CASE AUTH/3888/4/24

COMPLAINANT/CHIEF EXECUTIVE v PFIZER

Alleged promotion on Twitter and a breach of undertaking

CASE SUMMARY

This case was in relation to allegations about posts on Twitter (now X), including from the Pfizer UK Twitter account. These tweets dated from 19 November 2020 and related to information about a Phase 3 study of Pfizer's Covid-19 vaccine where all primary efficacy endpoints had been met. The allegations included that the tweets promoted an unlicensed medicine and made misleading claims. There were also two allegations about breach of undertakings given by Pfizer in previous cases.

The outcome under the 2019 Code was:

Breach of Clause 2	**Bringing discredit upon, and reducing confidence in, the pharmaceutical industry**
Breach of Clause 3.1	**Promoting a medicine prior to the grant of its marketing authorisation**
Breach of Clause 7.2	**Making a misleading claim**
Breach of Clause 9.1	**Failing to maintain high standards**

No breach of Clause 7.2	**Requirement that claims must not be misleading**
No breach of Clause 7.9	**Requirement that claims must reflect the available evidence regarding possible adverse reactions**
No breach of Clause 29	**Requirement to comply with an undertaking**

The outcome under the 2021 Code was:

Breach of Clause 3.3	**Failing to comply with an undertaking**

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 Pfizer Limited was received from a contactable member of the public.

The complaint concerned an alleged breach of undertaking. As the PMCPA was responsible for ensuring compliance with undertakings, 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:

> "Dear PMCPA,
>
> I have been reading closely the recently published case report for my complaint Case AUTH/3741/2/23. It seems to me that, as in other previous similar cases regarding non-compliant promotion of their covid vaccine, Pfizer are once again repeatedly asserting that they have the correct policies and procedures in place to prevent such occurrences and that they have simply been let down by a few errant individuals. In particular I was intrigued by their statement that, following three previous complaints about their misuse of social media to promote their covid vaccine,
>
> *'all UK based colleagues were instructed to review any social media posts that they might have issued, shared or liked that related to Pfizer's business and to remove any activity that they were not confident met all the requirements of Pfizer's social media policy and therefore the Code'*.
>
> I was also interested in their claim that following this latest case,
>
> *'a review would be undertaken by experienced members of the Pfizer Code Approval Team to check samples of employees' social media for consistency with Pfizer's UK policy and the Code.'*
>
> I therefore decided to conduct some very brief internet searches to check the veracity of these statements. As a result, I would like to now submit a complaint about yet another promotional tweet by Pfizer for their covid vaccine which is still accessible on Twitter today. It is a tweet about their covid vaccine which was posted on November 19th 2020 by the Pfizer UK account, and was retweeted the same day by [named senior employee].
>
> [Screenshot provided of named senior employee posting on Twitter (now X) on 19 November 2020 to state "*What a day!*" in their repost of a tweet by Pfizer UK. Pfizer's post was a thread, comprised of a series of four tweets, the first of which provided a link to the related press release on Pfizer's website. The thread of tweets read:
>
> "*We are proud to announced, along with @BioNTech_Group, that Phase 3 study of our #COVID19 vaccine candidate has met all primacy efficacy endpoints [1/4]".*
>
> *The study reached 170 confirmed cases of #COVID19, with the potential vaccine candidate demonstrating 95% efficacy beginning 20 days after the first dose. To date, no serious safety concerns related to the vaccine candidate have been reported [2/4].*
>
> *We plan to submit to a number of regulatory agencies around the world based on the totality of safety and efficacy data collected, as well as manufacturing data relating to the quality and consistency of the vaccine candidate [3/4].*
>
> *We also plan to submit the efficacy and safety data from the study for peer-review in a scientific journal once analysis of the data is completed [4/4].*"]

The Pfizer UK tweet, and it's retweet by [named senior Pfizer employee], breach your Code of Practice in exactly the same ways as the tweet which was the subject of my previous complaint Case AUTH/3741/2/23, namely:

Breach of Clause 3.1: Promoting an unlicensed medicine

Breach of Clause 7.2: Making a misleading claim (Claiming relative rates for efficacy without also quoting absolute rates)

Breach of Clause 7.9: Making claims that did not reflect the available evidence regarding possible adverse reactions

Breach of Clause 9.1: Failing to maintain high standards

Breach of Clause 2: Bringing discredit upon, and reducing confidence in, the pharmaceutical industry

Indeed, one could argue that this case is a more egregious disregard of the Code because the original tweet was posted by a Pfizer account based in the UK rather than by an account based in the USA. In addition, this Pfizer UK tweet contains a link to the twitter account of their partner BioNtech. The BioNTech account is not based in the UK and contains a plethora of material which does not comply with the UK Code. In particular, at the time of this Pfizer UK post, a UK reader, who linked through to the BioNTech account from it, would immediately see the following post about the same covid trial results:

[Screenshot of BioNTech's Twitter post stating:

"We have reached the final #efficacy analysis mark, indicating a high rate of protection against #COVID19 can be achieved very fast after the second 30µg dose. We will share further details with the [EMA, FDA] and other regulatory authorities.

This post also included six boxes which stated:
- 30µg dose
- 95% effective against COVID-19 beginning 28 days after the first dose
- Fatigue is the only Grade 3 adverse event greater than 2% in frequency at 3.8%
- 28 days after first of two doses high rate of protection indicated by data
- 94% observed efficacy in adults over 65 years of age
- Older adults tended to report fewer and milder solicited adverse events following vaccination]

As you can see, this BioNTech post is non-compliant with your UK Code for many of reasons. Some of which are the same as those for the previous case.

