CASE/0272/08/24

COMPLAINANT / CHIEF EXECUTIVE v GSK

Misleading claims and an alleged breach of undertaking

CASE SUMMARY

This case concerned the ongoing availability of three historical GSK press releases on its corporate website. The complainant made a number of allegations regarding the content of the press releases including that they contained misleading efficacy claims, similar to those ruled in breach in a previous case, Case AUTH/3760/4/23, and thus amounted to a breach of the undertaking given in that case.

There was an appeal by GSK of all of the Panel's rulings.

The outcome under the 2021 Code was:

Breach of Clause 6.1 (x4) [Panel's breach rulings upheld at appeal]	**Making a misleading claim**
Breach of Clause 6.2 [Panel's breach ruling upheld at appeal]	**Making an unsubstantiated claim**
Breach of Clause 6.4 [Panel's breach ruling upheld at appeal]	**Making claims that did not reflect the available evidence regarding possible adverse reactions**

No Breach of Clause 2 [Panel's breach ruling overturned at appeal]	**Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**
No Breach of Clause 3.3 [Panel's breach ruling overturned at appeal]	**Requirement to comply with an undertaking**
No Breach of Clause 14.4 [Panel's breach ruling overturned at appeal]	**Requirement that materials must encourage the rational use of a medicine by presenting it objectively and without exaggerating its properties**

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

FULL CASE REPORT

A complaint about GlaxoSmithKline UK Limited ("GSK") was received from a contactable complainant who described themselves as a member of the public.

Part of the complaint concerned an alleged breach of undertaking. As the PMCPA was responsible for ensuring compliance with undertakings, that aspect of the complaint was also taken up in the name of the Director (now known as the Chief Executive).

COMPLAINT

The complaint wording is reproduced below with some typographical errors corrected:

> "I recently complained to you was [sic] about a GSK press release for their covid vaccine (actually a joint venture with Sanofi), Case AUTH/3760/4/23. The Panel found that GSK had breached Clause 6.1 of your Code by misleadingly failing to present absolute efficacy rates alongside relative efficacy rates. GSK accepted this finding and did not appeal it. They did however, apparently, sign an undertaking. Although the PMCPA apparently does not currently publish details of these signed undertakings, the section of the PMCPA website entitled 'Sanctions' states that generally the undertaking given is that *'the practice in question has ceased forthwith and that all possible steps have been taken to avoid a similar breach in future'.* This section also states that *'an undertaking must be accompanied by details of the action taken to implement the ruling'.* I do not know the exact details of the action which GSK have been required to take as these have also not been published. However, I find it difficult to imagine that GSK will not have been expected, or indeed told, to ensure that there are no similarly offending materials currently accessible by the public.
>
> You will recall that I took exception to what I considered to be an inappropriately insulting and intimidatory section of the GSK response to my complaint. I said that I thought it was ill-judged and regrettable and offered GSK the opportunity to apologise and withdraw it. However, they declined to do so. The PMCPA also refused to publish my rebuttal of this GSK statement in the final case report but did publish the GSK statement.
>
> I notice that the case report for AUTH/3760/4/23 has now, at last, been published on your website. I have been reading it closely, in particular, the GSK assertions that :
>
> 1. '*One of the main targets for this* ("misinformation and conspiracy theories") *was (and remains) anti-vaccine misinformation',* and….
>
> 2. GSK were aware of the previous similar cases but apparently did not think that these findings should have any bearing on their behaviour, apparently because *'Importantly, neither Pfizer or AstraZeneca appealed the breaches of 7.2 (2019), and thus did not take full advantage of the self-regulatory process to argue their case at the Appeal Board.'* This statement is particularly intriguing partly because GSK themselves then also did not take the opportunity to *'take full advantage of the self-regulatory process to argue their case at the Appeal Board.'* when they were found guilty of a similar offence for the same reasons.
>
> I was also intrigued by the PMCPA statements that :
>
> 1. *'The Panel noted GSK's submission that it had in place a specific framework for the review, approval and issue of global press releases where materials were*

intended for global media and/or financial analysts and that this had been followed in relation to the press release at issue.' And….

2. *'In the particular circumstances of this case, the Panel did not consider the complainant had established that GSK took 'little interest in PMCPA decisions or had little incentive to learn from them' and based on the narrow allegations ruled no breach of Clause 5.1'*

I therefore decided to conduct a further very brief and simple internet search to check the effectiveness of this 'specific framework' and also the recent record of GSK in complying with clause 6.1 of your Code, the findings of Case AUTH/3760/4/23 and the requirements of the undertaking which they have apparently recently signed. As a result of this brief search, I would now like to submit a formal complaint concerning 3 other press releases about their covid vaccines which have been issued by GSK.

I am afraid that my simple search has revealed that GSK appear to have displayed a lack of respect for your Code and findings with regard to other published materials relating to their covid products and these materials still remain accessible to the general public. I have listed below links to three GSK press releases relating to covid-related products. Alongside each press release I have indicated where they have made misleading statements, about the efficacy of these products, which are neither compliant with your Code nor your findings in Case AUTH/3760/4/23. Therefore each is a further breach of Clauses 6.1, and also a breach of the undertaking they apparently signed as a result of the findings for AUTH/3760/4/23. In addition, one press release also makes a misleading statement about the safety of the product and an exaggerated and unsubstantiated claim for *'100% efficacy'*. In order to access these press releases (all originating in London, UK) I merely had to type the simple search terms 'GSK, Covid, Press Release' into Google and then click on the links provided.

1. Sanofi-GSK first to report a successful efficacy study against Omicron with COVID-19 Beta-containing vaccine | GSK US

In this press release (dated 24 June 2022) the following misleading statements are made :

- *'Primary vaccination with Beta-containing vaccine candidate delivers 64.7% efficacy against symptomatic infection in adults, and 75.1% efficacy in participants previously infected with COVID-19'*
- *'Against Omicron, sequencing analysis performed to date shows 72% efficacy in all adults and 93.2% in seropositives'*
- *'the Sanofi-GSK Beta-containing vaccine candidate demonstrated an efficacy of 64.7% (95% confidence interval [CI, 46.6, 77.2]) against symptomatic COVID-19 and 72% efficacy (95% confidence interval [CI, 45.8, 86.6]) in Omicron-confirmed symptomatic cases'*
- *'the Sanofi-GSK vaccine candidate demonstrates an overall efficacy of 75.1% (95% confidence interval [CI, 56.3, 86.6]) against symptomatic infection, and 93.2% (95% confidence interval [CI, 73.2, 99.2]) in Omicron-confirmed symptomatic cases'*

These are all relative efficacy rates and no absolute rates are given. They therefore all represent multiple breaches of Clause 6.1 and their continued accessibility by the general public represent breaches of undertaking.

2. Sanofi and GSK to seek regulatory authorization for COVID-19 vaccine | GSK

In this press release dated 23 February 2022 the following misleading statements are made:

- *'75% efficacy against moderate or severe COVID-19 disease'*
- *'57.9% efficacy against any symptomatic COVID-19 disease'*
- *'two doses of Sanofi-GSK vaccine generated an efficacy of 57.9% (95% confidence interval [CI, 26.5, 76.7]) against any symptomatic COVID-19 disease in the seronegative population.'*

These are all relative efficacy rates and no absolute rates are given. They therefore all represent further multiple breaches of Clause 6.1 and their continued accessibility by the general public represent breaches of undertaking.

In addition the following statement is made about the safety of this product :

- *'Across both studies, the Sanofi-GSK vaccine was well-tolerated in younger and older adults with no safety concerns.'*

'No safety concerns' is not an appropriate phrase to use when describing the safety profile of ANY medicine. Surely there should always be safety concerns when any medicine is being administered to anyone. Even if no short-term concerns at all had revealed themselves as a result of ANY of the vaccine administrations during these studies at the time this press release was written (and even that is something I find difficult to believe) then surely there were, or should have been, at least some concerns regarding any potential long-term, possibly unknown or unforeseen, adverse events. Such language implies a degree of complacency which does GSK and Sanofi no credit whatsoever. It is also a breach of clause 6.4 of your 2021 Code regarding the unqualified use of the word safe. The supplementary information of clause 6.4 also clearly states that *'The restrictions on the word 'safe' apply equally to grammatical derivatives such as 'safety'. For example, 'demonstrated safety' or 'proven safety' are prohibited under this clause.'*

I also note that the following claim is made for efficacy in the headline section at the top of the page:

- *100% efficacy against severe COVID-19 disease and hospitalizations*

However, it is only on reading much further down into the press release that it is made clear that *'The Sanofi-GSK vaccine provided 100% protection (0 vs 10 cases post-dose 1, 0 vs 4 cases post-dose 2) against severe disease and hospitalizations and 75% (3 vs 11 cases) efficacy against moderate-to-severe disease in seronegative populations.'* No detailed statistical justification (eg. level of statistical significance) is given for this claim, and no citation is given informing the reader how to access the trial data in order to check this claim's statistical basis. Therefore the reader only has the numbers of the participants falling into this category to fall back on to enable one to judge the validity of

this claim for 100% efficacy. These numbers are very small indeed and it is doubtful that the study was powered to detect a significant statistical difference between the two treatments arms based on such small numbers affected. As I say, it is not possible to know on what dataset this striking headline claim for '100% efficacy' is based but I believe this is the final analysis for the VAT008 study which was published in the Lancet Respiratory Medicine journal some months after this press release. This publication has some slightly more measured, balanced and accurate things to say about the efficacy demonstrated by the vaccine for serious infection and hospitalisations in this study :

- *'Of 121 symptomatic COVID-19 cases, five participants (three vaccine recipients and two placebo recipients) reported severe COVID-19'*
- *'Outcomes with too few cases to reliably calculate vaccine efficacy (severe COVID-19, moderate or worse COVID-19, and hospital admission due to COVID-19) are not shown'*
- *'The number of severe COVID-19 cases or hospital admissions due to COVID-19 in our study was small'*
- *'Our study had limitations. Due to the small number (approximately 6%) of adults aged 60 years and older enrolled in the trial, vaccine efficacy could not be accurately estimated in this age group (only three cases of symptomatic COVID-19 were reported in the vaccine group and two in the placebo group for adults aged ≥60 years)'*
- *'The small number of hospital admissions due to COVID-19 and severe cases of COVID-19 made it difficult to draw firm conclusions about vaccine efficacy against these outcomes'*

These statements seem somewhat at variance with the bold claim of '100% efficacy' with which GSK chose to lead in this press release. This discrepancy requires explanation as it suggests that the '100% efficacy' claim in the press release was exaggerated, unsubstantiated, egregiously misleading and irresponsible. GSK may wish to claim that it was 'preliminary' or 'interim' data targeted at a financial audience, but a desire to benefit their share price is no excuse for such behaviour.

