

CASE/0874/02/26

PMCPA CHIEF EXECUTIVE v GSK

Allegations about the completeness of GSK's responses in Case/0269/08/24

CASE SUMMARY

This case was about the completeness and accuracy of GSK's responses to the Panel and appeal in Case/0269/08/24. Following communication and documents from the UK Health Security Agency (UKHSA) at the completion of that case, a complaint was made in the name of the PMCPA Chief Executive. The Panel interpreted the allegations to be that GSK did not provide the Panel or the Appeal Board with an accurate representation of the information GSK had received regarding UKHSA's approval (or lack thereof) in relation to the Shingles Programme Awareness Campaign (SPAC) and Clause 26.1.

There was an appeal by GSK of four of the Panel's rulings (Clause 2 and three Clause 5.1 rulings).

The outcome under the 2024 Code was:

Breach of Clause 2 [Panel's breach ruling upheld at appeal]	Bringing discredit upon, or reducing confidence in, the pharmaceutical industry
Breach of Clause 5.1 (x4) [Panel's breach rulings upheld at appeal x3]	Failing to maintain high standards
No Breach of Clause 5.1 (x2)	Requirement for companies to maintain high standards at all times

The Panel reported GSK to the Appeal Board in accordance with Paragraph 10.2 of the Constitution and Procedure, for the Appeal Board to consider additional sanctions in relation to Paragraph 13.4.

The Code of Practice Appeal Board required GSK to be publicly reprimanded. Details of the reprimand are at the end of this case report.

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

FULL CASE REPORT

The Chief Executive of the PMCPA received information from which it appeared that GSK might have contravened the Code and decided, in accordance with Paragraph 5.1 of the Constitution and Procedure, to take the matter up as a complaint.

COMPLAINT

In accordance with Paragraph 5.1 of the Constitution and Procedure, the Chief Executive assigned a member of the Authority to be the case preparation manager. The wording from the case preparation manager's letter to GSK outlining the matter of complaint is reproduced below:

“At the conclusion of Case/0269/08/24, the PMCPA sent UKHSA [UK Health Security Agency] a copy of the case report (as a courtesy prior to publication) because it names UKHSA and refers to GSK's interaction with them as part of [GSK's] Shingles Programme Awareness Campaign (SPAC). UKHSA responded to [PMCPA] to suggest that the case report, and the extracts of minutes used by GSK in its appeal, were not an accurate reflection of [GSK's] engagement with them. UKHSA then chose to send [the PMCPA] correspondence and documents involving GSK and UKHSA, which are attached with this letter.

Considering this correspondence, [the PMCPA has] decided to delay publication of the case report for Case/0269/08/24 in its current form, and have taken up this new complaint against GSK in the name of the PMCPA Chief Executive to ensure an objective review of the facts.

I attach the relevant documents in this case (in date order):

1. 27 April 2023: email from GSK to UKHSA and NHSE [NHS England] (attaching minutes of 25 April 2023 meeting)
2. 18 August 2025: email from UKHSA to GSK stating that approving campaigns is not within their remit
3. 24 October 2025: GSK's appeal documents for Case/0269/08/24
4. 7 November 2025: GSK's slides for the Appeal Board in the hearing for the appeal of Case/0269/08/24
5. 12 November 2025: Transcript of GSK's oral submissions to the Appeal Board in the appeal of Case/0269/08/24
6. 25 November 2025: email from UKHSA to GSK reiterating that it had not approved the SPAC
7. 18 December 2025: email from GSK to PMCPA requesting amendments to the case report for Case/0269/08/24

I have considered these documents and compared them with GSK's initial response to Case/0269/08/24 and GSK's appeal documents, oral submissions at the appeal and subsequent correspondence in that case.

The self-regulatory system relies upon the provision of complete and accurate information by pharmaceutical companies when responding to a complaint. In this case, it appears to me that there may have been a breach of the Code in relation to GSK's handling of Case/0269/08/24. Specifically, GSK may not have provided the PMCPA or the Appeal Board with an accurate representation of the information GSK had received regarding UKHSA's approval role (or lack thereof) in relation to the SPAC at the following times:

- 25 April 2023 (before the complaint in Case/0269/08/24),
- 18 August 2025 (before the Panel had issued its ruling), and
- 25 November 2025 (after the Appeal Board hearing but before the draft case report was sent to [GSK] on 3 December 2025).

Please also respond in relation to UKHSA's query in their email of 25 November 2025, about whether the 25 April 2023 meeting minutes (that GSK shared with UKHSA on 27 April 2023), are the same as those provided by GSK on 24 October 2025 for the appeal hearing."

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

GSK'S RESPONSE

The response from GSK is reproduced below:

"We acknowledge receipt of your letter dated 17th February 2026 and the accompanying Enclosures relating to Case/0874/02/26. We have carefully and extensively considered the points you have raised in your letter and provide our responses below. As a preliminary matter, we confirm unequivocally that GSK takes both the requirements and the spirit of the ABPI Code extremely seriously.

We understand the essence of the complaint set out in your letter to be regarding whether GSK provided the PMCPA or the Appeal Board with an accurate representation of the information GSK had received regarding UKHSA's approval role (or lack thereof) in relation to the Shingles Programme Awareness Campaign (SPAC) meeting minutes on 25th April 2023 between GSK, UKHSA & NHS England (before the complaint in Case/0269/08/24), email correspondence from UKHSA on 18th August 2025 (before the Panel had issued its ruling) and email correspondence from UKHSA on 25th November 2025 (after the Appeal Board hearing and before the draft case report was provided to GSK).

GSK is very concerned by this complaint. We strongly maintain that there was no intention to mislead the PMCPA or the Appeal Board at any stage. Our actions and submissions were shaped by the information available to us at relevant times and our understanding of the position and role of UKHSA and the requirements of Clause 26.1 of the Code. Importantly, the PMCPA will be aware that the interpretation of

Clause 26.1 of the Code, particularly regarding what constituted “approval” by health ministers or their representatives in the context of vaccination programme awareness activities, was substantially unclear before the PMCPA updated the online clarifying Q&A for Clause 26.1 in June 2025. Prior to the updated Q&A, our understanding of the requirements was based on the substantial collective experience of GSK colleagues who have spent many years working within ABPI Code-governed environments across multiple pharmaceutical companies, an experience base we previously highlighted to the PMCPA during Case/0269/08/24. This experienced group had long understood that regular, substantive engagement with public health bodies such as UKHSA and NHS England, rather than a defined ministerial approval route, was the practical means of ensuring public health alignment, appropriate oversight and compliance with the requirements of Clause 26.1.

It was within this established, practical framework that GSK engaged extensively with UKHSA and NHS England and understood such engagement to be consistent with the intent of Clause 26.1. Following GSK’s consideration of the PMCPA updated Q&A in June 2025, and correspondence with UKHSA between June & August 2025, we also sought clarification from the Medicines & Products Regulatory Agency [sic] (MHRA) in September 2025 on the evolving interpretation of the approval pathway for vaccination programme awareness activities. This approach was consistent with GSK’s aim to “do the right thing” by engaging substantively with UKHSA, NHS England and the MHRA.

Accuracy of GSK’s response to Case/0269/08/24

Extracts of meeting minutes provided to the PMCPA by GSK

Regarding the 25th April 2023 meeting minutes (circulated 27th April 2023), GSK used extracts (supplied previously to the PMCPA as Annexes to its Appeal Letter and as part of the Appeal Board presentation) to evidence discussion topics, feedback, and alignment with UKHSA and NHS England in a readily accessible way, without unnecessary information that could detract from the substance of the complaint. There was no intention to omit any relevant material or contrary assertion regarding approval roles (or lack thereof) from UKHSA. We understood that the references to independence and professional distance of UKHSA in the full meeting minutes to refer to branding and organisational distance, not to a prohibition on continued engagement or a statement about formal approval authority, which aligns with the position GSK expressed to the Panel and Appeal Board.

It is important to highlight that on 22nd October 2025, GSK supplied UKHSA with a copy of the meeting minute extracts that are cited in the PMCPA letter, in a concerted effort to ensure that UKHSA had full visibility of material to be provided to the Appeal Board and to extend an opportunity for UKHSA to raise any comments. The extracts provided to UKHSA therefore included the specific minute extracts from 25th April, alongside extracts from other meetings held between 2023 and 2025, that we intended to submit to the PMCPA with our Appeal Letter. We explicitly sought UKHSA’s agreement to the inclusion of the minutes in extracted form. We engaged on repeated occasions with UKHSA ahead of the Appeal Board meeting to follow up on this, however GSK did not receive any substantive response from UKHSA as to the sharing of minutes of meetings or extracts in the period required to finalise our materials. Between 19th September and 13th October 2025, UKHSA informed us that their internal legal team

was reviewing the matter and therefore they could not yet comment on the sharing of any meeting minutes or extracts. During this period, UKHSA also requested additional information from GSK, including copies of PMCPA rulings and details of the complaint, which GSK supplied promptly, alongside offers of calls and follow-up discussions. By 13th October 2025, UKHSA indicated that their legal team was still reviewing the matter and requested copies of *all* documents involving UKHSA that GSK intended to use, but could not provide a position on whether extracts could be used in the context of the appeal, or whether full minutes were required. In the absence of any objection from UKHSA, we therefore submitted what we believed to be representative and appropriate information to the Appeal Board. We understood that, if UKHSA had any concerns regarding the accuracy of the extracts, they would have notified us accordingly prior to the hearing date.

