CASE/0615/06/25

COMPLAINANT v GOSSAMER BIO

Alleged pre-licence promotion at a meeting

CASE SUMMARY

This case was in relation to Gossamer Bio's presence at a meeting for health professionals. The complainant alleged that the Gossamer Bio stand at the meeting promoted the medicine seralutinib prior to the grant of its marketing authorisation.

There was an appeal by the complainant of one of the Panel's rulings.

The outcome under the 2024 Code was:

Breach of Clause 3.1	**Promoting a medicine prior to the grant of its marketing authorisation**
Breach of Clause 5.1	**Failing to maintain high standards**

No Breach of Clause 2 [Panel's no breach ruling upheld at appeal]	**Requirement that activities or materials must not bring discredit upon, or reduce confidence in the pharmaceutical industry**

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

FULL CASE REPORT

A complaint was received from an anonymous, contactable complainant about Gossamer Bio.

COMPLAINT

The complaint wording is reproduced below:

> "I am writing to lodge a formal and urgent complaint regarding a clear and serious breach of UK medicines advertising regulations by Gossamer Bio at a recent educational meeting in [location in Scotland].
>
> I am a UK healthcare professional who attended the [named regional meeting] on 10 June 2025. The event was sponsored by multiple pharmaceutical companies, including Gossamer Bio, [and named pharmaceutical companies]. While most companies behaved in line with UK regulatory expectations, Gossamer Bio's conduct stood out as brazenly non-compliant and deeply concerning. See attached pictures.
>
> Their exhibition stand was titled:

“Seralutinib – A Breath of New Promise”
This phrase is unambiguously promotional in tone and message. It directly associates an unlicensed product (Seralutinib) with a therapeutic claim, and positions it in an aspirational, market-ready light. This is not passive or incidental communication—it is an active, deliberate attempt to promote a medicine that has not yet received a marketing authorisation in the UK or any other jurisdiction.

The presence of a large, branded stand, promotional-style leaflet [a copy was provided], and active engagement from company representatives about the investigational use of Seralutinib in pulmonary arterial hypertension (PAH) is a textbook case of pre-license promotion. I personally witnessed numerous UK HCPs being drawn to the stand and engaging in discussions with Gossamer staff about the product. The combination of visual design, tagline, leaflet, and in-person dialogue constitutes a comprehensive promotional campaign in violation of:

Both the MHRA Blue Guide and ABPI codes of practise prohibits any activity that promotes a medicine before it has been granted a marketing authorisation.

This was not subtle. This was bold, calculated, and entirely deliberate. It took place in the presence of other pharmaceutical companies, multiple UK HCPs, and under the guise of a scientific meeting. It is staggering that Gossamer Bio would have the audacity to engage in such blatant non-compliance so publicly, which raises serious questions:

If this is how they conduct themselves in plain sight, what are they doing behind closed doors?
How many other healthcare professionals have been subject to illegal promotion of Seralutinib?
What internal governance allows this type of conduct to pass unchecked?

I urge the MHRA/ABPI to immediately investigate this incident and initiate a broader compliance review of Gossamer Bio’s UK and EU activities. If they are willing to openly flout UK promotional regulations at a national clinical meeting, there may be deeper systemic issues at play.

I request to remain anonymous for professional reasons but am willing to be contacted confidentially by phone or email if further information or testimony would assist your investigation.

Thank you for your attention to this serious matter. I trust that swift and appropriate regulatory action will follow.”

When writing to Gossamer Bio, the PMCPA asked it to consider the requirements of Clauses 3.1, 5.1 and 2 of the 2024 Code.

GOSSAMER BIO'S RESPONSE

The response from Gossamer Bio is reproduced below:

> "Further to your letter dated 17 June 2025, Gossamer Bio would like to respond to the complaint you received regarding our activity at the *[named regional meeting] in Scotland* held on 10 June 2025 (Meeting). The Complainant alleged Gossamer Bio engaged in pre-license promotion of seralutinib in violation of the Association of the British Pharmaceutical Industry (ABPI) Code of Practice for the Pharmaceutical Industry (Code).
>
> We respectfully disagree with the Complainant's allegations. Per your request, our response focuses on Code clauses 2, 3.1 and 5.1.
>
> **1. As a Foundational Matter, Gossamer Bio has not Promoted Seralutinib Prior to Receiving Marketing Authorization in Violation of Code Clause 3.1**
>
> Gossamer Bio is a research-based company which, to date, has not commercialized any of its investigational products in Europe. Gossamer Bio is enrolling patients in a global phase 3 trial of seralutinib in patients with pulmonary arterial hypertension (PAH) with no current plan for potential license applications in the United Kingdom.
>
> Per the included agenda, the Meeting was an educational programme focused on the diagnosis and management of pulmonary hypertension (PH) patients. Promotion by anyone in this setting – including the other companies Complainant mentions – would be inappropriate.
>
> We understand Clause 3.1 of the Code prohibits pre-license promotion. But like all companies present, our purpose was to engage in scientific exchange. And we note the Supplementary Information to Clause 3.1 acknowledges this is allowed "during the development of a medicine."
> Consistent with this scientific exchange intent, we note the following about the Complainant's photo of Gossamer Bio's exhibition stand:
>
> - The setup clearly shows a 3 x 6-foot folding table with 2 chairs, which objectively – and contrary to Complainant's assertion – is not large.
> - The tablecloth displays the Gossamer Bio logo with "Medical Affairs" prominently featured.
> - The surface of the tablecloth displays a handful of reprints.
>
> Complainant alleges use of a "promotional-style leaflet," which we assume refers to the reprint mentioned above, a photo of which was included. Regarding this, we note the following:
>
> - The piece reproduces a previously presented poster summarizing emerging science of seralutinib in a pre-clinical setting, exploring pathways that may be contributing to the mechanism of action of seralutinib in various animal models and *ex vivo* studies relevant for PAH, as opposed to the use of seralutinib in patients.
> - The poster does not mention efficacy outcomes, "brand name" or safety of seralutinib. Any Health Care Professional (HCP) expected to be in this medical educational forum