Claims for efficacy must be statistically supported and not exaggerated, their intended audience or interim nature do not change this fundamental principle. At the very least, this misleading claim in this press release represents breaches of the following clauses of your 2021 Code: Clauses 6.1, 6.2 and 14.4

3. Medicago and GSK announce positive Phase 3 efficacy and safety results for adjuvanted plant-based COVID-19 vaccine candidate | GSK

In this press release dated 7th December 2021 the following misleading statements are made :

- *'Efficacy demonstrated against all variants seen in the study, including 75.3% efficacy against COVID-19 of any severity caused by the globally dominant Delta variant'*
- *'The overall vaccine efficacy rate against all variants of SARS-COV-2 was 71% (95% CI: 58.7, 80.0; Per Protocol Analysis: PP).'*

- *'The corresponding number for people with an initial seronegative status indicating no previous exposure to COVID-19 was 75.6% (95% CI: 64.2-83.7; PP).'*
- *'The vaccine candidate demonstrated efficacy of 75.3% (95% CI: 52.8, 87.9; PP) against COVID-19 of any severity for the globally dominant Delta variant'*
- 'Efficacy was 88.6% (95% CI: 74.6, 95.6; PP) against the Gamma variant.'

These are all relative efficacy rates and no absolute rates are given. They therefore all represent further multiple breaches of Clause 6.1 and their continued accessibility by the public represent breaches of undertaking.

These press releases clearly demonstrate that GSK have failed to comply with the requirements of their undertaking to ensure that that, with regard to the findings in Case AUTH/3760/4/23, *'the practice in question has ceased forthwith and that all possible steps have been taken to avoid a similar breach in future'*. GSK have clearly not taken adequate steps to identify and remove these materials. Please can I remind you again that GSK were aware of the similar PMCPA findings against AstraZeneca and Pfizer since 2022 and yet still they chose to ignore these findings and allowed these posts to remain accessible and unamended. Furthermore, when GSK became aware of my current complaint Case AUTH/3760/4/23 over a year ago now, they still chose not to amend them or take them down. And again, when the PMCPA recently found against them and they accepted that finding, and signed their undertaking without appeal, they still did nothing to identify, amend or take down these 3 press releases. I am no IT or pharmaceutical expert but armed only with my laptop and Google I was able to identify these 3 press releases in a matter of minutes. Therefore one must ask why, despite being made aware of the risk on numerous occasions over the past two years, were a fabulously well-resourced global corporation the size of GSK unwilling or unable to do the same?

The serious, multiple *and repeated nature of the breaches listed above means that in addition to the specific clauses already suggested I think that breaches of clauses relating to failure to maintain high standards and breach of undertaking should also be considered along with breaches* of Clause 2.

Please be aware that these are just a sample of the press releases which GSK has produced regarding covid-related products. I have only looked at the first 3 GSK covid vaccine press releases that came to my attention as a result of my brief and simple search. Once this case is concluded you may wish to suggest to GSK that, rather than accusing other people of spreading misinformation, they might want to go back and do a serious clean-up, or clear-out, of their press release back-catalogue. As I have said above, GSK have had several years to get this sorted but have failed to do so. They have admitted that they were aware of all the previous Pfizer and AstraZeneca cases regarding misleading use of relative efficacy rates to promote covid vaccines (the first case report of which was published in June 2022). They will also have been aware of the complaint Case AUTH/3760/4/23 itself for over a year before the final findings against them and the signing of their undertaking a couple of months ago. Yet still they chose to do nothing about these other misleading press releases. They simply left them on the internet where they are easily accessible by anyone. If not a deliberate act then this is either incompetence, or arrogance, and complacency on literally an industrial scale. Misleading the public about the true efficacy of their covid vaccines by only

presenting the relative efficacy rates appears to have become established, even institutionalised, within the UK pharmaceutical industry. When it comes to presenting absolute and relative efficacy rates, scant regard appears to be taken, by any of these companies, of either the specific requirements of your Code (or indeed the specific requirements of the MHRA's [Medicines and Healthcare products Regulatory Agency] Blue Guide to the Medicines Advertising Regulations), or even the, now repeated, findings of the PMCPA. But what do you intend to do about it? Repeatedly giving these people tiny 'administrative charges', or publishing clause 2 adverts, that very few people actually read, is clearly not acting as any kind of deterrent to the spread of such disinformation by pharmaceutical companies. This problem of recidivism and lack of deterrence was also recently identified by Mulinari et al.

There are rules and regulations governing the promotion and communications relating to medicines in the UK. Regardless of the circumstances or the enormous potential profits available, pharmaceutical companies must be made to understand that these rules and regulations are to be taken seriously, cannot just be ignored, and will, eventually, be enforced."

When writing to GSK, the PMCPA asked it to consider the requirements of Clauses 2, 3.3, 6.1, 6.2, 6.4 and 14.4 of the 2021 Code.

GSK'S RESPONSE

The response from GSK is reproduced below:

"GSK is extremely disappointed and concerned to have received your letter dated 16 August 2024 informing the Company of a further complaint from a contactable individual describing themselves as a member of the public. The complainant has alleged a breach of an Undertaking given by GSK to the Prescription Medicines Code of Practice Authority in May 2024. GSK takes its responsibilities of abiding by the Code and all other relevant UK rules and regulations very seriously. GSK is especially cognisant of the importance of adhering to Undertakings as fundamental to the Pharmaceutical Industry maintaining its ability to self-regulate. As a result, GSK makes improvements where necessary based on rulings from its own as well as from other companies' cases, and we believe that this case could indeed be seminal for other organisations.

Historical press releases and their appropriate management under the Code, when they would generally be considered as no longer being 'newsworthy', raises several difficult considerations. GSK and, we understand, other Pharma companies have been grappling with such considerations given their inherent complexity, compounded by external factors such as the requirements placed on companies by, for example, Stock Exchange rules when releasing information that is of material interest to the investment community.

That said, GSK reviewed the contents of the complainant's letter very carefully in the light of the considerations raised by the need to retain historical press releases. As a result, GSK has concluded it does not agree with the complainant's allegation that the Undertaking, dated 25 May 2024, has been breached.

The complainant had previously complained to the PMCPA on 4 April 2023 about a GSK press release (10 November 2022) for an adjuvanted vaccine for COVID-19, VidPrevtyn Beta, developed by Sanofi and GSK to help address the COVID-19 pandemic (Case AUTH/3760/4/23). Following receipt of the original complaint (5 April 2024)(sic), GSK removed the relevant press release from its Corporate website on 12 April 2023. GSK confirms that the press release has not been reinstated on its Corporate website since.

With respect to Case AUTH/3760/4/23, the PMCPA wrote to GSK on 16 May 2024 following the Panel's detailed evaluation of the complaint and GSK's response to defend against the complaint. PMCPA informed the Company that the Panel had noted the omission of absolute risk data, and without any further trial data or explanation to contextualise the relative risk reduction rates cited in the press release, some readers might have assumed that the efficacy rate was, in effect, an absolute rate. As this was not the case, the Panel ruled a breach of Clause 6.1 of the Code. Nevertheless, the PMCPA confirmed the Panel had ruled no breach of Clause 5.1. This was on the basis that the complainant had not established GSK took 'little interest in PMCPA decisions' or had 'little incentive to learn from them'. GSK accepted the Panel's ruling of the single breach of Clause 6.1. In accordance with paragraph 7.1 of the Constitution and Procedure for the Prescription Medicines Code of Practice Authority, GSK completed the required Undertaking and Assurance. The Undertaking was signed in all good faith on 25 May 2024 by the General Manager UK. The Undertaking stated that "the Company would, forthwith, take all possible steps to avoid similar breaches of the Code occurring in the future" and the case completed on 5 June 2024.

GSK believes it has complied with the undertaking signed 25 May 2024. GSK considers that press releases issued before 25 May 2024 undertaking do not qualify as a similar breach of the Code occurring in the future, as referenced in the Undertaking. Nevertheless, GSK has reviewed processes and procedures related to issuing press releases on GSK's Corporate site and has taken the decision to establish an archive for press releases to make it clearer to the audience they are no longer current.

With respect to the three historical Press Releases cited by the complainant in Case AUTH 0272/08/24, these were issued prior to the date of the Undertaking, (25 May 2024). These Press Releases will be moved to the Press Release archive.

Press Releases are directed to our investors and media outlets and comply with the relevant laws and regulations. While it may be possible to change previously published press releases and stock exchange announcements hosted and managed by GSK UK headquartered entities after they have been published and may no longer be newsworthy, it would require complex and careful legal, compliance and regulatory considerations. Whilst GSK is revising the process concerning the maintenance and archival of historic corporate Press Release, we are very mindful of the difficulties outlined above in modifying historical press releases and Stock Exchange announcements. GSK contends that such corporate press releases are subject to multifaceted requirements with differing regulatory agencies and regulations in multiple jurisdictions.

Consequently, resolution of the treatment of historic Press Releases is not as straightforward as would generally be the case for promotional materials and specific

claims. Commonly, promotional items are not at all limited by being acutely time-bound or newsworthy in nature. As a result, they typically have greater longevity and utility. Indeed, where they remain relevant, Companies must re-certify them at intervals of no more than two years from their first Certification, or even subsequent re-certifications. Such items, in effect, are entirely within the control of Pharma companies. However, for the reasons cited above, treatment of historically issued press releases and stock exchange announcements pose very different and significant practical challenges for Companies. Such materials are subject to additional external requirements and regulations. These are complicated and extend beyond internal company controls. GSK are keen to receive the ruling and comments of the PMCPA in this case as soon as possible, as they will help us and other companies in navigating the complex issues outlined, within a robust framework of self-regulation in the future.

Therefore, and with respect, at this juncture GSK must disagree with the complainant and their allegations against the Company that it has breached its Undertaking to the PMCPA. Specifically, GSK holds that it is not in breach of Clauses 2, 6.1, 6.2 6.4 and 14.4 regarding the historical press releases dated 7 December 2021, 23 February 2022, and 24 June 2022 cited as evidence of a breach of GSK's undertaking. Moreover, following the ruling in Case AUTH/3760/4/23, GSK has either completed, initiated, or is planning the actions identified above to further strengthen its compliance and internal control frameworks.

Furthermore, based on all the above, GSK contends the Company is complying with the Undertaking given on 25 May 2024, we do not agree that Clause 3.3 has been breached."

PANEL RULING

The complaint concerned the ongoing availability of three historical GSK press releases on its corporate website. The complainant alleged that the press releases contained misleading efficacy claims similar to those ruled in breach by the PMCPA in Case AUTH/3760/4/23 and thus also amounted to a breach of the undertaking given in that case.

As the complaint could broadly be split into two limbs the Panel decided to consider the allegations relating to the content of each press release and then the alleged breach of undertaking.

Press Releases

The Panel noted the three press releases labelled "For media and investors only" had been issued from London on the following dates, which are in reverse chronological order to align with how they were set out in the complaint:

1. 24 June 2022 (Press Release 1)
2. 23 February 2022 (Press Release 2)
3. 7 December 2021 (Press Release 3)

In this ruling, these three press releases are referred to collectively as "the historical press releases".

The Panel noted that the historical press releases pre-dated the November 2022 press release, which was the subject of Case AUTH/3760/4/23. As no complaint was made about how the press releases were issued, or their intended audience, the Panel restricted its deliberations to the content and the individual statements at issue.

The Panel was concerned that whilst GSK's response denied breaches of Clauses 6.1, 6.2, 6.4 and 14.4 in relation to the historical press releases, its response was focused on whether those press releases amounted to a breach of undertaking, rather than providing a substantive response to the complainant's efficacy allegations. Nevertheless, the case preparation manager (in accordance with the Constitution and Procedure) had asked GSK to respond to these clauses and GSK had been sent an anonymised copy of the complaint. The Panel has considered the submissions of both parties in relation to the content of the individual press releases and made its ruling accordingly.

