CASE AUTH/3591/12/21

COMPLAINANT v PFIZER

Concerns about a Pfizer BBC news article

A complaint on behalf of UsForThem, a parent-led campaign group calling for children's needs to be prioritised during the Covid pandemic response, was received about an article and video posted on the BBC news website.

The item at issue, entitled 'Pfizer boss: Annual Covid jabs for years to come' consisted of an interview conducted by a BBC medical editor with Pfizer's Chief Executive Officer (CEO) and appeared in the 'Health' section of the BBC website on 2 December 2021.

COMPLAINT

The complainant stated that the tone, content and means of dissemination of this article and the associated video were extremely promotional in nature. The complainant strongly believed that it was not appropriate for Pfizer to promote its product in this way. The complainant referred to three earlier cases against Pfizer for promoting its Covid-19 vaccine illegitimately online (Cases AUTH/3422/11/20, AUTH/3438/12/20 and AUTH/3437/12/20). In these cases the Panel decided that Pfizer's Covid-19 vaccine regulatory status was that of a temporary approval for emergency use only and stated that the vaccine was not a licensed medicine, and that Pfizer was guilty of promoting an unlicensed medicine in breach of the Code. The complainant was not aware that the UK regulatory status of Pfizer's Covid-19 vaccine had changed since these cases and therefore alleged Pfizer was, with the material at issue, once again in breach of the Code. Furthermore, in view of the fact that Pfizer had had several findings of a similar nature in the past 6 months, the complainant alleged that Pfizer was also in breach of the Code for failing to comply with its undertaking.

The complainant made specific allegations about statements and claims made in the promotional piece relating to children:

1 'Immunising that age group [children under the age of 11] in the UK and Europe would be a very good idea.'

The complainant alleged that by recommending vaccinating healthy British children under the age of 11 against Covid-19, the Pfizer CEO was making a claim for the clinical efficacy and safety of Pfizer's product and its risk/benefit balance, even though the vaccine had not yet been included in the emergency use temporary approval for use in children this young in the UK.

2 'Covid in schools was thriving'. 'This was disturbing significantly the educational system and there were kids that would have severe symptoms.'

The complainant stated that severe Covid-19 was rare amongst children and school age in the UK and while the virus did circulate in schools, schools had typically reflected community transmission throughout the pandemic. Neither had Covid-19 itself had a significant impact on disturbing children's education in the UK. The 'disturbance' to the UK educational system had resulted from political decisions made by governments, not the virus. Indeed, the complainant knew that the UK had the second highest rates of school closures in Europe, except for Italy – a result of political decisions.

The complainant stated that there was simply no evidence that healthy school children in the UK were at significant risk from the SARS COV-2 virus and to imply that they were was disgracefully misleading.

3 'So, there was no doubt in my mind that the benefits completely were in favour of doing it.'

The complainant alleged that this was probably the most egregiously false and misleading of the Pfizer's CEO's statements. It completely neglected to consider that there were potential risks to healthy children associated with administration of the Covid-19 vaccine. The complainant referred to a number of documents including a Pfizer leaflet listing side-effects; Latest government advice regarding myocarditis to healthcare workers detailing rates of myocarditis in hospitalised children; and Latest adverse events reported for Pfizer.

The complainant stated that the conclusion of the Joint Committee on Vaccination and Immunisation earlier in 2021 when asked to give an opinion on this very subject in relation to the older cohort of children between 12 and 15 hardly seemed to be consistent with the opinion of Pfizer's CEO that there was 'no doubt' or that 'the benefits completely were in favour'. The complainant alleged that the failure to promote the rational use of the medicine, the misleading presentation of the risk/benefit profile and the use of exaggerated, all-embracing claims ('no doubt' and 'completely in favour') was in breach of the Code.

The complainant stated whether Pfizer, or indeed the BBC, liked it or not, opinion about the benefits and risks of vaccinating healthy children against an infection which posed little risk to them, and the ethical considerations of exposing healthy children to the risks of vaccination (no matter how rare those effects might be) in order to protect adults or vulnerable members of society, was not settled. For a pharmaceutical company to be behaving on a public platform as if it was, was wrong. The complainant alleged that the material was in breach of the Code in that 'emerging clinical and scientific opinions which had not been resolved in favour of one generally accepted viewpoint must be referred to in a balanced manner'.

The complainant understood that Pfizer's Covid-19 vaccine fell within the clause of the Code relating to temporary authorisation for sale or supply without a marketing authorisation. The complainant stated such was the poor quality of this activity and the materials which were the subject of this complaint in terms of their lack of compliance with the Code that the complainant found it difficult to believe that Pfizer had undergone the required prior scrutiny and approval by the MHRA on behalf of the ministers as set out in Clause 11.3 of the Code.

The complainant alleged a breach of the Code as no information, whatsoever, was provided about reporting of side-effects, or indeed the side-effects themselves.

The complainant had no way of knowing whether the interview was or was not solicited by Pfizer. Similarly, the complainant had no way of knowing whether Pfizer's CEO was formulating his answers based on briefing notes prepared by the Pfizer communications department or, indeed, whether the journalist prepared his written article with the aid of written briefing notes or press releases provided by Pfizer. This information would no doubt inform and guide judgements about this case.

In summary, the complainant alleged that the article, and associated video constituted promotion by Pfizer of its unlicensed medicine which fell within the scope of the Code. The complainant further alleged that Pfizer had failed to maintain high standards and brought discredit upon the industry. Furthermore, bearing in mind that Pfizer was found guilty of illegitimately promoting its Covid-19 vaccine using the internet less than six months ago, a breach of undertaking was alleged.

The detailed response from Pfizer is given below.

PANEL RULING

The Panel noted Pfizer's submission that it had been approached by the BBC for an interview with its CEO which was held on 22 November 2021. The news article and associated video interview, referred to by the complainant, were produced and published by the BBC on 2 December 2021. The Panel noted Pfizer's submission that the 45-minute interview was intended to cover news topics identified by the BBC about Pfizer's commitment to the global Covid-19 vaccine rollout and ongoing innovation to fight the pandemic.

The Panel noted that complaints about third party articles in the press etc were judged upon the acceptability of the information provided to that third party by the pharmaceutical company, such as any press release, unedited interview etc rather than the final published article. The Panel noted Pfizer's submission that it had no editorial control or right to review the excerpts of the interview chosen by the BBC for inclusion in their news articles and no Pfizer press briefing was issued to the BBC in association with the interview. The Panel also noted Pfizer's submission that it had not been able to obtain a full transcript of the interview from the BBC as the BBC's own policies did not allow this; it had, however, obtained some limited expanded excerpts from the interview. The Panel noted that it was obliged to make its rulings based on what Pfizer's CEO had actually stated rather than the edited published article and video. The Panel noted, therefore, that in relation to the quotations cited by the complainant, these could only be considered within the context of the overall interview based on the limited BBC transcript provided by Pfizer as part of its response.

The Panel did not have the full unedited transcript of the interview or the video. Whilst the complainant referred to the published video, it appeared that the substantive allegations related to the published article.

The Panel noted Pfizer's submission that prior to the interview, Pfizer UK had briefed the CEO who was based in the USA about the interview, the regulatory status of Covid-19 vaccines in the UK and the requirements of the ABPI Code.

The Panel noted the comments that had been included in the article which were attributable to Pfizer's CEO within the context of the limited interview excerpt provided by Pfizer particularly 'Immunising that age group [children under the age of 11] in the UK and Europe would be a very good idea' and 'So, there is no doubt in my mind that the benefits, completely, are in favour of doing it [vaccinating children against Covid-19]' and considered that the strong unqualified nature of the comments were such that they promoted Covid-19 vaccines including the Pfizer-BioNTech Covid-19 vaccine.

The Panel noted, that at the time the CEO's comments were made, and subsequently published, the Pfizer-BioNTech Covid-19 vaccine did not have a temporary supply authorisation, it was the subject of a conditional marketing authorisation. In the Panel's view, the medicine therefore had not been promoted prior to the grant of its marketing authorisation and no breach of the Code was ruled.

In relation to the alleged breach of undertaking, the Panel noted that the current case (Case AUTH/3591/12/21) concerned excerpts from an interview with Pfizer's CEO which were subsequently published in an article by the BBC and referred to Pfizer-BioNTech Covid-19 vaccine which had a conditional marketing authorisation at the time. In the Panel's view, the current case, Case AUTH/3591/12/21, was sufficiently different to the previous cases which involved promotion prior to the grant of the market authorisation as a result of individual employee's personal use of social media which did not follow company policy such that there had been no breach of the undertakings given in Cases AUTH/3422/11/20, AUTH/3437/12/20 and AUTH/3438/12/20 as alleged. The Panel therefore ruled no breach of the Code.

In relation to the quotation 'Immunising that age group [children under the age of 11] in the UK and Europe would be a very good idea' the Panel noted Pfizer's submission that at the time the article at issue, including excerpts from the Pfizer CEO's interview, was published, the Pfizer-BioNTech Covid-19 vaccine was approved for use in individuals 12 years and older; no Covid-19 vaccines were approved by the MHRA for use in children under the age of 12 years.

Whilst the Panel noted that the Pfizer-BioNTech Covid-19 vaccine was not licensed for use in under 12 year olds at the time the CEO's comments were made, and subsequently published within the BBC article, it did have a conditional marketing authorisation for use in those aged 12 and over. The Panel did not consider, therefore, that the clause which required that a medicine must not be promoted prior to the grant of its marketing authorisation which permits its sale or supply was relevant and no breach of the Code was ruled in relation to the quotation in question.

The Panel noted, however, that the Pfizer-BioNTech vaccine was not approved by the MHRA for use in children aged 5 to 11 years until 22 December 2021. At the time the CEO's comments were made and subsequently published within the BBC article, the Pfizer-BioNTech vaccine was not approved for use in children aged 5-11 years. In the Panel's view, the statements attributable to the Pfizer CEO promoted the Pfizer-BioNTech

vaccine in this age group and a breach of the Code was ruled. This ruling was appealed by Pfizer.

