance/scope of the material.
- Choice/or direct payment of the authors by the pharmaceutical company.

- Influence from the pharmaceutical company on the list of persons to whom the material is sent.

The first matter for the Panel to consider was whether the arrangements were truly arm's length. In the Panel's view, prior awareness that the material would mainly discuss the company's medicine might undermine the spirit of arm's length arrangements.

The Panel noted the two sessions to be delivered by a named US-based retinal specialist were titled "Is 16 weeks dosing the new expectation in AMD? Experience with emerging therapies" and "Managing side effects of emerging therapies for AMD". Bayer submitted it had no contact with the speaker and no involvement in developing the presentations, nor had it entered into any agreement to ensure aflibercept (2mg or 8mg) were mentioned.

The Panel accepted Bayer's submission that other therapies permitted sixteen-week dosing under a treat-and-extend regimen. The dosing intervals, as conducted in the PHOTON and PULSAR trials as per the SPC, were every twelve or sixteen weeks for aflibercept 8mg. While Roche had not established sixteen-week dosing was exclusive to aflibercept 8mg, it appeared to the Panel that the SPC for aflibercept 8mg was somewhat distinct in supporting maintenance dosing intervals at or beyond sixteen weeks.

The Panel further considered that the term "emerging therapies" which appeared in both presentation titles, would reasonably be interpreted to include new and potentially forthcoming treatments. In the Panel's view, reference to "experience with emerging therapies" in the title of the first presentation would have, on the balance of probabilities, suggested to Bayer that the speaker was likely to discuss aflibercept 8mg. The speaker, who was based in the US where aflibercept 8mg was already licensed and in use, was a named investigator in the aflibercept 8mg clinical trials (PULSAR and PHOTON). The meeting occurred in December 2023, one month before the expected UK launch of aflibercept 8mg, which received its marketing authorisation in January 2024.

Taking into account the cumulative effect of all the factors above, the Panel considered that while there was no evidence that Bayer had directly influenced the content or selection of the speaker, the company would have anticipated the discussion of aflibercept 8mg from the titles of the sessions and the speaker's known background. The Panel thus considered that, on the balance of probabilities, there was no strictly arm's length arrangement and in that regard the company was responsible under the Code for the content. In the Panel's view, the speaker's presentations promoted aflibercept 8mg which Bayer should have been aware was a likely outcome from the proposal and therefore, in funding the project, Bayer was responsible for the promotion of a medicine prior to the grant of its marketing authorisation. **A breach of Clause 3.1** was ruled.

Clause 3.6 stated materials and activities must not be disguised promotion. While noting the presence of the disclaimer that Bayer had no input into the content of the slides, the Panel did not consider that this, in itself, negated the impression created by the presentation titles. In the Panel's view, in the context of Bayer's sponsorship of the sessions, reference to "16-week dosing" would reasonably have been assumed to encompass various anti-VEGF therapies, including aflibercept, and "emerging therapies" would reasonably be interpreted by the audience to include new and forthcoming treatments. The Panel did not consider that the circumstances to amount to disguised promotion and, on balance, the Panel ruled no breach of Clause 3.6

With regard to Roche's concerns with the promotional presence of Bayer representatives at both sponsored presentations, the Panel noted Bayer's submission that it was common practice for company personnel to attend educational sessions at third-party events where there were sponsorship arrangements with pharmaceutical companies in place.

Clause 17.2 stated that representatives must maintain a high standard of ethical conduct in the discharge of their duties and comply with all relevant requirements of the Code. In the Panel's view, Roche had not established that the representatives' presence at the presentation(s), in and of itself, amounted to a failure to maintain a high standard of ethical conduct. There was no evidence that the representatives had any interactions related to the content of the presentations or otherwise acted in a manner contrary to the requirements of the Code. The Panel therefore ruled **no breach of Clause 17.2** in that regard.

The Panel noted its determination above that the arrangements for the sponsorship of the meeting were not strictly arm's length and that, on the balance of probabilities, Bayer would have known aflibercept 8mg would be discussed in the presentations prior to the grant of its marketing authorisation. The Panel noted the extent to which aflibercept 8mg had been discussed in the slides and queried whether it would ever be acceptable for a pharmaceutical company to sponsor an activity which it could not do itself. In the Panel's view, high standards had not been maintained and a **breach of Clause 5.1** was ruled.