Press release dated 24 June 2022 (Press Release 1)

Press Release 1 announced positive data from a vaccine trial which evaluated an adjuvanted bivalent D614 and Beta (B1351) vaccine candidate and was titled "Sanofi-GSK first to report a successful efficacy study against Omicron with COVID-19 Beta-containing vaccine".

The complainant cited four statements from the press release which they alleged were misleading on the basis that they all referred to percentage efficacy rates for the vaccines without explaining that these were relative efficacy rates rather than absolute efficacy rates:

- "Primary vaccination with Beta-containing vaccine candidate delivers 64.7%
- efficacy against symptomatic infection in adults, and 75.1% efficacy in participants previously infected with COVID-19"
- "Against Omicron, sequencing analysis performed to date shows 72% efficacy in all adults and 93.2% in seropositives"
- "the Sanofi-GSK Beta-containing vaccine candidate demonstrated an efficacy of 64.7% (95% confidence interval [CI, 46.6, 77.2]) against symptomatic COVID-19 and 72% efficacy (95% confidence interval [CI, 45.8, 86.6]) in Omicron-confirmed symptomatic cases"
- "the Sanofi-GSK vaccine candidate demonstrates an overall efficacy of 75.1% (95% confidence interval [CI, 56.3, 86.6]) against symptomatic infection, and 93.2% (95% confidence interval [CI, 73.2, 99.2]) in Omicron-confirmed symptomatic cases".

The Panel considered the press release in full (which provided some context for the claims) and also noted the ruling in Case AUTH/3760/4/23 referred to by the complainant. That ruling highlighted GSK's submission that communications about Covid-19 issued by the media, medical organisations and government bodies at the relevant time expressed vaccine efficacy in similar terms to those used within the press release to ensure information was easy for the audience to understand and not misleading. GSK submitted that relative risk reduction was the value most used and considered when discussing vaccine efficacy as it evaluated the risk of infection irrespective of the transmission setting.

The Panel was mindful that the Supplementary Information to Clause 6.1, concerning "reference to absolute risk and relative risk" had to be interpreted in the light of its associated clause, which included the requirement that materials should not be misleading and must be sufficiently

complete to enable the recipient to form their own opinion of the therapeutic value of the medicine.

The Panel took account of the Panel's conclusion in Case AUTH/3760/4/23 that:

> "the omission of absolute risk data, and without any further trial data or explanation to contextualise the relative risk reduction rates cited in the press release, some readers might have assumed that the efficacy rate was, in effect, an absolute rate and that was not so."

The Panel concluded that each of the four statements from Press Release 1 that were cited by the complainant did include claims that provided a relative efficacy rate without reference to the absolute rate. Having carefully considered those four statements, the press release and the parties' submissions, the Panel concluded that some readers might have assumed that the relative efficacy rates were in fact absolute rates and that was not so. This misleading implication was not negated or qualified elsewhere in the press release. Some readers might have been misled about the efficacy of the vaccine based on the wording of Press Release 1. The Panel ruled a **breach of Clause 6.1**.

Press release dated 23 February 2022 (Press Release 2)

This press release announced Sanofi and GSK's intention to seek regulatory authorisation for a Covid-19 vaccine based on data from their booster and Phase 3 efficacy trials.

In relation to Press Release 2, the Panel interpreted the complaint as alleging various breaches of the Code which the Panel dealt with under the following headings:

1. Misleading claims because no absolute efficacy rates provided (Clause 6.1)
2. The claim of "no safety concerns" was not qualified (Clause 6.4)
3. Claims for "100% efficacy" (Clause 6.1, 6.2 and 14.4).

- Misleading claims because no absolute efficacy rates provided (Clause 6.1)

The Panel noted a bulleted list of three messages at the start of Press Release 2, the second of these stated "In the VAT08 Phase 3 primary series trial, two doses of the Sanofi-GSK vaccine in seronegative populations demonstrated:". Three statements followed as sub-bullets, all of which referred to efficacy rates against varying levels of severity of Covid-19. The complainant alleged that two of the sub-bullets and a third statement in the body of the press release were misleading because they were relative efficacy rates and no absolute rates were given. The statements at issue were:

- "75% efficacy against moderate or severe COVID-19 disease",
- "57.9% efficacy against any symptomatic COVID-19 disease", and
- "Data from the VAT08 efficacy study showed that two doses of Sanofi-GSK vaccine generated an efficacy of 57.9% (95% confidence interval [CI, 26.5, 76.7]) against any symptomatic COVID-19 disease in the seronegative population.".

Based upon the same reasoning as set out above in relation to Press Release 1, the Panel ruled a **breach of Clause 6.1** in relation to Press Release 2 because none of the relative

efficacy statements cited above included reference to absolute rates and therefore some readers might have been misled about the efficacy of the vaccine.

- The claim of "no safety concerns" was not qualified (Clause 6.4)

Although the primary focus of Press Release 2 was the efficacy of the vaccine, it also included the following safety statements:

- that the vaccine had a "favourable safety profile following both primary series and booster vaccinations", and
- that "Across both studies, the Sanofi-GSK vaccine was well-tolerated in younger and older adults with no safety concerns."

The complainant alleged that the latter claim was a breach of Clause 6.4 because it used the phrase "no safety concerns" without qualification.

The Panel noted it was well-established that all medicines have the potential for side-effects and no medicine is completely risk-free. This was reflected in Clause 6.4 of the Code and its supplementary information which specified that the word 'safe', and grammatical derivatives, must not be used without qualification.

Noting that Press Release 2 concerned a vaccine candidate and therefore the available safety data at that stage of the product's lifecycle would be limited, the Panel considered that it was particularly important to ensure that safety messaging did not create a misleading impression. The Panel noted the statement at issue appeared as a separate paragraph with no additional information or references to provide context, qualification or balance. The Panel therefore ruled a **breach of Clause 6.4**.

- Claim for "100% efficacy" (Clauses 6.1, 6.2 and 14.4)

The complainant also complained about the claim "100% efficacy against severe COVID-19 disease and hospitalisations" which was the first sub-bullet to the second paragraph at the outset of Press Release 2. Although this statement was not qualified, the Panel acknowledged that a relevant statement appeared further down the press release:

> "The Sanofi-GSK vaccine provided 100% protection (0 vs 10 cases post-dose 1, 0 vs 4 cases post-dose 2) against severe disease and hospitalizations and 75% (3 vs 11 cases) efficacy against moderate-to-severe disease in seronegative populations."

In the Panel's view, the Code requirements for information provided by companies were clear; among other things it must be accurate and balanced, not mislead either directly or by implication, exaggeration or undue emphasis and must be capable of substantiation.

The Panel noted that while the press release included some additional information to support the 100% efficacy claim, this appeared after six paragraphs of intervening text and that it was a long-established principle of the Code that any qualification required to ensure compliance with the Code ought to be part of the relevant claim or within its immediate visual field. The Panel also noted all the cases of severe disease and hospitalizations were in the comparator arm but the number of cases was very small. The Panel queried whether it was appropriate to make such a strong unqualified claim and to include it as one of the key take-out messages at the

beginning of a press release, bearing in mind the limited evidence available at the time for the vaccine candidate. The Panel considered that the small numbers involved suggested that, at the relevant time, the data was unlikely to be sufficiently robust to draw firm conclusions. The Panel also noted that limited information was provided about the study design, all of which, in the Panel's view, meant that the claim at issue gave a misleading and exaggerated impression of the vaccine's efficacy which was not capable of substantiation.

The Panel ruled **breaches of Clause 6.1, 6.2 and 14.4** as cited by the complainant.

Press release dated 7 December 2021 (Press Release 3)

Press Release 3 announced positive Phase 3 efficacy and safety results for an adjuvanted plant-based COVID-19 vaccine candidate. The complainant cited five statements from the press release which they alleged were misleading, again because of their reference to relative efficacy rates without also referring to absolute rates.

The Panel noted all five statements did contain relative efficacy rates and that no absolute rates were given. For the same reasoning as applied in relation to Press Release 1 and Press Release 2, the Panel concluded that some readers of Press Release 3 might have been misled about the efficacy of the vaccine. The Panel therefore ruled a **breach of Clause 6.1**.

Alleged breach of undertaking

The complainant referred to Case AUTH/3760/4/23 in which the Panel ruled a breach of Clause 6.1 on the basis that the vaccine efficacy claims, expressed as relative risk reduction rates, failed to refer to absolute risk data. Following its acceptance of that breach ruling, GSK provided the PMCPA with an undertaking dated 24 May 2024 which stated that it had withdrawn the press release on 12 April 2023. The undertaking provided:

> "We hereby give an assurance that we will, forthwith, take all possible steps to avoid similar breaches of the Code occurring in the future"

The complainant alleged that the continued availability of the historical press releases (containing similar vaccine efficacy claims to those ruled in breach in Case AUTH/3760/4/23) meant that GSK had breached its undertaking.

The Panel noted that it was for the complainant to establish their case on the balance of probabilities. That a similar claim had been ruled in breach of the Code in a previous case did not necessarily mean that all similar future claims were automatically in breach of that undertaking. Whether a case was in breach of an undertaking depended on a consideration of all the circumstances and each case would be looked at on its individual merits. Relevant factors included, but were not limited to:

1. the nature of the materials or activities in question,
2. whether the materials or activities have been ruled in breach of the Code for the same or similar reasons,
3. the chronology of the materials or activities that led to the undertaking and the materials or activities in the subsequent complaint,
4. the steps the company has taken to comply with the undertaking and avoid similar breaches in the future,

5. any relevant correspondence between the PMCPA and the company regarding implementation of the undertaking, and
6. relevant requirements of the Constitution and Procedure.

It was not possible to determine whether there was a breach of undertaking merely based on breaches of the same clause.

The Panel considered that the reasons for the breaches of the Code and the material at issue in Case AUTH/3760/4/23 were closely similar to the reasons and material in the present case.

The Panel acknowledged the complainant's observation that GSK had been on notice for some time to take remedial action in relation to the historical press releases. This was partly because there had been several previous cases concerning relative efficacy claims since the Covid-19 pandemic, and partly because GSK had been aware of the outcome of Case AUTH/3760/4/23 since 16 May 2024 (this complaint was received on 16 August 2024). The Panel considered that good governance required companies to review their materials, policies and procedures promptly in relation to published cases. The Panel also took account of the wording of the undertaking itself, which required GSK to "forthwith, take all possible steps to avoid similar breaches of the Code occurring in future" (Panel's emphasis).

GSK submitted that there were challenges in the appropriate management of historical press releases and Stock Exchange announcements when they were no longer considered 'newsworthy'. The Panel noted GSK's submissions that:

1. "[removing the historical press releases] would require complex and careful legal, compliance and regulatory considerations",
2. "[there were] requirements placed on companies by, for example, Stock Exchange rules when releasing information that is of material interest to the investment community",
3. "corporate press releases are subject to multifaceted requirements with differing regulatory agencies and regulations in multiple jurisdictions", and
4. "materials are subject to additional external requirements and regulations. These are complicated and extend beyond internal company controls".

