CASE/0685/08/25

COMPLAINANT v ELI LILLY

Alleged pre-licence promotion in an online news article

CASE SUMMARY

This case related to an article published on the BBC News website which reported Phase 3 trial results for orforglipron, an investigational medicine. The complainant alleged that the article, which arose from a press release provided to the BBC by Lilly, constituted pre-licence promotion.

There was an appeal by Eli Lilly of the Panel's rulings.

The outcome under the 2024 Code was:

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

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

FULL CASE REPORT

A complaint was received about Eli Lilly and Company Limited from an anonymous, non-contactable complainant who described themselves as a member of the public.

COMPLAINT

The complaint wording is reproduced below:

> "Pre licence promotion in bbc article [URL provided]"

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

ELI LILLY'S RESPONSE

The response from Eli Lilly is reproduced below:

> "Thank you for your letter dated 11th August 2025, regarding a complaint under the Code of Practice by an anonymous individual who stated that he/she is a member of the public. We note the complaint refers to an article published on the BBC website on 7th August which reports the outcome of a Phase 3 weight loss trial for Orforglipron.
>
> Orforglipron is a medicinal product under investigation by Lilly for both type 2 diabetes and weight management. The news coverage in question was as a result of a press release issued on the 7th August about top line results from the ATTAIN 1 study of orforglipron in people with overweight and obesity.
>
> Further trials in the Phase 3 development program are ongoing. At this time no regulatory submission to the MHRA has been made and the product is not yet licensed in the UK or in any other country around the world.
>
> The BBC article referred to in the complaint was independently written by the BBC Medical Editor [named health journalist] after receiving an approved press release from Lilly which was issued on 7th August.
>
> Press releases about phase 3 clinical trial results are an established form of communication permitted under the ABPI Code of Conduct 2024 and widely used across the pharmaceutical industry to support transparency in clinical research. Press releases are non-promotional materials and we ensure they meet the relevant requirements of the Code.
>
> In response to the specific allegation in the complaint, we have provided below details on the press release in question, Lilly's involvement in the article, communication with the BBC journalist and addressed Clauses 3.1, 5.1 and 2 of the 2024 Code as requested.
>
> The ATTAIN-1 press release (enclosed) refers to the generic name of the investigational product in development, 'orforglipron'. The press release is factual and scientific in tone and is focused on the primary and first key secondary endpoints, i.e. only those that have been adjusted for multiplicity. Data is presented in the main body, but also in a table format to ensure clarity and enables all relevant information such as confidence intervals and p values to be displayed so the reader has all necessary context and information. Other results from non-primary or key secondary objectives have been mentioned only briefly and with clarity on the statistical hierarchy. Data was presented factually and no claims beyond the data were made. The most frequently reported and relevant adverse events were included.
>
> The licensing status of orforglipron is made clear from the outset of the press release. The headline sentences clearly refer to the drug as 'investigational' and the fourth headline sentence clearly states Lilly intends to submit orforglipron to regulatory authorities this year.

We therefore believe the information provided in the press release is presented in a non-promotional way and is factual, is scientifically appropriate and balanced.

The press release issued to UK media was examined by [named employee] in accordance with Clause 8.3 of the Code of Practice. [Named employee] is [professional qualifications] and is a listed signatory with the PMCPA. In accordance with clause 8.3 of the Code, Lilly examines all press releases by email, as set out in our SOP on Conducting Public Relations Activities. Supplementary guidance to our SOP includes information on when press releases can or cannot be issued, and the approvals required. Email approval records are retained in a sharepoint site.

The BBC article published on 7th August 2025 was independently written by the Health Editor at BBC News based on the Lilly press release. No additional information was provided to the Health Editor beyond the press release which was emailed to the Health Editor at BBC News (and to four other health journalists) on the morning of Thursday 7th August. We can confirm we did not arrange interviews or facilitate any quotations for the article. The data and quotes the BBC journalist used in the article were taken from the approved Lilly press release. Lilly did not see the BBC article prior to its publication and was not involved in the authoring or reviewing of the article.

Lilly refutes any breaches of the Code below, as based on previously published cases, Lilly is only responsible for the information provided to BBC News and not for the final article.

Clauses 3.1: A medicine must not be promoted prior to the grant of the marketing authorisation which permits its sale or supply.