would be aware – from the outset – that this information pertains to an investigational product.

- The front cover contains a title that would be understood by any HCP attending this type of meeting to be a reprint of a poster or publication.
- The inside consists of a poster that was presented at a previous medical conference. As you can see, this poster was presented at the International American Thoracic Society Meeting in May and contains a factual presentation of data and findings. It makes no claims of product efficacy, safety, price or availability for purchase in the UK.

Thus, we refute Complainant's allegation that our sharing previously presented scientific information about the mechanism of action of seralutinib constitutes promotion to the public.
Complainant next characterizes the phrase "Seralutinib – A Breath of New Promise" on the tablecloth as a "therapeutic claim positioned in an aspirational, market ready light" as Complainant claims. Again, we respectfully disagree. This statement is not promotional in intent or meaning; nothing about it claims therapeutic benefit, safety or "market readiness." Nor does it mention price or mislead readers to think seralutinib is available for sale. We do acknowledge this phrase may convey a feeling of hope; however, it makes no factual or objective assertion that would constitute a therapeutic claim.

Finally, Complainant alleges "….active engagement from company representatives about the investigational use of Seralutinib in PAH" and then jumps to the unsupported conclusion this "is a textbook case of pre-license promotion." We note: (1) discussing investigational use is the very essence of scientific exchange; and (2) the first quoted portion admitting our staff discussed investigational use wholly contradicts the second piece asserting Gossamer Bio was engaged in promotion.

Complainant goes on to say "I personally witnessed numerous UK HCPs being drawn to the stand and engaging in discussions with Gossamer staff about the product." Notably, Complaint's photo – depicting a table that appears abandoned both by our staff and Meeting attendees – does not support their assertion. Indeed, this photo captures only a moment in time. Still our subsequent investigation suggests this scene may have been closer to the norm. Our standard process requires Medical Affairs staff to record all interactions at medical meetings and congresses. The documentation from the Meeting shows our staff engaged with eight individuals, all of whom are current investigators on the seralutinib Phase 3 PROSERA study in PAH.

2. Gossamer Bio's Participation at The Meeting Met the High Standards and Suitability Requirements of Code Clause 5.1

Many of the items discussed above also support the conclusion Gossamer Bio's exhibition stand was appropriate in content, tone and scale for the Meeting, an educational programme that was attended by approximately 60 – 80 HCPs.

We add that Gossamer Bio has internal processes and controls appropriate to its size and status as a research company with no marketed products. The content complained of here was reviewed and approved by appropriately qualified senior members of the company.

Further, our Medical Affairs staff are trained in scientific exchange and communication with HCPs – whether attending a medical congress or in their day-to-day affairs. As discussed, they must document all conference interactions. Further, our ability to pinpoint the details afterward validates their compliance. Thus, we refute the Complainant's insinuation that our internal governance is somehow lacking.

3. Nothing Here Suggests the Company Has Not Upheld the Confidence in the Industry Expectations of Code Clause 2

We take our responsibility to patients and HCPs seriously and fully support PMCPA's efforts to ensure companies "never … bring discredit upon, or reduce confidence in, the pharmaceutical industry." From the Supplementary Information we understand a finding of breach "is a sign of particular censure and is reserved for such circumstances."

As discussed, we believe Complainant's accusations have no basis in law or the Code. Further, Complainant has taken troubling liberties with the facts. We trust you will agree Gossamer Bio has not promoted seralutinib prior to the UK's grant of a marketing authorization.

We also note that nothing in the complaint suggests the other instances where a Code 2 violation might lie. For example, there is no mention of patient safety, excessive hospitality, inducement, recalcitrance, etc. Thus, we also refute a breach of Clause 2."

PANEL RULING

This complaint related to Gossamer Bio's exhibition stand and associated material at the [name of regional meeting] which took place on 10 June 2025. The complainant alleged that Gossamer Bio's exhibition stand and the material available from the stand constituted pre-licence promotion. The complainant also raised general concerns regarding the governance of Gossamer Bio's activities in the United Kingdom in relation to compliance with local regulations.