The Panel recognised that there could be difficulties if companies' other regulatory obligations potentially conflicted with its obligations under the Code. However, the Panel considered it was unclear why GSK emphasised difficulties in modifying rather than withdrawing the material, given GSK had voluntarily withdrawn the press release at issue in Case AUTH/3760/4/23 from its corporate website on notification of that complaint 'out of an abundance of caution' and before it was notified of the Panel's ruling. It was entirely unclear to the Panel whether or why different obligations might prevent the historical press releases at issue in the present case from being removed from GSK's website, when those obligations did not appear to apply to the press release in Case AUTH/3760/4/23 (a formal Stock Exchange announcement to global business/financial media and labelled as such), which GSK *had* been able to remove. The Panel noted that the historical press releases at issue in the present case appeared to be similar: each was labelled 'For media and investors only' and had been issued from London in the period December 2021 to November 2022. The Panel was concerned that GSK had not provided a detailed submission on how the Code interacts with other regulatory requirements, nor identified the specific regulatory obligations on which they were relying, with any clarity. There was an implication in GSK's response that the historical press releases were Stock

Exchange announcements, however, the Panel noted that they were not labelled as such nor had GSK explained why the content of press releases at issue were such that they were formal Stock Exchange announcements. Given its comments above the Panel did not consider that GSK had established which other regulatory requirements prevented the removal of the press releases in question.

The Panel noted the wording of the undertaking given in Case AUTH/3760/4/23, the heading of which referred to it having been given in accordance with Paragraph 7.1 of the 2019 Constitution and Procedure and further noted the condition of membership of the ABPI to abide by the Code in both the spirit and the letter. GSK acknowledged that the undertaking was given under the auspices of Paragraph 7.1. of the 2019 Constitution and Procedure.

The Panel took account of the chronology of the press releases in relation to Case AUTH/3760/4/23 and GSK's submission that press releases issued prior to the date of the undertaking did not qualify as a similar breach of the Code occurring in the future as referenced in the undertaking (Panel's emphasis).

The Panel considered the Code of Practice Panel's ruling in Case AUTH/3760/4/23, GSK's comments set out above and acknowledged that the particular circumstances of the case gave rise to a question about the retrospective application of an undertaking. Whether and the extent to which an undertaking applied retrospectively would depend on the circumstances of each case including the ongoing accessibility/use of the material. The Panel noted that to ensure that it complied with an undertaking a company ought to review all closely similar claims in a range of materials, not limited to the type of material at issue in a case, if that material remained publicly available.

In this regard the PMCPA's 2021 Guidelines on Company Procedures Relating to the ABPI Code of Practice for the Pharmaceutical Industry stated:

> "In the event of a company being found in breach of the Code, its procedures should ensure that relevant information about the matter is communicated internally to all appropriate members of staff. Procedures must be in place to ensure that activities, materials, items etc found to be in breach of the Code, and any similar activity, material, item etc in any format, are quickly stopped and/or taken out of circulation, not forgetting those stored electronically and/or in the hands of others, such as printers and agencies or verbal claims which may be used by representatives. The procedure should cover how to recall, withdraw and suspend materials, items etc including the timelines for each. It is important for the reputation of the industry that companies comply with undertakings. Inadequate action leading to a breach of undertaking is likely to be in breach of Clause 2."

Noting that the Case AUTH/3760/4/23 press release had been voluntarily withdrawn from the corporate website in accordance with GSK's signed undertaking, and having carefully considered all the evidence before it, the Panel determined that compliance with the undertaking would reasonably include a review of previous press releases for similar claims. The Panel, therefore, ruled a **breach of Clause 3.3**.

Clause 5.1

The Panel noted that neither the complainant nor the case preparation manager cited Clause 5.1 expressly, although the complaint referred to the substance of that clause ("failure to

maintain high standards"). However, because this clause had not been raised by the case preparation manager, GSK had not responded to the complaint in relation to these requirements. In these circumstances the Panel considered that it was not appropriate to rule in relation to Clause 5.1. The Panel considered its comments and rulings above (in addition to its ruling in relation to Clause 2 below); in its view the allegations had been covered adequately by those rulings and therefore the Panel made no ruling in relation to Clause 5.1.

Clause 2

The Panel noted that Clause 2 was used as a sign of particular censure and reserved for such use. The Supplementary Information to Clause 2 included inadequate action leading to a breach of undertaking and prejudicing patient safety as examples of activities likely to be in breach of Clause 2. In considering Clause 2 the Panel took account of the following points.

The Panel considered this case raised issues in relation to the retrospective application of undertakings. It took account of the steps taken by GSK to comply with the undertaking given in Case AUTH/3760/4/23 and the ongoing work being undertaken including reviewing its processes and procedures related to issuing press releases on GSK's corporate website and establishing an archive for press releases to make clear those items that are matters of historical record and not current. The Panel was concerned that the historical press releases were not yet in a press release archive at the time GSK responded to the current complaint; a location which GSK acknowledged would now make it clear that they were not current.

Although GSK submitted that there were complex legal, compliance and regulatory challenges in the appropriate management of historical press releases and Stock Exchange announcements, the Panel did not consider that GSK had provided sufficient specific detail about these and thus had not established its case on this matter.

The Panel acknowledged that, when the press releases were published, communications about Covid-19 and vaccines were sensitive, with those relating to vaccine efficacy and safety likely to result in further coverage aimed at the public. It was therefore particularly important that information was balanced, fair, objective and not misleading.

In this regard, the Panel considered its comments above about the importance of context being provided for such claims. It noted that the Supplementary Information to Clause 6.1 (under the heading "absolute risk and relative risk") should be interpreted in the light of its associated clause, which required that material etc should not be, amongst other things, misleading and must be sufficiently complete to enable the recipient to form their own opinion of the therapeutic value of the medicine. Similarly, it was important to ensure that safety messaging did not create a misleading impression. The Panel also took account of its rulings of breaches relating to efficacy and safety statements in the historical press releases.

The Panel noted this case was the latest of several similar cases, in addition to Case AUTH/3760/4/23, concerning relative efficacy claims for Covid-19 vaccines being made without reference to absolute efficacy and therefore that GSK should have been on notice about the learnings from previous rulings.

The Panel also had regard to the PMCPA's 2021 Guidelines on Company Procedures Relating to the ABPI Code of Practice for the Pharmaceutical Industry which stated:

> "It is important for the reputation of the industry that companies comply with undertakings. Inadequate action leading to a breach of undertaking is likely to be in breach of Clause 2.

Having considered all the circumstances of this case, the Panel determined that the breach of undertaking was a serious matter which, taken together with the above matters, on balance, brought discredit upon, or reduced confidence in, the pharmaceutical industry. The Panel therefore ruled a **breach of Clause 2**.

REFERRAL UNDER PARAGRAPH 1.12 OF THE PMCPA CONSTITUTION AND PROCEDURE

Following receipt of the Panel's ruling, and at the request of the complainant, the Chair of the Code of Practice Appeal Board considered whether there had been a procedural error in accordance with Paragraph 1.12 of the PMCPA Constitution and Procedure (Set Aside for Procedural Error). The complainant's procedural concerns related to whether the Panel should have considered a breach of Clause 5.1 (even though it had not been raised by the case preparation manager in this case) and three breaches of Clause 6.1 in relation to each press release.

The Chair having considered detailed submissions from both parties determined;

- There was a procedural error by the Case Preparation Manager in not taking forward Clause 5.1 but the Panel acted entirely in accordance with the Constitution and Procedure and standard practice. The Panel's decision to proceed without considering Clause 5.1 was entirely in line with the overriding objective, particularly the need to avoid delay to this case and to other cases, and the need to deal with cases proportionately. The Panel's decision should therefore not be set aside.
- There was no procedural error by the Panel in relation to the number of breaches of Clause 6.1 because the Panel had a discretion as to how many breaches of each clause it considered in relation to each press release. The Panel's careful approach to the claimant's allegations was entirely logical, in line with the wording of the PMCPA Constitution and Procedure, and entirely supported by the overriding objective. There was no procedural error.

The Chair's decision was therefore that the Panel's decisions stand, and the case should proceed to appeal.

APPEAL BY GSK

GSK's written basis for appealing is reproduced below.

> "Thank you for the letter dated 11 March 2025, which details the Code of Practice Panel ruling following a complaint which alleged a breach of an undertaking ("Undertaking") given by GSK to the Prescription Medicines Code of Practice Authority ("PMCPA") in May 2024 (with respect to Case AUTH/3760/4/23 (the "First Case")). GSK strives to uphold all aspects of laws and regulations and takes any allegations of breaching the Association of the British Pharmaceutical Industry ("ABPI") Code of Practice for the Pharmaceutical Industry (the "Code") very seriously. GSK is especially cognisant of the fundamental importance of adhering to undertakings to the pharmaceutical industry maintaining its ability to self-regulate. We are committed to learning and improving our processes based on complaints and feedback.

GSK strives to ensure compliance with the Code, both in letter and spirit, and we treat the Undertaking with the utmost importance and seriousness. We gave the Undertaking in the First Case in good faith and took action to comply responsibly, while remaining mindful of all the legal, regulatory and self-regulatory duties we owe, including — as a listed company — to our investors, the financial community and stock markets. We firmly believe we followed a process that any listed company in our position, acting responsibly, ought to have followed.

We write to appeal the PMCPA's initial ruling in Case/0272/08/24 (the "Initial Ruling"). We strongly disagree that GSK has breached the Undertaking signed on 25 May 2024, and therefore also with the Panel's ruling of breaches of Clause 3.3 and Clause 2 of the Code. GSK is also appealing the PMCPA Panel's ruling of breaches of Clauses 6.1(x3), 6.2, 6.4 and 14.4 to the Code of Practice Appeal Board.

[Redacted - GSK provided legal advice, as part of its appeal, which was shared with the complainant and the Appeal Board. However, the parties agreed that such advice would remain confidential and therefore the substance of this advice does not form part of the Case Report.]

Executive Summary

Our appeal is based on the fundamental, yet overlooked, distinction between the press releases ("Historical Press Releases") at issue in Case/0272/08/24 (the "Current Case") and the press release in the First Case ("Press Release 4"). This distinction is important because it illustrates that GSK has not committed a similar (or, indeed, any) breach of the Code in the Current Case, and GSK's Undertaking therefore remains intact. Notwithstanding this, our appeal also addresses several key issues with respect to the Panel's application of specific provisions of the Code to the Historical Press Releases, which in our submission mean that GSK has complied with the Undertaking in good faith.

We set out the background to the Current Case in the section that follows. The Appeal Board will see that GSK has devoted significant effort to ensuring that it complied with the Undertaking it gave to the Panel, while balancing its obligations as a listed company to investors. We have implemented a process to archive press releases containing historical announcements to the investment community, which we continue to review and enhance, illustrating the company's commitment to compliance with the Code and the Undertaking. The archiving process makes clear these are out of use and GSK believes strikes the correct balance between GSK's obligations as a listed company, including to maintain a faithful and accurate record of what was announced to investors and to the markets, while being mindful of Code compliance.

The distinction between the Historical Press Releases and Press Release 4 at issue in the First Case is stark. Press Release 4 related to the announcement of the grant of marketing authorisation for VidPrevtyn Beta. Press Release 4 concerned an approved medicine available for prescription. GSK therefore accepts that, in principle, Press Release 4 had the potential to influence the public and healthcare professional ("HCP") prescribing decisions. Any such communication about an approved product must comply with Clause 6.1 of the Code – the applicable standard for communications relating to

licensed medicines. Following that case, GSK undertook to comply with the Panel's ruling in the First Case and to take all possible steps to avoid similar breaches of the Code occurring in the future. As discussed further below, the Historical Press Releases at issue in the Current Case all share two important features. First, they predate Press Release 4, so were not "future" breaches.