The Lilly press release was non-promotional and did not include any claims or emotive or persuasive language. It presented factual and balanced information in a format that provided the journalist with all the relevant information. The investigational status of the product was made clear. Lilly asserts that dissemination of scientific data from a Phase 3 trial, which contributes to the body of medical knowledge, supports transparency in clinical research is permissable [permissible] under the Code. The information was provided to health journalists only and not directly to members of the public.

Clause 5.1: Companies must maintain high standards at all times.
As described above, the press-release was prepared, approved and issued in accordance with Industry standards and Lilly's SOP. The dissemination of scientific data from a Phase 3 trial, which contributes to the body of medical knowledge, supports transparency in clinical research and is consistent with global ethical standards and public expectations is permissable [permissible] under the Code. This is also consistent with guidance around press releases in the UK in the Lilly internal procedure. Examination of the press release was completed as per Code guidance and all internal approval steps were completed.

Interaction with the BBC was limited to providing them with the approved press release via email. Thus our relationship and communication with them was legitimate, limited and followed a standard practice of disclosure.

Clause 2: Activities or materials must never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry.

We note that a ruling of breach of Clause 2 is a sign of particular censure, reserved for such circumstances. We do not consider that a press release factually disclosing the topline results of a key phase 3 trial to appropriate news outlets, done in accordance with the principles of transparency and disclosure would bring discredit upon, or reduce confidence in, the pharmaceutical industry. As such, we do not feel that it amounts to a breach of Clause 2.

In summary, the press release is permissable [permissible] under the Code and is factual, balanced, and avoids promotional tone or claims. Therefore, it does not constitute pre-licence promotion but rather fulfils obligations around transparency and scientific responsibility. Lilly refutes allegations of breaches in Clauses 3.1, 5.1 and 2.

We trust that this resolves the matter to your satisfaction and remain available to answer any questions you may have."

PANEL RULING

This case related to an article published in August 2025 on the BBC News website which reported Phase 3 trial results for orforglipron, an investigational medicine. The complainant alleged that the article constituted pre-licence promotion.

The Panel noted that the article was headed *"Daily weight loss pill could help patients lose 12% of body weight"* and began by stating that orforglipron was not yet licensed but could be available the following year. It went on to state:

> "*Preliminary results of a major trial show those on the highest dose lost an average of 12 kilos (nearly two stone) over 16 months but about one in 10 stopped taking the pills due to side effects, including nausea and vomiting. In addition to weight loss, participants also benefited from reductions in cholesterol, blood fats and blood pressure.*"

The article referred to a senior Lilly leader stating that the company was planning to submit the drug for licensing before the end of the year and preparing for a *"global launch to address this urgent public health need"*. The article went on to query where the medicine might fit within the blockbuster market and surmised that despite being less effective than injectables, there was *"likely to be a significant market for weight loss pills"* which were anticipated to be cheaper and available to more patients.

The Panel noted that when complaints were received about information that an independent journalist had published in the press, its rulings were made upon the material released by the company that might have prompted the article, and not the article itself. The tone, language and content of any relevant press release(s) provided by the company, and any interactions the company had with the journalist, would be important considerations in this regard.

The Panel therefore considered the content of the press release issued by Lilly, titled *"Lilly's oral GLP-1, orforglipron, delivers weight loss of up to an average of 12.4kg in first of two pivotal Phase 3 trials in adults with obesity"*.

The press release, which described orforglipron as an investigational once-daily pill that *"showed significant efficacy and a tolerability profile consistent with injectable GLP-1 therapies"*, detailed orforglipron along with the efficacy and safety results from the Phase 3 ATTAIN-1 trial, amongst other information relating to the ATTAIN clinical trial programme.

The Panel noted that the press release also included quotes attributed to a senior Lilly leader:

> *"Obesity is one of the most pressing global health challenges of our time, driving global chronic disease burden and impacting more than one billion people worldwide.*
>
> *With orforglipron, we're working to transform obesity care by introducing a potential once-daily oral therapy that could support early intervention and long-term disease management, while offering a convenient alternative to injectable treatments. With these positive data in hand, we are now planning to submit orforglipron for regulatory review by year-end and are prepared for a global launch to address this urgent public health need."*

Clause 3.1 – promoting an unlicensed medicine

The Panel understood that companies might want to communicate topline results from clinical trials by issuing a press release however language, context, intended audience and overall impression were important considerations, particularly when issuing information related to medicines that were not yet licensed.