Clause 2 was a sign of particular censure and reserved for such use. In this case, aflibercept 8mg had not yet been granted a licence in the UK at the time of the meeting but was licensed in the US, where the sponsored speaker was based and had acted as an investigator in key clinical trials. Aflibercept 8mg appeared to have been discussed in detail in both the presentations at a time when the product was due to be launched in the UK imminently. The Panel noted that the examples in the supplementary information to Clause 2 included promotion prior to the grant of a marketing authorisation. The Panel took all the circumstances into account and considered their cumulative effect, on balance, meant that Bayer had brought discredit upon, and reduced confidence in, the pharmaceutical industry. A **breach of Clause 2** was ruled.

APPEAL BY BAYER

Bayer's written basis for appealing is reproduced below.

> "Thank you for the PMCPA's letter of 29th August 2025, notifying Bayer plc ("Bayer") of the initial outcome of the above case relating to the allegation of promotion ahead of marketing authorisation. Further to our previous letter dated the 8th of September 2025, Bayer would like to appeal all breaches ruled in this case (clauses 3.1, 5.1 and 2) and to attend the hearing of the Appeal Board in due course.
>
> Bayer takes its responsibilities to abide by the ABPI Code of Practice ("the Code"), and to maintain high standards within our industry, very seriously. Bayer strongly believes the conduct surrounding the arm's length sponsorship of the [named healthcare organisation] [named event] 2023 did not breach the ABPI Code of Practice, either in intent or execution, and wishes, in particular, to assert that at no point did our actions bring the pharmaceutical industry into disrepute.

Bayer is pleased and agrees with the Panel's ruling of no breach of clause 17.2 and clause 3.6, and has no further comment on this matter.

1. Panel Ruling Overview

In the Panel's ruling, it states that "it is possible for a company to sponsor materials and activities in which its own products were mentioned and not be liable under the Code for its contents, but only if there had been a strictly arm's length arrangement with no input by the company and no use by the company". The Panel also notes that the company would be liable if it had been "able to influence the content of the material in a manner favourable to its own interests".

The Panel then identifies several factors that could indicate, in practice, that a company was able to influence the content of the material in a manner favourable to its own interests. These factors are:

i. Initiation of the material, or the concept for it, by the pharmaceutical company.
ii. Influence from the pharmaceutical company on the content, balance, or scope of the material.
iii. Choice of, or direct payment to, the authors by the pharmaceutical company.
iv. Influence from the pharmaceutical company on the list of persons to whom the material is sent.

The Panel also comments that, in its view, "prior awareness that the material would mainly discuss the company's medicine might undermine the spirit of arm's length arrangements." This aligns with the PMCPA guidance on arm's length arrangements, which similarly notes:

v. Awareness by the company prior to funding that the material would mainly discuss the company's medicine and/or positively position it above other treatments.

2 Bayer's Response to Panel Ruling

Bayer would like to address each of the points listed above in turn to highlight how it had no influence over the content of the material and how the sponsorship was truly "arm's length".

i. Initiation of the material, or the concept for it, by the pharmaceutical company.

Bayer was contacted by [named professor] through an unsolicited email request, accompanied by a letter previously shared with the PMCPA. In this (unsolicited) request, [named professor] sought sponsorship for the event, specifying that Bayer's contribution would be used to support the participation of US [named speaker]. Prior to receiving this approach, Bayer had no contact with [named professor] regarding sponsorship of the [named event]. From the outset, as documented in [named professor's] letter, it was clear that Bayer would have no control over the content of the presentations. Accordingly, this unsolicited request demonstrates that Bayer did not initiate either the material or its

concept, and that the sponsorship was provided solely in response to an unsolicited approach.

ii. Influence from the pharmaceutical company on the content/balance /scope of the material.

As documented in the letter from [named professor] and subsequently clarified by Bayer staff (due to a typo in the original letter) via email exchange and letter from [named professor], “Bayer would have no input or control to the content of [their] presentations". This was confirmed again via the declaration sent to and agreed by the [named healthcare organisation], stating "[named speaker’s] attendance has been supported through Bayer sponsorship of the [named event]. Bayer has had no input to the content of [named speaker’s] presentation”.