Email from UKHSA dated 18th August and subsequent transparency with the Appeal Board

GSK acknowledges receipt of the UKHSA email dated 18th August 2025 and recognises that its content forms part of the broader context being considered in this complaint. At the time the email was received by GSK, we understood it to be setting out UKHSA's interpretation of their role in relation to SPAC activities. This position was not aligned with GSK's understanding at that point and the wider implications of the email were unclear, necessitating further consideration with UKHSA prior to external discussion.

The email was received after GSK had already submitted its initial response to the complaint in Case/0269/08/24. Nevertheless, we took the email of 18th August extremely seriously and escalated this internally with senior leaders to agree on the most appropriate way to proceed that would respect UKHSA's professional remit and also adhere to the spirit and letter of the Code. GSK therefore sent UKHSA multiple emails between August and November 2025 to try to obtain clarity on their position. In GSK's initial email response to UKHSA on 22nd August 2025, we did not disregard UKHSA's comments; rather, we responded promptly, sought clarification, and confirmed our intention to pause activities while further information was obtained. In that same correspondence, GSK also reiterated that the Code does not prescribe a specific approval mechanism and explained that GSK's approach had been taken in line with our understanding at the time. Unfortunately, as highlighted above, due to internal legal deliberations at UKHSA, they could not provide a substantive response before the Appeal Board hearing.

With this in mind, through concerted discussions with senior leadership prior to the Appeal Board, it was decided that as the 18th August email would not alter the material facts that GSK intended to present specifically in relation to our interactions with UKHSA on SPAC activities, and our understanding of the requirements of Clause 26.1 at that time, it would have been inappropriate for GSK to present speculative or incomplete interpretations to the Appeal Board without substantive input from UKHSA. GSK prepared materials for the Appeal Board on this basis and shared our position with UKHSA prior to the hearing.

Prior to the Appeal Board hearing, GSK also took proactive steps to ensure compliance and mitigate risk. SPAC activities were paused on 31st August 2025 pending further

clarity, and GSK separately sought advice from the MHRA on the appropriate process under Clause 26.1, as documented in GSK's email to the MHRA of 8th September 2025. These actions reflect the seriousness with which GSK approached the evolving situation and demonstrate a responsible and measured response to emerging uncertainty.

Throughout the appeal process, GSK consistently and accurately stated that it had never asserted that UKHSA was providing formal ministerial approval for SPAC activities. Between June and August 2025, UKHSA and GSK engaged in multiple interactions – including emails on 11th July and 18th July, a meeting on 6th August, and the sharing of minutes on the same date – which supported GSK's genuine understanding that the level of input and frequency of engagement met the long-standing industry practice for satisfying Clause 26.1.

For these reasons, GSK remains confident that earlier disclosure of the 18th August email would not have altered the core arguments presented in either our written submission or the oral discussions at the Appeal Board, and that our decision not to disclose ongoing discussions between UKHSA and GSK that had not been resolved would have been inappropriate at the point in time when the Appeal Board hearing took place. At every stage, GSK acted transparently, responsibly, and with a commitment to clarifying the evolving interpretation of the actions required to satisfy Clause 26.1.

GSK's documentary evidence and oral submissions at appeal

We have reviewed all Enclosures provided in this case and have systematically cross-referenced them against the Enclosures submitted during the 2024 Case/0269/08/24 proceedings and Appeal Board. This assessment was conducted using all materials that the GSK colleagues involved in Case/0269/08/24 were able to identify and provide now, and therefore represents, to the best of our knowledge, the most complete reconstruction of the communications and documentation relevant to this matter. Based on our current assessment we are confident that all relevant information was provided to the Panel and Appeal Board in the extracts and other Enclosures. As asserted above, we believed at that time that the references to independence and professional distance of UKHSA in the full meeting minutes related to branding and organisational distance, not to a prohibition on continued engagement or a statement about formal approval authority. For completeness and transparency, we have now provided a tabular summary of the full minutes from all meetings held between GSK, UKHSA, and NHS England as Enclosures for the Panel's review.

GSK strongly refutes the suggestion that we may have intentionally not provided the Appeal Board with an accurate representation of the information GSK had received regarding UKHSA's approval role (or lack thereof) in relation to the SPAC. GSK has undertaken a detailed review of the transcript of the Appeal Board hearing on 12th November 2025 provided as Enclosures to this case, and believe that none of GSK's oral statements amounted to suggesting that UKHSA had refuted an approval role prior to being made aware of the initial complaint in Case/0269/08/24. Rather, each statement reflects GSK's understanding at the time, formed through extensive engagement with UKHSA and NHSE from early 2023 onward, that frequent, iterative review and alignment represented the appropriate operational mechanism for fulfilling Clause 26.1 in the absence of a formalised approval pathway.

Throughout the hearing, GSK described *its own intent and interpretation*, not any affirmative claim that UKHSA had validated a ministerial approval function. For example, when asked about how GSK approached UKHSA, GSK explained that we *sought* their agreement and alignment, and that our interpretation had been that repeated meetings and iterative adjustments constituted a pragmatic form of approval. This is supported by contemporaneous records, including the 25th April 2023 meeting minutes and the visual summary timeline we have created for this response, which document UKHSA's repeated input on messaging refinement, eligibility wording, call to action adjustments, and creative development. These materials substantiate that GSK's statements reflected a genuine, evidence based belief about process sufficiency, not an assertion that UKHSA had already taken a formal approval stance.

Similarly, in the Appeal Board exchange on whether UKHSA had ever told GSK that they were not the appropriate approval body further supports our position, as when asked whether UKHSA had corrected GSK or redirected us to health ministers, GSK stated that they had not. GSK's statement that UKHSA had not corrected or redirected us does not imply that we suggested UKHSA had affirmatively accepted an approval role; rather, it demonstrates only the absence of contrary instruction, in line with our understanding of Clause 26.1 at the time, and is an important distinction to recognise.

References to UKHSA being treated as a "*de facto Executive Agency appointed by the Minister*" also do not assert that GSK suggested UKHSA had confirmed this role. This phrasing described GSK's working assumption based on longstanding industry practice, our interpretation of the requirements of Clause 26.1, and UKHSA's established function across national immunisation programmes.

A lack of a clear position from UKHSA on this point prior to their email of 18th August 2025 was not presented by GSK as evidence of approval; it is noted only that UKHSA did not contradict this working assumption, coupled with repeated opportunities to do so. The transcript also shows that when describing the breadth of UKHSA and NHSE engagements leading up to SPAC launch, e.g., "*UKHSA and NHSE were also included, saw everything before it aired, and had opportunity to comment*", GSK framed the involvement strictly in terms of review, feedback, correction, and alignment, which is fully supported by the documentary record (e.g., meeting minutes from 7th March 2023 through late 2024; email confirmations from July 2023; and extracts in Enclosures). At no point did GSK state that such involvement equated to formal ministerial approval, nor that UKHSA had ever communicated that they possessed authority to provide formal approval.

Taken together, GSK's oral statements at appeal were consistent with our understanding at the time, based on recurring, substantive UKHSA engagement with the SPAC programme, the absence of any formal Clause 26.1 approval process or ministerial pathway before June 2025, the absence of any prior explicit statement from UKHSA refuting a formal approval role until August 2025, and the evidentiary material provided to the Appeal Board, which transparently reflected UKHSA's ongoing review and input, while never presenting this as formal approval.

Alongside the transcript, we have reviewed the PowerPoint deck presented to the Appeal Board during the hearing. In GSK's view, the presentation offered a

transparent, factual summary of the public health rationale for SPAC, roles of UKHSA and NHSE, the longstanding ambiguity surrounding Clause 26.1, and the extensive review and alignment process undertaken with UKHSA and NHSE. It did not state or imply that UKHSA had conferred ministerial approval, rather it clearly described the nature of UKHSA's involvement as iterative feedback, correction and alignment of materials. The slides explicitly acknowledged the absence of any defined approval pathway at the time of SPAC development, noted that the PMCPA's Q&A clarifying the MHRA route was only published in June 2025, and demonstrated that GSK's interpretation was based on our best understanding of the unclear process. All material shown in the presentation was consistent with the written evidence already shared during the case, and there was no intention to mislead the Panel or the Appeal Board.

Accordingly, none of the statements made during the presentation and oral discussion at the hearing imply or assert that UKHSA had previously accepted or refuted an approval role, rather they accurately reflect the genuine, contemporaneous understanding under which GSK was operating at the time.

Email from UKHSA dated 25th November and subsequent transparency with the PMCPA

The Panel have also asked us to consider the email sent to GSK by UKHSA on 25th November, which provided further clarification on its standpoint regarding UKHSA's role (or lack thereof) in approval of SPAC. GSK received UKHSA's 25th November 2025 email after the Appeal Board hearing; GSK had received the draft case report by this point, and so notified the PMCPA and requested changes to the draft report before publication (18th December 2025), explaining that UKHSA had since made GSK aware that they did not want to be viewed as providing "approval" for the campaign. In our correspondence with the PMCPA, we highlighted that despite multiple attempts to engage UKHSA after the ruling, we had been unable to clarify whether their concern related to "approval" or "endorsement", and therefore sought to ensure that the published case report would not mischaracterise their position.

We reaffirmed to the PMCPA that, while GSK continued to believe in good faith that the organisational relationship and iterative review of content with UKHSA constituted the practical form of approval required under Clause 26.1, in the absence of a defined process, we wished to transparently reflect UKHSA's current position and minimise any risk of undermining their organisational independence. Accordingly, GSK asked the PMCPA to incorporate two specific wording changes to address these concerns before the report was finalised. This conduct further demonstrates that we did not intend to mislead.