The Panel noted that with regard to the quotations 'Covid in schools was thriving' and 'This was disturbing significantly the educational system and there were kids which would have severe symptoms', Pfizer provided a BBC transcript of this part of the interview. The quotations in question were slightly different in the transcript: 'I think that Covid in schools was thriving' and 'I believe that this is disturbing, significantly the educational system'. They appeared as part of a response to a question about whether immunising 5 to 11 year olds was likely to happen in the UK and Europe. The Panel noted Pfizer's submission that the evidence showed rising levels of Covid-19 infection seen in UK school age children in autumn 2021 potentially representing a pool of infection and risk of transmission to peers, staff and families. An opinion piece published in the British Medical Journal (BMJ) December 2021 highlighted the key issues. Further, in the UK, the pandemic had resulted in two significant periods of school closures causing notable disturbance to the education system. The Panel noted Pfizer's submission that numerous reports documented the detrimental impact of the disruption on children's wellbeing and learning. This included The Office of Qualifications and Examinations Regulation (OFQUAL) review published in July 2021, which stated that the nature of learning loss varied depending on the phase of education. Primary leaders were most likely to report significant learning loss, with the youngest pupils apparently most negatively affected by the pandemic. The Panel further noted Pfizer's submission that whilst data concerning long Covid-19 were limited in young children, there was documented evidence of the occurrence of long Covid-19 in children aged 11 to 17 years; the BMJ reported that one in seven children in the UK might still have symptoms 15 weeks after infection. The Panel did not consider that the complainant had established that the cited quotations were misleading or incapable of substantiation on the basis that there was no evidence that healthy school children in the UK were at risk from the SARS COV-2 virus as alleged. Based on the very narrow allegation, no breaches of the Code were ruled.

With regard to the allegations about the statement 'So, there is no doubt in my mind that the benefits completely are in favour of doing it [vaccinating children against Covid-19]' the Panel noted that a transcript of this part of the interview was provided to Pfizer by the BBC. The Panel noted Pfizer's submission that it showed that its CEO was asked a specific question about vaccinating 5 to 11-year-old children against SARS-CoV-2 infection. The interviewer asked 'In October the FDA, the American regulator approved your vaccine for 5-to 11-year-olds after successful trials. Do you think immunising that age group is likely to happen in the UK and Europe? And if so, why is it a good idea?'. The CEO responded 'I think it will happen. I don't want to speak about specific candidates I don't want to speak about for the health authorities or the regulatory authorities of UK. It's up to them to approve it and use it or not. I believe it's a very good idea. I think that COVID in schools is thriving. I believe that this is disturbing, significantly, the educational system. I think is becoming the pool of infection for the adults. It is becoming a pool of infection for a pool of where the virus keeps replicating and that creates variants. At the end of the day, although the symptoms are not very severe, there is the long COVID. That is very worrisome. And there are kids that will have severe symptoms. So there is no doubt in my mind about the benefits completely are in favour of doing it'.

The Panel noted Pfizer's submission that the CEO made it clear that the decision on whether to authorize the vaccines in the 5 to 11 year age group was the responsibility of the MHRA and he was not speaking on its behalf. He also explained that he was answering the question in the context of Covid-19 vaccination in general rather than specifically the Pfizer-BioNTech vaccine. Pfizer's CEO then went onto express his opinion that the wider benefits of vaccinating the 5 to 11 year age group were in favour of vaccination. The Panel noted from the transcript that there was a clear inference that a risk/benefit analysis would be undertaken by the regulator. On balance, however, the Panel considered that the subsequent strong opinion statements, including 'So, there was no doubt in my mind that the benefits completely were in favour of doing it [vaccinating children against Covid-19]' and 'I believe it's a very good idea' might infer to the ultimate audience, including members of the public, that there was no need to be concerned about potential side-effects which was not so. The Panel considered that this implication was incapable of substantiation and through phrases such as 'no doubt' and 'completely in favour', Pfizer's CEO did not encourage the rational use of a medicine. Breaches of the Code were ruled. These rulings were appealed by Pfizer.

The Panel noted that at the time the CEO's comments were made and subsequently published within the BBC article, there appeared to be differing opinion on the benefit of vaccinating children under 12. Whilst the Panel noted the CEO's statement that he/she 'did not want to speak for the health authorities or the regulatory authorities of UK, it was up to them to approve it and use it or not', the Panel considered that the CEO's opinion statements, including 'So there is no doubt in my mind about the benefits completely are in favour of doing it' might infer to the ultimate audience, including members of the public, that the benefits outweighed the risks when the regulatory authorities had not yet made any conclusions in relation to the vaccination of 5 to 11 year olds; the Pfizer-BioNTech Covid-19 vaccine was not licensed in the UK in that age group when the article at issue was published and the Panel therefore ruled breaches of the Code. These rulings were appealed by Pfizer.

The Panel noted that, at the relevant time, the Pfizer/BioTech vaccine had a conditional marketing authorisation. The clause of the Code which applied to medicines with a temporary supply authorisation, was therefore not applicable and no breach was ruled.

The Panel did not consider that the complainant had established that the interview with the CEO, excerpts of which were subsequently included in the BBC article, was a campaign approved by health ministers and thereby required a reference to reporting of side-effects. No breach of the Code was ruled.

The Panel did not consider that the complainant had established that the interview in question was intended for patients taking the Pfizer-BioNTech Covid-19 vaccine and therefore the requirements of the Code which related to material related to a medicine intended for patients taking that medicine were not relevant. No breach of the Code was ruled.

The Panel noted its comments and ruling above and considered that Pfizer had failed to maintain high standards and a breach of the Code was ruled. This ruling was appealed by Pfizer.

The Panel noted its comments and rulings above, including that the statements made by the Pfizer CEO did not encourage the rational use of the medicine, and considered that the briefing document by Pfizer UK did not sufficiently brief the CEO on how to address questions on children aged 5 to 11, despite this being described as a hot topic; the briefing was limited to stating that there were no current plans to authorise the vaccine for ages 5 to 11 and that Pfizer would submit data on the 5 to 11 population to the UK regulator in the coming weeks. [See post Panel consideration note]. Further, whilst the briefing instructed the CEO not to promote nor state messages which could appear to encourage individuals to specifically ask their doctors for a prescription based on the information provided, it provided key messages, contradictory to this instruction such as 'I encourage anyone who is on the fence about receiving a vaccine to think again and to look at the science' and 'This is a decision that will not only affect your life but those you spend the most time with including your family and loved ones'. The Panel noted its comments and rulings above and considered that Pfizer had brought discredit upon, and reduced confidence in, the industry in this regard and a breach of Clause 2 was ruled. This ruling was appealed by Pfizer.

[Post Panel consideration note: Following notification of the Panel's rulings, Pfizer pointed out that the briefing stated 'No current plans to authorize the vaccine for ages 5-11 but this is hot topic behind closed doors within Government (not publicly in media)'].

Pfizer considered the briefing document to be confidential and initially did not want it to be shared with the complainant. The briefing document was not provided to the complainant when notified of the outcome of the Panel's consideration of the case as it was not considered relevant to enable him/her to decide whether or not to appeal the Panel's rulings of no breach of the Code. Upon Pfizer's appeal the issue of confidentiality of the enclosure which Pfizer re-submitted as part of its appeal was reviewed. A redacted version of the briefing document was settled by the Director as set out in Paragraph 7.5 of the PMCPA Constitution and Procedure. The terms of its disclosure to the complainant, however, could not be settled with the parties. The complainant declined to receive the redacted Enclosure based on the terms of confidentiality and was originally sent Pfizer's appeal papers without it. The Chair of the Appeal Board was asked to decide how to proceed and decided that relevant sections, quoted directly from the Enclosure, were to be included in one document titled 'Relevant extracts from Enclosure 22, a briefing document from Pfizer for an interview with the BBC on November 22, 2021.' and that this was shared with the complainant, Pfizer and the Appeal Board.

The appeal from Pfizer and the complainant's detailed comments upon it are given below.

APPEAL BOARD RULING

The Appeal Board noted Pfizer's submission that the 45-minute interview was intended to cover news topics identified by the BBC about Pfizer's commitment to the global Covid-19 vaccine rollout and ongoing innovation to fight the pandemic. Pfizer's objective for the interview was to reiterate its continued commitment to delivering equitable access to its COVID-19 vaccine across low- and middle-income countries which was a topic of particular media interest at the time. Pfizer submitted that it had reasonably considered that the topic of childhood vaccination would not be a specific focus of the interview. At

the appeal Pfizer stated that its CEO who was based in the USA had been given the briefing document and verbally briefed by an experienced media relations team and senior staff. Pfizer UK had briefed the CEO about the regulatory status of Covid-19 vaccines in the UK and the requirements of the ABPI Code. In response to a question at the appeal, Pfizer acknowledged that perhaps additional wording could have been added to the briefing to help the CEO navigate the more complicated areas.