Both point 1 and 2 above are supported by a subsequent email from [named professor], who confirmed that “[their] request, on behalf of the [named healthcare organisation] for financial support to bring an international speaker was unsolicited and by no way prompted by Bayer or any other external organisation. We agreed that the topic, which was provisional, would not be influenced in any way by Bayer or any other organisation. The topic choice was mine and mine alone and agreed by the speaker”. This statement by [named professor] should not be undervalued, as [they are] bound by their own professional code of practice.

Bayer was sent a draft agenda for the [named event] as part of this unsolicited request. It is normal practice to check the overall arrangements via a draft agenda/overview before proceeding with arm’s-length sponsorship to check that the meeting agenda are appropriately scientific and educational, with, for example, no inappropriate events/entertainment that would prohibit sponsorship. Importantly, the draft titles of the talks to be given by [named speaker] were already suggested in the initial unsolicited correspondence via the draft agenda. Therefore, it was clear that that Bayer was in no way involved in suggesting the titles or content of the talks given by [named speaker], and that these had been already suggested by [named healthcare organisation]. These titles were solely agreed and decided between [named healthcare organisation] and [named speaker], as confirmed by [named professor] (“The topic choice was mine and mine alone and agreed by the speaker”). This was reinforced with further email correspondence and disclosure statement. Bayer had no input, influence or control over the titles of the talks, nor their content, at any stage of the process. It is also important to note that, at this stage, the agenda and associated titles, were stated to have "draft” status and so were subject to change; again, a decision and process Bayer made clear it had no input into. Therefore, Bayer couldn’t predict what [named speaker] would discuss in [their] final slides as this agenda and titles were only in draft format.

iii. Choice of, or direct payment to, the authors by the pharmaceutical company.

As documented by the Invoice from [named healthcare organisation], the entire sponsorship payment was made by Bayer to [named healthcare organisation], and not directly to any speakers. Bayer had no involvement in any discussions, travel plans or payment to the speaker or any other individual at [named healthcare organisation]. This

was acknowledged by the Panel who state that there was "no evidence that Bayer had directly influenced the content or selection of the speaker".

iv. Influence from the pharmaceutical company on the list of persons to whom the material is sent.

There has been no suggestion that Bayer had any influence over the invited attendees to the [named event] or the distribution of any material.

v. Awareness by the company prior to funding that the material would mainly discuss the company's medicine and/or positively position it above other treatments

The Panel's view was one that "while there was no evidence that Bayer had directly influenced the content or selection of the speaker, the company would have anticipated the discussion of aflibercept 8mg from the titles of the sessions and the speaker's known background." Bayer, respectfully, disagrees with the Panel on this and details the rationale for this below.

2. Detailed Response on Factor v. – Prior Awareness that [named event] material would discuss Bayer's medicine

As outlined previously, the Panel concluded that Bayer "would have anticipated the discussion of aflibercept 8mg from the session titles and the speaker's known background" and consequently determined that the arrangement could not be considered strictly at arm's length. We set out below Bayer's rationale for respectfully disagreeing with the Panel's assessment on these matters.

3.1 Titles of the sessions

In the Panel ruling, there is focus on the draft titles suggested by the [named healthcare organisation] in its draft agenda, specifically the titles of [named speaker's] presentations (whose attendance was supported by Bayer's sponsorship) and whether Bayer should have known that unlicenced aflibercept 8mg would be discussed.

Bayer would like to re-iterate that:

- Bayer had no input and did not suggest [named speaker] as a speaker;
- at no point did Bayer have any communication with the speaker regarding these talks, or
- involvement in the development of presentation titles, or the written or verbal content of any presentations;
- there was no agreement, suggestion or discussion with [named healthcare organisation] or the speaker at any point that any of Bayer's products (including aflibercept 2mg or aflibercept 8mg) should be mentioned in any talks delivered at the meeting, including the ones given by [named speaker];
- the agreement was strictly arm's length, with complete control of content sitting between [named healthcare organisation] and the speaker;
- Bayer had not input and did not make any suggestions or comments that the titles or content of the speaker's talks should be changed.