The Panel noted that the press release was not marked as being directed to a particular audience and had been proactively emailed to the Health Editor at BBC News along with four other health journalists. The Panel considered the BBC was a mainstream media outlet with a broad audience, including the public.

In this context, the Panel disagreed with Lilly's submission that the press release was non-promotional and did not include any claims or emotive or persuasive language. In the Panel's view, the language used in the press release, including references to "*transform obesity care", "convenient alternative to injectable treatments", "with these positive data in hand"* and being *"prepared for a global launch to address this urgent public health need"*, went beyond the provision of factual, non-promotional information relating to clinical trial data.

Clause 3.1 prohibited the promotion of a medicine prior to the grant of its marketing authorisation. Lilly submitted that at the time of complaint, no regulatory submission in the UK had been made for orforglipron, which was not yet licensed anywhere in the world, and further trials within the development programme were ongoing. Noting the press release concerned the results of a Phase 3 trial, and that it referred to planned submission for regulatory review by year-end, the Panel determined that orforglipron was not so early in its development that it could not be considered a medicine for the purposes of Clause 3.1.

Taking all of the above into account, the Panel considered the cumulative effect of the language used in the press release, in the context of its audience, meant that the press release promoted orforglipron prior to the grant of its marketing authorisation. The Panel therefore ruled a **breach of Clause 3.1**.

Clause 5.1 – failing to maintain high standards

The Panel noted Lilly's submission that it had provided the press release to a small number of health journalists and not directly to members of the public. However, the Panel considered that in proactively providing the press release to a mainstream media outlet and national broadcaster, it was foreseeable that the information would be disseminated to a wide audience including members of the public.

The Panel was concerned that despite its submission that the press release had been prepared, approved and issued in accordance with its SOP and the Code, Lilly had failed to recognise that the positive language used in the quotations was promotional, in the context of its foreseeable audience.

For these reasons, taken together with its ruling of a breach above, the Panel considered that Lilly had failed to maintain high standards and ruled a **breach of Clause 5.1**.

Clause 2 - Bringing discredit upon, or reducing confidence in, the pharmaceutical industry

A breach of Clause 2 was a sign of particular censure and was reserved for such circumstances. The promotion of an unlicensed medicine was an example of an activity likely to be in breach of Clause 2.

The Panel noted the press release referred to "anticipated demand at launch". In the context of a therapy area that was sensitive and attracted substantial public interest, the Panel considered that Lilly should have exercised particular caution.

The Panel considered its determination above that the press release, which was proactively issued by the UK to mainstream media, constituted promotion of a medicine prior to the grant of its marketing authorisation to a broad audience.

Taking the circumstances into account and considering their cumulative effect, the Panel considered, on balance, that Lilly had brought discredit upon, and reduced confidence in, the pharmaceutical industry. A **breach of Clause 2** was ruled.

APPEAL BY ELI LILLY

Eli Lilly's written basis for appealing is reproduced below.

> "We refer to your letter of 31 March 2026 notifying Eli Lilly of the PMCPA's rulings in the above matter, and to our email dated 8 April 2026 giving notice of appeal against the PMCPA's ruling on Clauses 3.1, 5.1 and 2 of the 2024 ABPI Code ("the Code").
>
> Eli Lilly respectfully submits that the Panel's findings of breaches of Clauses 3.1, 5.1 and 2 are based on an interpretation and application of the Code that is inconsistent with established PMCPA practice and fundamental legal principles of certainty and proportionality; and are not supported by the evidence when considered in its proper context. The Appeal Board is invited to reconsider the matter having regard to the full context of the communication and established PMCPA precedent, noting that the complainant bears the burden of proof on the balance of probabilities, which is not met on the facts of this case.

In relation to Clause 3.1, the Panel erred in concluding that the press release constituted promotion of an unlicensed medicine. The press release was a factual, balanced and data-driven communication of Phase 3 clinical trial results for an investigational product; and no material capable of constituting promotion was disseminated to the public. The Panel placed undue emphasis on selectively extracted wording, failed to consider the communication in its full context, and attributed significance to language that was not disseminated to the public. The Panel further placed disproportionate weight on the provision of the press release to journalists, notwithstanding that such engagement is routine, expressly contemplated by MHRA guidance ("MHRA Blue Guide"), and not equivalent to communication to the public. In doing so, the Panel departed from established PMCPA practice requiring materials to be assessed as a whole.