Further Supporting Information

Engagement with UKHSA/NHSE: frequency, purpose, and feedback

Considering the evolving interpretation of Clause 26.1, it is important to explain how our engagements with UKHSA and NHS England informed assumptions we held at the time, during the case hearing and Appeal Board, and why we believed our approach was consistent with established practice.

Between March 2023 through to May 2025, GSK had 18 meetings with UKHSA and NHS England, plus additional substantial email correspondence, to maintain regular, structured engagement with these organisations on the programme's awareness activities (i.e. SPAC). We regularly discussed messaging, operational points, eligibility language, and patient-facing message clarity. Across these interactions, no party instructed GSK not to proceed; rather, we recorded iterative feedback and alignment (e.g., wording refinements, call to action, cohort eligibility clarity). Moreover, we feel that it was reasonable for us to interpret the language used by UKHSA in meetings and correspondence to be an instruction for GSK to continue with SPAC activities. For example, on 28th February 2025 UKHSA engaged with GSK via email, requesting changes to be made to SPAC to reflect the different health system in Scotland. UKHSA stated *"I think continue as is with the remainder of the radio adverts, but if you can consider this for any future campaigns that would be helpful."* This pattern of engagement underpinned GSK's good-faith belief that substantive discussion and alignment with the appropriate public health bodies would suffice to meet the functional expectation of Clause 26.1, with the absence of clarity on the precise "health ministers' approval" route.

Approval vs. endorsement: our understanding at the time

To be clear, GSK has at no point asserted that UKHSA provided "formal approval" of the campaign in a ministerial sense. In the absence of a clear process, we believed – based on industry practice – our extensive engagement with UKHSA and NHS England, and the absence of contrary direction that active, ongoing review, correction and alignment by UKHSA and NHS England was a reasonable, good-faith way to meet the practical intent of Clause 26.1 in the period before the PMCPA's June 2025 Q&A took steps to clarify a route via the MHRA.

Why inclusion of MHRA material further evidences no intent to mislead

Ahead of the Appeal Board hearing, GSK provided evidence of exchange with the MHRA that took place in September 2025 that demonstrated our attempts to clarify the approvals process for vaccine awareness campaigns. If GSK had intended to mislead, it would have been illogical for us to include MHRA correspondence and references within our appeal Enclosures.

We provided those materials precisely to assist the Appeal Board's understanding of an ambiguous and uncertain approval pathway under Clause 26.1, and to be transparent about our attempts to clarify that pathway post-publication of the PMCPA Q&A (June 2025). This inclusion supports the proposition that GSK was not intentionally concealing facts pertinent to the case.

Clause 2 and Clause 5.1

In our response you have asked us to consider Clauses 2 and 5.1 of the 2024 Code. GSK's approach of proactive engagement with UKHSA and NHSE, transparency with the PMCPA and Appeal Board based on our clearest understanding at the time, behaviours and activities in line with established practice up to and after the hearing, and willingness to stop SPAC activities in August 2025 following correspondence with UKHSA, reflects an earnest effort to uphold high standards, not diminish them. The

Appeal Board's findings in Case/0269/08/24 acknowledged the uncertainty at the time and accepted that GSK sought to satisfy the requirements of Clause 26.1 in good faith. The Enclosures that have been provided in Case/0874/02/26 do not provide evidence to overturn these findings.

For the same reasons, and considering the Appeal Board's reasoning that it would not be appropriate to find breaches of 26.1 or 26.2 in Case/0269, a Clause 5.1 breach should not be inferred. GSK's behaviours of consultation during minuted meetings and additional email correspondence, evidence-based refinement, and post-hoc transparency with UKHSA, NHS England and the MHRA are consistent with maintaining high standards.

We always uphold the spirit and the principles of the Code, and decisions were made at the time based on our good-faith understanding in circumstances that were complex and evolving. In preparing the materials submitted in Case/0269/08/24, GSK informed UKHSA that we would be providing extracts from meeting minutes, and we shared these with UKHSA for their review and confirmation, consistent with the collaborative approach we had established together. We sincerely regret that a misunderstanding subsequently arose between our organisations regarding how those materials would be used within the PMCPA process. Our intention was always to ensure transparency and alignment, and we remain appreciative of UKHSA's engagement throughout. While we recognise that aspects of our internal process, for gathering and presenting meeting minute extracts could benefit from clearer structure, and that the absence of a formal SOP presents an opportunity for improvement, this reflection is focused on strengthening our own internal consistency and documentation, not on any shortcoming in our interactions with UKHSA, or any breach of the Code.

Conclusion

As noted in previous submissions, Clause 26.1's operational pathway (who, how, and what documentation) was unclear for vaccination programme awareness campaigns, and this ambiguity persisted even as the PMCPA Q&A emerged in mid-2025. GSK's outreach to UKHSA and MHRA sought to resolve this ambiguity. It is worth reflecting on the fact that GSK are not the only company presently engaging with UKHSA in this way, nor has this changed over the last 20-plus years.

Based on the long established industry understanding that sustained, detailed collaboration with public health bodies forms the practical mechanism for ensuring alignment under Clause 26.1, and given the depth, frequency, and iterative nature of UKHSA's feedback throughout the programme's development, we believed at the time that our approach was fully consistent with the practical expectations of Clause 26.1. Given UKHSA's extensive involvement across meetings, email exchanges, and detailed discussions on messaging, it did not appear reasonable to us to anticipate that UKHSA might later raise concerns about the SPAC or its alignment to their approval role (or lack thereof). Nonetheless, through the course of this case and the subsequent clarifications provided by the PMCPA, we now fully acknowledge now that our prior interpretation may not have been wholly aligned with the recently clarified requirements of Clause 26.1. Going forward, we will ensure that all activities of this nature operate within the clearer framework that has emerged through this process, and we welcome the additional guidance that has helped to crystallise expectations for all companies.

GSK reiterates that there was absolutely no intent to mislead UKHSA, NHS England, the PMCPA or Appeal Board. Our record shows transparent engagement, and a good-faith interpretation of Clause 26.1 amid genuine ambiguity. Prompt corrective steps were taken once new positions were made explicit. We therefore respectfully refute the suggested breaches of Clause 2 and Clause 5.1 and remain fully committed to assisting the PMCPA in concluding this matter swiftly and accurately.”

PANEL RULING

This case was about the completeness and accuracy of GSK’s response and appeal in Case/0269/08/24. Following communication and documents from UKHSA at the completion of that case, a complaint was made in the name of the PMCPA Chief Executive.

The Panel interpreted the allegations to be that GSK did not provide the Panel or the Appeal Board with an accurate representation of the information GSK had received regarding UKHSA’s approval (or lack thereof) in relation to the Shingles Programme Awareness Campaign (SPAC) and Clause 26.1. The allegations concerned three documents provided to the PMCPA by UKHSA:

1. Minutes of a meeting between GSK, UKHSA and NHSE held on 25 April 2023
2. An email from UKHSA to GSK dated 18 August 2025
3. An email from UKHSA to GSK dated 25 November 2025

The Panel considered each allegation in relation to both the Panel and the Appeal Board.

The Panel noted that there was case precedent in relation to the PMCPA taking up complaints about the accuracy and completeness of company responses, including Case AUTH/2780/7/15, Case AUTH/3757/3/23 and Case/0316/10/24.

Summary of Case/0269/08/24

Case/0269/08/24 was in relation to a GSK video about an NHS shingles vaccination programme that was shown as an advertisement on several TV channels.

GSK’s response to the Panel in Case/0269/08/24 stated that “GSK therefore sought to rely on the exemption to Clause 26.1 at the point in time at which there became only one vaccine available” and that “GSK can confirm that the TV video in this case [was] developed in consultation with, and with approval from, the UKHSA and NHSE”.

The Panel in Case/0269/08/24 concluded that because:

- (a) the advert was not a disease awareness campaign (as acknowledged by GSK),
- (b) the advert was promotional of an NHS vaccine campaign in which GSK had the only approved vaccine for NHS use, and
- (c) GSK had not provided evidence of approval by health ministers,

the advert amounted to advertising a prescription only medicine to the public and was a breach of Clause 26.1. The Panel in Case/0269/08/24 also ruled GSK in breach of Clauses 26.2 and 5.1 and ruled no breach of Clauses 6.1 and 2.

GSK appealed the Panel's breach rulings. GSK's appeal stated that Clause 26.1 lacks any information regarding which organisation (or organisations) would provide the de facto approval to satisfy the "approved by the health ministers" exemption to Clause 26.1 and that at the time the complaint was received, there was no other information, guidance or case precedence specifying the MHRA as the sole authority for health minister approval. GSK stated that it "firmly believed UKHSA (an Executive Agency of the Department of Health and Social Care) was the appropriate party to provide the approval by health ministers for the 'vaccination' campaigns referred to in the exemption to Clause 26.1." GSK provided the dates of meetings it had had with UKHSA and NHSE. GSK submitted that "Relevant extracts from the meeting minutes – with unrelated topics and personal identifiers removed" had been provided to the Appeal Board.

The Appeal Board accepted GSK's evidence at the Appeal Board meeting that these minutes had been shared with UKHSA who had not raised any objections to the content of the minutes. Following questioning, GSK representatives told the Appeal Board that the exemption in Clause 26.1 and the requirement for approval from "health ministers" were explicitly discussed with UKHSA.