As mentioned previously, Bayer reviewed the draft agenda sent by [named healthcare organisation], which included the following potential titles by the speaker:

a) “Is 16 weeks dosing the new expectation in AMD? Experience with emerging therapies” and
b) “Managing side effects of emerging therapies for AMD”

Neither draft title of the proposed talks specifically mentions aflibercept 8mg, or even aflibercept in general. The Panel asserts that the phrase "emerging therapies" would reasonably be interpreted as "new and forthcoming treatments". Bayer asserts that the term "emerging therapies" lacks clear definition, however, it is usually used to describe investigational drugs in Phase I/II development, not newly approved medicinal products. Scientific articles describing “emerging therapies” focus on novel methods of action or treatment pathways, or therapies which are still under investigation, without known safety or efficacy profiles. Aflibercept 8mg does not fit this definition, and would not generally be considered an “emerging therapy” in common scientific parlance. Within the field of AMD, the number of potential therapies and discussion topics that could be described as "emerging" is vast. To demonstrate that it was not a foregone conclusion that the presentations would allude to aflibercept 8mg, we have set out below some topics which would fit within the description of “emerging therapies” and “new and forthcoming treatments”

3.1.1 Evolution of UK anti-VEGF treatment landscape

Figure 1: UK Anti-VEGF treatment landscape 2012 until 2023

To give context, the treatment landscape for neovascular AMD (nAMD) (a subset of patients with AMD) changed significantly in the 2 years preceding the [named event] in 2023, with 2 innovative treatments and 2 biosimilars being launched. In contrast, the previous 8 years had seen no anti-VEGF launches for this indication. Either of Beovu or Vabysmo could have been considered as novel, as both were new molecules, with novel mechanisms of action. Therefore, within the proposed "new and forthcoming" criteria suggested by the Panel, any of these aforementioned products could reasonably be expected to be discussed in either presentation by [named speaker].

The inclusion of the timescale "16 weeks" in the title "Is 16 weeks dosing the new expectation in AMD?" does not, in the view of Bayer, narrow this further down to aflibercept 8mg. For example, in the pivotal clinical trials for faricimab (TENEYA and LUCERNE), the pooled 2-year results showed roughly two thirds of patients (63.1%) had 16-week dosing at the end of year 2.

Beovu ® (brolucizumab), another anti-VEGF injection, also had nearly a third of patients on 16-week dosing intervals (28.4%) shortly after 1 year of commencing treatment (week 64 results). [Named speaker] has been a recipient of research funding for the development of both of these agents. Therefore, a title asking if 16 weeks is the new expectation could easily be discussing either or both of these products, or comparing either of them to aflibercept 2mg (the standard of care for a decade). It does not automatically mean aflibercept 8mg is going to be discussed, and certainly not mainly discussed as per the PMCPA guidance.

3.1.2 Drugs in Development

A further option is that "emerging therapies" could encompass any therapeutics in development for AMD. At the time of the [named event], there were many "emerging" treatments in the nAMD landscape, covering new molecules and new methods of administration, with varied efficacy, safety, and dosing profiles. These include, but were not limited to:

- Port Delivery systems e.g. Susvimo (Roche) [URL provided], where 95% of patients receiving dosing every 24 weeks did not need to receive supplementary anti-VEGF injections in the 2-year results from the Archway clinical trial
- Tyrosine Kinase Inhibitors e.g. CLS-AX (Clearside Biomedical) [URL provided], where 67% of patients receiving a single dose did not require additional therapy for at least 6 months in the extension of the Phase I/IIa OASIS trial. Other TKI inhibitors in development include Axpaxli.
- Novel anti-VEGF Inhibitors e.g. KSI-301 (Kodiak Sciences) [URL provided], where 59% of patients in the KSI-301 arm of the phase IIb/III study achieved five-month dosing intervals with visual acuity gains and anatomic improvements comparable to the control. Other novel anti-VEGF compounds include OPT-302, efdamrofusp alfa, and RC28-E.
- Gene Therapy e.g. ABBV-RGX-314 (RegenXBio) [URL provided], a one-time subretinal treatment that contains a gene encoding for a monoclonal antibody fragment. Other gene therapies currently under investigation include Ixoberogene soroparvovec.

These medications represent a possible quantum shift in the management of nAMD, with intervals far beyond current treatment of care, utilising novel treatment pathways, and unfamiliar methods of administration. Using CLS-AX as an example, the suprachoroidal approach of delivery is typically not done by Medical Retina specialists, and carries with it a potentially different risk profile, and the possibility to require complete service overhauls to deliver on a national scale. Discussion of this molecule could easily be relevant to either of the titles proposed by [named speaker].

Based on the vast array of therapies alluded to above that could be included within the "emerging therapies" description and also relevant to a title mentioning 16-week interval, it is reasonable that Bayer would not anticipate [named speaker] to necessarily discuss aflibercept 8mg.