In relation to Clause 5.1, the finding is wholly derivative of the alleged breach of Clause 3.1 and does not identify any independent failure of standards. Eli Lilly applied robust internal review and examination processes and acted in accordance with both the Code and established industry practice. The Panel has not articulated any standalone conduct capable of amounting to a breach of Clause 5.1.

In relation to Clause 2, the Panel applied a disproportionate and inconsistent standard. Clause 2 is reserved for serious conduct of particular concern, yet the present case involves a controlled communication of clinical trial data with no misleading content, no public dissemination of the key wording relied upon, and no evidence of impact on public confidence, nor is there any evidence of intent to promote the medicine. Therefore, this case falls well below that threshold. The Panel further relied on the "sensitive" nature of the therapy area as an aggravating factor. However, the Code does not require that a different or higher standard should apply depending on the therapy area or level of public attention. This introduces uncertainty into the application of the Code and departs from the principle that regulatory standards must be applied consistently and objectively, in breach with the principle of legal certainty and legitimate expectation.

More broadly, the Panel's approach risks extending the scope of the Code in a manner that lacks predictability and clarity for companies seeking to comply with their obligations. In particular, the suggestion that routine engagement with journalists, or the use of measured and evidence-based language in communicating clinical data, may give rise to findings of promotion or discredit introduces an unwarranted degree of uncertainty for companies committed to complying with the Code.

We set out in more detail below our grounds of appeal on Clauses 3.1, 5.1 and 2 of the Code.

1. Clause 3.1

Eli Lilly disputes that it promoted orforglipron prior to the grant of its marketing authorisation ("MA"). The Panel's finding under Clause 3.1 is flawed for three reasons: (i) the press release was a factual, balanced and non-promotional communication of clinical trial data; (ii) the Panel assessed selectively extracted wording rather than the communication as a whole; and (iii) no material capable of constituting promotion was disseminated to the public.

As we understand it, the Panel's ruling on Clause 3.1 is, in essence, as follows:

- The language used in the press release including references to "*transform obesity care*", "*Convenient alternative to injectable treatments*", "*with these positive data in hand*" and being "*prepared for a global launch to address this urgent public health need*" went beyond the provision of factual, non-promotional information relating to clinical trial data.

- "[O]*rforglipron was not so early in its development that it could not be considered a medicine for the purposes of Clause 3.1*", given that the press release concerned the results of a Phase 3 trial, and that it referred to "*planned submission for regulatory review by year-end*".

- Eli Lilly's press release upon which the Article is based was not marked as being directed to a particular audience and had been proactively emailed to the Health Editor at BBC News along with 4 other health journalists.

- "[T]*he cumulative effect of the language used in the press release, in the context of its audience*", meant that the press release promoted the product prior to the grant of its MA.

i. The language used in the Press Release was not promotional

Eli Lilly respectfully submits that the Panel erred in finding that the language in the press release was promotional. The press release constituted a factual, balanced and evidence-based communication of Phase 3 clinical trial results in line with Clause 6.1 of the Code according to which "*information, claims and comparisons must be accurate, balanced, fair, objective and unambiguous and must be based on an up-to-date evaluation of all the evidence and reflect that evidence clearly. They must not mislead either directly or by implication, by distortion, exaggeration or undue emphasis.*". In accordance Clause 6.1, the press release presented the data in a scientifically appropriate manner, including primary and key secondary endpoints, relevant statistical context, and a balanced description of adverse events.

The Panel placed significant reliance and undue emphasis on selectively extracted wording from a quotation attributed to a senior Eli Lilly representative within the press release rather than assessing the communication as a whole and in its proper context.

For example, the Panel refers to "*transform obesity care.*" However, the actual wording of the statement was that Eli Lilly is "***working*** *to transform obesity care*", which is clearly forward-looking and aspirational in nature. It does not constitute a claim that such transformation has been achieved, nor does it present a concluded or proven outcome. Moreover, the Panel's presentation of this wording is incomplete, as it omitted the key qualifying language "***working to*** *transform*". Furthermore, this wording was not presented to the public in the form relied upon by the Panel.