GSK's appeal was successful and the Panel's breach rulings were overturned. The case report for Case/0269/08/24, amended following a request by GSK which was approved by the Chair of the Appeal Board, stated that "...the Appeal Board concluded that it would not be appropriate to find GSK in breach of Clause 26.1 because it had sought, and believed in good faith that the collaboration and agreed meeting minutes amounted to, approval for the vaccination campaign from government via the UKHSA, and the UKHSA had not told GSK that it needed approval from MHRA, from any other government body or from the health ministers directly in order to meet the exemption."

Chronology of key dates in the complaints process for Case/0269/08/24

- 14 August 2024 – the PMCPA received the complaint
- 27 September 2024 – the PMCPA received GSK's response to the complaint
- 25 June 2025 – the Panel requested further information from GSK
- 2 July 2025 – GSK provided further information
- 17 September 2025 – the Panel sent GSK its ruling
- 25 September 2025 – GSK notified the PMCPA of its intention to appeal
- 24 October 2025 – GSK provided its appeal documentation
- 12 November 2025 – Appeal Board hearing
- 18 December 2025 – GSK requested amendments to the case report

1. Alleged failure to provide minutes of the 25 April 2023 meeting between GSK, UKHSA and NHSE

The minutes of the 25 April 2023 meeting set out the purpose and cadence of the meetings between GSK, NHSE and UKHSA. They stated that while keen to work together, UKHSA had emphasised the importance of maintaining a professional distance, reflective of the independent nature of each organisation. The purpose of the meetings was stated as an opportunity to align on the messaging/content/timing for GSK's activities. They detailed UKHSA and NHSE feedback to GSK on the messaging and content of the SPAC. There was no reference to Clause 26.1 or to either UKHSA or NHSE having any approval role.

a. Failure to provide to the Panel

No meeting minutes or relevant emails were provided to the Panel in Case/0269/08/24. Following a request from the Panel in that case for “documentation demonstrating approval for this campaign by health ministers”, GSK provided a document detailing the dates and attendees from UKHSA and NHSE at meetings where GSK’s SPAC was discussed. GSK submitted that it had not received permission from UKHSA or NHSE to share the minutes of these meetings and that, should these be required, it would require additional time and consent from both organisations.

The Panel bore in mind that it was the responsibility of GSK to ensure that it provided a complete response irrespective of whether the PMCPA requested specific material and noted that the Panel in Case/0269/08/24 had provided GSK with a second opportunity in June 2025 to provide a complete response. That GSK required consent to disclose source documentation ought not, in the Panel’s view, to preclude the provision of a fair and accurate summary of relevant matters as part of its response. Further, it was difficult to understand why GSK had not sought the requisite consents at the outset when notified of the complaint in August 2024.

The Panel in Case/0269/08/24 did not request that GSK obtain permission so the minutes could be shared with the Panel. The Panel’s ruling in Case/0269/08/24 stated that “... *by only seeing a list of meeting dates, and without knowing what was discussed at those meetings, or having any information about the role of the MHRA, the Panel was not satisfied that approval had actually been given in accordance with Clause 26.1. If there was a documented approval, the Panel considered it likely that GSK would have provided it in its response. On the balance of probabilities, and based on the evidence before it, the Panel considered that there likely was no such approval document.*”

Noting the Panel’s decision in Case/0269/08/24, including its ruling of a breach of Clause 26.1, and bearing in mind the content of the 25 April 2023 minutes, the Panel did not consider that the failure to provide those minutes materially affected the Panel’s consideration in Case/0269/08/24 and therefore the Panel considered that GSK had not failed to maintain high standards by not providing the 25 April 2023 meeting minutes to the Panel in Case/0269/08/24. The Panel therefore ruled **no breach of Clause 5.1**.

b. Failure to provide to the Appeal Board

GSK’s written appeal submission stated that “relevant extracts from the meeting minutes – with unrelated topics and personal identifiers removed” had been provided to the Appeal Board. GSK’s appeal further stated that “In the absence of any publicly available information to the contrary, GSK firmly believed that this way of working with UKHSA would be sufficient to satisfy the requirements for the exemption to Clause 26.1.”

While GSK had submitted in its appeal that it had removed “unrelated topics and personal identifiers”, it appeared to the Panel that the extracts provided to the Appeal Board omitted relevant information from the minutes, including the following:

“While keen to work together, UKHSA emphasised the importance of maintaining a professional distance, reflective of the independent nature of each organisation.”

“The group agreed to continue meeting monthly and reflected a common goal of achieving a successful shingles programme. The purpose of these meetings was stated as an opportunity to align on the messaging/content/timing for GSK’s programme awareness activities and to discuss programme implementation questions”

The Panel considered that the above statements, towards the beginning of the minutes, were key statements that set the tone for the rest of the minutes. They highlighted UKHSA’s emphasis on maintaining a professional distance and what the purpose of the meetings was. Given the subject matter of the appeal, the Panel considered that this was important information.

The Panel took account of GSK’s submission that it supplied UKHSA with a copy of the meeting minute extracts, two days before they were submitted to the Appeal Board, to ensure that UKHSA had full visibility of material to be provided to the Appeal Board and to extend an opportunity for UKHSA to raise any comments. However, UKHSA did not reply until after the Appeal Board hearing, at which point it raised concerns about the extracts being misleading and requested that complete minutes be disclosed (with only personal identifiers removed).

In the Panel’s view, self-regulation relied upon the provision of complete and accurate information by pharmaceutical companies and full responsibility in that regard lay with GSK. While the Panel acknowledged that companies may not always be able to provide source documents, what companies communicated about such documents must be fair and accurate. GSK should have recognised (without the need for UKHSA to point it out) that the extracts of the minutes of the 25 April 2023 meeting were not a fair and accurate representation of the full minutes – they omitted key details about UKHSA’s role in the campaign, which was the crux of the appeal.

The Panel considered that GSK’s failure to provide the Appeal Board with all the relevant information from the 25 April 2023 meeting minutes, and its written appeal submission which implied it had done so, was such that GSK had failed to maintain high standards and the Panel ruled **a breach of Clause 5.1**.

2. Alleged failure to provide the email from UKHSA to GSK dated 18 August 2025

GSK wrote to UKHSA on 15 August 2025 to follow up on a conversation that took place on 6 August 2025 in relation to Case/0269/08/24. The email from GSK to UKHSA included:

“As part of the response we have sited [*sic*] the checks and measures we have taken internally and with UKHSA/NHSE to ensure 1. A public need for the campaign; 2. A balanced, well thought-out campaign; 3. That we have engaged with and sought approval from UKHSA/NHSE.

I wanted to make you aware specifically that while we have summarised our process of seeking UKHSA approval, we have not provided any minutes or redacted emails. I flagged that this may be a next step if the PMCPA should either ask for more information or rule us in breach, and hence necessitate an appeal.”

UKHSA’s response to GSK on 18 August 2025 included (emphasis added by the Panel):

“It is helpful to have this understanding of where things are with this complaint. I do however just need to provide correction on some of the wording used below, particularly around approval.

UKHSA were brought into the meetings around the original campaign relatively late in the day – the meetings had commenced with NHSE some time prior to this and the creatives and first stage of the campaign were already developed. We did not ask for or commission the campaigns, and did make clear from the outset that whilst we would be able to review the materials to ensure that they were in line with the clinical and eligibility advice provided in NHS / UKHSA national materials, and generally in terms of our opinions on acceptability, **we would not be able to endorse them**. You will be aware that at the outset, for example, there was some misalignment of the campaign information which did cause some difficulties and which we did have to work on rapidly with you to correct, and we have continued to work together with you collaboratively on that basis. As such, we have reviewed and provided feedback on the campaign materials and have made suggestions as they have been developed, but as this is not a UKHSA commissioned or endorsed campaign **it is not within our remit to give any formal approvals and we have not provided this function**.

Whilst we very much value the positive collaborative relationship we have developed with GSK colleagues, we have been very clear from the outset that there are limits on what we are able to do as part of this work together and that includes **not being in a position to endorse any such industry activity**, which must be undertaken in line with the principles of the Blue Guide and in a way that maintains our independence from each other, as this is itself important for maintaining public trust.

Very happy to discuss, but I hope this clarifies our position.”

a. Failure to provide to the Panel

The Panel noted that this email exchange occurred approximately six weeks after GSK had responded to a request from the Panel in Case/0269/08/24 for further information, and approximately four weeks prior to the Panel in Case/0269/08/24 issuing its ruling.

The Panel considered that the email from UKHSA on 18 August 2025 was fundamental information in relation to Case/0269/08/24, in particular UKHSA’s statement that “it is not within our remit to give any formal approvals and we have not provided this function.” In the Panel’s view, this was in direct contradiction to the response GSK had given to the Panel in Case/0269/08/24 on 2 July 2025, which stated:

“GSK would respectfully suggest that UKHSA is the appropriate government body for approval of vaccination campaigns referred to within the context of ‘vaccination and other campaigns’ in Clause 26.1” ... “GSK can confirm that the TV video in this case [was] developed in consultation with, **and with approval from**, the UKHSA and NHSE, who also reviewed a version of both before they were aired on television.” (emphasis added by the Panel)

Further, the email from UKHSA stated that it had made “clear from the outset that whilst we would be able to review the materials to ensure that they were in line with the clinical and eligibility advice provided in NHS/UKHSA national materials, and generally in terms of our

opinions on acceptability, we would not be able to endorse them". It thus appeared to the Panel that at the beginning of the relationship UKHSA had attempted to make clear the limitations of its role when reviewing material. There was no written evidence before the Panel to indicate whether UKHSA intended a difference in meaning between the terms 'endorse' and 'approval'. While noting that there was no direct mention of Clause 26.1 within the 18 August 2025 email, the Panel considered that the statement "it is not within our remit to give any formal approvals and we have not provided this function" was of direct relevance to the question of whether GSK's SPAC had fulfilled the requirements of Clause 26.1.