Exhibition stand and associated material

The [name of] meeting was a local event intended to promote the referral of patients to the Pulmonary Hypertension Expert Centre in [location] and focused on the diagnosis and management of pulmonary hypertension patients. The meeting was attended by approximately 60-80 health professionals, primarily pulmonologists, cardiologists and specialist nurses. Gossamer Bio, along with all other meeting sponsors, were assigned exhibition space. The complainant provided photos of the Gossamer Bio exhibition stand and the material which was available from the stand. The stand consisted of a table covered with a grey Gossamer Bio tablecloth. The front of the tablecloth stated *'Gossamer Bio Medical Affairs'* superimposed on the corporate logo. The top of the tablecloth included the text *'Seralutinib'* in large light green font and, directly beneath, *'A breath of new promise'*. A number of booklets were displayed on the right-hand side of the table which contained a reprint of a poster presentation. The front cover of the booklet included the poster name *'Seralutinib in pulmonary arterial hypertension (PAH): Exploring mechanisms of reverse remodelling versus vasodilation'*. The study authors, details of the original poster presentation at the American Thoracic Society International Conference in May 2025 and the statement *'Research supported by Gossamer Bio, Inc'* were also included on the front cover. The double page inside spread of the booklet contained the poster reprint. The stand was staffed by a Gossamer Bio medical affairs representative.

Timeline of the complaint

The Panel noted that the complaint related to matters which pre-dated Gossamer Bio's agreement to join the list of non ABPI member companies that comply with the Code and accept the jurisdiction of the PMCPA. The Panel bore in mind the long-established principle that if the subject matter of the complaint could very broadly be described as potentially a matter covered by UK legal requirements then the complaint would be considered in the usual way. As such the Panel limited its consideration to the allegations concerning matters covered by UK law, namely the allegation of pre-licence promotion of seralutinib.

Pre-licence promotion of seralutinib

Clause 3.1 of the 2024 ABPI Code states '*A medicine must not be promoted prior to the grant of the marketing authorisation which permits its sale or supply'*. The Panel noted Gossamer Bio's submission that seralutinib was an investigational molecule. Prior to determining if seralutinib had been promoted, the Panel first dealt with the question of whether seralutinib was a medicine or an early-stage investigational molecule. The Panel noted Gossamer Bio's submission that it was enrolling participants in a global phase III trial in patients with pulmonary arterial hypertension (PAH). The Panel noted that phase III studies were often pivotal studies that formed the basis for any marketing authorisation application. The Panel queried whether a product subject to phase III trials would be considered an early-stage investigational molecule. The Panel also considered that given Gossamer Bio's presence at a specialist meeting for PAH, which was attended by, amongst others, current investigators on the seralutinib Phase 3 PROSERA study in PAH and that the leaflet similarly concerned PAH that it was reasonably clear that PAH was likely a proposed future indication for seralutinib. In the Panel's view it was likely that health professionals at the meeting were likely to view seralutinib as a pre-licence medicine.

Having concluded that seralutinib was a pre-licence medicine, the Panel sought to determine if the medicine had been promoted. The Panel considered Gossamer Bio's submission that their presence at the [named] meeting constituted legitimate exchange of medical and scientific information during the development of a medicine as allowed under the supplementary information to Clause 3.1. The Panel observed that the legitimate exchange of medical and scientific information during the development of a medicine must be non-promotional and should involve debate that enhances the current state of scientific knowledge. The nature and depth of the discussion was relevant and thus parties to such an exchange should have sufficient expertise such that they could meaningfully contribute. To avoid being seen as promotional, it should not be a one-way flow of information. Gossamer Bio had submitted that during the meeting the medical affairs representative staffing the stand had engaged a number of health professionals in 'scientific exchange' but the exact nature of these discussions was not available. In their submission Gossamer Bio had provided details of the specific individuals who had been engaged both at the stand and more generally at the [named] meeting. The Panel noted that the list of individuals provided included Principal Investigators, Sub-investigators, Study Nurses and Study assistants all related to the seralutinib Phase III PROSERA study. The status and link or otherwise to the study was not given for all individuals.

The Panel queried if all of the individuals engaged were appropriate for the legitimate exchange of medical and scientific information. The Panel noted that the complainant had not provided details of any discussions that took place at the Gossamer Bio exhibition stand. In addition and

irrespective of whether any interaction amounted to the legitimate and scientific exchange of information about a medicine it appeared that the stand which was the subject matter of the complaint was not always manned. In the Panel's view it was possible that the reprints were proactively disseminated from the stand but further it was clear that they were available for all delegates to take or peruse when the stand was unmanned. The Panel therefore considered that Gossamer Bio's presence at the [named] meeting did not fulfil the criteria for legitimate exchange of medical and scientific information.

The Panel noted that the exhibition stand included the prominent display of the non-proprietary name of the medicine alongside the tagline '*A breath of new promise'*. The Panel accepted Gossamer Bio's submission that this was an aspirational statement. In the Panel's view, the use of the aspirational statement alongside the non-proprietary name in the context of a specialist meeting on PAH meant that the exhibition stand was promotional. In addition, the availability of the leaflet alongside the generic name and aspirational statement might solicit questions about seralutinib and such consequent discussions would thereby be promotional. In light of these findings, the Panel considered that an unlicensed medicine, seralutinib, had been promoted prior to the grant of its marketing authorisation and ruled a **breach of Clause 3.1.**

In relation to Clauses 5.1 and 2 the Panel noted the complaint raised broad matters of compliance and bore in mind the Panel's view above that given the company's status at the date of the meeting it could only consider matters potentially covered by UK law. The Panel therefore did not consider the broader compliance points raised but limited its consideration of compliance matters solely to the exhibition stand in question.