I will admit that, unlike case AUTH/3741/2/23, this [2020] Pfizer UK tweet does make a very brief statement about adverse events. However, it merely says *'To date, no serious safety concerns related to the vaccine candidate have been reported'*. There is no mention of any other safety information whatsoever. This still therefore constitutes a breach of clauses 7.2 and 7.9 of the 2019 code which say:

Clause 7.2: 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. Material must be sufficiently complete to enable the recipient to form their own opinion of the therapeutic value of the medicine.

Clause 7.9: Information and claims about adverse reactions must reflect available evidence or be capable of substantiation by clinical experience. It must not be stated that a product has no adverse reactions, toxic hazards or risks of addiction or dependency.

Please note that, in addition to [named senior Pfizer employee] retweet, the Pfizer UK post was liked and retweeted by several other Pfizer UK employees.

This tweet, and its retweet, clearly demonstrate that Pfizer's claims that, both at the time of the first 3 social media complaints and following this latest complaint, they had *'taken all of the appropriate steps that could reasonably be expected of a pharmaceutical company'* to identify and remove such materials, are false. Please can I remind you that Pfizer have now had almost 4 years to identify this material and take it down. They have failed to do so. You may also recall that 3 years ago, case AUTH/3438/12/20, I complained about a LinkedIn post by the same [named senior employee]. In that case Pfizer were found to have breached clauses 7.9, 9.1 and 2 of the 2019 Code. This will have been one of the cases that Pfizer claim led to all their UK based colleagues being,

'instructed to review any social media posts that they might have issued, shared or liked that related to Pfizer's business and to remove any activity that they were not confident met all the requirements of Pfizer's social media policy and therefore the Code'.

This edict did not apply to the Twitter account of their [named senior employee] apparently. Why not ? More recently, they were notified about Case AUTH/3741/2/23 over 12 months ago and yet still they took no action to identify and remove the material which is now the subject of this complaint. Even if [named senior employee] now works for [named pharmaceutical company], rather than Pfizer, at least they should have identified this problem and flagged it up to the PMCPA as part of their response to Case AUTH/3741/2/23. I am no IT or pharmaceutical expert but armed only with Google and a bit of common sense I was able to identify [named senior employee's] retweet in a matter of minutes. Despite being warned of the risk on numerous occasions, why were a global corporation the size of Pfizer unwilling or unable to do the same during the past 4 years?

In summary I would like you to treat this as a formal complaint about the above tweet by Pfizer UK and its retweet by [named senior employee]. As a minimum, please consider breaches of clauses 3.1, 7.2, 7.9, 9.1 and 2 of the 2019 Code. In addition, I do not know what kind of undertaking document was signed by Pfizer as a result of Case AUTH/3741/2/23 (or case AUTH/3438/12/20 for that matter) but surely their failure to identify and remove this material must be a breach of undertaking of some sort. Therefore, a breach of clause 29 of the 2019 Code should also be considered.

This further example of non-compliance must surely add the mounting pile of evidence that casts doubt over Pfizer's continuing assertion that there was no 'determined, coordinated and concerted effort to use social media to actively promote our COVID-19 vaccine misleadingly and in advance of its approval.' In the circumstances, considering all of the above, and the findings of all the other cases of non-compliant promotion of their covid vaccine, at the very least surely some sort of external audit of Pfizer's compliance procedures must now be called for.

In view of the enormous amount of public interest generated by Case AUTH/3741/2/23 I would like to ask that your consideration of this case be expedited. Many people, myself included, will be extremely disappointed if it turns out that, like Case AUTH/3741/2/23, this complaint is yet another one that ends up sitting on a PMCPA desk for over a year. I would like to remind you that in Case AUTH/3741/2/23 Pfizer did not contest any of the breaches put to them by the PMCPA, so why it took 13 months to conclude that case is difficult to understand.

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

When writing to Pfizer, the PMCPA asked it to consider the requirements of:

1. Clauses 3.1, 7.2, 7.9, 9.1, 29 and 2 of the 2019 Code, and
2. Clause 3.3 of the 2021 Code regarding the alleged breach of undertaking in Case AUTH/3741/2/23.

PFIZER'S RESPONSE

The response from Pfizer is reproduced below:

"Thank you for your letter dated 25th April 2024 concerning a complaint about the alleged promotional use of Twitter and a breach of undertaking. Pfizer takes its commitment to the ABPI Code extremely seriously and we are very concerned by this complaint. We have conducted a thorough investigation and our response to the complainant's allegations is set out below.

1: Background Context:

The Covid-19 pandemic had an unprecedented impact on the day-to-day life of the UK population. In November 2020 Covid-19 infection rates were increasing significantly and modelling indicated that the capacity of UK hospitals would be exceeded within the month. Increasing levels of restrictions were being reintroduced to the UK aimed at reducing Covid-19 transmission to '*save lives and protect the NHS*'.

At this time the UK government was delivering daily televised Covid-19 news briefings where data on transmission rates, hospital admissions and deaths were presented to the general public. Much of the UK population believed that the availability of Covid-19 vaccines would play a significant role in bringing the pandemic under control and

ending the associated restrictions. There was consequently an unprecedented intensity of widespread interest amongst the general public in the progress that the pharmaceutical industry and academia were making towards developing vaccines and treatments for Covid-19, and a vast array of sources of information of variable quality were being accessed. Widespread misinformation about Covid-19 and the vaccine development programmes was particularly being disseminated and amplified on social media.

The original Twitter post that is the subject of this complaint was posted by Pfizer UK on November 19, 2020. The tweet was intended to be a factual public announcement of the headline efficacy and safety results of the Pfizer BioNTech Covid-19 vaccine study and to also inform the public of the next steps from a regulatory and scientific publication perspective. The post directly linked to the full press release hosted on Pfizer.co.uk which was the only publicly available source of information on the phase 3 study results at that time. In this exceptional public health situation and with a unique level of public interest and potential for misunderstanding, Pfizer issued these communications in good faith to avoid intermediaries and to ensure that an authoritative, factual, non-promotional disclosure from the company was available to everyone.