In its response to the current case (Case/0874/02/26), GSK submitted that the 18 August 2025 email was escalated internally to senior leaders to agree on the most appropriate way to proceed and an internal decision was made not to disclose the email to the Appeal Board. GSK's response to the current case is silent on whether there was any discussion as to whether the email should be disclosed to the Panel in Case/0269/08/24, given GSK was yet to receive the Panel's ruling at that time; the Panel ruling was not issued until 17 September 2025.

The Panel considered that GSK was in possession of information on 18 August 2025 that clearly contradicted the information it had previously provided to the Panel. As the Panel in Case/0269/08/24 was yet to issue its ruling, the Panel considered that GSK had a responsibility to inform the Panel in Case/0269/08/24 of the new information it had received that was fundamental to the matter at issue. Self-regulation relied on complete and transparent company responses. The Panel considered that failure to provide the 18 August 2025 email to the Panel in Case/0269/08/24 was such that GSK had failed to maintain high standards and **a breach of Clause 5.1** was ruled.

b. Failure to provide to the Appeal Board

The Panel noted GSK's response to the current case stated, "Throughout the appeal process, GSK consistently and accurately stated that it had never asserted that UKHSA was providing formal ministerial approval for SPAC activities". The Panel considered this was a wholly disingenuous statement.

GSK's written appeal submission, made on 24 October 2025, included the following statements:

"In the absence of any publicly available information to the contrary, GSK firmly believed that this way of working with UKHSA would be sufficient to satisfy the requirements for the exemption to Clause 26.1."

"As the government agency charged with the design, planning, communication (to the public and healthcare professionals) and implementation of UK vaccination programmes, UKHSA is considered the relevant stakeholder for vaccination campaigns and – in the absence of any information to the contrary – was also considered the defacto health minister for the purposes of the exemption to Clause 26.1"

"GSK strongly asserts that it acted in-line with the available information regarding the 'health minister' approval exemption to Clause 26.1. GSK believed that UKHSA, given its direct role in the communication and implementation of the Programme, was an appropriate organisation, both from a practical and legal perspective, to engage with to fulfil the requirements of Clause 26.1 for its Programme awareness campaign."

Furthermore, the Panel took account of the transcript of the Appeal Board hearing that had been provided by the case preparation manager, including the following extracts from the questions and answers:

“Appeal Board member:

[...] Do I understand correctly that you assume that UKHSA has delegated authority from health ministers. Is that your assumption? And did you check with anyone if this is the case? How did you how did you decide on that?

GSK rep:

And so we have provided some publicly available documents which actually stipulate that information. But as we have detailed, we have extensive experience in all elements of vaccination programme, decision making, delivery and evaluation, and UKHSA say they are the stakeholder. [...]

“Appeal Board member:

[...] In your conversations with this agency, when you were saying to them ‘we would like your approval for the campaign’ and did they at any stage say ‘no, that's not our role’?

GSK rep:

No, I wouldn't say that was the case. [...]

“Appeal Board member:

[...] So firstly, were they aware that you were asking for their approval because of this bit of the Code?

GSK rep:

Yes.

Appeal Board member:

Yes, ok. And did they at any point say ‘no, we're not the right people - you actually need to go to the health minister’?

GSK rep:

No.”

“Appeal Board member:

So they said they were providing the ministers’ approval?

GSK rep:

I mean, we concluded, and they did not disagree, that they were the de facto Executive Agency appointed by the Minister.”

“Appeal Board member:

[...] So it's your assumption then that the UKHSA has the delegated authority for the Minister?

GSK rep:

Yes”

While GSK may assert it was speaking in relation to its assumption of UKHSA's role at the time of the activity in question, some of the Appeal Board's questioning was in the present tense. In addition, considering the amount of questioning on this point and that it was a fundamental part of the case, in the Panel's view it was misleading for GSK representatives not to point out that they had received an email from UKHSA on 18 August 2025 which clearly stated "it is not within our remit to give any formal approvals and we have not provided this function".

The Panel considered that GSK's failure to provide the Appeal Board with the email of 18 August 2025, which clearly stated UKHSA's position, was grossly misleading. This was compounded by the answers the GSK representatives gave at the appeal hearing. The Panel was particularly concerned that the 18 August 2025 email was discussed internally with GSK senior leaders and a decision taken at senior level not to disclose the evidence to the Appeal Board. The Panel considered that GSK's failure to provide the 18 August 2025 email to the Appeal Board was such that it had failed to maintain high standards and **a breach of Clause 5.1** was ruled.

3. Alleged failure to provide the email from UKHSA to GSK dated 25 November 2025

The email from UKHSA on 25 November 2025 included the following statements:

"As I stated in my email to you of 18th August, UKHSA has neither approved nor endorsed your campaign"

"At no point in that meeting [25 April 2023] or any other meetings did UKHSA say that its role was to approve and/or endorse the content of GSK's programme"

"... UKHSA providing feedback on whether your campaign materials were in line with the clinical and eligibility advice provided in NHS/UKHSA national materials, and generally providing our expert opinion on acceptability, is not approval within the meaning of Clause 26.1. In any event, Clause 26.1 requires approval from health ministers not UKHSA"

"Therefore, UKHSA does not support your statements to the Appeal Board as UKHSA did not approve and/or endorse your campaign, and in any event, even if it could be argued that it did, UKHSA's approval and/or endorsement is meaningless as it has no authority to provide any such approval/endorsement under Clause 26.1."

"Finally, UKHSA reserves its right to write to the Appeal Board/PMCPA to clarify our position with respect to the points raised above."

a. Failure to provide to the Panel

By 25 November 2025, the Panel no longer had an active role in Case/0269/08/24 and the case had already been heard by the Appeal Board.

The Panel considered there was no requirement or obligation for GSK to provide additional information to the Panel in Case/0269/08/24 at the time GSK received UKHSA's email of 25 November 2025. The Panel ruled **no breach of Clause 5.1** in that regard.

b. Failure to provide to the Appeal Board

The Appeal Board hearing was on 12 November 2025. On 18 December 2025, GSK requested amendments to the wording of the Appeal Board's ruling in the case report. The Panel noted that GSK requested the changes because "UKHSA has made us aware that they do not want to be viewed as providing approval". GSK did not refer directly to or provide a copy of the 25 November 2025 email when it made this request.

GSK's requests for amendments to the wording of the Appeal Board's ruling was escalated to the Chair of the Appeal Board. The Chair of the Appeal Board agreed to make amendments.

The Panel considered that GSK's request for amends to the case report should have been accompanied by the 25 November 2025 email from UKHSA. To request amends to the Appeal Board's ruling in the case report without providing this important email was not transparent. It was not simply that UKHSA "do not want to be viewed as providing approval" as stated by GSK when requesting the case report amends, but more importantly and categorically that UKHSA "does not support [GSK's] statements to the Appeal Board as UKHSA did not approve and/or endorse [GSK's] campaign".

The Panel considered that the 25 November 2025 email from UKHSA to GSK provided significant context to the amendments requested by GSK and, as such, should have been provided by GSK alongside its request.

The Panel further considered that the 25 November 2025 email was fundamental information about the case and that GSK should have provided it to the PMCPA irrespective of where in the process the case was. The Panel considered that the allegations related to the provision of information to both the PMCPA and Appeal Board and therefore covered the interaction with the Chair of the Appeal Board about the case report after Case/0269/08/24 had completed.

The Panel considered that the failure of GSK to provide the 25 November 2025 email when requesting amendments to the Appeal Board ruling in the case report was such that GSK had failed to maintain high standards and **a breach of Clause 5.1** was ruled.

Clause 2

The Panel was deeply concerned and disappointed by the conduct of GSK. The integrity of self-regulation relied upon the provision of complete and accurate information by pharmaceutical companies. A lack of transparency in this regard was of considerable concern. The Panel was particularly concerned that the 18 August 2025 email from UKHSA was not provided to the Appeal Board and that this was an active decision made by senior GSK leaders. The Panel was also concerned that it appeared UKHSA was troubled by GSK's communication with the Appeal Board. The Panel considered that in failing to include all relevant information in its submission and communications for Case/0269/08/24, GSK had brought discredit upon, and reduced confidence in, the pharmaceutical industry. The Panel ruled **a breach of Clause 2**.

Report to the Appeal Board

In reference to the appeal in Case/0269/08/24, it appeared to the Panel that there were other emails and minutes (in addition to the three ruled upon above) for which complete disclosure of all relevant details had not been provided. For example, an extract of the minutes for a meeting

on 28 November 2023 provided to the Appeal Board stated that “UKHSA/NHS reiterated that they are happy with the SPAC” but failed to disclose an earlier part of the minute which stated that for future work UKHSA would value “increased visibility of the SPAC campaign plan (including channels/content, such as cinema/radio) and a clear structure/formal process (e.g. who is leading meetings)”.