The Panel was concerned that Gossamer Bio had failed to recognise that the exhibition stand was promotional. The Panel bore in mind the SOP 'Procedure for the Medical, Legal, Regulatory Committee for Submission, Review and Approval of Materials' which covered the review of reprints (Section 2.2.4) and stated at Section 4.11 that 'Scientific exchange may also occur in response to an unsolicited question or request for information from a healthcare professional.' There was no reference to the display and availability of reprints soliciting requests for information and therefore not satisfying the requirements for scientific exchange. Taking all the circumstances into account, the Panel considered that high standards had not been maintained. A **breach of Clause 5.1** was ruled.

With regard to the alleged breach of Clause 2, the Panel noted that Clause 2 was a sign of particular censure and reserved for such use. The supplementary information for Clause 2 provides examples of activities that are likely to beach Clause 2, including promotion of a medicine prior to the grant of a marketing authorisation. The Panel considered Gossamer Bio's submission that they had not commercialised any of their products in Europe and that seralutinib was subject to ongoing clinical trials. In the Panel's view, any future marketing authorisation for seralutinib was someway off and therefore the potential for the pre-licence promotion to prejudice patient safety was low. The Panel was concerned about Gossamer Bio's activity at the meeting however, on balance, given the circumstances of this particular case, the Panel felt that the breaches of Clauses 3.1 and 5.1 adequately covered the matter and ruled **no breach of Clause 2.**

APPEAL BY THE COMPLAINANT

The complainant's written basis for appealing is reproduced below.

‘Executive Summary

The Panel correctly found that Gossamer Bio **promoted an unlicensed medicine** (seralutinib) at a UK professional meeting and breached Clauses **3.1** and **5.1**. The Panel nonetheless declined a **Clause 2** finding, citing “low” patient-safety prejudice. That approach misapplies Clause 2, which addresses conduct that **brings discredit upon, or reduces confidence in, the pharmaceutical industry**.

On the Panel’s own findings — **public promotion to 60–80 HCPs**, prominent branding and aspirational messaging, unattended materials capable of soliciting promotional discussion, and **gaps in SOPs and compliance culture** — the conduct squarely falls within Clause 2. Worse, refusal to apply Clause 2 creates a **regulatory back door** for companies to deliberately promote pre-licence products, reap commercial benefit, and treat minor Clause 3.1/5.1 penalties as negligible “costs of doing business.”

The Appeal Board should therefore substitute a **Clause 2 breach** and impose appropriate remedies, including **public reprimand, corrective communication to attendees, and a formal audit of Gossamer Bio’s UK compliance framework**, in line with the ABPI Code’s own SOP and compliance requirements.

Part A — Factual Recitation

1. Event: [named regional meeting], 10 June 2025; attendance approximately **60–80 HCPs**.
2. Exhibition: Gossamer Bio’s stand bore the name **“Seralutinib”** and strapline **“A breath of new promise”.** Booklets reproducing a poster presentation were **freely available**; the stand was at times **unmanned**.
3. Product status: seralutinib was in a **Phase III trial in PAH** (PROSERA). Attendees would reasonably regard it as a **pre-licence medicine** intended for PAH.
4. Panel findings:
    - Breach of **Clause 3.1** — unlawful pre-licence promotion.
    - Breach of **Clause 5.1** — high standards not maintained; SOPs failed to recognise that display of materials itself solicits promotion.
    - **No breach of Clause 2**, due to “low” patient-safety risk and sufficiency of 3.1/5.1.

Part B — Legal Framework

5. **Clause 2**: activities or materials must never bring discredit upon, or reduce confidence in, the industry. Supplementary Information cites **pre-licence promotion** as activity “likely” to be a Clause 2 breach.
6. **Clause 3.1** prohibits promotion of medicines prior to licence. **Clause 2 is cumulative**: where conduct undermines confidence, Clause 2 applies in addition.
7. The Panel erred by applying patient-safety prejudice as the decisive test for Clause 2. The correct test is **reputational harm and discredit**.

Part C — Application: Why Clause 2 Must Follow

8. **Scale and publicity**: 60–80 HCPs exposed at a national meeting. Not all were trial investigators — the majority were **ordinary clinicians** now exposed to a promotional pitch for a Phase III product. This visibly undermines the credibility of the industry's compliance system.
9. **Design and intent**: Prominent branding + strapline "A breath of new promise" + freely available poster booklets = **structured, deliberate promotional architecture**. This seeded early **market recognition and expectation**.
10. **Governance failure and SOP deficiency**:

- The Panel itself noted SOPs failed to address the reality that **display and availability of materials can themselves constitute promotion**.
- The ABPI Code guidance is explicit: *"It is important for companies to have policies and standard operating procedures (SOPs) to communicate corporate standards, expectations and behaviour … Company documents should support compliance, ensure consistency, manage risk and provide a platform for continuous improvement. … These policies and SOPs are minimum requirements."*
- Gossamer's conduct demonstrates its SOPs are not fit for purpose: they failed to prevent promotion, failed to anticipate common risks, and staff failed to recognise the breach. This is not a single oversight but evidence of **systemic weakness in compliance culture**.
- The Panel's finding that staff **insisted** the stand was "scientific exchange" confirms a **cultural gap**: staff did not even recognise the activity as unlawful.