The Panel also criticised the statement that Eli Lilly is "*prepared for a global launch to address this urgent public health need*" as not being factual. However, this statement reflects the forward-looking position set out in the executive summary, namely that

"*Lilly remains on track to submit orforglipron to global regulatory agencies by year-end* ***and is making substantial investments to meet anticipated demand at launch.***" It is therefore a factual statement regarding corporate planning and preparedness to meet anticipated patients' needs in the relevant market, rather than a promotional claim regarding the medicine. The fact that Eli Lilly is making substantial investments to support future supply is, in itself, factual information. With regard to "*urgent public health need,*" Eli Lilly respectfully submits that this reflects the widely recognised and well-documented burden of obesity as a major global health challenge. In that context, the wording is grounded in established public health evidence and does not constitute a promotional or exaggerated claim.

The Panel refers to the phrase "*with these positive data in hand.*" Eli Lilly respectfully submits that this is an objective description of trial results reflecting that the study demonstrated a statistically significant effect of the product. It is therefore a factual statement of the study outcome, rather than a promotional conclusion.
It should further be noted that the press release does not include comparative claims, exaggerated or highly emotive language, or any misleading statements. PMCPA precedent demonstrates that such language is ordinarily present where communications are found to be promotional. In case 0583/05/25, the Panel found that language suggesting a medicine offered "*benefits beyond any GLP-1 therapy patients are taking*" and describing it as a "*blockbuster*" was found to be promotional. The wording used in the present case does not include such strong statements. It does not claim superiority, does not overstate efficacy, and does not present the medicine in a misleading or unbalanced way. It was directed to a limited number of health journalists and contained no call to action or encouragement for patients to seek prescription.

The inclusion of measured, forward-looking or contextual language within a quotation does not render an otherwise factual communication promotional, particularly where the underlying data are presented accurately and without exaggeration. Eli Lilly's view is that the information contained in the press release can reasonably be characterised as factual disclosures of material information that a publicly listed company has a duty to communicate, including in accordance with its legal and regulatory disclosure obligations.

The Panel's conclusion therefore rests on isolated wording rather than the overall impression of the communication, contrary to established PMCPA practice.

ii. The press release was provided to health journalists only and not directed to the public

Eli Lilly respectfully submits that the Panel placed undue weight on the fact that the press release was proactively provided to a small number of health journalists, including the BBC.

The provision of press releases to journalists is a routine and accepted practice within the pharmaceutical industry and is expressly contemplated by the MHRA Blue Guide as part of legitimate media engagement. Such communications are directed to professional recipients who exercise independent editorial judgment and are not equivalent to direct dissemination to members of the public.

The Panel's reasoning risks establishing a position whereby routine media engagement, which is an accepted and necessary part of communicating scientific developments, would itself be treated as inherently problematic, which is inconsistent with regulatory guidance. Change in this area would mark a significant departure from current practice and would impact many other organisations.

The Panel noted that the press release was not marked as being directed to a particular audience. However, there is no requirement under the Code for press releases to be so labelled.
It should further be noted that the press release was not made available on Eli Lilly's website, social media channels or any other public-facing platform but was provided exclusively to a small number of health journalists. Foreseeability of onward publication does not convert a communication to journalists into promotion to the public. The Code draws a clear distinction between materials directed to journalists and materials directed to the public and does not regulate independent editorial content.

iii. Orforglipron was an investigational product at the time of the press release and not close to being launched

Eli Lilly disagrees with the Panel's contention that orforglipron was "*not so early in its development*". As noted by Eli Lilly and noted by the Panel, at the time of the complaint, no regulatory application had been submitted in the UK, or anywhere in the world, and therefore no marketing authorisation had been granted and further trials in the development programme were ongoing.

The press release expressly and prominently stated, from the outset and without ambiguity, that the product is investigational and that Eli Lilly planned to submit it for regulatory review by year-end.

By way of example, the first line of the executive summary states that "[I*]n ATTAIN-1, the* ***investigational*** *once-daily oral pill showed* […]". Similarly, the opening line of the press release states: "*Eli Lilly and Company (NYSE: LLY) today announced positive topline results from the Phase 3 ATTAIN-1 trial, evaluating orforglipron, an* ***investigational*** *oral* […]".

In addition, the forward-looking nature of the communication is reinforced by the statement in the executive summary that "*Lilly remains on track* ***to submit orforglipron to global regulatory agencies by year-end*** *and is making substantial investments to meet anticipated demand at launch.*"

The product had therefore not yet been submitted to the relevant authorities and remained at a pre-authorisation stage of development. There was no immediate prospect of the product being prescribed or accessed in clinical practice.

The mere fact that a product is in Phase 3 development does not, in itself, give rise to promotional effect, particularly where no marketing authorisation has been submitted or granted and no prescribing decisions can be influenced. In these circumstances, the product's stage of development could not give rise to any realistic promotional effect.