In the Panel’s view it was difficult to understand why approval of the campaign material under Clause 26.1 had not been dealt with clearly and unambiguously in writing at the outset so that each party could clarify their respective roles and responsibilities. The Panel noted that there was no reference to Clause 26.1 or ‘approval’ in any of the disclosed emails/minutes between GSK and UKHSA/NHSE, until after the date GSK was informed of the PMCPA complaint. Documentation provided by GSK for Case/0874/02/26 referred to a number of materials and activities which were discussed with UKHSA/NHSE in a series of meetings/emails with terms including ‘supportive’, ‘happy’ and ‘alignment’ used interchangeably and across several projects irrespective of the nature of the material or agreement required.

The Panel was seriously concerned about GSK’s conduct in Case/0269/08/24, including its conduct at the Appeal Board hearing and its failure to provide a full and frank disclosure. GSK’s lack of transparency, which had only come to light due to UKHSA contacting the PMCPA, was totally unacceptable.

The Panel bore in mind that Case/0269/08/24 concerned the approval or lack thereof by a public body, the UKHSA, in a therapeutic area where public confidence was paramount. To not accurately reflect the position of that public body was unacceptable.

The Panel considered that its serious concerns warranted **reporting GSK to the Appeal Board in accordance with Paragraph 10.2** of the Constitution and Procedure, for the Appeal Board to consider additional sanctions in relation to Paragraph 13.4.

APPEAL BY GSK

GSK’s written basis for appealing is reproduced below.

“Further to our Notice of Appeal of 26th May 2026, we now provide GSK’s reasons for appealing breaches of the Code as ruled by the Panel in Case/0874/02/26 and respond to the Panel’s decision to refer the case to the Appeal Board.

This appeal relates to:

- The ruling of breach of Clause 5.1 [1b] regarding alleged failure to provide the Appeal Board minutes of 25th April 2023 meeting between GSK, UKHSA and NHSE;
- The ruling of breach of Clause 5.1 [2a] regarding alleged failure to provide to the Panel the email from UKHSA to GSK dated 18th August 2025;
- Certain aspects of the reasoning of the panel ruling in reference to an alleged failure to provide to the Appeal Board the email from UKHSA to GSK dated 18th August 2025 but not the conclusion of a breach of Clause 5.1 [2b];
- The ruling of breach of Clause 2.

GSK does not seek to appeal:

- The ruling of breach of Clause 5.1 [3b] regarding alleged failure to provide the Appeal Board the email from UKHSA to GSK dated 25th November 2025.

Preliminary observations

We have reflected very carefully on the Panel's findings, both at UK operating company leadership level and with Global organisational colleagues responsible for governance, compliance and medical oversight across the entire business, as well as seeking external legal counsel. We are grateful to the PMCPA for the extension to the response timeline to proceed as such.

At the outset, GSK would like to state clearly and unequivocally that it regrets that certain aspects of its handling of Case/0269/08/24 were not dealt with in line with the standards we have as a company, and this is reflected in our acceptance of the ruling of breach of Clause 5.1 regarding alleged failure to provide the Appeal Board the email from UKHSA to GSK dated 25th November 2025, and the panel ruling for the breach of Clause 5.1 in reference to an alleged failure to provide to the Appeal Board the email from UKHSA to GSK dated 18th August 2025.

We fully recognise the seriousness of the Panel's findings in these respects and the Panel's concerns regarding the standards required to uphold the integrity and effectiveness of the self-regulatory system. We acknowledge without reservation, the importance of transparency in all interactions with the PMCPA and the Appeal Board.

Through this appeal we would like to draw the Board's attention to the facts that we set out in our ongoing correspondence with the PMCPA regarding this case, together with clear evidence, the context and rationale for the decisions taken, including our strong assertion as to why these were not motivated by any intent to conceal material facts from the PMCPA or to disregard its role.

The factual background to this case is fundamental to a proper understanding of the matters under appeal. For reasons of brevity, it is not repeated in full within this letter; instead, a summary is provided as [an] Enclosure for the Appeal Board's consideration.

GSK's Response and the Panel's Ruling

GSK was seriously concerned by the matters raised in the PMCPA's letter of 17th February 2026 and have conducted a careful review of events in Case/0269/08/24. In its response, GSK addressed the dates identified in the PMCPA's letter of 17th February 2026 as well as the minutes of 25th April 2023 meeting with UKHSA. We sought to explain the background to GSK's response to Case/0269/08/24 and the context underlying the differences in interpretation between UKHSA and GSK, and disputed any breaches of the Code.

In light of the above and the Appeal Board's consideration of this matter, we set out below our reasons for appeal in relation to certain rulings of breaches of the Code, as well as our responses to the referral under Paragraph 10.2 of the Constitution and Procedure.

GSK's Appeal

The Appeal Board already has access to the full documentary record in this matter. In this submission, GSK has therefore not revisited the background to Case/0269/08/24 or Case/0874/02/26, which are also summarised in [an] Enclosure. This letter focuses on those matters where the Panel ruled a breach of the 2024 Code, using the numbering set out in the Panel's letter of 30th April 2026.

Appeal of the ruling of breach Clause 5.1 regarding the alleged failure to provide minutes of 25th April 2023 meeting between GSK, UKHSA and NHSE to the Appeal Board.

GSK respectfully submits that the redactions made in preparing extracts of the minutes for appeal did not impact the underlying factual position, but rather the manner in which the information was presented and the exercise of contemporaneous judgement as to its relevance.

It is standard and proportionate practice in such circumstances to provide extracts of documents, particularly where full minutes contain material that is not directly relevant to the issues under consideration. The extracts provided to the Appeal Board were selected in good faith to highlight those aspects of the discussion considered most relevant to the specific question before the Board at that time regarding satisfaction of the requirements of Clause 26.1 for the SPAC campaign specifically. This necessarily involved a judgement as to relevance, rather than any intention to omit material that would have altered or undermined the position presented.

GSK accepts that, in retrospect, it would have been preferable to provide the full minutes to the Appeal Board. Nevertheless, the extracts that were disclosed were not misleading and accurately reflected the substance of the discussion. The wording of these extracts is identical to that shared with UKHSA, as set out in [an enclosure to] our original response letter, demonstrating consistency in GSK's communication. The further text referenced by the PMCPA, including the independence of UKHSA and the common goal of the meetings to achieve a successful shingles programme, does not change the overall sense or context of the information provided.

Importantly, GSK maintains that the meeting extracts represent a fair and accurate reflection of the key points relevant to the issues before the Appeal Board. In this context, and given that the redacted material did not contradict the position presented, GSK respectfully submits that the provision of extracts should not, of itself, be equated with the creation of a misleading impression, particularly where the underlying facts remain unchanged.

GSK therefore does not believe that the conditions are met on this point to support a finding of breach of Clause 5.1.

Appeal regarding the ruling of breach Clause 5.1 on alleged failure to provide to the Panel the email from UKHSA to GSK dated 18th August 2025

GSK did not disclose the email of 18th August to the Panel in view of GSK's wish to investigate the conflict between UKHSA's statement in that email with GSK's understanding of an established position of prior interactions with the organisation, and wider industry practice. At the time, GSK did not consider the email represented a settled or authoritative position that should supersede the broader body of interactions and subsequent clarification being actively sought.

In the period following receipt of 18th August email from UKHSA, as set out in our initial response letter and enclosures, GSK took a number of steps to resolve this inconsistency and seek authoritative clarification, including:

- Halting all SPAC activities pending clarification with UKHSA
- Requesting via email that UKHSA advise on the appropriate MHRA contact for us to reach out to for formal guidance
- Independently seeking advice from MHRA in the absence of a response from UKHSA
- Engaging NHS England via email to seek their perspective on the differing positions

These actions demonstrate that GSK treated the issue with appropriate seriousness and urgency, and was actively seeking to resolve the ambiguity in a responsible manner. However, as the Panel issued its decision on 17th September 2025 before this process had been concluded, GSK did not reach a point of clarity on the position prior to the Panel's determination, which found a breach of Clause 5.1 in any event.

GSK therefore does not consider that the conditions are met on this point to support a finding of breach of Clause 5.1.

Appeal of specific aspects of the reasoning of the panel ruling on a breach of Clause 5.1 [2b] in reference to an alleged failure to provide to the Appeal Board the email from UKHSA to GSK dated 18th August 2025.

While we have explained GSK's attempts to responsibly address the email of 18th August 2025 during the period in which the Panel was reviewing evidence, we accept that we should have concluded that the ongoing reasons to defer providing this email pending clarification were outweighed by other factors in favour of disclosure, and that failure to provide this material did not reflect the standards expected under the Code. We deeply regret this omission and accept the ruling of breach of Clause 5.1 by the Panel in this respect.

However, without resiling in any way from the above acceptance, in reference to PMCPA's findings, we strongly disagree that the references to questions at the appeal hearing being in the present tense rather than reflecting GSK's understanding at the time of the SPAC was being considered, are fair or reasonable. An appeal hearing is necessarily a stressful event and inevitably matters may be inferred following review of a written transcript after the event, that were not identified at the time. To construe somewhat ambiguous wording on a transcript "So it's your assumption then that the

UKHSA has the delegated authority for the Minister...” as indicating that GSK’s response was intended to be in the present tense and as such was ‘misleading’ does not, in our view, fully reflect the context in which the response was given.

Secondly, we recognise the Panel’s concern regarding the reference to “senior leaders” in GSK’s response, and the importance of accountability at all levels of the organisation, particularly in matters relating to transparency and engagement with the PMCPA. We are concerned that some of the language used in the Panel’s ruling may be misinterpreted as implying that GSK acted from the highest level of leadership with a deliberate intention to mislead or conceal information from the PMCPA or the Appeal Board.