The tweet formed part of a series of posts that Pfizer made over the course of the pandemic informing the general public of the work we were doing to develop and test a Covid-19 vaccine candidate. The information was intended to educate the public about the process of vaccine development, the progress of our clinical trials and the data that would be required by the MHRA to complete the regulatory assessment of our candidate vaccine.

In this specific set of circumstances, we believed that the achievement of both the study's primary efficacy endpoint in parallel with the study meeting the FDA's pre-specified safety milestone, represented important information that was not only of relevance to journalists and investors but was of direct relevance to the general public in the UK. We therefore took the exceptional decision to make the press release available from the homepage of Pfizer.co.uk and to issue related social media posts on Twitter, Facebook and Instagram.

2: Pfizer UK Twitter post – General Information

The original post that was issued by Pfizer UK, was a Twitter thread consisting of a headline post including an image, followed by 3 further connected posts. Twitter identifies a bundle of linked posts by the inclusion of connecting lines between the posts and Pfizer used the standard social media practice of numbering the posts [*n*/4] and including a downwards pointing finger to further signal to readers that the posts were intended to be viewed as a bundle. The image in the post provided a direct link to the full press release hosted on Pfizer.co.uk.

In November 2020 the Pfizer UK Twitter account had 14,500 followers, the majority of whom were members of the public. The Pfizer UK post that is the subject of this complaint was seen 4,539 times (impressions) with the content being retweeted 18 times and the link to Pfizer.co.uk being followed 26 times.

We would like to point out that neither at the time of issuing the post when around 80% of the 4,539 views took place, nor in the intervening three and a half years, has Pfizer received any other complaints about the appropriateness of the announcement. Those viewing the post at that time would have included healthcare professionals, pharmaceutical Industry professionals, regulators, government officials and others with awareness or expertise in the Code of Practice. We believe that the fact that no complaints were received at the time when the post was intended to be viewed demonstrates that this was a significant and newsworthy announcement, that was of direct relevance to all those viewing it at the time.

Pfizer's normal practice is for an Appropriately Qualified Person (AQP) signatory to examine company announcements and press releases, in line with the requirements of the Supplementary Information to Clause 14.3 (8.3). On this occasion as the press release and associated social media posts contained non-promotional information about the Pfizer BioNTech vaccine and were both intended for a general public audience, the items were non-promotionally certified by a full medical final signatory. As is our usual practice for social media posts, the Twitter thread was certified as a '*one time use*' item. We use this categorisation for items that have an inherently limited lifespan and are unlikely to be retrievable following their distribution. We do not require such items to be withdrawn when their certification expires as they are considered obsolete at this point.

The Twitter thread comprised the following text:

1. 'We are proud to announce, along with @BioNTech_Group, that the Phase 3 study of our #COVID19 vaccine candidate has met all primary efficacy endpoints [1/4] [downward finger emoji]'

2. 'The study reached 170 confirmed cases of #COVID19, with the potential vaccine candidate demonstrating 95% efficacy beginning 28 days after the first dose. To date, no serious safety concerns related to the vaccine candidate have been reported [2/4] [downward finger emoji]'

3. 'We plan to submit to a number of regulatory agencies around the world based on the totality of safety and efficacy data collected, as well as manufacturing data relating to the quality and consistency of the vaccine candidate [3/4] [downward finger emoji][']

4. 'We also plan to submit the efficacy and safety data from the study for peer-review in a scientific journal once analysis of the data is completed [4/4]'

3: Clause 3.1 - A medicine must not be promoted prior to grant of marketing authorisation

We understand that Clause 26.2 of the Code allows for certain non-promotional announcements and press releases about a company's medicines to be provided to relevant journalists if the business, financial or public interest is clearly evident. The MHRA's guidance on the advertising and promotion of medicines reinforces the requirement for such releases to be genuinely newsworthy rather than having the intention of promoting a product.

In the context of the pandemic, our Twitter thread formed part of a highly newsworthy company announcement of direct relevance to the public and as such we believe was fully consistent with the requirements of the Code for provision of non-promotional information about a medicine to the public. Indeed, such disclosure, without intermediaries, played an important role in ensuring the provision of an accurate update from the data's original source amid intense public interest. The first post simply announced that the study had met its pre-specified primary efficacy endpoints. This linked to the second post which included the primary efficacy result presented as the absolute number of events and relative risk reduction. This efficacy data was balanced by the inclusion of the headline safety information. The third and fourth posts went on to summarise the next steps in terms of the regulatory and publication plan.

The thread was non-promotional, accurate, presented in a factual and balanced manner and did not mislead the general public in any way. The announcement was based on the most up to date evidence available at the time and did not raise unfounded hopes of successful treatment. It was made clear that the data were yet to be submitted to regulators and the tweets therefore were not designed to encourage members of the public to ask their healthcare professional to prescribe the vaccine. In the specific and exceptional situation of the global pandemic with extensive restrictions on the UK population's day to day life, we believe the Twitter thread and linked press release represented a relevant and newsworthy announcement that did not promote our candidate vaccine prior to the grant of marketing authorisation. **We therefore refute the allegation of a breach of clause 3.1 of the Code of Practice.**

4: Clause 7.9 (6.4) – Information and claims about adverse reactions must reflect the available evidence