The Appeal Board noted Pfizer's submission that it had no editorial control or right to review the excerpts of the interview chosen by the BBC for inclusion in its news articles and no press briefing was issued to the BBC in association with the interview. The Appeal Board also noted Pfizer's submission that it had not been able to obtain a full transcript of the interview from the BBC as the BBC's own policies did not allow this; it had, however, obtained some limited expanded excerpts. Pfizer stated at the appeal that whilst the topic of vaccination in children appeared to be a focus in the online article, it formed only a small part of the complete 45 minute interview. The Appeal Board agreed with the Panel that it was obliged to make its rulings based on what Pfizer's CEO had actually stated rather than the edited published article and video. The Appeal Board noted that whilst it did not have the full unedited transcript of the interview, it had before it two questions and answers in relation to vaccination in children. One was not included within the online article and was not the subject of the complaint. The other was:

> **BBC medical editor: 'In October the FDA, the American regulator approved your vaccine for 5 to 11-year-olds after successful trials. Do you think immunising that age group is likely to happen in the UK and Europe? And if so, why is it a good idea?**
>
> **Pfizer CEO: 'I think it will happen. I don't want to speak about specific candidates I don't want to speak [about] for the health authorities or the regulatory authorities of UK. It's up to them to approve it and use it or not. I believe it's a very good idea. I think that COVID in schools is thriving. I believe that this is disturbing, significantly, the educational system. I think is becoming the pool of infection for the adults. It is becoming a pool of infection for a pool of where the virus keeps replicating and that creates variants. At the end of the day, although the symptoms are not very severe, there is the long COVID. That is very worrisome. And there are kids that will have severe symptoms. So there is no doubt in my mind about the benefits completely [completely] are in favour of doing it.'**

The Pfizer-BioNTech vaccine was not approved by the MHRA for use in children aged 5 to 11 years until 22 December 2021, after this interview.

The Appeal Board noted Pfizer's submission that its CEO was asked a specific question about vaccinating 5 to 11-year-old children against SARS-CoV-2 infection. At the appeal Pfizer submitted that it was not unreasonable to talk about the principles of vaccination in this age group in general and that at the time, there were two other vaccine candidates being investigated in children under 12.

The Appeal Board considered the comments by Pfizer's CEO particularly 'Immunising that age group [children under the age of 11] in the UK and Europe would be a very good idea' and 'So, there is no doubt in my mind that the benefits, completely [completely], are in favour of doing it [vaccinating children against Covid-19]'. The Appeal Board

determined that the strong unqualified nature of the comments were such that they promoted the use of Covid-19 vaccines in the 5-11 age group in general, but in the context of the whole answer the Appeal Board considered that those comments did not promote the Pfizer-BioNTech Covid-19 vaccine in isolation.

The relevant clause which stated that the promotion of a medicine must be in accordance with the terms of its marketing authorisation and must not be inconsistent with the particulars listed in its summary of product characteristics (SPC) had not been raised in relation to the allegation that the Pfizer-BioNTech vaccine had been promoted for use in 5 to 11 year olds for which it was not approved at the time of the interview and so the Panel had considered the matter under the clause relating to maintaining high standards. The Appeal Board, noting its comments above, did not consider that Pfizer's CEO had specifically promoted Pfizer's Covid-19 vaccine for use in the 5-11 age group and no breach of the Code was ruled in this regard. The appeal on this point was successful.

The Appeal Board noted Pfizer's submission that its CEO made it clear that the decision on whether to authorize the vaccines in the 5 to 11 year group was the responsibility of the MHRA and that he was not speaking on its behalf. He also explained that he was answering the question in the context of Covid-19 vaccination in general rather than specifically in relation to the Pfizer-BioNTech vaccine. Pfizer's CEO then went on to express his opinion that the wider benefits of vaccinating the 5 to 11 year age group were in favour of vaccination.

In the Appeal Board's view the alleged clauses of the Code would apply if classes of medicines were referred to and not only a specific medicine.

The Appeal Board considered that the subsequent strong opinion statements, including 'So, there was no doubt in my mind that the benefits completely [completely] were in favour of doing it [vaccinating children against Covid-19]' and 'I believe it's a very good idea' might infer to the ultimate audience, including members of the public, that there was no need to be concerned about potential side-effects of vaccination in healthy children aged 5-11 which was not so. The Appeal Board considered that this implication was misleading and incapable of substantiation. The Appeal Board therefore upheld the Panel's rulings of breaches of the Code. The appeal on this point was unsuccessful.

The Appeal Board, however, did not consider the claim failed to 'encourage the rational use' of a particular medicine and it therefore ruled no breach of the Code. The appeal on this point was successful.

Whilst the Appeal Board noted the CEO's statement that he/she 'did not want to speak for the health authorities or the regulatory authorities of UK, it was up to them to approve it and use it or not', the Appeal Board considered that the CEO's opinion statements, including 'So there is no doubt in my mind about the benefits completely are in favour of doing it' might infer to the ultimate audience, including members of the public, that the benefits outweighed the risks when the UK regulatory authorities had not yet made any conclusions in relation to the vaccination of 5 to 11 year olds; no Covid-19 vaccine was licensed in the UK in that age group when the article at issue was published and the Appeal Board therefore upheld the Panel's rulings of breaches of the Code. The appeal on this point was unsuccessful.

The Appeal Board noting the unique circumstances of the Covid-19 pandemic and its comments above including that Pfizer UK had briefed the CEO about the regulatory status of Covid-19 vaccines in the UK and the requirements of the ABPI Code, considered that in the particular circumstances of this case its concerns were covered by its rulings above, and further rulings of breaches of the Code in relation to high standards and Clause 2 were not warranted. The Appeal Board ruled no breach including of Clause 2. The appeal on these points was successful.

A complaint on behalf of UsForThem, a parent-led campaign group calling for children's needs to be prioritised during the pandemic response, was received about an article and video posted on the BBC news website [https://www.bbc.co.uk/news/health-59488848].

COMPLAINT

The complainant stated that the item consisted of an interview with the Chief Executive Officer (CEO) of Pfizer, conducted by a BBC Medical Editor, which appeared in the 'Health' section of the BBC website. It was entitled 'Pfizer boss: Annual Covid jabs for years to come' and was posted on 2 December 2021. The item was not written by a BBC financial journalist and did not appear in the 'Business' section of the BBC website. Therefore, the complainant stated that Pfizer could not claim any exemptions under the Code that might be applicable to business-related materials as set out in Clause 26.2.

The complainant stated that the item published by the BBC and the interview was conducted by a British-based journalist and included much specific discussion of the management of Covid-19 using Pfizer's product in the UK. Therefore, it fell within the scope of the Code.

Alleged promotional nature of the material

The complainant stated that the tone, content and means of dissemination of this article and the associated video were extremely promotional in nature. The Code defined promotion in Clause 1.17 as:

> 'Promotion means any activity undertaken by a pharmaceutical company, or with its authority, which promotes the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicines.'

The complainant stated that much of what the CEO said in this interview, and was reported to have said, clearly fulfilled the definition of promotion of a Pfizer product, namely their Covid-19 vaccine. Some examples were as follows:

> 'People will be likely to need to have annual Covid vaccinations for many years to come.
> '….to maintain very robust and very, very high levels of protection.'
>
> 'I believe we have saved the global economy trillions of dollars.'
>
> 'Vaccines have helped save millions of lives during the pandemic and without them the fundamental structure of our society would be threatened.'
>
> 'Immunising that age group [children under the age of 11] in the UK and Europe would be a very good idea.'

> ‘So, there was no doubt in my mind that the benefits completely are in favour of doing it [vaccinating children against Covid-19].’

The complainant stated that in addition to promotion of the Pfizer vaccine, there were also promotional statements about another Pfizer product in development:

> ‘Pfizer has also developed an antiviral pill Paxlovid which in trials cut hospital admissions and deaths by nearly 90%.’

The complainant stated that he/she made few comments at this stage about the truth, accuracy or substantiability of any of these statements except to say that none of them were substantiated within the article, and very few of them were capable of being evidenced. Furthermore, several exaggerated and superlative claims were made and statements were unbalanced in that they gave no information about potential risks associated with the use of their vaccine, or of its unlicensed status. Breaches of Clauses 6.1, 6.2 and 14.4, at the very least, had taken place. However, at this stage, the complainant was principally using these statements to clearly establish that the content and tone of this material were promotional.

Alleged inappropriate and illegitimate promotion

The complainant stated that having established the promotional nature of this material, it was then necessary to ask whether it was appropriate for Pfizer to promote its product in this way. The complainant strongly believed that it was not. The complainant referred the Panel to three earlier cases of complaints against Pfizer for promoting their Covid-19 vaccine illegitimately online (Cases AUTH/3422/11/20, AUTH/3438/12/20 and AUTH/3437/12/20). In these cases, it was the judgement of the Panel that Pfizer’s Covid-19 vaccine regulatory status was that of a temporary approval for emergency use only. The Panel clearly stated in these judgements that the vaccine was not a licensed medicine, and that Pfizer was guilty of promoting an unlicensed medicine in breach of Clause 3.1 of the Code. The complainant was not aware that the UK regulatory status of Pfizer’s Covid-19 vaccine had changed since these judgements were made and therefore Pfizer was, with the material at issue, once again in breach of Clause 3.1 of the Code. Furthermore, in view of the fact that Pfizer had had several findings against them of a similar nature in the past 6 months, it would be appropriate to say that they were also in breach of Clause 3.3 (Compliance with undertakings).

The complainant turned to specific complaints about statements and claims made in this promotional piece (some of these statements and claims had been listed above). As explained earlier, UsForThem was an organisation established to help protect the interests of children during the pandemic response, and so the complainant confined comments to those statements and claims relating to children:

1 ‘Immunising that age group [children under the age of 11] in the UK and Europe would be a very good idea.’

The complainant stated that here, the Pfizer CEO recommended vaccinating healthy British children under the age of 11 against Covid-19. He was making a claim for the clinical efficacy and safety of his product, its risk/benefit balance, even though the vaccine had not yet been included in the emergency use temporary approval for use in children this young in the UK. This was alleged to be a breach of Clause 3.1.

2 ‘Covid in schools was thriving.’ ‘This was disturbing significantly the educational system and there were kids that would have severe symptoms.’

The complainant stated that severe Covid-19 was rare amongst children and school age in the UK (linking this statement to an article) and while the virus did circulate in schools, schools had typically reflected community transmission throughout the pandemic. Neither had Covid-19 itself had a significant impact on disturbing children’s education in the UK. The ‘disturbance’ to the UK educational system had resulted from political decisions made by governments, not the virus. Indeed, the complainant knew that the UK had the second highest rates of school closures in Europe, except for Italy – a result of political decisions (linking this statement to an article).