11. **Commercial advantage**: Gossamer gained real benefit — brand seeding, clinician exposure, trial recruitment momentum. Those benefits far outweigh the cost of a Clause 3.1/5.1 sanction.
12. **Perverse incentive**: Without Clause 2, companies will deliberately replicate this behaviour. The penalty becomes negligible compared to the commercial upside. This creates a **back door route** for pre-licence marketing.
13. **Therefore**: On the Panel's own facts, this was deliberate, public, and governance-deficient pre-licence promotion. That is the very definition of conduct requiring "particular censure" under Clause 2.

Part D — Remedies Sought

I respectfully request that the Appeal Board:

1. **Set aside** the "no breach" finding under Clause 2 and substitute a **breach of Clause 2**.
2. **Public censure**: Require publication of the Clause 2 breach and a **public reprimand**.
3. **Corrective action**:
    - A **corrective communication** to all [named meeting] attendees, approved by PMCPA, clarifying the unlawful promotion and steps to remediate.
    - A **corrective statement** on Gossamer's UK website and in relevant professional channels.
4. **Independent compliance audit**:

- Mandate a PMCPA-led audit of Gossamer Bio's UK compliance framework, specifically:
  • Policies and SOPs on scientific exchange, stand governance, and exhibition approvals;
  • Staff training and awareness processes;
  • Implementation of ABPI Principles and Code obligations.
- This is fully consistent with the Code's own framework, which authorises the Appeal Board to require audits of company procedures.

5. **Binding undertakings**: Require evidence of revised SOPs, retraining, and proof of implementation.

Annex: Two-Point Legal Checklist

1. **Pre-licence promotion?** Yes — Panel found Clause 3.1 breach.
2. **Reputational discredit?** Yes — large scale, promotional set-up, SOP/culture failings, commercial gain. Clause 2 applies

Conclusion

The Panel's refusal to apply Clause 2 rested on a misdirected safety-based threshold. Clause 2 protects confidence in the industry. Here, an unlicensed medicine was **deliberately promoted to 60–80 HCPs**, with **non-compliant SOPs and compliance culture**, yielding clear **commercial benefit**. To treat this as a minor Clause 3.1/5.1 infraction is to invite systemic abuse and erode trust.

For deterrence, credibility, and consistency with the Code's own SOP obligations, the Appeal Board must impose a **Clause 2 breach** and require a **formal audit** of Gossamer Bio's compliance systems.'

On receipt of the appeal, it was decided that the complainant should now be provided with enclosure 5 to the response to the complaint to fully participate in the appeal. The complainant's written submission in relation to that enclosure is reproduced below.

'Thank you for providing the redacted SOP in response to my appeal. Having reviewed the document, I now make the following additional submissions.

1. Core Issue: Deliberate Breach of SOP and Code

Section 2.1 of Gossamer Bio's SOP could not be clearer: all employees *"are expected to follow this SOP."* Section 2.2 then expressly requires that booth materials, visual aids, reprint materials, and booklets undergo MLR review. Yet the materials in question—plainly promotional in nature—either were not reviewed at all or were reviewed in such a perfunctory manner as to be meaningless. The evidence points to a probable failure to submit the materials for proper approval.

Section 4.10 confirms Gossamer's knowledge of the definition of promotion. This is mirrored in Clause 1.17 of the ABPI Code, which defines promotion broadly as *"any activity undertaken by a pharmaceutical company or with its authority which promotes the administration, consumption, prescription, purchase, recommendation, sale, supply*

or use of its medicines" ABPI code 2024. By any objective measure, the booth and associated collateral fall squarely within that definition.

Section 4.11 of the SOP attempts to invoke "scientific exchange," but the SOP provides no meaningful definition or framework. Gossamer's claim that it was engaged in scientific exchange is unsustainable. What occurred was not scientific exchange—it was promotion. The booth was left unmanned, with overtly promotional messaging and materials freely available for collection by any passer-by. This is the very essence of promotional activity as defined in Clause 1.17 of the Code.

2. Breaches of the ABPI Code

The conduct in question is directly contrary to the following provisions:

- **Clause 3.1**: Pre-licence promotion is expressly prohibited.
- **Clause 5.1**: Companies must maintain high standards at all times.
- **Clause 2**: Activities or materials *"must never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry."* The supplementary information to Clause 2 is clear that promotion prior to marketing authorisation is among the most serious breaches warranting censure. ABPI code 2024.

Although this is Gossamer's first case from what I can tell, the seriousness lies not in repetition but in the deliberate nature of the misconduct. This was not a technical oversight or misunderstanding. It was a conscious attempt to circumvent both the SOP and the ABPI Code by mischaracterising straightforward promotion as "scientific exchange," while leaving a booth unmanned with promotional materials and messaging freely available. Such behaviour represents a serious disregard for compliance obligations and goes to the heart of industry integrity.