3.2 Bayer's obligation to establish subject matter

It was not deemed necessary, and it would have been inappropriate, for Bayer to probe [named healthcare organisation] or the speaker further on the meaning of these titles, as this would have contradicted the arm's length nature of the agreement. Furthermore, the agenda was clearly a draft agenda, sent a month and a half prior to the meeting and, as previously stated, it was clear that Bayer would have no input into any content or title changes. Therefore, it is reasonable to expect these titles may change and so predicting the final content is unrealistic. Bayer would also like to note that the titles were in fact

changed by the speaker or [named healthcare organisation] prior to the event, unbeknownst to Bayer. This reinforces that all parties considered Bayer involvement to be arm's length, with no influence or control over the content.

Given the initial ambiguity of the session titles, which were clearly in draft form and subject to change without input from Bayer, and the fact that the speaker's expertise spans a wide range of AMD products, Bayer disagrees that we could reasonably have anticipated a discussion of aflibercept 8mg from the draft titles.

3.3 Speaker's Background

There was suggestion that Bayer should have known the content of [named speaker's] talks based on [their] involvement with aflibercept 8mg clinical trials. We would like to provide some context on this point:

- [Named speaker] is a world-renowned ophthalmologist based in the US, who regularly speaks at international conferences.
- [They are] a prolific researcher and has been [information regarding named speaker's achievements].
- [They have] over 300 scientific publications and abstracts to [their] name with >32,000 citations which vary across [numerous topics].

It was therefore unsurprising that the [named healthcare organisation] considered [them] to be ideally placed to provide a balanced and authoritative overview of current expert opinion to their attendees.

3.3.1 Speaker's Financial Disclosures

[Named speaker] is involved in the research of numerous drugs in development [details provided].

3.3.2 Speaker's Involvement in Emerging Therapies

At the time of the [named event], three companies with whom [named speaker] had financial and/or consultancy agreements were developing drugs with dosing intervals in excess of 16 weeks for the treatment of nAMD. All of these drugs could legitimately be described as true emerging therapies due to their novel method of administration, novel mode of action, or novel molecule. These points of novelty carry with them new side effect profiles, which require analysis and management. It is worth noting that the title of the second talk, "Managing the side effects of emerging therapies in AMD", suits far better these novel emerging therapies than aflibercept 8mg, whose active pharmaceutical ingredient is molecularly the same as aflibercept 2mg, a product with over a decade of clinical use. It has been alleged that, as an investigator on an aflibercept 8mg clinical trial, [named speaker] would by default speak about aflibercept 8mg. This is counterintuitive given that aflibercept 8mg has the same side effect profile as aflibercept 2mg, therefore requiring no difference in management. The same cannot be said for the novel emerging therapies [named speaker] was heavily involved in [table provided].

Clearly, [named speaker's] involvement in a clinical trial on aflibercept 8mg is only a very small part of [their] research activity. Further, there was no suggestion in the presentation titles that [their] talks would focus only on therapies on which [they are] carrying out

research. As an eminent ophthalmologist, it is reasonable to assume that [they are] also up to date with all the latest developments and research [they are] not involved in. For these combined reasons, Bayer would not assume that [their] talk would necessarily include reference to aflibercept 8mg.

In summary, we have shown that there are numerous medicines that could have fallen within the meaning of the phrases “emerging therapies” and “new and forthcoming treatments”, many of which offer the possibility of treatment intervals of 16 weeks or more and many of which were the subject of [named speaker’s] research. We have also argued that it would not have been appropriate for us to enquire further about the proposed subject matter.

Indeed, the PMCPA guidance (1) states that “Awareness by the company prior to funding that the material would mainly discuss the company’s medicine and/or positively position it above other treatments”. Based on all of the above arguments, Bayer strongly disagrees that there could be reasonable anticipation that any talks given by the speaker would discuss, and certainly not mainly discuss, aflibercept 8mg, as per the PMCPA guidance. The photographic evidence of the slides sent by Roche show that aflibercept 8mg was mentioned in around 18 of the 82 slides that were presented over the two presentations given by [named speaker]. Bayer asserts that this does not constitute "mainly discussing" aflibercept 8mg. Similarly, Bayer could not anticipate any positive positioning above other treatments, particularly when the pivotal Phase II/III studies have a non-inferiority primary endpoint.