Second, given that the nature of the Historical Press Releases differs fundamentally from Press Release 4, any resulting breach could not be "similar" to the breach in the Initial Case. The Historical Press Releases were non-promotional press releases about GSK's product pipeline intended for the investment community. They related to research and development milestones for a candidate therapy that was unavailable for prescription at the time of their publication. Since the Historical Press releases discussed products that were not available for prescription, unlike Press Release 4, it cannot be said that these Historical Press Releases had the potential to influence HCP or public prescribing decisions.

This distinction has significant implications. If any Code provision was to apply to the Historical Press Releases, it is Clause 26.2 and its Supplementary Information. Among other things, the Supplementary Information to Clause 26.2 requires financial information provided to the investment community (including shareholders, the Stock Exchange, etc.) to be accurate, balanced and not misleading, taking into account the information needs of the target audience. The information needs of the investor community regarding pipeline products are different to the needs of HCPs and patients about approved products.

If, hypothetically, the Historical Press Releases are subject to the Undertaking as a future action (which we deny), the relevant provisions of the Code would be the Supplementary Information to Clause 26.2, not Clauses 6.1 (which was the subject of the First Case and GSK's Undertaking), 6.2, 6.4 and 14.4. Accordingly, GSK could not have committed a breach in the Current Case similar to that in the First Case, so has not breached its Undertaking. In this light, we submit that GSK has not breached Clause 2 of the Code.

Background

Publicly traded companies, such as GSK, have a regulatory obligation to communicate material and relevant information to shareholders without delay. Such communications build a pipeline development story over time, attracting investor interest and investment in our company.

Announcements to the investment community are not intended to promote medicines or provide information to HCPs and/or the general public regarding prescribing or administering a treatment. Their purpose is to comply with the regulatory obligations of listed companies to keep investors informed, foster confidence in GSK's corporate strategy and update the market on financial performance, and generally keep the market updated on progression of our pipeline.

This is the nature of the Historical Press Releases dated 24 June 2022 ("Press Release 1"), 23 February 2022 ("Press Release 2") and 7 December 2021 ("Press Release 3") at issue in the Current Case (Case/0272/08/24).

Press Release 3 was a Stock Exchange announcement; Press Release 1 and Press Release 2 were announcements intended for a business and financial audience. They all related to the development progression of an unapproved candidate therapy which was not available for prescription and mentioned no product name.

The First Case (Case AUTH/3760/4/23) related to Press Release 4 — a COVID vaccine press release jointly issued by GSK and Sanofi on 10 November 2022, which announced the authorisation of VidPrevtyn Beta.

The Historical Press Releases pre-dated Press Release 4.

GSK received the complaint regarding Press Release 4 in the First Case in April 2023, at which point we removed Press Release 4 from the company website out of an abundance of caution and respect for compliance with the Code, while retaining the right to reinstate it. GSK defended this approach, but the PMCPA Panel ruled the company in breach of the Code in May 2024 — over a year after the initial complaint and 15 months after Press Release 4 was issued.

GSK accepted the Panel's ruling in the First Case in May 2024 and provided the Undertaking to take all possible steps to avoid similar breaches of the Code occurring in the future. By this time, GSK was instituting a new organisational structure designed to provide more global ABPI expertise and visibility, again signalling GSK's commitment to and recognition of the importance of compliance with the Code.

Following the First Case, GSK conducted training amongst its population of ABPI signatories as well as its corporate affairs organisation to reiterate the Code's requirements when discussing relative efficacy from clinical studies in press releases. Further, GSK began a process to review and analyse where it had published material that may have some relationship to Press Release 4, and in June 2024 obtained informal advice from the PMCPA regarding what should be done with such materials. In line with this advice, GSK created an archive for these materials on the company's Global website, to indicate to site visitors that the material was not current but remained online for archiving purposes only.

In August 2024, GSK received the complaint in the Current Case, pertaining to the Historical Press Releases (i.e. Press Releases 1, 2 and 3). At this time, GSK was in the process of implementing procedures to ensure compliance with its Undertaking (pertaining to the First Case), including establishing a press release archive on its website. GSK was mindful of the need to remain compliant with its broader obligations as a listed company.

GSK moved the Historical Press Releases to the newly established archive following its construction. Setting up the archive required advice and sign-off from senior management, together with close liaison with corporate and legal teams both in the UK and USA. It involved a restructuring of GSK's corporate website which was both time consuming and required investment.

Alleged Breach of Undertaking – Clauses 2 and 3.3

GSK takes the Undertaking very seriously and has undertaken significant efforts to ensure ongoing compliance with it. GSK disagrees that it has breached its Undertaking to "forthwith, take all possible steps to avoid similar breaches of the Code occurring in the future." By its very nature, the Undertaking is forward-looking. Its primary purpose is to ensure there is no future publication of the same or similar materials to those that the PMCPA found in breach of the Code from the time the First Case was decided.

GSK did not re-issue or re-publish the Historical Press Releases, which predates publication of Press Release 4. To the extent the Historical Press Releases breach the subsequent Undertaking (which we deny, please see further discussion below), any breach could only have occurred before the date of the First Case and not after it. It is therefore incorrect to find the Historical Press Releases to constitute a breach of the subsequently issued Undertaking.

As PMCPA acknowledged in its Initial Ruling, whether (and the extent to which) undertakings can apply retrospectively raises complex considerations. The Panel notes that whether there has been a breach of an undertaking requires consideration of all relevant circumstances, including:

- the nature of the materials.
- the chronology of publication; and
- the steps the company has taken to comply with the undertaking and avoid similar breaches in the future.

Further complexities arise where dealing with historical investor-related materials. Investor materials are subject to other rules and regulations applicable to listed companies, in the UK and internationally.

The nature of the Historical Press Releases fundamentally differs from Press Release 4. The Historical Press Releases were investor communications related to an unapproved and unnamed candidate in development. Each of the Historical Press Releases clearly refers to the product as a candidate and, indeed, no product name is mentioned at all. Press Release 1 refers to an "adjuvanted bivalent D614 and Beta (B.1.351) vaccine candidate" and the "Sanofi-GSK vaccine;" Press Release 2 refers to the "refrigerator temperature-stable adjuvanted protein- based Sanofi-GSK vaccine;" and Press Release 3 refers to "Medicago's plant-based COVID-19 vaccine candidate in combination with GSK's pandemic adjuvant." It is abundantly clear that the Historical Press Releases relates to development milestones for unapproved candidate therapies.

By contrast, Press Release 4 announced the marketing authorisation of VidPrevtyn Beta, and therefore related to an approved medicine available for prescription. This is a key, and in our view overlooked, difference between the Historical Press Releases and Press Release 4.

This distinction has important implications under the Code. The Historical Press Releases did not relate to a named medicine, were updates on GSK's pipeline directed to an investor audience. Even if the Historical Press Releases do engage the Undertaking (which we deny), any such breach would relate to the Supplementary Information to Clause 26.2 and not Clause 6.1 (which was the subject of the First Case), or any of the other clauses that are also the subject of the Current Case.

Notwithstanding the above, given the seriousness with which GSK takes the Undertaking, the company has implemented a process to archive its investor-directed press releases to make clear these are out of use. We submit that this strikes the correct balance between GSK's obligations as a listed company, including maintaining a faithful and accurate record of what was announced to investors and to the markets, while being mindful of Code compliance.

We address these and other factors in further detail below.

a. GSK's Compliance with the Undertaking

As a general principle, when the PMCPA finds a company in breach of the Code and the latter provides an Undertaking, the company in breach should review other materials for the same or closely similar claims and promptly take these out of use or circulation, or otherwise ensure they are not in the public eye, if the claims in these materials similarly breach the Code. This principle is reinforced in the PMCPA's Guidelines on Company Procedures.

GSK has complied with this principle responsibly, proportionately and in good faith.

Following the First Case, GSK reviewed its published material that may have some relationship to Press Release 4. This process commenced in May 2024, following receipt of the PMCPA's ruling in the First Case and continued during the Summer of 2024.

As PMCPA is aware, GSK obtained informal advice from PMCPA in June 2024. In line with these discussions, GSK created an archive on the company's Global website (GSK.com). This would clearly signal to site visitors that the material was not current but had been kept online for archiving purposes only.

However, creating this archive was not an instantaneous process. It required re-engineering of GSK's website, along with a review of materials for archiving. While GSK acknowledges this step took some weeks, this was not an unrealistic or delayed timeframe, given the complexity of the task.

Before the archiving process for press releases could reasonably be completed, we received the complaint in the Current Case (on 16 August 2024).

We acknowledge the importance of implementing such processes in a timely manner. However, in this case, we submit that GSK acted carefully and responsibly in the circumstances.

b. Nature of the Materials

Press releases for investors are not intended to provide the public or HCPs with reference information about their health or medicines. Their purpose is to inform investors about developments in the company's pipeline and operations.

General online information about medicines is intended to be "living," in the sense that it needs to be updated or edited as the circumstances and scientific information change. By extension, a cache of historical press releases is, by definition, not intended to be "living." Its purpose is not to provide up-to-date medical or scientific information, but to

be a true and accurate record of what the company has announced at a point in time in the past.

While it can be relatively straightforward for companies to edit, suspend, or permanently/ temporarily withdraw routine reference materials from websites, announcements to stock markets are not so straightforward. [reference to legal advice].

Members of the investment and business community who access historical press releases do so in the expectation that they accurately reflect the position at the date of the announcement. A potential investor might, for example, be interested in understanding the health of a company's product pipeline and its track record in navigating through the various phases of clinical research, before making an investment decision. It is not reasonable or appropriate to expect listed companies to edit past announcements or pull down previously published investor materials. GSK is listed in both the US and the UK. A clear public record of historic investor announcements must be maintained under applicable rules and regulations in both countries. The Code should not be interpreted to cut across these requirements.

By way of a different example, where a company announces that a medicine has been authorised for a particular indication, and that indication is later changed or expanded, there is no expectation under the Code that the company must go back and edit its past press releases to correct for the expanded indication.

Ultimately, listed pharmaceutical companies must strike a balance between maintaining an accurate record of their historic investor announcements and their obligations under the Code. In this case, we consider that the only way to strike this balance correctly was to build an archive for historic press releases (including Press Releases 1, 2 and 3).

In the Initial Ruling, the Panel questioned why the company had considered it appropriate to withdraw Press Release 4 during the First Case, but did not consider it appropriate to withdraw the Historical Press Releases. Upon receipt of notice of the complaint in the First Case, through an abundance of caution and frankly in haste — reflective of the seriousness with which the company takes compliance with the Code — GSK took the decision to immediately remove Press Release 4 from its website prior to conducting a thorough review, irrespective of competing legal and regulatory obligations.

To comply with PMCPA's ruling, GSK did not re-issue Press Release 4 upon the conclusion of the First Case. However, on reflection, we acknowledge that the withdrawal was undertaken without full consideration of GSK's broader regulatory obligations.