By way of comparison in case 2927/1/17 where no breach of Clause 3.1 was found, the Panel noted that "*it was clear from the press release* [reporting Phase III results from Roche's product] *that the product was investigational and that the marketing authorisation applications were under review.*" In the present case, orforglipron had not even been submitted for regulatory review at the time of the press release.

As such, there was no immediate prospect of the product being prescribed or accessed in clinical practice. In these circumstances, the potential for the press release to have any practical promotional effect was inherently null. Members of the public would not have been in a position to access the product, nor to act upon the information in a manner consistent with promotion. Furthermore, no material capable of constituting promotion was disseminated to the public.

For all the reasons set out, Eli Lilly refutes the Panel's finding that the cumulative effect of the language used in the press release, in the context of its audience, meant that the press release promoted the product prior to the grant of its MA and that Eli Lilly has breached Clause 3.1 of the Code. Furthermore, the Panel's reliance on a 'cumulative effect' does not cure the absence of any individual element capable of constituting promotion.

2. Appeal of PMCPA's ruling on Clause 5.1

Eli Lilly respectfully submits that the Panel erred in concluding that it had failed to maintain high standards in breach of Clause 5.1.

As Eli Lilly understands it, the Panel's ruling on Clause 5.1 is, in essence, as follows:

- In proactively providing the press release to a mainstream media outlet and national broadcaster, it was foreseeable that the information would be disseminated to a wide audience including members of the public.

- Despite its submission that the press release had been prepared, approved and issued in accordance with its SOP and the Code, Eli Lilly had failed to recognise that the positive language used in the quotations was promotional in the context of a foreseeable audience.

- For these reasons taken together with its ruling on the breach of Clause 3.1, the Panel considered that Eli Lilly had failed to maintain high standards.

i. The Provision of the press release to health journalists was appropriate and consistent with accepted practice

As stated in paragraph 1.(ii) above, the provision of press releases to journalists is a routine and accepted practice within the pharmaceutical industry and is expressly contemplated by the MHRA Blue Guide as part of legitimate media engagement. Such communications are directed to professional recipients who exercise independent editorial judgement and are not equivalent to direct dissemination to members of the public.

Eli Lilly further notes that the Panel appears to draw a distinction, which is not grounded in the Code or guidance, between mainstream media and more specialist or targeted outlets, finding that proactive distribution to the BBC made it foreseeable that the public would be reached. However, neither the Code nor MHRA Blue Guide makes such distinction between media types.

The press release was provided only to a limited number of health journalists, including the BBC Health Editor, and was not directed to members of the general public.

In these circumstances, Eli Lilly submits that the Panel placed undue weight on the provision of the press release to a mainstream media outlet – which is not in breach of the code – and that this does not support a finding that Eli Lilly failed to maintain high standards.

ii. Eli Lilly applied robust and appropriate review processes prior to providing the press release to health journalists

Eli Lilly maintains robust internal procedures to ensure compliance with the Code and sets high standards across all of its communications.

The press release underwent a rigorous, multi-stage review and examination process to ensure that it was non-promotional, newsworthy, factual and balanced, and compliant with both the Code and Eli Lilly's internal policies and standards for the intended audience.

There is no evidence of carelessness, lack of oversight, or failure to apply the Code. Nor is there any evidence of misleading content or inappropriate targeting. In these circumstances, the Panel's conclusion that Eli Lilly failed to maintain high standards is not justified.

iii. The finding under Clause 5.1 is wholly derivative of Clause 3.1

The Panel's finding of a breach of Clause 5.1 is predicated on its conclusion that the press release was promotional.

As already explained in paragraph 1.(i) above, Eli Lilly disagrees with the Panel that the language used in the press release was promotional. Indeed, the press release does not claim superiority, does not overstate efficacy, and does not present the medicine in a misleading or unbalanced way.

In the absence of a breach of Clause 3.1, the necessary factual predicate for a finding under Clause 5.1 does not arise. The Panel has not identified any act or omission independent of the alleged promotion, which could constitute a failure to maintain high standards. The finding under Clause 5.1 should therefore be set aside.

3. Appeal of PMCPA's ruling on Clause 2.

Eli Lilly respectfully submits that the Panel erred in concluding that it had brought discredit upon, or reduced confidence in, the pharmaceutical industry in breach of Clause 2 of the Code.