3. Seriousness and Culpability

This conduct strikes at the core of the self-regulatory system. Gossamer knew its obligations, codified them in its own SOP, and then ignored them. To claim that the activity was "scientific exchange" when it was in fact straightforward promotion is a direct attempt to mislead. Such behaviour undermines trust, discredits the industry, and cannot be dismissed as a misunderstanding.

4. Required Sanctions

Given the gravity, only the most serious sanctions are appropriate:

- A **Clause 2 ruling** to reflect the gravity of the misconduct.
- Findings under **Clauses 3.1 and 5.1**.
- An **audit of Gossamer Bio's compliance procedures** to test whether the SOP is being implemented in practice.
- A requirement for **pre-vetting of future materials**.
- A **serious public reprimand**, to make clear that attempts to circumvent the Code will not be tolerated, and that pharmaceutical companies must act with integrity and ensure their staff are properly trained in Code compliance.

5. Conclusion

In short, Gossamer's conduct is indefensible. It represents a conscious disregard of both internal SOPs and the ABPI Code. It is precisely the type of misconduct Clause 2 exists to censure. To preserve the credibility of the Code and the integrity of the industry, the Appeal Board should impose the most serious sanctions available.'

On appeal Gossamer Bio agreed that the complainant could now be provided with a redacted copy of its enclosure to its response to the complaint "Best Practices for Trade Shows". The complainant's written basis for appealing in relation to that enclosure, is reproduced below.

'Thank you for providing Gossamer Bio's *"Best Practices for Trade Shows"* presentation. Having reviewed it carefully, I make the following submissions.

1. Core Issue: Absence of UK Regulatory Framework

Slide 2 purports to define dissemination of scientific information by reference only to "unsolicited requests" and "peer-reviewed articles." The slide deck contains not a single reference to the ABPI Code, the PMCPA, or the MHRA. For a company conducting activity in the UK, this omission is indefensible. It evidences, at best, a fundamental lack of competence, and at worst, a deliberate disregard of the UK's regulatory framework.

It is axiomatic that FDA standards differ materially from UK and EU requirements. Any responsible pharmaceutical company operating internationally must provide clear, country-specific compliance guidance. Gossamer Bio has not done so. The absence of such guidance demonstrates a systemic failure to integrate UK obligations into its compliance programme.

2. Mischaracterisation of "Scientific Exchange"

The slide deck does not attempt to define "scientific exchange." By contrast, the ABPI Code and PMCPA provide precise boundaries. Gossamer has instead reduced the term to an amorphous concept to legitimise overtly promotional conduct.

The booth itself was plainly promotional: the product name was displayed prominently, bold claims were made, and materials were left for unrestricted collection. The presence and conduct of Gossamer's medical representative went further still, actively soliciting questions through promotional statements. This conduct is the very antithesis of unsolicited enquiry. To describe it as "scientific exchange" is untenable.

3. Breach of SOP and ABPI Code

Gossamer's SOP requires MLR review and approval of all booth materials. It is inconceivable that the stand and collateral, promotional by any objective measure, were approved in accordance with those requirements. If they were, the review process was manifestly deficient.

The conduct breaches the following ABPI provisions:

- **Clause 3.1** – prohibition on pre-licence promotion.
- **Clause 5.1** – obligation to maintain high standards.
- **Clause 2** – prohibition on activities liable to bring discredit on, or reduce confidence in, the industry.

The training materials compound these breaches by failing to reference any UK or European regulatory body. This is not a technical oversight but a systemic failure.

4. Sanctions

The slide deck and associated conduct expose a profound failure of compliance culture. Gossamer Bio has ignored its own SOP, disregarded the ABPI Code, and attempted to justify clear promotion under the guise of "scientific exchange."

The Appeal Board should impose the most serious sanctions available:

- A **Clause 2 ruling**, to reflect the gravity of the misconduct.
- Findings under **Clauses 3.1 and 5.1**.
- An **audit** of Gossamer Bio's compliance systems, including SOP implementation, training materials, and approval processes.
- A requirement for **pre-vetting** of all future materials.
- A **serious public reprimand**, to make plain that companies cannot evade local regulations or mischaracterise promotional activity as scientific exchange.

5. Conclusion

The "Best Practices" slide deck and the booth activity together demonstrate that Gossamer Bio has failed to grasp, or has chosen to ignore, the most basic requirements of UK compliance. The conduct was not inadvertent; it was deliberate, and it strikes at the heart of the self-regulatory system. To uphold the credibility of the Code and the integrity of the industry, the Board must censure Gossamer Bio in the strongest possible terms.'

RESPONSE FROM GOSSAMER BIO

Gossamer Bio's written basis for responding to the appeal is reproduced below.

'This case centres around a "tagline" that consisted of five words on a tablecloth at a medical conference and the availability of a single handout of a recent scientific poster presentation (focused on preclinical exploration of PAH mechanisms) without a medical affairs representative present at all times. PMCPA has made the decision that this tagline and the availability of the handout without legitimate scientific exchange constitute promotion and a breach of Clauses 3.1.and 5.1. However, the Panel concluded that, given Gossamer's status as a clinical development company and the stage of clinical investigation, in upholding breach of Clauses 3.1 and 5.1, the risk of prejudicing patient safety was low, and since Clause 2 is a sign of particular censure and reserved for such use, therefore, Gossamer was not in breach of this clause.