The complainant stated that there was simply no evidence that healthy school children in the UK were at significant risk from the SARS COV-2 virus and to imply that they were was disgracefully misleading. Once again, these were breaches of Clauses 6.1 and 6.2.

3 ‘So, there was no doubt in my mind that the benefits completely were in favour of doing it.’

The complainant stated that this was probably the most egregiously false and misleading of the Pfizer CEO’s statements. It completely neglected to consider that there were potential risks to healthy children associated with administration of the Covid-19 vaccine. The complainant referred the Panel to a number of documents and provided links:

> Pfizer leaflet listing side-effects https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/information-for-uk-recipients-on-pfizerbiontech-covid-19-vaccine.
>
> Latest government advice regarding myocarditis to healthcare workers detailing rates of myocarditis in hospitalised children https://www.gov.uk/government/publications/myocarditis-and-pericarditis-after-covid-19-vaccination/myocarditis-and-pericarditis-after-covid-19-vaccination-guidance-for-healthcare-professionals.
>
> Latest adverse events reported for Pfizer https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1038175/COVID-19_mRNA_Pfizer-BioNTech_Vaccine_Analysis_Print_DLP_24.11.2021.pdf.

Indeed, the conclusion of the Joint Committee on Vaccination and Immunisation earlier in 2021 when asked to give their opinion on this very subject in relation to the older cohort of children of between 12 and 15, was as follows:

> ‘The available evidence indicates that the individual health benefits from COVID-19 vaccination are small in those aged 12 to 15 years who do not have underlying health conditions which put them at risk of severe COVID-19. The potential risks from vaccination are also small, with reports of post-vaccination myocarditis being very rare, but potentially serious and still in the process of being described. Given the rarity of these events and the limited follow-up time of children and young people with post-vaccination

> myocarditis, substantial uncertainty remains regarding the health risks associated with these adverse events.
>
> Overall, the committee is of the opinion that the benefits from vaccination are marginally greater than the potential known harms (tables 1 to 4) but acknowledges that there is considerable uncertainty regarding the magnitude of the potential harms. The margin of benefit, based primarily on a health perspective, is considered too small to support advice on a universal programme of vaccination of otherwise healthy 12 to 15-year-old children at this time. As longer-term data on potential adverse reactions accrue, greater certainty may allow for a reconsideration of the benefits and harms. Such data may not be available for several months.'

The complainant stated that this conclusion hardly seemed to be consistent with the opinion of the CEO of Pfizer that there was 'no doubt' or that 'the benefits completely were in favour'. In the circumstances, the complainant thought it clear that not only had there been breaches of Clauses 6.1 and 6.2, but also alleged that the failure to promote rational use of the medicine, the misleading presentation of the risk/benefit profile and the use of exaggerated, all-embracing claims ('no doubt' and 'completely in favour') represented a breach of Clause 14.4 too.

The complainant stated whether Pfizer, or indeed the BBC, liked it or not, opinion about the benefits and risks of vaccinating healthy children against an infection which posed little risk to them, and the ethical considerations of exposing healthy children to the risks of vaccination (no matter how rare those effects might be) in order to protect adults or vulnerable members of society, was not settled. For a pharmaceutical company to be behaving on a public platform as if it was, was wrong. This material was therefore also alleged to be in breach of the requirement of Clause 6.1 that 'emerging clinical and scientific opinions which had not been resolved in favour of one generally accepted viewpoint must be referred to in a balanced manner'.

The Relationship of Pharmaceutical Companies with The Public

The complainant referred to Clause 26 'Relations with the Public, Including Patients and Journalists' and that Clause 26.1 required that 'Prescription only medicines must not be advertised to the public'. This clause also stated that:

> 'This prohibition did not apply to vaccination and other campaigns carried out by companies and approved by the health ministers.'

The complainant was aware that, in previous cases (Cases AUTH/3422/11/20, AUTH/3438/12/20 and AUTH/3437/12/20), the Panel had judged that the prohibition within Clause 26.1 relating to promotion to the public did not apply to Covid-19 vaccines as they were unlicensed and therefore could not be described as prescription only medicines. The Panel described this as a decision based on a 'narrow technical point'. The complainant was, however, also aware that there was a new clause in the Code, Clause 11.3, which dealt with temporary authorisation for sale or supply without a marketing authorisation:

> 'In response to certain types of public health emergency, under UK law, the licensing authority might temporarily authorise the sale or supply of a medicine without a marketing authorisation.'

The complainant stated that Pfizer's Covid-19 vaccine fell within the scope of this clause. Clause 11.3 required that:

> 'a medicine with a temporary supply authorisation must not be promoted unless it was part of a campaign that had been approved by the health ministers.'

and

> 'The campaign must be approved by the health ministers and all relevant requirements of the Code would apply.'

Furthermore, Clause 11.3 required that:

> 'Companies should contact the MHRA [Medicines and Healthcare products Regulatory Agency] for information regarding approval of materials and activities.'

The complainant stated such was the poor quality of this activity and these materials which were the subject of this complaint in terms of their lack of compliance with the Code that the complainant found it difficult to believe that Pfizer had undergone the required prior scrutiny and approval by the MHRA on behalf of the ministers. Therefore, the complainant alleged a breach of Clause 11.3.

Furthermore, Clause 26.1 included:

> 'In addition, such campaigns should include a general reference to the reporting of side-effects as it was unlikely that the requirements of Clause 26.4 would apply as the relevant material was not intended for patients taking a particular medicine.'

The Panel would be aware that Clause 26.4 related to the provision of information about reporting of side-effects. It was not clear to the complainant whether Clause 26.4 was applicable here or not but as no information, whatsoever, was provided about reporting of side-effects, or indeed the side-effects themselves, then there must have been a breach of either Clause 26.4 or 26.1.

The complainant stated that, as referred to, the supplementary information to Clause 26 which included some excellent advice to pharmaceutical companies when dealing with the media:

> 'Particular care must be taken in responding to approaches from the media to ensure that the provisions of this clause were upheld.
>
> Attention was drawn to the Blue Guide Appendix: Reporting to the public on medicines: Advice for journalists and patient organisations produced by the Medicines and Healthcare products Regulatory Agency (MHRA).'

The complainant took the Code's advice and consulted the MHRA document cited https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachmentdata/file/956846/BG_2020_Brexit_Final_version.pdf. It contained some useful statements and advice from the MHRA which were relevant to this case:

> ‘The key point is that these controls (and the penalties for breaches) apply to any person who promotes a medicine – not just the manufacturer. This could potentially include newspaper or magazine articles, or information disseminated by a patient organisation’ [Or presumably a broadcasting or web-based organisation].’
>
> ‘But articles should not actively encourage readers to seek a particular product from their healthcare provider and must take care not to exaggerate the potential benefits.’
>
> ‘Articles discussing healthcare issues, particularly medicines, ought to be factual, well balanced and accurate.’

The complainant was aware that the PMCPA was not responsible for ensuring adherence to the rules set out in the MHRA Blue Guide, but the complainant had copied the MHRA advertising standards unit into this letter in case they considered that additional investigations need to be carried out.

The supplementary information to Clause 26 of the Code stated that:

> ‘In the event of a complaint which related to the provisions of this clause, companies would be asked to provide copies of any information supplied, including copies of any relevant press releases and the like. This information would be assessed to determine whether it fulfils the requirements of this clause.’

The complainant had no way of knowing whether the CEO interview with the BBC was or was not solicited by Pfizer. Similarly, the complainant had no way of knowing whether the CEO of Pfizer was formulating his answers based on briefing notes prepared by the Pfizer communications department or, indeed, whether the journalist prepared his written article with the aid of written briefing notes or press releases provided by Pfizer. This information would no doubt inform and guide judgements about this case, and the complainant was sure that the Panel would be seeking it during its investigations.

Summary

In summary, the complainant alleged that this article, and the video associated with it, constituted promotion by Pfizer of its unlicensed medicine which fell within the scope of the Code. The material contained numerous breaches of Clauses 3.1, 6.1 and 6.2. It also contained breaches of Clauses 11.3, 14.4 and 26.1 (or 26.4). The complainant alleged that Pfizer had also failed to maintain high standards and brought discredit upon the industry so breaches of Clauses 2 and 5.1 must also be taken into consideration. Furthermore, the complainant alleged that bearing in mind that Pfizer was found guilty of illegitimately promoting its Covid-19 vaccine using the internet less than six months ago, a breach of Clause 3.3 (breach of undertaking) must also be considered.

When writing to Pfizer, the Authority asked it to consider the requirements of Clauses 2, 3.1, 3.3, 5.1, 6.1, 6.2, 11.3, 14.4, 26.1, 26.2 and 26.4 of the Code.

RESPONSE

Pfizer stated that it took its commitment to working within the framework of the Code very seriously. Pfizer was also very mindful of the continuing high level of public interest in the

Covid-19 vaccine as noted by the BBC National News' request to interview Pfizer's CEO. Pfizer took very seriously its responsibility to communicate appropriately with the public on the vaccine (a responsibility which Pfizer believed was shared by the BBC). Pfizer had therefore thoroughly investigated the concerns raised by the complainant and, as detailed below, strongly refuted all alleged breaches of the Code.

The complaint

The news article that was the subject of this complaint was produced and reported by the BBC. The article included excerpts from a pre-recorded interview held on 22 November 2021 between the BBC's medical editor and Pfizer's CEO. Pfizer had been approached by the BBC, a public service broadcaster, for an interview with its CEO. The 45-minute interview was intended to cover news topics identified by the broadcaster about Pfizer's commitment to the global Covid-19 vaccine rollout and ongoing innovation to fight the pandemic.