As Eli Lilly understands it, the Panel's reasoning in relation to Clause 2 may be summarised as follows:

- the press release referred to "*anticipated demand at launch.*" In the context of a therapy area that was sensitive and attracted substantial public interest, the panel considered Eli Lilly should have exercised particular caution.

- the press release, which was proactively issued by Eli Lilly to mainstream media, constituted promotion of a medicine prior to the grant of its marketing authorisation to a broad audience.

- Taking the circumstances into account and considering their cumulative effect, the Panel considered on balance that Eli Lilly had brought discredit upon, and reduced confidence in the pharmaceutical industry.

i. The Code does not permit a heightened standard based on therapy area or level of public attention

Eli Lilly notes that the Panel placed significant weight on the fact that the press release concerned a therapy area described as "*sensitive*" and attracting "*substantial public interest.*" Eli Lilly submits that the Code does not provide for the application of a heightened or different standard based on the therapeutic area or level of public interest. If accepted, the Panel's approach would introduce variable standards depending on the level of public interest in a therapy area, which is not provided for by the Code and would undermine its consistent and objective application.

The Code establishes an objective framework for assessing whether a communication is promotional or otherwise in breach, and that framework applies consistently across all therapy areas. To apply a stricter standard in circumstances where a disease area is considered high-profile or sensitive introduces uncertainty and inconsistency into the application of the Code and the relevant guidelines.

Although Eli Lilly recognises the importance of exercising appropriate care in all communications, the characterisation of obesity as a sensitive or high-profile therapy area does not, of itself, elevate conduct to a breach of Clause 2. The Panel's reliance on this factor as an aggravating consideration is therefore misplaced.

ii. The threshold for a breach of Clause 2 has not been met

Clause 2 is a sign of particular censure and is reserved for serious conduct that brings discredit upon, or reduces confidence in, the pharmaceutical industry.

A finding of a breach of Clause 3.1 does not, in itself, necessitate a breach of Clause 2; the Code requires a separate assessment of whether the conduct meets this high threshold.

In particular, none of the aggravating factors typically associated with a breach of Clause 2 are present. There is no allegation of misleading or false information, no concealment, no direct promotion to patients, and no repeated or systemic misconduct.

The press release was prepared and approved in accordance with Eli Lilly's internal procedures and the requirements of the Code. In addition, the press release has no impact on patient safety. It related to an investigational product that was not available for use and did not include any information that could influence treatment decisions or patient behaviour. It was limited to the factual reporting of clinical trial data.

The present case lacks the features typically seen in Clause 2 findings, such as misleading claims, exaggeration, patient-facing communications, or conduct suggesting a blatant disregard for the Code.

Furthermore, as stated above, Eli Lilly strongly refutes the allegation that it breached Clause 3.1 of the Code and therefore disagrees with the Panel's finding that the press release constituted promotion of a medicine prior to the grant of its marketing authorisation to a broad audience resulting in a breach of Clause 2. In any event, even if (which is denied) a breach of Clause 3.1 had been established, this would not automatically give rise to a breach of Clause 2.

The Panel has not identified any evidence that the press release had the effect of bringing discredit upon, or reducing confidence in, the pharmaceutical industry. In the absence of any material disseminated to the public which could constitute promotion, it is not possible to conclude that the conduct had any impact capable of bringing discredit upon the industry.

We believe the circumstances of the present case fall materially short of the level of seriousness typically required to justify a finding of a breach of Clause 2. The Panel's reliance on a "*cumulative effect*" does not remedy the absence of any individual element capable of meeting the high threshold required for a breach of Clause 2.

By way of comparison, in case 2528/8/12, the Panel found that the cumulative effect of misleading and comparative claims, together with the patient organisation-facing nature of the communication, was sufficiently serious to bring discredit upon, and reduce confidence in, the pharmaceutical industry.

The present case is fundamentally different. The press release at issue was factual and data-driven, was not directed to patients or the public, and did not contain misleading or comparative claims. The reference to "*anticipated demand at launch*" is a forward-looking statement concerning supply planning and corporate preparedness and does not constitute promotion or contribute to any alleged discredit.