The Twitter thread included the statement that '*To date no serious safety concerns have been reported related to the vaccine candidate'*. This accurately reflected the available evidence at the time. For those users of Twitter who were interested in understanding more information, clicking on the image in the post took them directly through to the page on Pfizer.co.uk where the full press release was hosted. The press release reiterated the information about the absence of serious safety concerns and provided details of the Grade 3 (severe) solicited adverse events greater than or equal to 2% (fatigues 3.8%, headache 2.0%) occurring after the first or second dose. It also detailed that most solicited adverse events resolved shortly after vaccination. The press release also confirmed that older adults tended to report fewer and milder solicited adverse events following vaccination. The Twitter thread and press release did not claim that the vaccine had no side effects nor that it was 'safe'. The safety information appropriately reflected the available evidence and did not mislead with respect the safety profile of the candidate vaccine. **For this reason, we strongly deny the alleged breach of clause 7.9 (6.4).**

5: Clause 7.2 (6.1) Information and claims must not mislead (use of absolute risk and relative risk)

As discussed in Case AUTH/3519/5/21 the traditional framework used for communicating the efficacy of a medicine used to treat a disease is not as directly relevant to presenting the benefit of vaccines designed to protect against development

of disease. Estimates of vaccine efficacy (using data from randomised clinical trials) and vaccine effectiveness (using data from real world observational studies) are always expressed as relative risk reduction. This is the case in the summary of product characteristics for the Pfizer BioNTech Covid-19 vaccine published by the Medicines and Healthcare products Regulatory Agency (MHRA) and also in vaccine effectiveness publications for Covid-19 by Public Health England (UK Health Security Agency). It was challenging to attribute a meaningful absolute risk of acquiring Covid-19 for unvaccinated participants in the context of the trial as the risk of an unvaccinated person acquiring the virus was dynamic and increasing over the duration of the study and continued to increase after the study concluded. Furthermore, the risk of acquiring Covid-19 also varied between countries participating in the trial depending on the extent to which local lockdowns were enforced and specific containment strategies used.

The debate as to how to most meaningfully report and communicate Covid-19 vaccine trial results has continued. The epidemiology of Covid-19 is not yet stable and continues to fluctuate considerably across the year with a regular temporal pattern yet to be established (e.g. regular seasonal epidemics over the winter period). Some experts believe therefore that relative risk provides the most meaningful measure as it clearly reflects the level of protection provided by the vaccine following exposure to the pathogen and can be interpreted in the context of the prevailing Covid-19 transmission rate which is likely to be very different from the transmission rate seen in the phase 3 studies. Absolute risk reduction requires considerable contextual explanation to be meaningfully interpreted for vaccine studies conducted over a short period during a rapidly changing pandemic with evolving containment strategies being applied. The idea that absolute risk reduction has not been widely presented alongside Covid-19 vaccine efficacy estimates because the effect looks less impressive and is therefore a deliberate act to mislead, is fundamentally flawed. This argument has been repeatedly manipulated and exploited by certain groups to support conspiracy theories and to foster vaccine hesitancy.

Irrespective of the scientific debate on the best way of reporting and communicating vaccine efficacy, we recognise through the PMCPA's rulings in Case AUTH/3519/5/21 that the Code does not differentiate between the requirements for vaccines and other medicines and we accepted breaches of the Code for not having included the required information.

5a: Press Release

In addition to the relative risk reduction presented in the press release related to this case, it also includes details of the total number of trial participants, the number of Covid-19 cases (all cases and severe cases) and the number of cases in each arm of the trial (all cases and severe cases). **We believe that this provides the additional absolute risk information required by clause 7.2 (6.1) of the Code and deny a breach of Clause 7.2 (6.1) in relation to the press release.**

5b: Twitter Thread

The second post within the Twitter thread referred to '*the potential vaccine candidate demonstrating 95% efficacy beginning 28 days after the first dose*'. It also included the

total number of confirmed cases (170) to provide context as to the scale of the trial and the vaccine efficacy data. We recognise that this combination of endpoint data was subsequently considered in case AUTH/3519/5/21 and the Panel ruled Pfizer in breach of the Code as it determined that further details were required to support certain sectors of the ultimate audience to interpret the study results.

The ruling in case AUTH/3519/5/21 was received by Pfizer in February 2022. We did not delete this Twitter thread as part of our corrective actions associated with that case AUTH/3519/5/21 as in the context of social media we believed the post to already be obsolete.

Twitter analytics indicate that the post has had a total of 4,576 impressions/views. Pfizer's internal analytics system monitors social media activity for 70 days following a posting and these analytics indicate that 79% (3,593) of impressions occurred between 19th November 2020 and 31st January 2021. It is also reasonable to assume that the majority of the remaining impressions (983) were generated during 2021 when the information was still newsworthy and relevant. Since November 2020 to date a further 1742 posts have been issued via the Pfizer UK Twitter channel, 700 of which were posted in 2021. The post that is the subject of the complaint was therefore very quickly hidden by new posts and to date is obscured by some 1,700 subsequent posts, and the thread is not now viewable by simply scrolling through Pfizer UK's Twitter feed. For people using Twitter as intended, as a real time source of news and commentary, by February 2022 when we implemented our corrective actions, the post would not have been readily viewable in anyone's news feed or by scrolling through Pfizer UK's feed.

The detailed scrutiny of the complainant has helped us identify that the tweet can still be found if specifically searched for in Twitter's search function, or through scrolling through the other Twitter accounts that also shared the original post. **This complaint has helped us identify how our approach could be further improved and we accept a breach of Clause 7.2(6.1) in relation to the Twitter thread. The thread has now been removed.**

6: @BioNTech Link

On the 18th November 2020 Pfizer Inc and BioNTech SE released identical press releases announcing that the phase 3 study of our Covid-19 candidate vaccine had been concluded. This press release was subsequently shared on the Pfizer.co.uk website and was linked to from the Pfizer UK Twitter post that is the subject of this complaint. As highlighted by the complainant the Pfizer UK Twitter post included an @BioNTech tag. This is a standard social media practice used to alert a third party, in this case our vaccine co-development partner BioNTech and its social media followers, to the presence of a new Pfizer UK post of relevance to them. Whilst such tags do create a link between Twitter accounts, the primary purpose is to bring the third party's followers to the account that has tagged the 3rd party.