In contrast, upon receipt of the complaint in the Current Case, GSK was already amid a procedure to ensure compliance with its Undertaking, while also ensuring that it did not contravene any of its other regulatory obligations as a listed company. This procedure encompassed a review of the Historical Press Releases. As noted above, there is an important distinction between Press Release 4 (relating to a marketed product) and Press Releases 1, 2 and 3 (relating to assets in clinical development and not marketed). GSK reasonably concluded that the immediate removal of the Historical Press Releases was unnecessary, and GSK maintains this position. The Historical Press Releases have now been archived, and GSK believes this approach complies with GSKs broader regulatory obligations as a listed company, as well as its obligations under the Code and the Undertaking.

This experience has provided valuable learning. Going forward, we are committed to ensuring that any such decisions are made with a comprehensive understanding of all relevant implications – Code and more broadly— so that we act in a manner that aligns with both the letter and spirit of the Code and avoids creating confusion around our approach to compliance.

c. Balancing of Legal and Regulatory Obligations and Potential Risks

The PMCPA's Initial Ruling appears to suggest that compliance with the Undertaking requires GSK to withdraw or retrospectively edit the Historical Press Releases. We submit that doing so is entirely inappropriate for a listed company, for the reasons detailed below and in the [named law firm] Letter.

Virtually every listed company maintains a cache of their press releases in an appropriate section of their corporate website, as an accurate and complete record of announcements made at the relevant time. Retrospectively editing these materials or pulling them down could lead to a dangerous inconsistency between what the company had announced publicly and the materials on its corporate website. In certain contexts, it is unlawful to do so, such as where a company has issued materials containing inside information.

In other contexts, it is considered highly irregular and non-transparent, particularly given that sophisticated investors are likely to be interested in monitoring the progress of products through their development and whether the company is delivering on its strategic goals. That would involve looking at all the company's announcements, including both formal announcements to the markets and its press releases to the investor community that do not necessarily contain inside information. To retrospectively edit or pull down these press releases runs the risk of materially misleading investors and the investment community, which has potentially significant adverse implications for listed companies and their directors under securities laws.

Amendments and withdrawals of press releases may also expose companies to allegations of tampering with historical records. To highlight the risk discussed above, consider Press Release 4, which announced the approval of VidPrevtyn Beta. The EU marketing authorisation for VidPrevtyn Beta was withdrawn on 18 March 2024 by Sanofi (the EU marketing authorisation holder) for commercial reasons. We received PMCPA ruling in May 2024 which found the Press Release in breach for other reasons than why it was withdrawn by Sanofi. For GSK to have edited or withdrawn press releases relating to the development of VidPrevtyn Beta only a few weeks after the EU marketing authorisation had been withdrawn would have risked adding unnecessary speculation and intrigue to the already sensitive issue of public perceptions of COVID vaccines. Moreover, there can be legal consequences for withdrawing a Stock Exchange announcement, depending on the jurisdiction, the nature of the announcement, and the reason for the withdrawal.

Considering the above, and the reasoning set out in the [named law firm] Letter, we are deeply concerned that the PMCPA's Initial Ruling in this case would set a dangerous precedent and have unintended consequences. If a press release were in future to be found in breach of the Code, the company concerned would not only have to take measures to stop re-use or re- publication (which GSK has clearly done), but it would also require companies to pull down investor information that may be in the public domain. That could, for example, include historical prospectuses or brochures, which are

filed under stock market rules and remain accessible through Stock Exchange records. We respectfully submit that it would be perverse to interpret undertakings given to the PMCPA so broadly and, accordingly, that GSK has not breached its Undertaking.

Alleged Breaches of Clauses 6.1, 6.2, 6.4 and 14.4 – the Historical Press Releases Relate to Development Milestones Not an Approved Product

As noted above, there are important differences between Press Releases 1, 2 and 3 and Press Release 4. With respect, we submit that the Panel did not appropriately consider these differences in its Initial Ruling, which led to the finding that GSK had breached Clauses 6.1, 6.2, 6.4 and 14.4 of the Code.

GSK acknowledges that we did not provide a substantive reply to the alleged breaches of Clauses 6.1, 6.2, 6.4 and 14.4 of the Code in our response dated 3 October 2024 to the complaint in the Current Case. Our focus at the time, was on whether the Historical Press Releases fell within the scope of the Undertaking. We understood that given the nature of press releases that the Undertaking had to apply to future press releases and not to press releases which are viewed as historical and no longer in active use. However, we accept that we could have provided a more comprehensive explanation in our original response.

Regarding the Historical Press Releases, Press Release 3 was a Stock Exchange announcement; Press Release 1 and Press Release 2 were announcements intended for a business and financial audience. The Historical Press Releases were issued to inform shareholders, the Stock Exchange and the wider investment community of media announcements relating to candidate development milestones.

Press Release 4 announced the authorisation of VidPrevtyn Beta, which from the point of authorisation and that announcement was an approved medicine in the EU and Northern Ireland, and shortly after became authorised in Great Britain (on 20 December 2022). The Historical Press Releases pre-date Press Release 4 and, moreover, the marketing authorisation of VidPrevtyn Beta. Therefore, when GSK published Press Releases 1, 2 and 3, the product was unapproved and a candidate therapy in development. The Historical Press Releases were not intended for HCPs and/or the general public, and, indeed, there was no product for HCPs to prescribe or for patients to request. Thus, GSK argues that Clauses 6.1, 6.2, 6.4 and 14.4 of the Code were not applicable to the Historical Press Releases and that if any Clause were to apply that would be Clause 26.2 and its Supplementary Information.

Below we discuss the impact of the distinction between Press Release 4 and the Historical Press Releases on the specific relevance of Clauses 6.1, 6.2, 6.4 and 14.4 of the Code below.

Clause 6.1 of the Code and its Supplementary Information

Clause 6.1 requires materials to be sufficiently complete to enable recipients to form their own opinion of “the therapeutic value of a medicine.”

The Supplementary Information to Clause 6.1 — which is relevant to three breaches in the Initial Ruling — states that referring only to relative risk, especially regarding risk reduction, “can make a medicine appear more effective than it actually is.” Further, to assess “the clinical impact of an outcome, the reader also needs to know the absolute risk involved.”

The clear intention behind this provision is to prevent companies misleading HCPs and members of the public about the safety and efficacy of a medicine they are considering prescribing or may be prescribed.

The Historical Press Releases were published in June 2022, February 2022 and December 2021 – at times when VidPrevtyn Beta was an unapproved medicine in development and unavailable for prescription. Each of the Historical Press Releases clearly refers to the product as a candidate and, indeed, no product name is mentioned at all. We submit that the Panel ought to have assessed the Historical Press Releases within that context, as this directly affects whether or not the intended audience – investors - could have been materially misled, and the Code therefore breached.

Cases concerning similar subject matter (Case AUTH/3518/5/21, Member of the Public v AstraZeneca; Case AUTH/3519/5/21, Member of the Public v Pfizer; and Case AUTH/3760/4/23, Complainant v GSK) concerned press releases about authorised (or temporarily authorised) medicines — in other words, medicines in use. As these medicines were therefore available for prescription, in principle at least, HCPs or members of the public could access materials published online about those medicines and gain information about the safety and efficacy of medicines they may prescribe or be prescribed (although we maintain that HCPs or members of the public would be unlikely to use investor press releases for this purpose). These cases are therefore distinguishable from the Current Case. For completeness, we note that in Case AUTH/3741/2/23 Complainant v Pfizer, the PMCPA held a re-Tweet of a Tweet relating to an announcement to the markets about phase 3 trial results for an unapproved medicine to be both promotional and also in breach of the requirements of Clause 7.2 of the 2019 Code (Clause 6.1 of the 2021 Code). While the case confirms the need for communications to be factual and balanced, we note: (i) it did not relate to the Supplementary Information to Clause 6.1/7.2, which is the main issue here; (ii) the communication in question was a promotional Tweet and re-Tweet under the PMCPA's rules relating to social media; and (iii) the Tweet and re-Tweet was not a non-promotional press release for the investment community about a product development milestone, posted on a company's website (as in the Current Case). Its relevance to the current case is therefore limited.

The intended purpose of the Supplementary Information to Clause 6.1 is evidently not to regulate how companies communicate to their investors and the business community about development milestones for unapproved candidate products, which HCPs cannot yet prescribe. Indeed, it would be unreasonable to expect every communication about product development intended for the investment community — including press releases, corporate prospectuses, and information on investor calls, etc. — to have to comply with the Supplementary Information to Clause 6.1 (the applicable standard for communications for licensed medicines, once the candidate therapy has been approved). We submit that this is not the standard expected under the Code and indeed would stretch the application of the Code far beyond its accepted remit.

It would be even more unreasonable, indeed entirely unworkable, to expect companies to historically edit communications published about product development once the relevant candidate has been approved, or when communication relating to the approved medicine is found in breach of the Code.

Once a product has received marketing authorisation, we are unaware of any legal, regulatory or self-regulatory obligation for the marketing authorisation holder to review

prior publications or press announcements relating to the development phases of the product and edit or withdraw statements on the basis they could mislead HCPs or the public about the product as approved. For example, a company might issue a press release about promising Phase II results that mention a particular indication. Years later, the approved indication could, conceivably, be narrower or broader than the indication that was assessed during the Phase II studies.

However, once the product is approved, the marketing authorisation holder does not need to edit or withdraw the older press release discussing the Phase II results. This is not the intended application of the Supplementary Information to Clause 6.1. However, this is what PMCPA's Initial Ruling in the Current Case would require from GSK and other listed companies.

As far as we are aware, PMCPA has not previously expressly opined on the specific issues of whether it (a) expects all corporate materials that are potentially accessible by the public about product development and candidate products to comply with the Supplementary Information to Clause 6.1; and, if so, (b) expects historically published corporate materials relating to product development to be edited or withdrawn if/when the company has given a forward- looking undertaking about materials relating to an approved medicine. Such an expectation seems excessive, disproportionate, and out of line with the principles of self-regulation (namely, protecting the public and patients). This is especially so when listed companies, such as GSK, consider their duties to investors, investor communications obligations, and good market practices for listed companies, and consider the corporate/investor relations risks that may flow from withdrawing investor communications or somehow tampering with the public record (as discussed above).

Given the above, we respectfully submit that the Panel failed to adequately consider how the clear distinction between Press Release 4 (relating to an approved medicine) and the Historical Press Releases (relating to candidates in development and unavailable for prescription) affected the application of the Supplementary Information of Clause 6.1. We submit that the Supplementary Information to Clause 6.1 is in this context not relevant to communications intended to inform shareholders, the Stock Exchange and the wider investment community about developmental milestones for a candidate therapy, which should not be used as a reference point for up-to-date information about an approved drug.

Clauses 6.2, 6.4 and 14.4 of the Code

We also appeal against the Panel's rulings in respect of Clauses 6.2, 6.4 and 14.4 of the Code for essentially the same reasons as set out above.

The purpose of these clauses is to prevent companies making exaggerated or unsubstantiated claims about their products that could mislead HCPs or the public about the therapeutic value of an authorized medicine.

These clauses are not intended to require companies to retrospectively edit or pull-down historical investor materials that may be in the public domain but are not intended be used as a reference point for up-to-date information about approved medicines available for prescription.

In addition, we note the following

Press Release 2 – Clause 6.4:

In the Initial Ruling, the Panel held that the phrase "Sanofi-GSK vaccine was well-tolerated in younger and older adults with no safety concerns" in Press Release 2 amounted to an unqualified safety claim for a medicine, and therefore breached Clause 6.4 of the Code. As above, we submit the Panel has misapplied Clause 6.4 and has not given proper consideration to the particular context of this Case. The purpose of Clause 6.4 is to regulate safety claims about approved medicines. Press Release 2 summarizes information about the findings of a particular trial relating to a developmental therapy. We therefore object to Clause 6.4 being used as the applicable standard here.