4 Conclusion

- Bayer contends that the arm’s length sponsorship provided to [named healthcare organisation] in [date] 2023 was legitimate, was conducted in response to an unsolicited request and constituted neither pre-licence promotion nor failure to maintain high standards.

- The terms under which the sponsorship was provided by Bayer were abundantly clear as to the arm’s length nature of the sponsorship from the outset. Furthermore, all arrangements conformed to the guidance set out by the PMCPA on appropriate arm’s length arrangements.

- The Panel acknowledged there was no evidence that Bayer had directly influenced the content or selection of the speaker, and this has been confirmed by the meeting organiser.

- Bayer believes that its response to the Appeal Board has addressed the concerns raised by the Panel and clarified those areas

Bayer therefore respectfully submits that the sponsorship provided to the [named healthcare organisation] in [date] 2023 was fully adherent to the letter and spirit of the Code. Bayer made every effort to maintain high standards. The arrangements were accordingly not in breach of clauses 3.1, 5.1 nor clause 2.

Clause 2 is reserved as a sign of special censure and, respectfully, Bayer does not believe that the facts of this case merit ruling a breach of clause 2."

RESPONSE FROM ROCHE

Roche's written basis for responding is reproduced below.

"Roche Products Ltd UK (Roche) acknowledges receipt of Bayer's letter of 22 September 2025 appealing the Panel's rulings in Case AUTH/0216/06/24 and is grateful for the opportunity to comment. Roche recognises the importance of maintaining the integrity of the self-regulatory system and ensuring that the Code is applied consistently and fairly. While Bayer asserts that its sponsorship of the [named event]in [date] 2023 was strictly "arm's length", we respectfully submit that the Panel's rulings on Clauses 3.1, 5.1 and 2 were entirely appropriate and should be upheld.

While PMCPA guidance acknowledges that companies may, in principle, provide sponsorship on a non-promotional, arm's length basis, Roche agrees with the Panel that the nuanced and cumulative nature of the arrangements in this case meant such an arrangement could not credibly be regarded as arm's length. The combination of the draft agenda, the timing of the meeting so close to marketing authorisation, and the speaker's prominent role in pivotal aflibercept 8mg trials made it impossible for the sponsorship to be perceived as anything other than connected with Bayer's unlicensed product.

Bayer points to the unsolicited nature of the request, the routing of payments via [named healthcare organisation], and disclaimers in the meeting materials. However, as the Panel observed, technical formalities cannot negate the foreseeable perception that Bayer had supported discussion of its unlicensed product. Having seen a draft agenda entitled *"Is 16 weeks dosing the new expectation in AMD?"* and knowing the speaker's prominent role in aflibercept 8mg trials, Bayer could and should have anticipated that its unlicensed product would be discussed.

Bayer argues that session titles such as *"emerging therapies"* are broad and could have encompassed many products. The Panel, however, considered that aflibercept 8mg was distinct in having an SPC supporting maintenance dosing at or beyond 16 weeks. Taken together with the session themes, the speaker's leading role in aflibercept 8mg trials, their US practice where the product was already licensed, and the timing immediately prior to UK authorisation, it was more likely than not that aflibercept 8mg would be a focus.

Bayer emphasises [named speaker's] wide-ranging research across 25 companies and 23 products, suggesting aflibercept 8mg was a minor element of [their] portfolio. Roche agrees with the Panel that breadth does not alter the balance of probabilities. Given the 16-week dosing theme and [named speaker's] pivotal role in aflibercept 8mg studies, it was highly foreseeable that the product would be presented. The perception for attendees was that Bayer's pipeline product would be discussed, regardless of the speaker's wider research interests.

Bayer argues that aflibercept 8mg was not the main focus, noting it appeared in only 18 of 82 slides (around 22%). Such quantitative arguments are immaterial. Those 18 slides presented pivotal trial data and formed the scientific heart of the presentations. From the

perspective of the audience, and in terms of overall perception, aflibercept 8mg would have been seen as a major subject of discussion, amounting to pre-licence promotion.

Bayer should have undertaken appropriate due diligence given the issues already apparent; reliance on paperwork alone is not sufficient. Roche considers that the Panel was correct to find that Bayer failed to maintain high standards. From the draft agenda and the speaker's profile, it should have been clear that there was a risk of pre-licence discussion, and Bayer ought to have acted accordingly. Bayer contends that probing further would have undermined the arm's-length principle. Roche respectfully submits that this position is not sustainable. The Code requires foresight and proactive compliance; the appropriate course would have been to clarify or decline sponsorship. In the circumstances, Bayer ought reasonably to have recognised the likely outcome.