Once the complaint was received, Gossamer voluntarily joined PMCPA even though there is no intention to submit for a marketing authorization for seralutinib in the UK, accepted the PMCPAs ruling, and immediately began the implementation of PMCPA's recommendations, notably:

- Reviewing and refining our processes, policies and training materials to address the deficiencies cited.
- A revised training curriculum for all medical affairs and clinical operations employees working in Europe that requires annual training on the Code of Practice issued by the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), the European Federation of Pharmaceutical Industries and Associations (EFPIA), and the Prescriptions Medicine Code of Practice (PMCPA) in the United Kingdom.
- Our "Trade Show Training" materials (currently focused on the USA) are undergoing revision to include global requirements, specific definitions and clear instructions that govern scientific exchange and interactions with healthcare professionals.
- A requirement for any booth or tabletop display be attended by a minimum of two Gossamer employees, wherein one is always available at the display, and that any reprints of scientific information be distributed only after a scientifically qualified Gossamer employee has engaged in discussion of the materials with the requesting party.
- Prohibition of display of a non-proprietary name at medical conferences and immediate cessation of the use of the tagline in this case worldwide.

However, none of this has satisfied the complainant, who has submitted an appeal with the intention of changing the PMCPA's ruling to include a breach of Clause 2, and demands sanctions that include, amongst others, public shaming, and an audit of Gossamer's promotional practices. The appellant accuses the panel of "error" by applying patient-safety prejudice as the decisive test for Clause 2, and alleges the correct test is reputational harm and discredit. The appellant further alleges this was "deliberate, public, and governance deficient pre-license promotion".

Given the circumstances, we question the motivation behind this appeal and speculate it can only be intended to cause loss of reputation for Gossamer, which we consider unreasonable and disproportionate. Our reasons are as follows:

1. Gossamer is a small development company based in the USA, that is still building its commercialization capabilities as it proceeds to the end of its first Phase 3 clinical program and eventual submission for marketing authorization of seralutinib to the US FDA.

2. Gossamer holds no commercialization rights for seralutinib in Europe. This helps explain why our policies are "US-centric".

3. Gossamer was made aware of the meeting in Scotland where a number of its clinical trial investigators would be present. A "booth" space (actually just a table and two chairs) was available, and Gossamer asked a member of its medical liaison staff (not a sales representative) to be present to address any questions from participants. The

table was only vacated during normal staff breaks, and the staff member primarily spoke with health care professionals from Gossamer's phase 3 clinical trial sites.

4. Contrary to the complainant's allegation of governance failure and SOP deficiency, we submit that our processes and governance are appropriate for a company of our size and at our stage of development. The display materials did undergo review consistent with the medical, legal and regulatory (MLR) SOP for review of all external and patient facing materials, with the MLR committee composed of 3 executive members of Gossamer's management and governance committee. In addition, all medical liaison staff receive compliance training before attending a medical conference.

In conclusion, the complainant's appeal and framing involve a high degree of subjectivity and judgment and the weakness of the complainant's position is underscored by a somewhat hyperbolic characterization of the alleged transgressions and purported "harm".

The PMCPA has sufficient written documentation, and ample precedent, to support its initial decision to reject a breach of clause 2 on the basis that the potential for the alleged pre-license promotion to prejudice patient safety was low and deny the appellant's attempt to create ongoing obligations that are both disproportionate to Gossamer's alleged transgression and wasteful of PMCPA's resources.

We submit that Gossamer gained no commercial advantage from attending this small meeting in Scotland, there was no discernible negative outcome to patient safety, and Gossamer's actions and internal controls, while needing improvement, do not show a deliberate pattern of misconduct. We contend this does not meet the test for a breach of Clause 2 and the complainant's appeal should be dismissed.'

FINAL COMMENTS FROM THE COMPLAINANT

The complainant's written basis for its final comments on Gossamer Bio's response to the appeal is reproduced below.

'I write in response to Gossamer's letter and the Panel's ruling concerning Gossamer's conduct at the recent meeting in Scotland, where the company established a branded stand displaying the name of its product still in Phase 3 trials, made scientific materials available, and engaged directly with an audience of approximately 50–100 UK healthcare professionals (HCPs). While I note the Panel's finding of breaches of Clauses 3.1 and 5.1 of the ABPI Code, I respectfully submit that this case warrants the application of **Clause 2**, together with **sanctions and an immediate independent audit of Gossamer's UK operations**.

1. Duty to Know and Apply the Code

Any company choosing to operate in the United Kingdom pharmaceutical environment is under a strict duty to understand and apply the ABPI Code. Ignorance of, or reliance on "US-centric" policies, cannot excuse breaches. The conduct here demonstrates not a mere technical lapse, but a **fundamental disregard of UK regulatory standards**, at a time when commercial advantage was plainly sought through pre-licence promotion.