Furthermore, PMCPA precedent demonstrates that a finding of a breach of Clause 3.1 does not automatically give rise to a breach of Clause 2. In Cases AUTH/3212/6/19 and AUTH/3262/6/19 (Health Professional v Otsuka UK and Otsuka Europe), the Panel considered that a press release relating to an investigational medicine contained promotional language and breached Clause 3.1. However, the Panel did not consider that the circumstances warranted a finding of a breach of Clause 2, noting that such a finding is reserved as a "*sign of particular censure.*" This demonstrates that even where a communication crosses the threshold into promotion of an unlicensed medicine, a further finding of discredit to the Industry is not automatic and requires a higher level of seriousness. In the present case, even if (which is not accepted) aspects of the press

release were considered to be promotional, the circumstances fall well short of the level of concern required to justify a finding of a breach of Clause 2.

The purpose of Clause 2 is to address conduct which undermines confidence in the pharmaceutical industry and is contrary to the spirit of the Code. In the present case, the press release reflects the opposite: it is a transparent, factual and responsible communication of clinical trial data, consistent with the standards expected of a pharmaceutical company and aligned with the spirit and intent of the Code.

Therefore, Eli Lilly is of the view that the Panel's ruling of Clause 2 is disproportionate.

To apply Clause 2 in circumstances such as the present would risk lowering the threshold for its application and expanding its scope beyond that envisaged by the Code.

In summary, the press release did not constitute promotion and was a compliant, factual and balanced communication of Phase 3 clinical trial results, prepared and disseminated in accordance with the Code. Therefore, Lilly respectfully requests that the Appeal Board set aside the Panel's findings of breaches of Clauses 3.1, 5.1 and 2 of the Code."

RESPONSE FROM THE COMPLAINANT

The complainant was not contactable.

APPEAL BOARD RULING

The Appeal Board observed that the press release, issued in August 2025, concerned the results of a Phase 3 trial for orforglipron and referred to planned submissions for regulatory review by year-end. The Appeal Board further observed that the press release had been proactively emailed to the Health Editor at BBC News, which it considered to be a mainstream media outlet with national coverage and a broad audience that included members of the public.

The press release referred to Lilly *"making substantial investments to meet anticipated demand at launch".* The quote attributed to the senior leader included references to "*working to transform obesity care", "convenient alternative to injectable treatments", "with these positive data in hand"* and being *"prepared for a global launch to address this urgent public health need"*. In the Appeal Board's view, the cumulative effect of this language, particularly in the context of its foreseeable audience, went beyond the provision of factual, non-promotional information relating to clinical trial data.

Taking all the circumstances into account, the Appeal Board considered the proactive dissemination of the press release, which included language of a promotional and emotive nature, to a mainstream media outlet with a broad public reach, meant that orforglipron had been promoted prior to the grant of its marketing authorisation. Orforglipron was not so early in its development that it could not be considered a medicine for the purposes of Clause 3.1 and the Appeal Board therefore upheld the Panel's ruling of a **breach of Clause 3.1**. The appeal on this point was unsuccessful.

The Appeal Board noted that the MHRA Blue Guide included that material should be appropriate for the target audience and written in terms likely to be understood by the majority of readers. The Appeal Board considered that pharmaceutical companies should consider the likely audience of the media outlets to whom press releases were provided. In the Appeal Board's view, the language, tone, content and overall impression for press releases intended for a lay audience might differ to those directed principally to investor and medical audiences.

The Appeal Board was concerned that Lilly had failed to recognise the promotional nature of the language used and that the proactive provision of the press release to the BBC meant that promotional content would be disseminated to members of the public.

The Appeal Board considered it was apparent that Lilly had failed to maintain high standards and upheld the Panel's ruling of a **breach of Clause 5.1**. The appeal on this point was unsuccessful.

The supplementary information to Clause 2 included promoting a medicine before the grant of its marketing authorisation as an activity likely to be in breach of Clause 2. Clause 2 was reserved as a sign of particular censure.

The Appeal Board took account of the broad reach and large public audience of the BBC. The Appeal Board considered that Lilly should have anticipated significant public interest relating to weight management medicines and that it should have exercised particular caution.

The Appeal Board was concerned with the overall impression created by the press release, including that orforglipron was soon to be available as a treatment option, and considered that members of the public might ask their health professional for the upcoming oral alternative to injectable treatment.

Taking all the circumstances into account, the Appeal Board considered that Lilly had brought discredit upon, and reduced confidence in the pharmaceutical industry. The Appeal Board upheld the Panel's ruling of a **breach of Clause 2**. The appeal on this point was unsuccessful.

Complaint received **7 August 2025**

Case completed **3 July 2026**