Press Release 3 – Clauses 6.2 and 1.4:

Clause 6.2. The Panel's Initial Ruling presupposes there is a promotional claim being made, or other relevant information about an approved medicine, which must then be capable of substantiation. We respectfully submit that the information provided had been appropriately qualified — taking into account the context of a corporate press release rather than promotional material for HCPs — and was not an unqualified claim incapable of substantiation. As above, we consider the Panel has not applied Clause 6.2 appropriately.

Clause 14.4. This clause clearly relates to promotional claims for approved medicines. Indeed, it is found in the section of the Code specifically dealing with promotion to HCPs. The first words of the clause state: "Promotion must encourage the rational use of a medicine by presenting it objectively and without exaggerating its properties." This was not a licensed medicine; therefore, it is not possible to encourage the use of an unapproved medicine, and an unapproved medicine cannot by definition be presented in a manner that is consistent with its SmPC and rationally. We respectfully submit that the Panel misapplied Clause 14.4, which is the relevant standard for promoting licensed medicines, to Press Release 3 — a non-promotional press release about a development milestone of an unapproved, candidate therapy.

Moreover, we disagree that such a press release, published at a time when a product was unapproved, is to be expected to be brought into line with the standard for promoting licensed medicines once the candidate treatment has received regulatory approval.

We therefore disagree that GSK breached Clauses 6.1, 6.2, 6.4 or 14.4 in the Current Case.

Applicable Standard

We submit that the more relevant standard in the current case is Clause 26, and in particular the Supplementary Information to Clause 26.2:

"Information made available in order to inform shareholders, the Stock Exchange and the like by way of annual reports and announcements etc may relate to both existing medicines and those not yet marketed. Such information must be non-promotional, accurate, presented in a factual and balanced way and not misleading, taking into account the information needs of the target audience. Business press releases should identify the business importance of the information and should only be aimed at the intended financial and investment audience."

The above provisions require announcements to the investment community to be balanced and not misleading, taking into account the information needs of the target audience. For the avoidance of doubt, the complainant has not alleged a breach of these provisions in the Current Case.

Press releases for investors are a specialized type of communication not intended to provide the public with reference information about their health or medicines — this is recognized under the provisions cited above. In addition, we note that the Supplementary Information to Clause 26.2 in the 2019 iteration of the Code expressly disapplied Clause 7 of the 2019 Code (i.e., Clause 6 in the 2021 Code) with respect to information provided to the investment community. We submit that the information and details related to an investigational product that are relevant and material to business and investor audiences are different to information for an HCP and public audience related to a licensed medicine that is available to prescribe. Given that the target audience of the Historical Press Releases was investors interested in candidate development milestones, rather than HCPs and/or patients interested in whether they could prescribe or be prescribed an approved medication, the information provided in the Historical Press Releases complied with the requirements of the Supplementary Information to Clause 26.2. However, GSK seeks to further understand from PMCPA and Appeal Board the requirements for these different audiences based on the comments above.

To support compliance with its Undertaking, GSK implemented training across its ABPI signatory and corporate affairs personnel explaining that when discussing relative efficacy from clinical studies in press releases, care is needed to ensure that enough information is provided for the reader to understand the absolute efficacy or risk in each arm of the study. We conducted further follow-up training in this area following receipt of the complaint in the Current Case.

Our press release archive currently extends back to 2009, containing approximately 1,500 documents. In this context, we seek clarification from PMCPA on how best to meet the requirements of the Code when signing an undertaking, particularly in relation to historical press release materials no longer in active circulation. In addition to the legal, regulatory and financial challenges discussed above and in the [named law firm] Letter, the practical challenge lies in reviewing a substantial volume of archived content to understand the legal and regulatory implications of withdrawal — press releases that, while no longer live on our website, may still exist digitally on third-party platforms beyond GSK's control.

Ultimately, GSK did not breach its Undertaking, but rather actively pursued good faith compliance. Consequently, GSK has not breached Clause 3.3 of the Code and, in turn, has not breached Clause 2. To conclude otherwise sets an unsound precedent with far-reaching and unreasonable implications for the well-established conduct of listed pharmaceutical companies.

We are available to answer any questions the PMCPA may have regarding this appeal letter and look forward to bringing the matter before the Appeal Board.''

RESPONSE FROM THE COMPLAINANT

The complainant's written basis for responding to the appeal is reproduced below:

"Thank you for providing me with an opportunity to respond to this rather lengthy GSK appeal letter and accompanying legal advice. The GSK appeal seems to me to rest essentially on 4 pillars :

1. An assertion that, as these press releases are "historical" rather than "future" material, no undertaking has been broken.
2. An assertion that press releases dealing with information about a product in development need not comply with the same standards of accuracy and honesty that are required of press releases about a licenced product.
3. An assertion that press releases aimed at investors and the financial community need not comply with the same standards of accuracy and honesty that are required of press releases aimed at Healthcare Professionals (HCP's) or the public.
4. An assertion that it is unreasonable to expect pharmaceutical companies to amend or withdraw historical press releases (or other material) about their products if they are subsequently found to be in breach of the Code.

1. An assertion that, as these press releases are "historical" rather than "future" material, no undertaking has been broken.

Nobody is denying the historical nature of these press releases. However, the breach of undertaking lies not in the date of creation of these materials but in the failure of GSK to deal with them when it had ample notice and opportunity. Even though it was aware of earlier similar PMCPA findings and even after the previous judgement against it, GSK continued to allow these press releases to remain easily accessible to the general public. The undertaking which GSK signed required it to review all materials that contained "closely similar claims" " if that material remained publicly available". This was not done and therein lies the breach of undertaking.

2. An assertion that press releases dealing with information about a product in development need not comply with the same standards of accuracy and honesty that are required of press releases about a licenced product.

This assertion, in one form or another, appears several times in the appeal letter.

GSK appears to believe that the standards required in clauses 6 and 14 only apply to material promoting a licenced product. If that were the case then it would leave pharmaceutical companies free to make all sorts of wildly inaccurate and unsupportable statements in non-promotional material such as press releases. The requirements of these clauses exist to ensure that all pharma communications adhere to the highest standards, whether the product discussed is licenced or not, and whether the material is promotional or not. GSK appears to think that clause 26 is the only clause which should be applied to these press releases and is careful to point out that I did not specifically refer to a breach of clause 26.2 in my complaint. Well, that is true of course. Not being a pharma person, I am perhaps not as familiar with the individual clauses of the Code as perhaps I could be. However, after reading the GSK appeal letter I did go away and check exactly what the current supplementary information to clause 26 says. It says this : ***"Attention is drawn to other relevant clauses of the Code, in particular, the quality standards Clauses 5 to 10".*** This seems to me to make it clear that other clauses are indeed relevant to this case. I do not wish to make a complaint about a breach of clause 26. If GSK wishes to self-report a breach then it is of course free to do so.

GSK's assertion is that the quality standards relating to its claims set out in these other clauses, should not apply because there is no prescribing decision to be made. This, I believe, demonstrates a lack of understanding of the ethical basis of your Code principle that communications by pharmaceutical companies should always be accurate and honest. These press releases were not accurate and honest and the GSK assertion that this is OK because the drugs concerned were not licenced seems to me to be shockingly at odds with what I believe is referred to as "the spirit of the Code". GSK have presented no case for why the offending claims and statements are not misleading or not exaggerated but appear to be relying entirely on their very narrow (and incorrect) interpretation of which clauses do or do not apply here.

GSK's assertion that because a product is not licenced, such claims will not result on pressure on an HCP to prescribe it, also demonstrates a poor understanding of what actually goes on in clinical practice. It is, I believe, not uncommon for HCPs to be berated with requests for the latest wonder drug in development, which patients have heard, seen or read about in the media as a result of press releases such as these. This is bad enough, but when such demands are based on claims and statements which are false, misleading, exaggerated or unsubstantiated then it must be even more annoying and frustrating for the HCP.

3. An assertion that press releases aimed at investors and the financial community need not comply with the same standards of accuracy and honesty that are required of a press release aimed at HCP's or the public.

The Panel noted that these press releases were labelled "For media and investors only", rather than "For financial media and investors only". It was very easy for me, a member of the public to search for and obtain access to them. I am not a member of their investor or financial community and my search which turned up these materials was simply based on typing 6 words into Google: "GSK", "Covid", "Vaccine", "Press", "News", "Release" and then pressing "Enter". It was not necessary for me to have to access and search any specialist repository, archive or regulatory website.

It seems to me that a misleading or exaggerated claim for efficacy or safety is as reprehensible when directed at an investor as it is when directed at an HCP or a member of the public.

Please can I remind the Appeal Board about the nature of the misleading claims and statements in these press releases:

a) Repeated misleading claims about the efficacy of the vaccines. Only reporting relative efficacy rates and not discussing absolute rates gives an enormously misleading impression about the efficacy of any pharmaceutical product in a clinical trial.

b) Exaggerated claims regarding safety and efficacy.

c) Making exaggerated claims for efficacy which cannot be substantiated and are not supported by the currently available trial data.

It seems to me that all of these claims and statements are no less egregiously misleading because they are directed at an investor or potential investor than if they were directed at an HCP or a member of the public. For example, it seems to me that the Code requirement regarding absolute and relative risk and efficacy exist largely to prevent the massive and misleading overstatement of the efficacy of a drug. Failure to comply with this requirement (also to be found in the MHRA Blue Guide in addition to the Code) is

very likely to have misled any reader into thinking the vaccine was much more effective than it actually was.

4. An assertion that it is unreasonable to expect pharmaceutical companies to amend or withdraw historical press releases (or other material) about their products if they are subsequently found to be in breach of the Code.

There appears to be 2 principal reasons given for this assertion:

a) GSK says that to uphold the Panel decision would set a precedent that would require companies to review **all** historical materials when any information or data relating to a product is changed or updated. This is nonsense. To illustrate this point GSK gives an example ***"where a company announces that a medicine has been authorised for a particular indication, and that indication is later changed or expanded there is no expectation under the Code, that the company must go back and edit its past press releases to correct for the expanded indication".*** Of course there is not. Not if the press releases were accurate and Code-compliant at the time they were released. That is totally different from the situation under consideration here. Here we have three historic press releases that were in breach of the Code even at the time they were released and have remained in breach ever since. GSK has never shown its vaccine to be 100% effective or free of safety concerns and has not appropriately presented efficacy results in them. So of course, if the company did not wish to withdraw those press releases from the public domain (as GSK clearly did not because it left them there) it should be required to amend them appropriately.

b) Despite the fact that GSK did indeed voluntarily withdraw the press release that was the subject of the previous case, it now claims that it would be too onerous or that it would give rise to legal or regulatory issues for it if it were to do the same for other similarly violative press releases. It says ***" It would be even more unreasonable, indeed entirely unworkable to expect companies to historically edit communications*** [I assume this is intended to be "edit historical communications"] ***published about product development once the relevant candidate has been approved, or when communication relating to the approved medicine is found to be in breach of the Code."*** Again, this is nonsense. If the original document was Code-compliant at the time it was released then absolutely no further action is necessary. If a historical document can still be accessed by the public and was in breach of the Code at the time it was released, and this breach is brought to the attention of the company then it is not unreasonable for the company to be obliged to do something about it.