Finally, the Panel ruled that Bayer's conduct warranted a Clause 2 ruling. Bayer contends that Clause 2 should be reserved for "special censure" and that it acted responsibly with no intent to promote. Roche strongly agrees with the Panel that intent is not decisive. What fundamentally matters are effect and perception. A Bayer-sponsored UK meeting held weeks before marketing authorisation, which included aflibercept 8mg trial data, inevitably undermined confidence in self-regulation. The timing magnified the seriousness, and the Clause 2 ruling was fully justified.

In summary, Bayer's appeal rests on procedural arguments. The Code, however, is applied on the balance of probabilities and with full regard to overall impression and perception. The Panel carefully assessed those factors and reached the correct conclusions. Roche therefore fully supports the Panel's reasoning and submits that the rulings under Clauses 3.1, 5.1 and 2 should be upheld."

APPEAL BOARD RULING

The Appeal Board noted that these were concerns raised by Roche following unsuccessful intercompany dialogue, about the inclusion of Bayer's aflibercept 8mg in two presentations which had been sponsored by Bayer. The meeting at issue took place in December 2023, just over one month before Bayer's aflibercept 8mg received its marketing authorisation in the UK.

Both Roche and Bayer had been approached to sponsor the December meeting. The sponsorship request for Bayer included supporting a US-based named speaker to deliver two presentations at the meeting. The Appeal Board noted that the sponsorship agreement was such that Bayer would have no input or control over the content of the presentations but had received a draft agenda at the time of the sponsorship request that listed the name of the speaker and the titles of the two sessions: "Is 16 weeks dosing the new expectation in AMD? Experience with emerging therapies' and 'Managing side effects of emerging therapies for AMD".

The Appeal Board considered the crux of the matter to be whether this was truly an arm's length arrangement. In its consideration it noted the PMCPA guidance which listed a number of factors which might mean there had not been a strictly arm's length arrangement. This included "awareness by the company prior to funding that the material would mainly discuss the company's medicine and/or positively position it above other treatments".

The Appeal Board observed that the US named speaker, who was known to Bayer, was a leading investigator on Bayer's aflibercept 8mg clinical trials (PULSAR and PHOTON) and had hands on experience with the medicine as it was already licensed in the US where they were based. The Appeal Board also noted the proximity of the meeting to the grant of marketing authorisation for aflibercept 8mg and that it should have been anticipated by Bayer that it would be discussed by this speaker in a presentation about "emerging therapies" in AMD. In the Appeal Board's view, a company should not sponsor an activity that it could not perform itself under the Code, which included pre-licence promotion. Taking everything into account, the Appeal Board considered that the arm's length arrangement had been undermined and Bayer was responsible under the Code for the content of the presentations.

The presentations at issue had included reference to aflibercept 8mg on 18 of the 82 slides presented, including details of the clinical trials. At the Appeal Board meeting the representatives from Bayer confirmed that Bayer would have withdrawn its participation at the meeting if it had had sight of the slides in advance. In the Appeal Board's view, the speaker's presentations promoted aflibercept 8mg prior to the grant of its marketing authorisation which Bayer should have anticipated was a likely outcome given the information Bayer had at the time of the sponsorship request. The Appeal Board upheld the Panel's ruling of a **breach of Clause 3.1**. The appeal on this point was unsuccessful.

The Appeal Board considered that Bayer should have anticipated that it would be highly likely that aflibercept 8mg would be discussed in the presentations and that its due diligence in this regard was lacking. The Appeal Board considered that high standards had not been maintained and it upheld the Panel's ruling of a **breach of Clause 5.1**. The appeal on this point was unsuccessful.

The Appeal Board noted that the examples in the supplementary information to Clause 2 included promotion prior to the grant of a marketing authorisation. The Appeal Board took all the circumstances into account, including the proximity of the meeting to the receipt of the marketing authorisation and considered that Bayer had made assumptions without adequate assessment of the risks. The Appeal Board considered the activity was such that Bayer had brought discredit upon, and reduced confidence in, the pharmaceutical industry and it upheld the Panel's ruling of **a breach of Clause 2**. The appeal on this point was unsuccessful.

Complaint received **07 June 2024**

Case completed **02 February 2026**