General concerns raised by the complainant about the interview

Pfizer did not view this interview as provision of information to inform shareholders, the Stock Exchange and the like via annual reports and announcements etc as described in the supplementary information to Clause 26.2 'Financial Information'. The interview was held in response to a direct enquiry from a journalist, the outputs of which were subsequently disseminated by the BBC via television and website news reports as described in the supplementary information to Clause 26.2 'Information to the Public'. Pfizer believed that the BBC's medical editor's request for an interview with its CEO indicated that the topics discussed were considered relevant news of interest to the public, and the key newsworthy elements of the interview were then selected by the BBC for inclusion in their reports broadcast on live news programmes and the BBC website. Pfizer had no editorial control or right to review the excerpts of the interview chosen by the BBC for inclusion in their news articles. Nor did Pfizer have any influence over where the interview was reported on the BBC news website. Pfizer did not believe that the participation of its CEO in an interview with the BBC Medical Editor, rather than the Business or Financial Editor, in itself represented a breach of the Code and Pfizer therefore denied a breach of Clause 26.2 in this regard.

The complainant also asserted that the tone and means of dissemination of the article and associated video were promotional in nature. In all media communications, it was a well-established principle of the Code that a pharmaceutical company was only responsible for the information it provided to journalists and that it was the responsibility of the journalist and news outlet to determine the way in which that information was presented to the public. Given that Pfizer had no editorial control or right to review the news reports featuring excerpts from the interview with its CEO, the company did not believe Pfizer could be held responsible for the overall tone and means of dissemination of the interview.

Prior to the interview taking place, Pfizer UK briefed the CEO on the context of the interview, the current landscape with respect to the management of the pandemic in the UK and the requirements of the Code when talking to the media. No press briefing was issued to the BBC in association with the interview. Pfizer had not been able to obtain a full transcript of the interview from the BBC as the broadcaster's own policies did not allow this. Pfizer had obtained some limited expanded excerpts from the interview, and Pfizer would therefore focus its response on substantiating the responses provided by its CEO and, where possible, explaining the context and nature of the questions that those responses addressed.

Background Information on the UK regulatory status of Pfizer-BioNTech's Covid-19 vaccination

The Pfizer-BioNTech Covid-19 vaccine was initially granted an authorisation for temporary supply under Regulation 174 by the UK Department of Health and Social Care and the MHRA on 2 December 2020. At this time, the product did not have a marketing authorisation, but the temporary supply authorisation permitted the medicine to be used for active immunisation to prevent Covid-19 disease caused by SARS-CoV-2 virus in individuals aged 16 years and older. Conditional Marketing Authorisation (CMA) was issued by the European Medicines Agency (EMA) on 21 December 2020 and was automatically converted to a CMA in Great Britain on 1 January 2021. The CMA issued by the EMA had continued to have effect in Northern Ireland since 21 December 2020. The supply of the branded Pfizer-BioNTech vaccine Comirnaty▼ (tozinameran) to the UK under the CMA, commenced at the end of July 2021 with the last batch of the vaccine supplied under the temporary supply authorisation being delivered to the UK at the end of July 2021.

On 4 June 2021 CMA was granted by the MHRA for use of Comirnaty in 12 to 15 year olds and CMA for use in 5 to 11 year olds was issued on 22 December 2021.

At the time of the interview, no Covid-19 vaccines were approved by the MHRA for use in children under the age of 12 years. The Pfizer-BioNTech vaccine was approved by the MHRA for use in children aged 5 to 11 years on 22 December 2021.

At the time of the interview the Pfizer-BioNTech Covid-19 vaccine was being supplied to the UK as the branded vaccine Comirnaty under the CMA. There was no ongoing provision of the vaccine under the temporary supply authorisation. Pfizer therefore did not believe that Clause 11.3 of the Code was relevant to this case and denied any associated breaches of the Code.

The summaries of product characteristics (SPCs) for Comirnaty current at the time of Pfizer's response (January 2022) were provided for reference.

Background information on UK guidance relating to the use of Pfizer-BioNTech's Covid-19 vaccination

Throughout the pandemic the Joint Committee on Vaccination and Immunisation (JCVI) provided advice to the UK government on vaccination against Covid-19, with the primary aim of reducing severe disease (hospitalisation and mortality) across the population. The JCVI at the time of Pfizer's response (28 January 2022) recommended that all adults receive a primary course of two Covid-19 vaccinations followed 3 months later by a single booster dose of either the Pfizer-BioNTech or Moderna vaccine.

Use of Covid-19 vaccines in Children

At the time of interview both the Pfizer-BioNTech and Moderna Covid-19 vaccines were approved for use in individuals, 12 years and older, indicating that the MHRA considered the benefits of these vaccines in this age group to outweigh any risks. On 3 September 2021, the JCVI recommended that children aged 12 to 15 years with underlying health conditions should be offered a course of Covid-19 vaccination. Subsequently, on 13 September 2021, the UK Chief Medical Officers (CMOs) recommended that children aged 12 to 15 years who were not

already covered by the JCVI advice receive a first dose of the Pfizer-BioNTech Covid-19 vaccine. On 29 November 2021, JCVI updated its advice about Covid-19 vaccination in response to the Omicron variant which included recommendation that all children and young people aged 12 to 15 years should be offered a second dose of the Pfizer-BioNTech Covid-19 vaccine at a minimum of 12 weeks from the first dose.

Concerns raised by the complainant about specific quotes and statements included in the BBC news article

Pfizer stated that the complainant had raised concerns about several quotes and statements included in the BBC News article. Pfizer addressed each of these in turn.

> **'People would be likely to need to have annual Covid vaccinations for many years to come.' ….to maintain very robust and very, very high levels of protection.'**

This quote formed part of Pfizer's CEO's response to a specific question posed by the BBC medical editor. The transcript provided below had been taken from the short film of the interview hosted on the BBC News website accessed via the link provided by the complainant (https:www.bbc.co.uk/news/health-59488848).

> **BBC medical editor**: 'Do you predict that we are going to end up seeing 4th dose, 5th doses?'.
>
> **Pfizer CEO**: 'If we have to make a guess based on everything that I have seen so far, I would say that likely would be needed annual vaccinations to maintain very robust and very, very high levels of protection'.

Pfizer stated that it was clear from the question posed by the interviewer that the Pfizer CEO was being asked for an opinion or prediction. In his response, Pfizer's CEO clearly indicated that he was expressing an opinion based on his own experience and knowledge gained during the pandemic. His full response was not, and did not, give the impression of being a statement of fact. Whilst no UK strategy had been announced in this area, given that many governments around the world had, and/or were seeking, ongoing supply agreements with pharmaceutical companies, it was reasonable to believe that annual vaccination was a strategy currently under consideration by governments and advisory groups around the world. Pfizer's CEO's response referred to Covid-19 vaccination in general and did not make specific reference to the Pfizer-BioNTech vaccine. Pfizer did not believe that its CEO's response to this question could be considered promotion of the Pfizer-BioNTech vaccine.

> **'I believe we have saved the global economy trillions of dollars.'**

This quote was taken from part of Pfizer's CEO's response to a specific question about business performance as detailed below. This had been transcribed from the short film of the interview hosted on the BBC News website accessed via the link provided by the complainant (https:www.bbc.co.uk/news/health-59488848):

> **BBC medical editor**: 'You expect to generate I think more than $35 billion dollars in sales this year. What would you say to those who regard it as immoral to cash in during a pandemic?'.

> **Pfizer CEO**: 'I believe that we have saved the global economy trillions of dollars. I believe that it is strong incentive for innovation for the next pandemic, that if they step up to the game, to bring something that saves lives, that saves money, there is also financial reward. We did not do it for that, but I think it is good thing that there is a financial reward.'.

Taken in the context of the question, and with the full answer provided, it was clear that the focus of this part of the interview was to discuss Pfizer's financial performance and business ethics related to the commercialisation of vaccines during a pandemic. The description of the financial impact of Covid-19 vaccination provided by Pfizer's CEO reflected the full economic effect on direct healthcare costs associated with reducing the global burden of disease as well as the impact of the easing restrictions on the global economy. For example, in the UK alone, it was estimated that the pandemic had increased the costs of running frontline NHS services by £4-5bn per year and the government's package of support for the economy was estimated at £315bn. It was therefore a reasonable estimate that the easing of Covid-19 restrictions that had accompanied the roll out of the Covid-19 vaccines in countries across the world had saved the global economy a significant amount of money, referred to by Pfizer's CEO as 'trillions of dollars'. The response given was fair and substantiable. It did not make reference to a specific vaccine and Pfizer did not believe represented an exaggerated claim that promoted the Pfizer-BioNTech vaccine.

> **'Vaccines had helped save millions of lives during the pandemic and without them the fundamental structure of our society would be threatened.'**

Pfizer had not been able to establish the exact context in which this response was provided. However, Pfizer's CEO was clearly referring to the impact of Covid-19 vaccination in general and did not refer specifically to the Pfizer-BioNTech vaccine. The data supporting the impact of Covid-19 vaccination on mortality were well documented as were the broader effects of the pandemic on society. As of the 24 September 2021, the UK Health Security Agency and University of Cambridge MRC Biostatistics Unit estimated that 127,500 deaths had been prevented as a result of the UK Covid-19 vaccination programme. Similarly, a Eurosurveillance report published in November 2021 estimated that the widespread implementation of Covid-19 vaccination programmes for older people had averted a median of 469,186 deaths (sensitivity range: 129,851–733,744) in people 60 years and older in 33 countries in the WHO European region. In the United States, the national Covid-19 vaccination programme was estimated to have prevented 1.1 million deaths in the first year. Based upon these examples, it was reasonable to expect that a similar impact on mortality would have been seen in other countries and regions where Covid-19 vaccination programmes had been similarly implemented. It was therefore reasonable to expect that the cumulative effect on Covid-19 mortality across the globe would be a reduction in the order of millions of deaths prevented. The response provided by Pfizer's CEO referred to Covid-19 vaccination in general and was consistent with the available published mortality data for the overall impact of Covid-19 vaccination. Pfizer did not believe that the response represented an exaggerated claim that promoted the Pfizer-BioNTech vaccine.