As to intent, such inference fundamentally conflicts with GSK’s core beliefs and the standards which guide our interactions and conduct. GSK stand by our firm assertion conveyed in our response letter that there was at no time any intention on the part of GSK deliberately to mislead either the Panel or the Appeal Board. Instead, as set out in our response, the relevant decisions by GSK were taken in the context of genuine contemporaneous judgments about relevance, timing, and completeness against a backdrop of a developing interpretation of Clause 26.1, including in the context of input requested from the PMCPA and MHRA.

In addition, GSK wishes to clarify the meaning of this reference to “senior leaders” in our response letter. The term was intended to refer to appropriately senior individuals within the UK operating company organisation with direct responsibility for the matter in question, specifically [job titles provided]. It was not intended to suggest, and it would not be accurate to infer, that the decisions in question were escalated to, or directed by, executives at the most senior levels of the organisation, such as executive or global leadership.

Rather, the reference was intended to reflect that the matters in question were escalated and considered within the appropriate UK operating company governance structures, by individuals with the relevant expertise and accountability, in the context of what was understood at the time to be a complex and evolving situation.

We fully acknowledge that, as reflected in the Panel’s findings, certain decisions did not meet the standard expected under the Code. However, we want to make it clear that the reference to “senior leaders” should be understood in this context, as part of a local governance and escalation process, rather than being suggestive of evidence of a broader organisational failing.

We do not therefore believe that these matters should be included in the reasoning for a finding of breach of Clause 5.1 or the final case report for this matter.

Appeal of the ruling of breach of Clause 2

GSK fully recognises the seriousness of the issues identified and accepts two of the Panel’s findings of breach of Clause 5.1. However, GSK respectfully submits that, when considered in full context, the circumstances do not meet the high threshold required for a finding of breach of Clause 2.

The Panel's reasoning refers in particular to the non-disclosure to the Appeal Board of the email of 18th August 2025, a failing which GSK accepts. GSK also notes the Panel's reference to this being "an active decision made by senior GSK leaders". As set out elsewhere in this letter, GSK considers that this characterisation does not fully reflect the context of the internal discussions at the time, which involved good faith and contemporaneous judgements regarding relevance, timing and completeness, rather than any intention to mislead or conceal.

The Panel also states that "it appeared UKHSA was troubled by GSK's communication with the Appeal Board". At no stage did GSK represent to the Appeal Board that UKHSA had provided formal approval; rather, GSK set out its own understanding at the time, informed by the nature and extent of its engagement. GSK had actively and repeatedly engaged with UKHSA, as well as the MHRA and NHS England, between 2023 and 2025, including sharing materials and seeking input to ensure alignment and clarity in a developing and uncertain environment. While UKHSA did not provide substantive input ahead of the Appeal Board hearing, the contemporaneous materials demonstrate consistency in GSK's communications as its understanding of Clause 26.1 evolved in the context of differing interpretations of "approval by health ministers".

Importantly, there is no evidence of any deliberate concealment, falsification, or attempt to secure any commercial, promotional, or strategic advantage. GSK took the independent decision to cease SPAC following UKHSA's email of 18th August, and the non-disclosure did not alter the outcome of the Panel's consideration. In these circumstances, there was no discernible benefit to GSK arising from the omission.

Nor do the circumstances indicate any systemic or egregious failure of governance. On the contrary, the evidence demonstrates that matters were actively escalated and considered within GSK, reflecting governance processes that were engaged and functioning, albeit imperfectly in a complex and evolving context.

While GSK acknowledges that aspects of its approach to transparency with the Appeal Board fell short of the standards expected under the Code, these matters are properly characterised as errors of judgement in a developing regulatory environment, rather than conduct that is dishonourable, misleading in any intentional sense, or such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry.

In these circumstances, GSK respectfully submits that the evidence does not support a conclusion that it acted intentionally or recklessly so as to justify a finding of breach of Clause 2.

The referral under Paragraph 10.2 of the Constitution and Procedure to consider additional sanctions

GSK accepts that the way in which certain aspects of its response to Case/0269/08/24 were handled did not fully reflect the requirements of the Code or the standards set by GSK for its own behaviour. Although we assert this to be an isolated incident, GSK has taken it very seriously, hence the initial review of Case/0269/08/24 by independent personnel. That review provides a basis for UK operating company leadership (under a new General Manager) to make appropriate adjustments to procedures and reinforce the significance of transparency.

However, GSK respectfully submits that the circumstances of this case do not warrant the imposition of additional sanctions under Paragraph 10.2. The issues identified arise from a series of contemporaneous judgements regarding the handling, timing and presentation of information in a complex and evolving situation, rather than from any deliberate or reckless disregard for the Code. As set out in this appeal, GSK actively sought to clarify areas of uncertainty with key stakeholders, engaged proactively, and stopped SPAC activities whilst it took steps to ensure that collective positions were appropriately understood.

GSK has accepted those areas where its approach fell short. There is no evidence of deliberate intent to mislead, concealment for advantage, or systemic failure in governance or culture. In these circumstances, GSK respectfully submits that the matters identified are appropriately addressed through the findings made by the Panel and accepted by GSK in this response, and that the threshold for the imposition of additional sanctions under Paragraph 10.2 is not met.

Conclusion

GSK is grateful to the Appeal Board for its careful consideration of this matter, and of the issues arising from what we recognise has been a complex and challenging case.

We reiterate that GSK accepts a number of the Panel's overall findings, and the seriousness of the concerns identified. We acknowledge that aspects of our approach fell short of the standards expected under the Code, and we are committed to ensuring that the learnings from this case are fully embedded in our processes and behaviours going forward.

GSK are seeking the Appeal Board to:

- Overturn the ruling of breach Clause 5.1 [1b] regarding alleged failure to provide the Appeal Board minutes of 25th April 2023 meeting between GSK, UKHSA and NHSE;
- Overturn the ruling of breach Clause 5.1 [2a] regarding alleged failure to provide to the Panel the email from UKHSA to GSK dated 18th August 2025;
- Overturn specific aspects of the reasoning regarding the breach of Clause 5.1 [2b] in reference to an alleged failure to provide to the Appeal Board the email from UKHSA to GSK dated 18th August 2025;
- Overturn the ruling of breach of Clause 2.

We raise these points in a spirit of respect for the self-regulatory system and the Appeal Board's role within it, and to ensure that the public record accurately reflects the nature of the findings made. GSK remains committed to the highest standards of transparency, integrity and compliance, and to reinforcing confidence in the self-regulatory framework.

We would be pleased to provide any further clarification that may assist the Appeal Board."

RESPONSE FROM THE COMPLAINANT

The complainant (PMCPA Chief Executive) was not entitled to appeal the Panel's rulings of no breach of the Code or to respond to GSK's appeal.

APPEAL BOARD RULING

Alleged failure to provide minutes of the 25 April 2023 meeting between GSK, UKHSA and NHSE to the Appeal Board [1b]

While GSK submitted that, in retrospect, it would have been preferable to provide the full minutes to the Appeal Board in Case/0269/08/24, the Appeal Board disagreed with GSK's assertion that the extracts provided accurately reflected the substance of the discussion.

The Appeal Board considered that relevant statements were not included in the extracts of the 25 April 2023 meeting minutes that GSK provided to the Appeal Board in Case/0269/08/24, namely:

“While keen to work together, UKHSA emphasised the importance of maintaining a professional distance, reflective of the independent nature of each organisation.”

“The group agreed to continue meeting monthly and reflected a common goal of achieving a successful shingles programme. The purpose of these meetings was stated as an opportunity to align on the messaging/content/timing for GSK's programme awareness activities and to discuss programme implementation questions”.

The Appeal Board considered that relevant information from the minutes, which set out the framework and purpose of the meetings and the nature of the relationship between the parties, had not been provided to the Appeal Board in Case/0269/08/24 and such information was directly relevant to the appeal in that case.

The Appeal Board noted that the decision to provide an extracted copy of the 25 April 2023 minutes to the Appeal Board in Case/0269/08/24 was made by GSK after it had received the email from UKHSA dated 18 August 2025 (see below). GSK would, therefore, have been aware of the relevance of those paragraphs from the 25 April 2023 minutes that were not included in extractions provided and aware that the extractions did not provide the full picture.

The Appeal Board considered that self-regulation relied upon the provision of complete and accurate information by pharmaceutical companies. GSK should have recognised that the extracts of the minutes of the 25 April 2023 meeting were not a fair and accurate representation of the full minutes – they omitted key details about UKHSA's role in the campaign, which was the crux of the appeal.

The Appeal Board considered that GSK's failure to provide it with all the relevant information from the 25 April 2023 meeting minutes, and its written appeal submission in Case/0269/08/24 which implied it had done so, was such that GSK had failed to maintain high standards and the Appeal Board upheld the Panel's ruling of **a breach of Clause 5.1**. The appeal on this point was unsuccessful.

Alleged failure to provide the email from UKHSA to GSK dated 18 August 2025 to the Panel [2a]

The Appeal Board observed that the email from UKHSA to GSK on 18 August 2025 stated that “it is not within our remit to give any formal approvals and we have not provided this function.” This was received by GSK approximately four weeks prior to the ruling in Case/0269/08/24 being issued by the Panel.