The reasons given by GSK and its lawyers, for why it is unreasonable to expect them to do something about it, all seem to revolve around the excuse that it would make life difficult for them commercially or financially. Examples of such excuses given in the appeal letter include:

"For GSK to have edited or withdrawn press releases relating to the development of VidPrevtyn Beta only a few weeks after the EU marketing authorisations had been withdrawn would have risked adding unnecessary speculation and intrigue to the already sensitive issue of public perceptions of COVID vaccines"
Unnecessary? Really? By whose definition?

"In other contexts, it is considered highly irregular and non-transparent particularly given that sophisticated investors are likely to be interested in monitoring the progress of products through their development and whether the company is delivering on their strategic goals. That would involve looking at all the company's announcements. Including both formal announcements to the markets and its press releases to the investor community that do not necessarily contain inside information. To retrospectively edit or pull down these press releases runs the risk of materially misleading investors and the investment community which has potentially significant adverse implications for listed companies and their directors under securities laws". When I read this passage as a member of the public I am shocked by the double standards on display here. GSK appears to be concerned about not ***"materially misleading investors and the investment community".*** One is bound to ask why GSK is so concerned about not misleading them in this way whereas it was not concerned about misleading them by exaggerating efficacy and safety data and claims in its actual press releases. Could it be that its real concern here is the ***"potentially significant adverse implications for listed companies and their directors under securities laws"*** ? However, these concerns should not be concerns for the PMCPA if it is truly independent of ABPI influence. If a company fails, on multiple counts to comply with the requirements of the Code then it should face the legal and financial consequences of that non-compliance. What those consequences are, beyond those imposed by the PMCPA, should not be a matter for consideration by PMCPA. It would be a concern for the UK public if they thought that regulators of pharmaceutical companies were being guided in their judgements by concerns about what the subsequent legal, commercial and financial implications of those judgements will be for the companies and their directors. Furthermore, if regulatory transparency and consistency are really the issues here, and withdrawal or amendment are truly not options in certain circumstances, then surely a simple qualifying note or flag added to the filed/archived press release informing the reader that the contents of the press release have been found to be misleading and explaining how and why, can only add to the transparency and detail of the public record. That should be a good thing which would surely be welcomed by investors and the financial regulatory authorities would it not? Perhaps not so good for the reputation of GSK but the answer to that is surely to adhere to the Code and do not mislead people about the efficacy and safety of their drugs in press releases.

There are several such examples of special pleading to be found in the appeal letter. I will not go through them all as they are all very similar to the two examples that I have given above.

However, in addition GSK has provided a letter from [named law firm] which also attempts to provide explanations of and justifications for this special pleading. Two particular sections of this letter provide good examples of these, and illustrate the double standards shown by attempting to use them to justify inaction:

[Text (extract from legal letter) available to complainant and Appeal Board but redacted for case report]

If removal or amendment of violative material is not an option then surely the fact that GSK has been found by its own industry's self- regulatory body to have included misleading and exaggerated information in a particular press release is something that the market is entitled to know about is it not? Surely including or adding of such

information to the record can only help investors and the financial community by [Text (extract from legal letter) available to complainant and Appeal Board but redacted for case report]

Furthermore, I see nothing in any of the information with which I have been provided that suggests that addition of such a qualifying note or flag to the record would not be possible, if withdrawal or amendment was truly not an option. The onerousness in, or embarrassment caused by, doing this for GSK should not be the primary consideration here.

[Text (extract from legal letter) available to complainant and Appeal Board but redacted for case report]

If GSK did not think or even intend that these press releases might influence investment activity why did it release them and direct them at this audience in the first place ? This statement is then followed by a series of bullet points explaining the possible consequences for GSK of doing what the PMCPA has required it to do. These include :

[Text (extract from legal letter) available to complainant and Appeal Board but redacted for case report]

- To this one is tempted to ask: So what ? The initial statements were misleading. If the Code has been breached then GSK should face up to the consequences of its actions. The risk of additional sanctions imposed by other regulators is not an excuse for ignoring an undertaking given to the PMCPA.

[Text (extract from legal letter) available to complainant and Appeal Board but redacted for case report]

- Once again: So what? Investors would be correct to draw negative inferences. Whether or not GSK may be likely to be exposed to risk of subsequent litigation as a result of PMCPA decisions and undertakings imposed should not be a matter which should dictate decision-making by the PMCPA or indeed decisions about whether GSK needs to comply with those decisions and undertakings or not. If GSK wishes to reduce its exposure to such risks then it should desist from making misleading and exaggerated statements in its press releases.

[Text (extract from legal letter) available to complainant and Appeal Board but redacted for case report]

- Once again: So what? The PMCPA does not make the law. Any potential legal consequences for respondents resulting from PMCPA decisions is not a matter for the PMCPA and should not influence its judgements about whether the Code has been breached or what resulting sanctions and undertakings are required by its rules and constitution.

The lawyers conclude [Text (extract from legal letter) available to complainant and Appeal Board but redacted for case report]

- However, any risk is of GSK's own making. Many people would judge that there is nothing "unwarranted" about having to face up to the consequences of your actions. The truth is that GSK has misled people repeatedly in its press releases and then failed to take the appropriate action when it was told to do so. Legal and financial regulatory discomfort is no excuse for a company not doing what it promised the PMCPA it would do. Violative documents cannot be allowed to remain in the public domain simply

because it will cause GSK further embarrassment, cost or regulatory/legal consequences in order to amend, remove or qualify them.

In summary I do not believe that GSK and [named law firm] have succeeding in demonstrating why the Panel findings relating to all the breaches of clauses 6.1, 6.2, 6.4 and 14.4 should be overturned. As a result I also do not think that they have demonstrated why the findings of breaches of clauses 3.3 and 2 should be overturned either."

APPEAL BOARD RULING

The Appeal Board took account of the press releases in question, their content and the chronology in relation to Case AUTH/3760/4/23 where GSK had provided the undertaking that had allegedly been breached.

The Appeal Board observed that the undertaking had been signed on 24 May 2024 and that it related to a breach of Clause 6.1 on the basis that the vaccine efficacy claims, expressed as relative risk reduction rates, failed to refer to absolute risk data. The complaint in the current case was submitted on 16 August 2024. The Appeal Board acknowledged that the undertaking given in that previous case did not (unlike some other undertakings) include a statement confirming that use of the material in question and any similar material, if not already discontinued or no longer in use, will cease forthwith. However, the Appeal Board agreed with the Panel's view that compliance with the undertaking would reasonably include a review of whether previous press releases with similar claims were still publicly available.

The Appeal Board noted the number of working days between providing the undertaking and receipt of the complaint and considered the various actions taken and workstreams implemented by GSK to comply with the undertaking.

The Appeal Board, having considered all the evidence before it, determined that GSK, in the context of the scale of the task at hand, was taking all reasonable steps to comply with its undertaking. The Appeal Board, therefore, ruled **no breach of Clause 3.3**. The appeal on this point was successful.

In relation to the three breaches of Clause 6.1 about the relative efficacy claims within the three press releases, GSK contended that the presentation of vaccine efficacy was complex with differing opinions on the most appropriate way to present it. GSK submitted that a number of national and international bodies presented vaccine efficacy as relative risk. GSK maintained that, in the light of the ruling and undertaking given in the previous case, its focus had been to ensure that where absolute risk reduction was not included relative risk had been presented with appropriate and sufficient context; GSK believed that the press releases at issue contained appropriate context given the investor audience. GSK asserted that the purpose of the supplementary information to Clause 6.1 was to regulate how companies communicate about medicines that are available for prescription and not how companies communicate to their investors about unlicensed products in development. The Appeal Board rejected GSK's assertion on this point, noting that Clause 6 appears in the 'Grey' section of the Code (Overarching Requirements) and is thus not limited in its application to licensed medicines.

The Appeal Board considered the supplementary information to Clause 6.1, which referred to "absolute risk and relative risk". This stated that "referring only to relative risk, especially with

regard to risk reduction, can make a medicine appear more effective than it actually is" and therefore "relative risk should *never* be referred to without also referring to the absolute risk". Clause 6.1 required that information must not be misleading and must be sufficiently complete to enable recipients to form their own opinion of the therapeutic value of the medicine. The Appeal Board acknowledged the difficulties of reporting efficacy in the context of vaccines but was very mindful that in the absence of absolute risk a relative efficacy statement had the potential to be misleading. The Appeal Board considered that the Code did not differentiate between vaccines and other medicines in Clause 6.1 and therefore upheld the Panel's rulings of a **breach of Clause 6.1 in relation to each of the three press releases.** The appeal on this point was unsuccessful.

The allegation in relation to the breach of Clause 6.4 related to the statement "Across both studies, the Sanofi-GSK vaccine was well-tolerated in younger and older adults with no safety concerns" in Press Release 2. The supplementary information to Clause 6.4 specified that the word 'safe', and grammatical derivatives, must not be used without qualification. The Appeal Board noted the absence of additional information or references to provide appropriate context, qualification or balance and therefore upheld the Panel's ruling of a **breach of Clause 6.4**. The appeal on this point was unsuccessful.

The Appeal Board observed that while Press Release 2 included some additional information to support the claim, "100% efficacy against severe COVID-19 disease and hospitalisations" that additional information did not immediately follow the 100% efficacy claim, and appeared after six paragraphs of intervening text. The additional information stated that "The Sanofi-GSK vaccine provided 100% protection (0 vs 10 cases post-dose 1, 0 vs 4 cases post-dose 2) against severe disease and hospitalizations and 75% (3 vs 11 cases) efficacy against moderate-to-severe disease in seronegative populations." The Appeal Board was concerned that the small numbers involved in the study meant that the data was unlikely to be sufficiently robust to draw firm conclusions. The Appeal Board considered that the claim, in isolation, was misleading and exaggerated the impression of the vaccine's efficacy which was not capable of substantiation. The Appeal Board upheld the Panel's ruling of a **breach of Clause 6.2** and therefore it followed that the Panel's ruling of **a breach of Clause 6.1** was also upheld. The appeal on these points was unsuccessful.

The Appeal Board observed that Clause 14.4 (which was in the Blue section of the Code, which relates to promotion to health professionals and other relevant decision makers) stated that 'Promotion must encourage the rational use of a medicine…'. The Appeal Board considered that at the time of the press release, which was aimed at an investor audience, there was no licensed vaccine available and therefore there was no question about promoting it for rational use and thus it did not fall within Clause 14.4. On this narrow technical point, the Appeal Board ruled **no breach of Clause 14.4.** The appeal on this point was successful.

The Appeal Board observed that, outside the context of the Code, other stakeholders, including UK government bodies, had communicated about vaccine efficacy by reference to relative risk without including absolute risk, due to the nature of vaccines. The Appeal Board further took account of the age of the press releases and the fact they were aimed at an investor audience. Despite its concerns in relation to certain claims within the press releases, the Appeal Board considered that the circumstances of this case, including its finding that GSK had not breached its undertaking, meant that GSK had not brought discredit upon, or reduced confidence in, the

pharmaceutical industry. The Appeal Board therefore ruled **no breach of Clause 2**. The appeal on this point was successful.

Complaint received **16 August 2024**

Case completed **20 August 2025**