> **'Immunising that age group [children under the age of 11] in the UK and Europe would be a very good idea.'**

> **'So, there was no doubt in my mind that the benefits completely were in favour of doing it [vaccinating children against Covid-19].'**

The transcript of this part of the interview was provided by the BBC and showed that Pfizer's CEO was asked two specific questions by the journalist about vaccinating children against SARS-CoV-2 infection, the first about 5 to 11-year-olds and the second about children under 5 years.

> **BBC medical editor**: 'In October the FDA, the American regulator approved your vaccine for 5- to 11-year-olds after successful trials. Do you think immunising that age group was likely to happen in the UK and Europe? And if so, why was it a good idea?'.
>
> **Pfizer CEO**: 'I think it will happen. I do not want to speak about specific candidates I do not want to speak about for the health authorities or the regulatory authorities of UK. It's up to them to approve it and use it or not. I believe it's a very good idea. I think that COVID in schools was thriving. I believe that this is disturbing, significantly, the educational system. I think was becoming the pool of infection for the adults. It was becoming a pool of infection for a pool of where the virus keeps replicating and that creates variants. At the end of the day, although the symptoms were not very severe, there was the long COVID. That was very worrisome. And there were kids that would have severe symptoms. So there was no doubt in my mind about the benefits completely were in favour of doing it.'.
>
> **BBC medical editor**: 'You are also doing trials in the under-fives. Do you think eventually we all see the under-fives being immunised?'.
>
> **Pfizer CEO**: 'We wait to see the studies. We were using very, very small doses. So we want to make sure that we were perfectly safe. The question was are we going to be effective in those low doses and this was what we were waiting to see. If the studies prove that these very low doses were effective. In this case I think it was a very good way to utilise those vaccines to protect them'.

The transcript clearly showed that Pfizer's CEO responded to two direct questions on vaccination of children. In the response he provided to the first question, he made it clear that the decision on whether to authorise the vaccines in the 5 to 11 years age group was the responsibility of the MHRA and that he was not in any way speaking on its behalf. He also explained that he was answering the question in the context of Covid-19 vaccination in general rather than specifically the Pfizer-BioNTech vaccine. He then went on to express his opinion that the wider benefits of vaccinating the 5 to 11 years age group were in favour of vaccination. His opinion aligned with the following evidence:

- Rising levels of Covid-19 infection seen in UK school age children in autumn 2021(UK Health Security Agency. Weekly national Influenza and Covid-19 surveillance report Week 46 report (Figure 5). 18 November 2021.) potentially representing a pool of infection and risk of transmission to peers, staff and families. An opinion piece in the BMJ published December 2021 highlighted the key issues.

- In the UK, the pandemic had resulted in two significant periods of school closures causing notable disturbance to the education system. Numerous reports document the detrimental impact of the disruption on children's wellbeing and learning. This included the OFQUAL review published in July 2021, which stated that the nature of learning loss varies depending on the phase of education. Primary leaders were most

likely to report significant learning loss, with the youngest pupils apparently most negatively affected by the pandemic.

- Whilst data concerning long Covid-19 are limited in young children, there was documented evidence of the occurrence of long Covid-19 in children aged 11 to 17 years. An article in the BMJ reported that one in seven children in the UK might still have symptoms 15 weeks after infection.

- The rare but concerning incidence of severe Covid-19 symptoms in children.

Pfizer submitted that the opinion provided by Pfizer's CEO in response to the interviewer's questions was fair, balanced and substantiable. Consistent with the requirements of the Code, Pfizer's CEO avoided reference to specific vaccines and their associated data. It was made clear in his responses when he was expressing a personal opinion and he clearly indicated that it was for the Regulator to determine whether any specific vaccine should be approved for use in the 5 to 11 years age group. Where the data were not yet available in the under-fives age group, he clearly stated that he was waiting to see these studies and described the safety versus efficacy balance that must be considered when assessing the results of those studies.

The complainant specifically highlighted the conclusions drawn by the JCVI in September 2021 on vaccination of children between the ages of 12 and 15 years old. However, the complainant did not appear to be aware of two subsequent updates to the guidance on vaccination of children that had been issued prior to the submission of their complaint on 11 December 2021:

i) On 13 September 2021, the UK CMOs subsequently recommended vaccination of children aged 12-15 years who were not already covered by the JCVI advice. The CMOs made this recommendation considering the likely benefits of lowering transmission of Covid-19 in schools and the consequent reduction in public health harm from educational disruption, in addition to the marginal advantage of vaccination at an individual level in this age group. They noted that the risks of vaccination, (mainly myocarditis) were also very rare. The CMOs therefore recommended on public health grounds that Ministers extend the offer of universal vaccination with a first dose of Pfizer-BioNTech Covid-19 vaccine to all children and young people aged 12-15 years not already covered by existing JCVI advice.

ii) On 29 November 2021, JCVI updated its advice about Covid-19 vaccination in response to the Omicron variant which included recommendation that all children and young people aged 12 to 15 years should be offered a second dose of the Pfizer-BioNTech Covid-19 vaccine at a minimum of 12 weeks from the first dose.

Pfizer stated that its CEO expressed an informed evidence-based opinion that was aligned with the conclusions of the UK's Chief Medical Officers and the vaccination strategy being implemented in the UK at the time of the interview. Pfizer therefore strongly rejected the complainant's allegations that the responses were exaggerated and did not support the rational use of medicines. Pfizer denied all breaches of Clauses 6.1, 6.2 and 14.4.

Pfizer had also developed an antiviral pill Paxlovid which in trials cut hospital admissions and deaths by nearly 90%.

Pfizer stated that the information provided in the article on the effectiveness of Pfizer's antiviral treatment candidate had not been attributed as a quote from Pfizer's CEO.

Clause 5.1 High Standards and CEO briefing

Prior to this interview with the BBC, Pfizer UK had briefed the CEO who was based in the USA, about the interview, the regulatory status of Covid-19 vaccines in the UK and the requirements of the Code. The company believed that Pfizer UK's approach to briefing its CEO and the response he provided to the BBC medical editor's questions maintained the standards expected of the industry. Pfizer therefore strongly refuted a breach of Clause 5.1 of the Code.

Clause 3.3 Alleged breach of Undertaking

Pfizer stated that the complainant cited three previous complaints where Pfizer was ruled in breach of the Code. These complaints related to the use of social media by two individual Pfizer colleagues and errors made by those colleagues in the application of Pfizer's Social Media policy to information related to Pfizer's Covid-19 vaccine that they liked and shared on LinkedIn. In accordance with the assurances provided to the Panel in relation to those cases, Pfizer had further enhanced its Social Media policy and training taking all possible steps to avoid similar breaches of the Code occurring in the future. Pfizer could not see any similarities between those cases and the interview that was the subject of this complaint which could represent a breach of undertaking and Pfizer therefore strongly denied a breach of Clause 3.3 of the Code.

Summary

Pfizer stated that it did not believe that the participation of its CEO in an interview with the BBC medical editor, rather than the business or financial editor, in itself, represented a breach of the Code and Pfizer therefore strongly denied a breach of Clause 26.2 in this regard.

The responses provided by Pfizer's CEO to specific questions from a journalist were balanced, fair, objective, unambiguous and were not misleading. They reflected evidence that were current at the time of the interview and were capable of substantiation. The responses were not promotional in nature and were appropriate for a media interview. Pfizer therefore strongly refuted any breaches of Clauses 5.1, 6.1, 6.2 and 14.4 of the Code.

In all media communications, a pharmaceutical company could only be held responsible for the information that it provided directly to the journalist, it was the responsibility of the journalist and news outlet to determine which elements of the information provided were considered newsworthy and were of public interest. Pfizer believed that the information provided by its CEO in response to these questions did not promote a prescription only medicine to the public and was factual and presented in a balanced way. It did not raise unfounded hopes of successful treatment and was not misleading with respect to the safety of Pfizer's vaccine. Pfizer therefore strongly refuted any breaches of Clause 26.1 and 26.2 of the Code.

Clause 26.4 of the Code set out the requirements for inclusion of instructions on 'Reporting of side effects' in materials related to a medicine intended for patients taking that medicine. Pfizer did not believe that this clause was relevant to this case and strongly denied a breach of Clause 26.4.

At the time of the interview, the Pfizer-BioNTech Covid-19 vaccine was being supplied to the UK as Comirnaty under a Conditional Marketing Authorisation. The provisions set out in Clause 11.3 of the Code related to temporary supply authorisation were therefore not applicable to any part of this complaint and Pfizer denied a breach of Clause 11.3. As Comirnaty was subject to a CMA, Pfizer did not believe that Clause 3.1 was relevant to this complaint and denied any associated breaches.

Pfizer stated that it did not believe the information provided by the Pfizer CEO during the pre-recorded media interview constituted, directly or indirectly, promotion to the public and nor did the information encourage members of the public to ask their health professional for a specific medicine Pfizer believed that high standards were maintained. The answers provided by Pfizer's CEO were factual and accurate, and aligned with published medical knowledge about Covid-19 at the time of the interview. Thus, Pfizer believed that high standards had been maintained and the company denied a breach of Clause 5.1. Pfizer did not believe that this situation had brough discredit upon, or reduced confidence in, the pharmaceutical industry and the company denied a breach of Clause 2 of the Code.