At the time of issuing the Pfizer post, if anyone did click the @BioNTech link it would have transferred them from the Pfizer UK feed to the BioNTech feed where they would have been able to see BioNTech's announcement of the same phase 3 trial results. The BioNTech post, which comprised a headline statement and an embedded image, focused on the study results that were believed to be of greatest interest to the general public. These included key efficacy and safety endpoints as well as data on the speed

of onset of protection. As many people were concerned about the risk of Covid-19 infection in the elderly, key data from the older adult population were also included. The link provided in the post took visitors directly to the BioNTech press release which was identical to the Pfizer press release that has already been discussed earlier in this letter of response.

As described above in relation to the Pfizer Twitter post, we believe that the BioNTech post was a newsworthy, accurate and balanced announcement of significant relevance to the general public. It was based on the most up to date evidence available at the time and did not raise unfounded hopes of successful treatment. It did not claim that the vaccine had no side effects nor that it was "safe". The safety information appropriately reflected the available evidence and did not mislead with respect the safety profile of the candidate vaccine. It made clear that the data were yet to be submitted to regulators and the tweet was therefore not designed to encourage members of the public to ask their healthcare professional to prescribe the candidate vaccine. **The post was not misleading with regards the safety profile of the candidate vaccine and it did not promote the vaccine prior to the grant of marketing authorisation. We therefore deny a breach of Clause 7.9(6.4) and 3.1 in relation to the @BioNTech tag included in the Pfizer tweet.**

As we have discussed in relation to the Pfizer Twitter post, we accept that more details about the numbers of participants in the study and absolute number of events in each arm should have been included to help the reader form their own opinion of the efficacy of the medicine. We have already acknowledged above a breach of Clause 7.2(6.1) for this omission in relation to the Pfizer Twitter post and we assume that as the two posts were directly linked, the same omission in the BioNTech post is covered in our acceptance of the breach of Clause 7.2 above.

7: Clause 29 (3.3) alleged breach of undertakings for cases AUTH/3438/12/20 and AUTH/3741/2/23

We believe that the activity that is the focus of this current complaint, is significantly different from the activities that led to breaches of the Code in cases AUTH/3438/12/20 and AUTH/3741/2/23. The current case relates to colleagues interacting with Pfizer UK certified content, whereas the previous two cases cited relate to colleague interactions with unapproved social media content not originating from Pfizer UK.

All content posted via Pfizer UK social media accounts goes through a UK approval or certification process for dissemination to a general public audience. Pfizer UK's social media policy therefore allows colleagues to Like, Share or Comment (within guidelines) on any content published on Pfizer UK owned accounts as the approval or certification process is intended to ensure that the content is also appropriate for onward dissemination through colleagues' own personal social media accounts.

The social media post shared by [named senior employee] that is the subject of this current complaint was a retweet of a certified Pfizer UK post. Due to the passage of time, colleague turn over and the use of Twitter handles that do not include individuals' names, it is difficult to confirm the exact number of other Pfizer colleagues that interacted with the post. To the best of our knowledge, we believe that approximately 10 other colleagues liked or shared the post. The actions of both [named senior

employee] and these other colleagues were consistent with Pfizer's social media policy that was in effect at the time.

7a: Case AUTH/3438/12/20:

In case AUTH/3438/12/20 content posted by the BBC relating the Pfizer BioNTech vaccine was shared on [named senior employee's] personal LinkedIn account. That 3rd party content had not been certified by Pfizer and sharing such 3rd party content was not consistent with Pfizer UK social media policy and the Code.

On receiving complaint AUTH/3438/12/20, [named senior employee] was asked to remove the shared BBC content from [their] LinkedIn feed and to check that all other social media activity was consistent with our policy requirements. This was completed on 10/12/20. In addition to this corrective action, we further enhanced our social media policy and training and all colleagues completed the enhanced training in September 2021. Our one-page quick reference guide was refreshed and a Covid-19-specific one-page quick reference guide was also created. In parallel with the retraining, all UK based colleagues were instructed to review any social media posts that they may have issued, shared or liked that related to Pfizer's business and to remove any activity that they were not confident met all the requirements of Pfizer's social media policy and therefore the Code. These actions would not have led to the removal of the likes and shares of the tweet that is the subject of this complaint.

We believe that the current case is materially different from Case AUTH/3438/12/20 and does not represent a breach of undertaking and we therefore deny a breach of clause 29 (3.3).

7b: Case AUTH/3741/2/23

Similarly, Case AUTH/3741/2/23 also involved a Pfizer colleague unintentionally interacting with social media content that was not consistent with our UK policy. The original content was posted on the personal social media account of a US based Pfizer colleague and was therefore not certified for dissemination in the UK.

On receipt of complaint AUTH/3741/2/23 in February 2023, Pfizer issued a communication to all UK colleagues instructing them to review Pfizer's UK social media policy and the one-page guidance and to then examine and correct if required, their own personal social media activity for the period January 2020 – February 2023 to ensure consistency with our policy and therefore the Code.

As complaint AUTH/3741/2/23 raised concerns specifically regarding the use of social media by senior leaders, an additional communication in February 2023 was sent to 250 UK based senior leaders asking them to review and actively confirm that their social media was in line with the Pfizer policy. Furthermore, due to the complexity of this area, the social media activity of the 22 most senior and high-profile UK based Pfizer leaders was audited by Pfizer's Code Approval Team. This audit did not include any former employees of Pfizer and therefore the Twitter account of [named senior employee] was not reviewed. The social media related Code complaints that Pfizer had received all focused on individual colleagues' interactions with non-Pfizer UK generated content that was not consistent with our UK social media policy. The audit

therefore focused on senior leaders' interactions with non-Pfizer UK content and did not re-examine content shared by colleagues that was originally certified or approved prior to posting on Pfizer UK social media channels.