2. Seriousness of the Breach and Application of Clause 2

Clause 2 is reserved for **serious breaches that bring discredit upon, and reduce confidence in, the pharmaceutical industry**. This case falls squarely within that threshold for several reasons:

- **Deliberate Promotion Pre-Licence**: The company's actions went far beyond scientific exchange. By hosting a branded medical stand, displaying materials, and permitting a representative to engage with HCPs, Gossamer engaged in clear promotional activity for a medicine not yet licensed.
- **Scale of Impact**: Approximately 50–100 UK HCPs were directly exposed to unlawful promotion. This was not an isolated misjudgment but a coordinated, premeditated activity with significant reach.
- **Commercial Benefit Despite No UK Submission**: Gossamer has confirmed there is no current intention of submitting seralutinib for marketing authorisation in the UK. In that context, the decision to host a branded medical stand at a UK congress is illogical from any legitimate regulatory or scientific perspective. The only reasonable conclusion is that the objective was to generate awareness, create "noise" around the drug, and indirectly support clinical trial recruitment. That is promotion by any other name, and in a jurisdiction where the company has no planned regulatory filing, it can only be understood as an act of deliberate commercial opportunism.
- **Industry Outlier**: Importantly, at the same meeting, every other company — both large and small, UK and international — limited themselves to standard tabletop displays and non-promotional scientific engagement, consistent with the ABPI Code. Gossamer alone chose branded promotional materials and engagement. This shows that compliance was both possible and understood, and that Gossamer chose not to comply in order to gain a competitive advantage.
- **Governance Failure Evidenced by Post-Event Policy Changes**: Gossamer asserts that its display materials underwent full MLR review. If that is correct, then the approval of materials that were effectively promotional demonstrates that the internal review process itself was gravely deficient. Conversely, if the materials were deployed outside or contrary to proper review, that is equally a compliance failure. Either way, governance was lacking. This is only reinforced by Gossamer's subsequent wholesale revision of policies, SOPs, and training. If there had been no governance failure, such sweeping reforms would have been unnecessary.
- **Not an Accident but a Planned Act**: The establishment of a branded stand, staffed with a representative, required logistical planning, budget approval, materials preparation, and senior authorisation. This was not a spontaneous oversight but a calculated activity, knowingly undertaken in breach of the Code.

These factors demonstrate conduct which is **deliberate, reputation-damaging, and wholly incompatible with the integrity expected under the Code**. Clause 2 is therefore both necessary and proportionate.

3. Why Sanctions and an Audit Are Required

The breaches here reveal systemic failings in governance, training, and compliance. Gossamer's after-the-fact commitments to training and policy revision cannot remedy the fact that UK HCPs have already been unlawfully promoted to. It is not sufficient to rely on assurances; independent verification is required.

- **Sanctions** are necessary to serve as a deterrent to Gossamer and to the wider industry, underscoring that pre-licence promotion will not be tolerated.
- **An Audit** is critical given the admitted "US-centric" approach, the approval of promotional materials under allegedly compliant review, and the subsequent reactive governance overhaul. Gossamer's compliance systems must be independently reviewed to ensure they are fit for UK practice before further engagement with UK HCPs is permitted.

4. Protecting Public Confidence and Patient Safety

The pharmaceutical industry relies on maintaining the trust of both the medical profession and the public. Unlawful pre-licence promotion not only prejudices fair competition, but undermines confidence in the integrity of the sector as a whole. It creates unfair influence on HCPs, risks skewing clinical trial recruitment, and erodes the ethical foundation of medicines development.

Clause 2 of the 2024 ABPI Code is specifically intended to address **deliberate, egregious misconduct which brings the industry into disrepute**. This case is a textbook example: clear intent, commercial motivation, patient safety implications, and reputational harm to the entire sector.

5. Conclusion

In light of the above, I respectfully but firmly submit that:

1. A finding under **Clause 2** should be applied to this case.
2. **Sanctions** should be imposed to reflect the seriousness of the misconduct.
3. An **independent audit of Gossamer's UK operations** should be mandated without delay.

The Panel must send an unequivocal message: companies cannot promote pre-licence medicines in the UK with impunity. This case should stand as a clear precedent that where a company engages in deliberate pre-licence promotion, the full force of the PMCPA and ABPI will be brought to bear. Only a Clause 2 ruling, combined with sanctions and an audit, will serve to uphold the integrity of the Code and safeguard public trust in the industry.'

APPEAL BOARD RULING

The Appeal Board observed that the supplementary information to Clause 2 provided examples of activities that were likely to breach Clause 2, including promotion of a medicine prior to the grant of its marketing authorisation. However, the Appeal Board took account of the fact that at the time of the meeting at issue any potential marketing authorisation was not certain and would be some way off. The Appeal Board considered that the potential for the pre-licence promotion

to prejudice patient safety was low. In addition, Gossamer Bio had submitted that it had no intention to submit for a marketing authorisation for seralutinib in the UK although it would receive a royalty if the company that owns the commercial rights were to launch the product here.

The Appeal Board took account of the small scale of the stand and meeting at issue. Although the Appeal Board was concerned about Gossamer Bio's activity at the meeting and its understanding of the requirements of the Code, it considered that, on balance, given the circumstances of this particular case, the activity was not such that it brought discredit upon the industry and the Panel's rulings of breaches of Clauses 3.1 and 5.1 adequately covered the matter. The Appeal Board upheld the Panel's ruling of **no breach of Clause 2**. The appeal was unsuccessful

Complaint received **10 June 2025**

Case completed **17 October 2025**