PANEL RULING

The Panel noted Pfizer's submission that it had been approached by the BBC for an interview with its CEO which was held on 22 November 2021. The news article and associated video interview, which were referred to in the complaint, were produced and published by the BBC on 2 December 2021. The Panel noted Pfizer's submission that the 45-minute interview was intended to cover news topics identified by the broadcaster about Pfizer's commitment to the global Covid-19 vaccine rollout and ongoing innovation to fight the pandemic. The Panel noted that complaints about third party articles in the press etc were judged upon the acceptability of the information provided to that third party by the pharmaceutical company, such as any press release, unedited interview etc rather than the final published article. The Panel noted Pfizer's submission that it had no editorial control or right to review the excerpts of the interview chosen by the BBC for inclusion in their news articles and no press briefing was issued to the BBC in association with the interview. The Panel also noted Pfizer's submission that it had not been able to obtain a full transcript of the interview from the BBC as the BBC's own policies did not allow this; it had, however, obtained some limited expanded excerpts from the interview. The Panel noted that it was obliged to make its rulings based on what Pfizer's CEO had actually stated rather than the edited published article and video. The Panel noted, therefore, that in relation to the quotations cited by the complainant, these could only be considered within the context of the overall interview based on the limited BBC transcript provided by Pfizer as part of its response. The Panel noted that the link to the video of the interview within the article was not active within the material before it. The Panel noted that the complainant bore the burden of proof whilst bearing in mind the evidence provided by both parties.

The Panel did not have the full unedited transcript of the interview nor had Pfizer provided a copy of the video. Whilst the complainant referred to the published video, it appeared that the substantive allegations related to the published article.

The Panel noted Pfizer's submission that prior to the interview, Pfizer UK had briefed the CEO who was based in the USA about the interview, the regulatory status of Covid-19 vaccines in the UK and the requirements of the ABPI Code.

The Panel noted that Clause 1.17 of the 2021 Code defined promotion broadly as any activity undertaken by a pharmaceutical company or with its authority which promotes the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicine. The Panel noted the comments that had been included in the article which were attributable to Pfizer's CEO within the context of the limited interview excerpt provided by Pfizer particularly 'Immunising that age group [children under the age of 11] in the UK and Europe would be a very good idea' and 'So, there is no doubt in my mind that the benefits, completely, are in favour of doing it [vaccinating children against Covid-19]' and considered that the strong unqualified nature of the comments were such that they promoted Covid-19 vaccines including the Pfizer-BioNTech Covid-19 vaccine.

The Panel noted Pfizer's submission that the Pfizer-BioNTech Covid-19 vaccine was initially granted an authorisation for temporary supply under Regulation 174 by the UK Department of Health and Social Care and the MHRA on 2 December 2020. A conditional marketing authorisation (CMA) was issued by the European Medicines Agency (EMA) on 21 December 2020 and was automatically converted to a CMA in Great Britain on 1 January 2021. The CMA issued by the EMA had continued to have effect in Northern Ireland since 21 December 2020. The Panel further noted Pfizer's submission that the supply of the branded Pfizer-BioNTech vaccine Comirnaty▼(tozinameran) to the UK under the CMA, commenced at the end of July 2021 with the last batch of the vaccine supplied under the temporary supply authorisation being delivered to the UK at the end of July 2021. The Panel noted, therefore, that at the time the CEO's comments were made, and subsequently published within the BBC article on 2 December 2021, the Pfizer-BioNTech Covid-19 vaccine did not have a temporary supply authorisation, it was the subject of a conditional marketing authorisation. In the Panel's view, the medicine therefore had not been promoted prior to the grant of its marketing authorisation and no breach of Clause 3.1 was ruled.

With regard to the alleged breaches of undertakings, the Panel noted that Case AUTH/3422/11/20 concerned a Pfizer UK employee 'liking' a post by Pfizer US via the Global Pfizer LinkedIn account which discussed the positive efficacy results of Pfizer's unlicensed Covid-19 vaccine. The Panel considered that, on the balance of probabilities, its subsequent proactive dissemination to all of the employee's connections, constituted promotion of the vaccine prior to the grant of its marketing authorisation in breach of Clause 3.1 of the 2019 Code.

The Panel noted that Case AUTH/3437/12/20 concerned a senior employee placing an uncertified promotional post on his/her personal LinkedIn account which linked to an article about the company's vaccine prior to the grant of its marketing authorisation which was 'liked' by a further employee. Both employees had acted in breach of company policy resulting in the promotion of the vaccine prior to the grant of its marketing authorisation on LinkedIn and was found in breach of Clauses 9.1 and 2. (Clause 3.1 was not raised).

The Panel noted that Case AUTH/3438/12/20 concerned a LinkedIn post from a senior UK employee which read 'So proud of the whole Pfizer team. What an amazing achievement #vaccines #proud' which was linked to a BBC article entitled 'Covid-19: The Panel noted that Pfizer/BioNTech vaccine judged safe for use in UK'. The Panel considered that it appeared that the senior employee had acted in breach of company policy and training resulting in the uncertified promotion of the vaccine on social media prior to the grant of its marketing authorisation and was found in breach of Clauses 9.1 and 2. (Clause 3.1 was not raised).

Turning to the current case (Case AUTH/3591/12/21), the Panel noted that it concerned excerpts from an interview with Pfizer's CEO which were subsequently published in an article by the BBC and referred to Pfizer-BioNTech Covid-19 vaccine which had a conditional marketing authorisation at the time. In relation to the alleged breach of undertaking, in the Panel's view, the current case, Case AUTH/3591/12/21, was sufficiently different to the previous cases such that there had been no breach of the undertakings given in Cases AUTH/3422/11/20, AUTH/3437/12/20 and AUTH/3438/12/20 as alleged. The Panel therefore ruled no breach of Clause 3.3.

In relation to the quotation 'Immunising that age group [children under the age of 11] in the UK and Europe would be a very good idea' and the alleged breach of Clause 3.1, the Panel noted Pfizer's submission that at the time the article at issue, including excerpts from the Pfizer CEO's interview, was published, the Pfizer-BioNTech Covid-19 vaccine was approved for use in individuals 12 years and older; no Covid-19 vaccines were approved by the MHRA for use in children under the age of 12 years. The Panel noted Pfizer's submission that the Pfizer-BioNTech vaccine was approved by the MHRA for use in children aged 5 to 11 years on 22 December 2021.

The Panel noted that the reasons for the alleged breach of Clause 3.1 here were slightly different to those ruled upon above and thus this matter was ruled on separately here. Whilst the Panel noted that the Pfizer-BioNTech Covid-19 vaccine was not licensed for use in under 12 year olds at the time the CEO's comments were made, and subsequently published within the BBC article, it did have a conditional marketing authorisation for use in those aged 12 and over. The Panel did not consider, therefore, that Clause 3.1, which required that a medicine must not be promoted prior to the grant of its marketing authorisation which permits its sale or supply was relevant and no breach of Clause 3.1 was ruled in relation to the quotation in question.

The Panel noted, however, that the Pfizer-BioNTech vaccine was not approved by the MHRA for use in children aged 5 to 11 years until 22 December 2021. Clause 11.2 stated that the promotion of a medicine must be in accordance with the terms of its marketing authorisation and must not be inconsistent with the particulars listed in its SPC. The Panel noted that Clause 11.2 had not been raised and so it considered the matter under Clause 5.1. The Panel noted that at the time the CEO's comments were made and subsequently published within the BBC article on 2 December 2021, the Pfizer-BioNTech vaccine was not approved for use in children aged 5-11 years. In the Panel's view, the statements attributable to the Pfizer CEO promoted the Pfizer-BioNTech vaccine in this age group and a breach of Clause 5.1 was ruled in this regard. This ruling was appealed by Pfizer.

The Panel noted that the complainant had referred to matters that were explicitly referred to in the relevant supplementary information to Clause 26.2 when stating that Pfizer could not claim any exemptions under the Code that might be applicable to business-related materials as set out in Clause 26.2 and when referring to the advice given to pharmaceutical companies about dealing with the media. The case preparation manager had raised Clause 26.2 and Pfizer had commented on it. The Panel noted the broad overlap between Clauses 6.1 and 26.2 in relation to quality standards and, noting the ultimate audience, considered that Clause 26.2 was directly relevant in relation to allegations raised by the complainant under Clause 6.1.

The Panel noted that the quotations 'Covid in schools was thriving' and 'This was disturbing significantly the educational system and there were kids which would have severe symptoms' were highlighted by the complainant. The Panel noted that Pfizer provided a BBC transcript of

this part of the interview. The quotations in question were slightly different in the transcript: 'I think that Covid in schools was thriving' and 'I believe that this is disturbing, significantly the educational system'. They appeared as part of a response to a question about whether immunising 5 to 11 year olds was likely to happen in the UK and Europe. The Panel noted the complainant's allegation that there was no evidence that healthy school children in the UK were at significant risk from the SARS COV-2 virus and to imply that they were was misleading; further, that Covid-19 itself had not had a significant impact on disturbing children's education in the UK and that the disturbance had resulted from political decisions made by government. The Panel noted Pfizer's submission that the evidence showed rising levels of Covid-19 infection seen in UK school age children in autumn 2021 potentially representing a pool of infection and risk of transmission to peers, staff and families. An opinion piece in the British Medical Journal (BMJ) published in December 2021 highlighted the key issues. Further, in the UK, the pandemic had resulted in two significant periods of school closures causing notable disturbance to the education system. The Panel further noted Pfizer's submission that numerous reports documented the detrimental impact of the disruption on children's wellbeing and learning. This included The Office of Qualifications and Examinations Regulation (OFQUAL) review published in July 2021, which stated that the nature of learning loss varied depending on the phase of education. Primary leaders were most likely to report significant learning loss, with the youngest pupils apparently most negatively affected by the pandemic. The Panel further noted Pfizer's submission that whilst data concerning long Covid-19 were limited in young children, there was documented evidence of the occurrence of long Covid-19 in children aged 11 to 17 years; an article in the BMJ reported that one in seven children in the UK might still have symptoms 15 weeks after infection. In relation to the cited quotations, the Panel did not consider that the complainant had established that the quotations were misleading or incapable of substantiation on the basis that there was no evidence that healthy school children in the UK were at risk from the SARS COV-2 virus as alleged. Based on the very narrow allegation, no breach of Clauses 6.1, 6.2 and 26.2 were ruled.