We believe that the current case is therefore materially different from Case AUTH/3741/2/23 and does not represent a breach of undertaking and we therefore deny a breach of clause 3.3.

8: Clause 9.1 (5.1) Clause 2: Maintaining High Standards and Upholding Confidence in Industry

In the exceptional circumstances of a global pandemic, national lockdowns, daily government Covid-19 briefings and an unprecedented level of public interest in the development of potential vaccines for Covid-19, Pfizer took the rare and exceptional decision to share the announcement of our candidate vaccines' headline study results directly with the general public. We did this in good faith and with the intent of ensuring that the Pfizer BioNTech press release, which underpinned all news coverage during that period, was freely available to any member of the UK public who wished to access it. There were no other official sources of up to date information about the study results publicly available at the time and Pfizer's communication drew attention to the future role of the regulatory authorities in assessing the data further. We believe the appropriateness of this decision is demonstrated by the fact that we did not receive a single complaint in relation to the tweet or the press release at the time when it would have been widely viewed including by many with expertise in the Code.

The information we shared was fair and balanced and accurately reflected the current available evidence. We accept that additional information on the absolute numbers of participants and events in the study should have been included in Pfizer UK's tweet, however the way we presented the efficacy data of the candidate vaccine was consistent with the standard approach to presenting estimates of vaccine efficacy. Neither the tweet nor the linked press release promoted, nor were issued with the intention of promoting, our candidate vaccine to the public.

The colleagues that interacted with the Twitter post acted in accordance with our UK social media policy and we believe that the circumstances of this case are materially different from those of the previous two cases cited by the complainant and therefore do not represent a breach of prior undertaking. We strongly believe that throughout the pandemic the extensive measures that we have put in place around the personal use of social media represent a comprehensive and responsible approach. We of course continue to enhance our framework as our learning and experience in the area grows.

Once again, we wish to re-emphasise that contrary to the complainant's repeated allegations, Pfizer has had no such 'determined, coordinated and concerted effort to use social media to actively promote our Covid-19 vaccine misleadingly and in advance of its approval'. On the contrary, we believe that Pfizer UK's dissemination of information relating to the development of our Covid-19 vaccine through all channels and to all audiences has been conducted in an appropriate and responsible manner.

We believe that high standards have been maintained and we deny a breach of clause 9.1 (5.1). We do not believe that our use of social media at an exceptional

point in time three and a half years ago has brought discredit upon, or reduced confidence in our industry and we strongly refute the allegation of a breach of Clause 2 of the Code."

PANEL RULING

This complaint raised several allegations, which stem from a post on Twitter (now X) by the Pfizer UK Twitter account, and a retweet of that post by a senior Pfizer employee. Although Twitter has been rebranded as X, this ruling uses the terms "Twitter" and "tweets" as these were in use at the time - these tweets were dated 19 November 2020.

The Tweets

The content of the tweet from Pfizer UK's Twitter account is set out in the complaint and in the response above and is not repeated here. In short, it contained a thread of four tweets that provided information about a Phase 3 study of Pfizer's Covid-19 vaccine where all primary efficacy endpoints had been met.

The tweet included "@BioNTech_Group" – a link to the corporate account for BioNTech; a German pharmaceutical company (not subject to the ABPI Code) with whom Pfizer were collaborating on the vaccine. At the time of the Pfizer tweet, a user clicking on the @BioNTech_Group handle would have seen a tweet from BioNTech, reporting the same study results. The Panel noted in particular, that the tweet included the statement "*a high rate of protection against #COVID19 can be achieved very fast after the second 30µg dose".*

The Panel had regard to the PMCPA's Social Media Guidance 2023 (updated in October 2024). Although this guidance postdates the tweets that are the subject of this complaint, it codifies the general principles that already applied in relation to the Code. Page 10 of that guidance states:

- "*Any material associated with a post, for example, a link within a LinkedIn post, would normally be regarded as being part of that post*."

- "…*pharmaceutical companies/employees that include tags as part of their posts and therefore direct readers to other accounts, need to be satisfied that the content on those accounts are appropriate as far as the ABPI Code is concerned*."

- "*Whether a linked account came within the scope of the ABPI Code has to be decided on a case-by-case basis, taking into account all of the circumstances including, among other things, the content of the linked/tagged account and the chronology of the link*."

The Panel also took account of the Pfizer tweet and the BioNTech tweet being very closely connected in relation to when they were posted and their very similar content. Although it will not necessarily always be the case, in the circumstances of this complaint and based on the above general principles, the Panel interpreted the tweet that appeared prominently via the link to @BioNTech_Group (which included the statement "*a high rate of protection against #COVID19 can be achieved very fast after the second 30µg dose")* to be 'linked content' and therefore part of the Pfizer tweet for the purposes of this case.

For similar reasons, the Panel concluded that the content of the linked press release on the Pfizer website also amounted to 'linked content' and was therefore part of the original tweet by Pfizer.

The senior Pfizer employee had retweeted the Pfizer tweet and added "*What a day!*"

The Panel considered the Pfizer thread of tweets, the content of the linked tweet that could be seen by clicking on @BioNTech_Group, the linked press release on Pfizer's website, and the retweet by the senior Pfizer employee, as one activity for the purposes of this ruling. This ruling refers to them collectively as "**the Tweets**".