The Appeal Board considered that this statement from UKHSA was in direct contradiction to the response GSK had previously given to the Panel in Case/0269/08/24 which stated that “GSK would respectfully suggest that UKHSA is the appropriate government body for approval of vaccination campaigns referred to within the context of ‘vaccination and other campaigns’ in Clause 26.1” ... “GSK can confirm that the TV video in this case [was] developed in consultation with, and with approval from, the UKHSA ...”.

The 18 August email from UKHSA stated that it had made “clear from the outset that whilst we would be able to review the materials to ensure that they were in line with the clinical and eligibility advice provided in NHS/UKHSA national materials, and generally in terms of our opinions on acceptability, we would not be able to endorse them”. The Appeal Board considered that the communication supported some agreement for alignment between GSK and UKHSA on clinical and eligibility messaging but this was entirely different from formal approval of the campaign which had been expressly rejected by UKHSA.

GSK submitted that it did not disclose the email of 18 August to the Panel as it wished to investigate the conflict between UKHSA’s statement in that email and GSK’s understanding. GSK’s representatives at the appeal in Case/0874/02/26 submitted that GSK had found no evidence that the decision not to disclose this email to the Panel was a deliberate attempt to mislead. The Appeal Board considered that this decision was totally unreasonable. UKHSA’s position was clear from the 18 August email and there was no legitimate reason for it not to have been provided to the Panel as soon as it came to the attention of GSK.

The Appeal Board considered that GSK was in possession of information on 18 August 2025 that clearly contradicted the information it had previously provided to the Panel in Case/0269/08/24. As the Panel in Case/0269/08/24 was yet to issue its ruling, the Appeal Board considered that GSK had a responsibility to inform that Panel of the new information it had received that was fundamental to the matter at issue. Self-regulation relied on complete and transparent company responses. The Appeal Board considered that failure to provide the 18 August 2025 email to the Panel in Case/0269/08/24 was such that GSK had failed to maintain high standards, and it upheld the Panel’s ruling of a breach of Clause 5.1. The appeal on this point was unsuccessful.

Alleged failure to provide the email from UKHSA to GSK dated 18 August 2025 to the Appeal Board [2b]

The Appeal Board observed that GSK had accepted the Panel’s conclusion of a breach of Clause 5.1 on this matter, but it had appealed the ruling on the basis of disagreement with some of the Panel’s wording. The Appeal Board considered the matter as an appeal in the usual way.

The Appeal Board understood that at least one of the GSK representatives that attended the appeal hearing in Case/0269/08/24 was a recipient of the email from UKHSA to GSK on 18

August 2025. GSK's representatives at the appeal in Case/0874/02/26 submitted that GSK had found no evidence that the decision by GSK's representatives not to disclose this email to the Appeal Board in Case/0269/08/24 was a deliberate attempt to mislead. The GSK representatives at the appeal in Case/0874/02/26 submitted that it was due to confusion that the GSK representatives at the appeal in Case/0269/08/24 thought they needed to answer to their understanding at the time of the campaign development rather than their understanding at the time of the appeal. The Appeal Board wholly rejected this assertion. It was clear and apparent that the email should have been provided to the Appeal Board in Case/0269/08/24 or at the very least referred to by GSK representatives at that appeal hearing following the multiple questions by Appeal Board members directly related to the subject matter of that correspondence. The Appeal Board considered that GSK's failure to provide the Appeal Board in Case/0269/08/24 with the email of 18 August 2025, which clearly stated UKHSA's position, was grossly misleading. This was compounded by the answers the GSK representatives gave at the appeal hearing in Case/0269/08/24. The Appeal Board inferred from the sequence of events that there was an intention to deliberately mislead the Appeal Board in Case/0269/08/24. The Appeal Board considered that GSK's failure to provide the 18 August 2025 email to the Appeal Board in Case/0269/08/24 was such that it had failed to maintain high standards and the Appeal Board upheld the Panel's ruling of **a breach of Clause 5.1**. The appeal on this point was unsuccessful.

Clause 2

The Appeal Board observed that GSK had multiple opportunities to provide a full and frank response and considered that the conduct of GSK in Case/0269/08/24 was totally unacceptable and represented a significant failure by GSK to comply with the crucial requirement expected of those enjoying the privilege of self-regulation to be transparent with the Panel and the Appeal Board. The Appeal Board was particularly concerned by the positive decisions made by GSK's representatives to not provide or refer to crucial correspondence that GSK had had with UKHSA that was unambiguously contradictory to the company's submissions. To claim confusion for this decision was disingenuous. The Appeal Board questioned the culture within GSK in this regard. The Appeal Board was also concerned that there appeared to be a lack of governance around GSK's approach to the campaign in relation to the requirements of Clause 26.1. The Appeal Board considered that if the Appeal Board in Case/0269/08/24 was made aware of the 18 August email from UKHSA to GSK it may have changed the outcome in Case/0269/08/24. The Appeal Board considered that in failing to provide a full and frank disclosure of all relevant information in its submission and communications for Case/0269/08/24, GSK had brought discredit upon, and reduced confidence in, the pharmaceutical industry. The Appeal Board upheld the Panel's ruling of **a breach of Clause 2**. The appeal on this point was unsuccessful.

APPEAL BOARD'S CONSIDERATION OF THE REPORT FROM THE PANEL

The Appeal Board took account of both its and the Panel's comments and rulings of breaches of the Code (including the ruling of a breach of Clause 2) and the reasons for the Panel's decision to report GSK to the Appeal Board.

Having considered the evidence before it, the Appeal Board was deeply concerned about the seriousness of the breaches in this case and GSK's conduct in relation to it. The Appeal Board considered the full range of options available to it by way of further sanctions under Paragraph 13.4 of the Constitution and Procedure. The Appeal Board discussed whether GSK should be audited or reported to the ABPI Board (Paragraph 14.1) due to its serious concerns about the company's conduct, including whether such conduct may represent a broader cultural issue

within the organisation. The Appeal Board took account of the GSK representatives' explanation at the hearing for Case/0874/02/26 that the conscious decisions made to not disclose certain information were taken by a very small number of individuals in the UK affiliate. Taking everything into account, the Appeal Board decided that GSK should be publicly reprimanded, for the reasons set out in the public reprimand below.

The Appeal Board agreed the following public reprimand:

"GSK has been publicly reprimanded by the Code of Practice Appeal Board under Paragraph 13.4 of the Constitution and Procedure, for its significant failure to comply with the crucial requirement, expected of all those enjoying the privilege of self-regulation, of complete transparency and openness with the Regulator.

In Case/0874/02/26, the Appeal Board upheld the Panel's findings of a breach of Clause 2 and breaches of Clause 5.1 for GSK's failure to provide a full and frank disclosure in a previous case (Case/0269/08/24). Following that determination, the Appeal Board considered the decision by the Panel to report GSK to the Appeal Board under Paragraph 10.2 of the Constitution and Procedure for consideration of additional sanctions.

The breaches in Case/0874/02/26 related to GSK's failure (in Case/0269/08/24) to provide both the Panel and the Appeal Board with minutes and correspondence between GSK and the UKHSA that was fundamental to the matter at issue.

The Appeal Board did not accept the submissions by those representing GSK at the hearing for Case/0874/02/26 that GSK's conduct in Case/0269/08/24 was simply a poor decision or error of judgment as to relevance of material. There were, rather, positive decisions in Case/0269/08/24 by those at GSK who responded to the complaint and then, more egregiously, by those who were involved in the appeal, to withhold material available to them from the UKHSA that was unambiguously contradictory to the company's submissions.

The Appeal Board considered, in particular, two of the points made by the Panel in reporting the case to the Appeal Board:

1. That GSK's conduct and failure of transparency in Case/0269/08/24, which only came to light as a result of the UKHSA contacting the PMCPA, was "totally unacceptable".
2. Further, that the failure to accurately reflect the position of a public body in regulatory proceedings in a therapeutic area where public confidence was paramount, was "unacceptable".

The Appeal Board agreed with the Panel's view. The Appeal Board agreed that the decision by senior UK leaders not to provide crucial material to the Appeal Board in Case/0269/08/24, and not to mention crucial correspondence during questioning by the Appeal Board, was clear evidence that a positive decision had been made not to be transparent in order to avoid undermining the company's submissions on appeal. That behaviour was indeed "totally unacceptable".

The Appeal Board recognised that those who represented GSK at the hearing for Case/0874/02/26 accepted that GSK "should have managed Case/0269/08/24 differently".

However, the Appeal Board did not consider that such an acceptance properly recognised the seriousness of GSK's behaviour.

For the public to have trust in the pharmaceutical industry, the public must have trust in the pharmaceutical industry's ability to self-regulate. Self-regulation is administered through the ABPI Code by the PMCPA, and the Appeal Board. Transparency is one of the four key ABPI Principles and is an important means to building and maintaining confidence. GSK's positive decision not to be transparent undermines the premise of the Code, the PMCPA, the Appeal Board and self-regulation.

The Appeal Board considered that GSK's failure to supply full and frank disclosure of relevant material in the company's possession led the Appeal Board to make a finding of no breach in relation to Case/0269/08/24 that it may otherwise not have done. The Appeal Board noted that the PMCPA's Constitution and Procedure does not allow for a setting aside of a decision by the Appeal Board in these circumstances; this may only be done where there has been a "procedural error" (Paragraph 1.12). The ruling made by the Appeal Board in Case/0269/08/24 cannot, therefore, be set aside, even though it was made without crucial information."

Complaint received 11 February 2026

Case completed 28 July 2026