The complaint

The complainant was very clear in their complaint that the alleged breach of the undertaking given in Case AUTH/3741/2/2 was an allegation *in addition* to the allegations relating to the Tweets. The Panel therefore interpreted this complaint, and ruled upon it, in two Parts.

Part A relates to the following allegations about the Tweets. These allegations have been considered under clauses of the 2019 Code - the Code that was in force at the time of the Tweets (18 November 2020):

1. Promotion of an unlicensed medicine (Clause 3.1 of the 2019 Code).

2. Citing relative rates (rather than absolute rates) for efficacy is misleading (Clause 7.2 of the 2019 Code).

3. Claims were misleading and did not reflect the available evidence regarding possible adverse reactions (Clauses 7.2 and 7.9 of the 2019 Code).

4. Failure to maintain high standards (Clause 9.1 of the 2019 Code).

5. Bringing discredit upon, or reducing confidence in, the pharmaceutical industry (Clause 2 of the 2019 Code).

6. Breach of the undertaking given by Pfizer following Case AUTH/3438/12/20 (Clause 29 of the 2019 Code).

However, because the undertaking in Case AUTH/3741/2/23 was given following the completion of that case on 1 March 2024, the applicable Code for the alleged breach of that undertaking is the code in force at that time: the 2021 Code. The Panel considered this separate breach of undertaking (under Clause 3.3 of the 2021 Code) in Part B of its ruling.

Part A – the Tweets and allegations under the 2019 Code

Promotion of an unlicensed medicine (Clause 3.1 of the 2019 Code)

Clause 3.1 prohibited the promotion of a medicine prior to the grant of its marketing authorisation. It is not disputed by Pfizer that, at the time of the Tweets, its Covid-19 vaccine did not have:

(a) a marketing authorisation, nor

(b) a temporary emergency use authorisation to supply in the UK by the Medicines and Healthcare products Regulatory Agency under regulation 174 of the Human Medicines Regulation 2012.

In its response to the PMCPA, Pfizer also accepted that, at the time of the Tweets, its UK Twitter account had 14,500 followers, the majority of whom were members of the public.

However, Pfizer submitted that the Tweets were "*non-promotional, accurate, presented in a factual and balanced manner*".

As with Case AUTH/3741/2/23, the Panel in the current case considered that in principle it was possible for a pharmaceutical company to refer to work it was doing in response to the Covid-19 pandemic, and the production of vaccines, in a way that was compatible with the Code. The context at the time meant there was considerable public interest in this matter.

However, language, location, layout, intended audience and overall impression were also important factors. For example, what is suitable for a press release may not be suitable for a social media post. In Case AUTH/3741/2/23, Pfizer mounted a similar defence that the tweets in that case were non-promotional and that it simply included statements of fact about efficacy endpoints. However, in that case, Pfizer ultimately accepted it had committed a breach of Clause 3.1 of the 2019 Code.

The Panel considered the Tweets in this case to be promotional given that they included positive statements regarding Pfizer's Covid-19 vaccine such as:

1. *"…Phase 3 study of our #COVID19 vaccine candidate has met all primary efficacy endpoints"*
2. *"…potential vaccine candidate demonstrating 95% efficacy…"*
3. *"…no serious safety concerns related to the vaccine candidate have been reported"*
4. *"…high rate of protection against COVID-19 only 29 days after the first dose…"*
5. *"…rapid protection this vaccine provides…"*
6. *"…a high rate of protection against #COVID19 can be achieved very fast…"*

That final quote is from the BioNTech tweet but, as mentioned above, the Panel considered it to be linked content and therefore part of the Tweets in this case.

Given the Panel considered that the Tweets were promotional and had been widely disseminated to the public in advance of the vaccine obtaining a marketing authorisation, the Panel ruled a **breach of Clause 3.1** of the 2019 Code.

<u>Citing relative rates (rather than absolute rates) for efficacy is misleading (Clause 7.2 of the 2019 Code)</u>

Clause 7.2 of the 2019 Code stated that:

"*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.

Material must be sufficiently complete to enable the recipient to form their own opinion of the therapeutic value of the medicine."

The Panel noted that the Tweets included the following statement "…*the potential vaccine candidate demonstrating 95% efficacy beginning 28 days after the first dose*". It was not disputed by Pfizer that this was a reference to relative risk rather than absolute risk. The Panel considered this to be incompatible with the requirements of Clause 7.2 and its supplementary information, which was clear that relative risk should never be referred to without also referring to the absolute risk. The Panel therefore ruled a **breach of Clause 7.2** of the 2019 Code, as acknowledged by Pfizer.

Claims were misleading and did not reflect the available evidence regarding possible adverse reactions (Clauses 7.2 and 7.9 of the 2019 Code)

The Tweets included the statement "*To date no serious safety concerns have been reported related to the vaccine candidate"*, as stated by the complainant.

However, the complainant also alleged "*There is no mention of any other safety information whatsoever*". The Panel disagreed with the complainant on this point because the Panel considered the linked press release to be part of the post. The press release provided information in relation to adverse reactions, such as:

1. the percentages of people experiencing Grade 3 (severe) fatigue or headaches after the first or second dose of the vaccine, and

2. that older adults had reported fewer and milder adverse events following vaccination.

The Panel also noted that the BioNTech tweet referred to fatigue as a possible adverse reaction.

In addition, the complainant has not provided evidence to suggest that the Tweets' statement "*To date no serious safety concerns have been reported related to the vaccine candidate"* did not reflect the available evidence at the time.

Pfizer submitted that the Tweets (including the linked press release) did not claim that the vaccine had no side effects, nor did they claim that it was "*safe*". The Panel accepted that submission and noted that a statement that there were "*no serious safety concerns*" is not the same as stating that there were *no* safety concerns. The Panel concluded that, because the complainant had provided no evidence to substantiate their allegation that the Tweets did not reflect the available evidence at the time, they had not discharged the burden of proving their complaint on the balance of probabilities.

On the basis of the above, the Panel did not consider that the complainant had established that the Tweets amounted to a breach of Clause 7.2 or Clause 7.9. The Panel therefore ruled **no breach of Clauses 7.2 and Clause 7.9** of the 2019 Code.

Failure to maintain high standards (Clause 9.1 of the 2019 Code)

The Panel acknowledged Pfizer's submission that the Tweets were historical and could only be found using specific search terms on Twitter.

However, the Panel would have expected Pfizer to be on notice to delete the Tweets, given the fact that there had been several PMCPA cases involving Pfizer (and other pharmaceutical companies that were involved in Covid-19 vaccines) in which the Panel had ruled that it was misleading to cite relative rates, rather than absolute rates, as regards efficacy.

In relation to the requirement to comply with the letter and the spirit of the Code, the Panel was concerned in particular that Pfizer had:

1. not removed the Tweets until the matter was raised by the complainant, and
2. not identified the Tweets as promotional during the development and approval process.

The Panel also took account of the fact that social media posts about prescription only medicines (especially unlicensed ones, as in this case) require careful consideration by companies, given the wide reach that these social media platforms have to the general public.

For all of these reasons taken together, the Panel considered that Pfizer had failed to maintain high standards and the Panel therefore ruled a **breach of Clause 9.1** of the 2019 Code.

Breach of the undertaking given by Pfizer following Case AUTH/3438/12/20 (Clause 29 of the 2019 Code)

The Panel acknowledged that, in general terms, the subject matter of Case AUTH/3438/12/20 was similar to the current case i.e. social media activity related to the Pfizer-BioNTech Covid-19 vaccine in the latter part of 2020.

However, the Panel considered that the previous case involved an error of judgment by one Pfizer employee acting contrary to company policy, by using a LinkedIn post to promote a BBC news article that referred to the vaccine as "*safe*". Neither the Pfizer employee's LinkedIn post, nor the BBC news article had been certified by Pfizer in that case. In contrast, the current case involved certified posts by Pfizer UK's official Twitter account and a linked press release. In addition to the differing circumstances, the allegations relating to the Tweets in this case corresponded to different matters than those raised in Case/3438/12/20, such as:

1. promotion of an unlicensed medicine,

2. use of relative efficacy rates instead of absolute efficacy rates,

3. references to "*no serious safety concerns*" (as opposed to unqualified use of the word *"safe"*).

In conclusion, the Panel considered that the circumstances of Case AUTH/3438/12/20 and the current case were sufficiently distinct, such that there had been no breach of undertaking. The Panel ruled **no breach of Clause 29** of the 2019 Code.

Bringing discredit upon, or reducing confidence in, the pharmaceutical industry (Clause 2 of the 2019 Code)

The Panel noted that Clause 2 was a sign of particular censure and reserved for such use.

The Panel acknowledged that these allegations related to historical matters during the Covid-19 pandemic, which was an unprecedented time for the pharmaceutical industry. There was heightened interest in information from companies working on Covid-19 vaccines. The Panel also accepted that the Tweets were no longer newsworthy and were highly unlikely to be seen by members of the public unless an historical and targeted search was undertaken.

However, the Panel took account of the following factors in concluding that, on balance, the circumstances of this case did reach the threshold for a Clause 2 breach:

1. This matter concerned promotion prior to a marketing authorisation, which is an example of an activity likely to be in breach of Clause 2 in the supplementary information to Clause 2 of the 2019 Code.

2. The Tweets were corporate posts, approved in the UK by a Pfizer signatory, as opposed to an error by an individual employee.

3. Twitter is not a restricted audience and Pfizer acknowledged that it had 14,500 followers, the majority of whom were members of the public. The Tweets were therefore intended to reach a wide audience.

Given these factors, the Panel ruled a **breach of Clause 2** of the 2019 Code.

Part B – the alleged breach of undertaking under the 2021 Code

Breach of the undertaking given by Pfizer following Case AUTH/3741/2/23 (Clause 3.3 of the 2021 Code)

Pfizer had been found in breach of several clauses of the 2019 Code in Case AUTH/3741/2/23. In accordance with paragraph 7.1 of the PMCPA Constitution and Procedure of the 2019 Code, Pfizer was therefore required to provide an undertaking. The terms of that undertaking included:

"*We accept the decision of the Panel. The retweets in question and any similar material, if not already discontinued or no longer in use, will cease forthwith.*

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

The Panel acknowledged that some elements of this case fell outside the terms of the undertaking given by Pfizer. For example, Case AUTH/3741/2/23 related to Pfizer UK employees interacting with the personal tweets of US colleagues which had not been certified for use in the UK. It was that activity about which Pfizer had given an undertaking. In contrast, the current case related to content that Pfizer had approved for use in the UK and disseminated from its official UK Twitter account.

Nevertheless, the Panel noted the specific wording of the undertaking and that it applied to discontinuing "*similar material*" and to taking "*all possible steps*". Given the Panel's rulings above in relation to the Tweets (breaches of Clauses 3.1, 7.2 and 9.1 of the 2019 Code), the

Panel concluded that it was clear that Pfizer had not withdrawn similar material referring to absolute rates instead of relative efficacy rates, because the Tweets in this case were still publicly available. Although Pfizer has since removed the Tweets, the Panel considered that Pfizer had not taken all possible steps to avoid similar breaches due to the continued existence of the Tweets beyond the date of the undertaking. This meant the undertaking had been breached and the Panel therefore ruled a **breach of Clause 3.3 of the 2021 Code**.

Complaint received **15 April 2024**

Case completed **14 April 2025**