The Panel noted the allegation that the statement 'So, there was no doubt in my mind that the benefits completely are in favour of doing it [vaccinating children against Covid-19]' completely neglected to consider that there were potential risks to healthy children associated with the administration of the Covid-19 vaccine and the statement was therefore false and misleading in breach of Clauses 6.1, 6.2 and 26.2. The Panel noted the complainant's further allegation that it failed to promote the rational use of the medicine; the misleading presentation of the risk/benefit profile and the use of exaggerated, all-embracing claims ('no doubt' and 'completely in favour') allegedly represented a breach of Clause 14.4.

The Panel noted that a transcript of this part of the interview was provided to Pfizer by the BBC. The Panel noted Pfizer's submission that it showed that its CEO was asked a specific question by the journalist about vaccinating 5 to 11-year-old children against SARS-CoV-2 infection. The interviewer stated

> 'In October the FDA, the American regulator approved your vaccine for 5-to 11-year-olds after successful trials. Do you think immunising that age group is likely to happen in the UK and Europe? And if so, why is it a good idea?'

The Pfizer CEO responded:

> 'I think it will happen. I don't want to speak about specific candidates I don't want to speak about for the health authorities or the regulatory authorities of UK. It's up to them to

> approve it and use it or not. I believe it's a very good idea. I think that COVID in schools is thriving. I believe that this is disturbing, significantly, the educational system. I think is becoming the pool of infection for the adults. It is becoming a pool of infection for a pool of where the virus keeps replicating and that creates variants. At the end of the day, although the symptoms are not very severe, there is the long COVID. That is very worrisome. And there are kids that will have severe symptoms. So there is no doubt in my mind about the benefits completely are in favour of doing it.'

The Panel noted Pfizer's submission that the CEO made it clear that the decision on whether to authorize the vaccines in the 5 to 11 year group was the responsibility of the MHRA and he was not speaking on their behalf. He also explained that he was answering the question in the context of Covid-19 vaccination in general rather that specifically the Pfizer-BioNTech vaccine. He then went onto express his opinion that the wider benefits of vaccinating the 5 to 11 year age group were in favour of vaccination. The Panel noted from the transcript that there was a clear inference that a risk/benefit analysis would be undertaken by the regulator. On balance, however, the Panel considered that the subsequent strong opinion statements, including 'So, there was no doubt in my mind that the benefits completely were in favour of doing it [vaccinating children against Covid-19]' and 'I believe it's a very good idea' might infer to the ultimate audience, including members of the public, that there was no need to be concerned about potential side-effects which was not so. The Panel considered that this implication was incapable of substantiation and through phrases such as 'no doubt' and 'completely in favour', Pfizer's CEO did not encourage the rational use of a medicine. Breaches of Clauses 6.1, 6.2, 26.2 and 14.4 were ruled. These rulings were appealed by Pfizer.

The Panel noted that the supplementary information to Clause 6.1, emerging clinical or scientific opinion, stated that when a clinical or scientific issue existed, which had not been resolved in favour of one generally accepted viewpoint, particular care must be taken to ensure that the issue was treated in a balanced manner in promotional material. The Panel noted that at the time the Pfizer CEO's comments were made and subsequently published within the BBC article, there appeared to be differing opinion on the benefit of vaccinating children under 12. Whilst the Panel noted the CEO's statement that he/she 'did not want to speak for the health authorities or the regulatory authorities of UK, it was up to them to approve it and use it or not', the Panel considered that the CEO's opinion statements, including 'So there is no doubt in my mind about the benefits completely are in favour of doing it' might infer to the ultimate audience, including members of the public, that the benefits outweighed the risks when the regulatory authorities had not yet made any conclusions in relation to the vaccination of 5 to 11 year olds; the Pfizer-BioNTech Covid-19 vaccine was not licensed in the UK in that age group when the article at issue was published and the Panel therefore ruled a breach of Clauses 6.1 and 26.2. These rulings were appealed by Pfizer.

The Panel noted that the complainant raised Clause 11.3 within a section headed 'the Relationship of Pharmaceutical Companies with the Public'. The Panel noted its comments above setting out the dates upon which an authorisation for temporary supply had been granted under Regulation 174 and the dates upon which a CMA had been granted. The Panel noted that, at the relevant time, the Pfizer/BioNTech vaccine had a conditional marketing authorisation. Clause 11.3, which only applied to medicines with a temporary supply authorisation, was therefore not applicable and no breach was ruled.

The Panel noted that the complainant alleged breach of Clause 26.1 appeared to be on the narrow point that there was no information about side-effects. The complainant stated that 'It

was not clear to the complainant whether Clause 26.4 was applicable here or not but as no information whatsoever was provided about reporting of side effects, or indeed the side effects themselves then there must have been a breach of either Clause 26.4 or 26.1'. The Panel noted that the supplementary information to Clause 26.1, Vaccination and other Campaigns, approved by health ministers stated, *inter alia*, that such campaigns should include a general reference to the reporting of side-effects as it was unlikely that the requirements of Clause 26.4 would apply as the relevant material was not intended for patients taking a particular medicine. The Panel did not consider that the complainant had established that the interview with the CEO, excerpts of which were subsequently included in the BBC article, was such an approved campaign and thereby required a reference to reporting of side-effects. It appeared to be an interview requested by the BBC rather than part of an approved campaign. No breach of Clause 26.1 was ruled.

The Panel noted that the requirements of Clause 26.4 of the 2021 Code in relation to a statement for reporting of side-effects applied to any material which related to a medicine and which was intended for patients taking that medicine. The Panel did not consider that the complainant had established that the interview in question fell within the scope of Clause 26.4 such that it was intended for patients taking the Pfizer-BioNTech Covid-19 vaccine and therefore the requirements of Clause 26.4 were not relevant, and no breach was ruled.

The Panel noted its comments and ruling above and considered that Pfizer had failed to maintain high standards and a breach of Clause 5.1 was ruled. This ruling was appealed by Pfizer.

The Panel noted its comments and rulings above, including that the statements made by the Pfizer CEO did not encourage the rational use of the medicine, and considered that the briefing document by Pfizer UK did not sufficiently brief the CEO on how to address questions on children aged 5 to 11, despite this being described as a hot topic [See post Panel consideration note]. In this regard, the Panel noted that the briefing document from the UK office to Pfizer's CEO stated that vaccination in children aged 5 to 11 was a hot topic but did not actually instruct the CEO on how to respond to such questions; the briefing was limited to stating that there were no current plans to authorise the vaccine for ages 5 to 11 and that Pfizer would submit data on the 5 to 11 population to the UK regulator in the coming weeks. [See post Panel consideration note]. Further, whilst the briefing instructed the CEO not to promote nor state messages which could appear to encourage individuals to specifically ask their doctors for a prescription based on the information provided, it provided key messages, contradictory to this instruction such as 'I encourage anyone who is on the fence about receiving a vaccine to think again and to look at the science' and 'This is a decision that will not only affect your life but those you spend the most time with including your family and loved ones'. The Panel noted its comments and rulings above and considered that Pfizer had brought discredit upon, and reduced confidence in, the industry in this regard and a breach of Clause 2 was ruled. This ruling was appealed by Pfizer.

[Post Panel consideration note: Following notification of the Panel's rulings, Pfizer pointed out that the briefing stated 'No current plans to authorize the vaccine for ages 5-11 but this is hot topic behind closed doors within Government (not publicly in media)'].

APPEAL BY PFIZER

Pfizer submitted that it strongly disagreed with the Panel's rulings that the responses given by Pfizer's CEO, in this BBC interview, constituted breaches of the Code. On the contrary, Pfizer's

CEO responded carefully and thoughtfully to unsolicited questions from the BBC's Medical Editor on matters of significant national public health interest, namely the COVID-19 pandemic and the important role of vaccination in the global response to the pandemic.

Pfizer submitted that the responses given maintained high standards in compliance with Clause 5.1 of the Code and, in particular, fully upheld confidence in, and maintained the reputation of, the pharmaceutical industry in line with Clause 2 of the Code.

Background context

The interview

Pfizer submitted that the news article that was the subject of this complaint was produced and reported by the BBC. The article included written and edited video excerpts from a pre-recorded interview held on 22 November 2021 between the BBC's medical editor and Pfizer's CEO. Pfizer had no editorial control or right to review the excerpts of the interview chosen by the BBC for inclusion in its news articles. Pfizer had not been able to obtain a full transcript of the entire interview from the BBC as their own policies did not allow provision of such. Pfizer had identified a 5-minute podcast containing the same excerpts as the online article. Upon request, the BBC had provided an expanded transcript for the specific section of the interview about childhood vaccination that the company understood to be the focus of the complaint.

Pfizer submitted that as management of the COVID-19 pandemic was a matter of significant national public health interest, based on its role in the Government's pandemic response it was entirely appropriate for its CEO to be interviewed by the BBC's Medical Editor. Whilst the interview opportunity was aligned to Pfizer's priorities of open and transparent communication throughout the company's pandemic response, Pfizer recognised the care and consideration that must be taken in responding to journalists' questions. In recognition of this, and fully in line with the Code's requirements, a detailed briefing was provided to its CEO prior to the interview. The briefing covered the following topics:

- Pfizer's purpose for and desired outcome of the interview.
- Key environmental and media issues for background awareness – this included background information on the UK regulatory status of the vaccine in children.
- Key messages on relevant topics related to the pandemic.
- Specific guidance on the key requirements of the ABPI Code relevant to the interview situation.

COVID-19 Vaccines UK Therapeutic Indications at the time of the interview – November 2021:

Pfizer-BioNTech COVID-19 Vaccine	Conditional Marketing Authorisation for active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, **in individuals 12 years of age and older**
Moderna Vaccine	Conditional Marketing Authorisation for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals, **in individuals 12 years of age and older**
AstraZeneca Vaccine	Conditional Marketing Authorisation for active immunisation to prevent COVID-19 caused by SARS-CoV-2, **in individuals ≥18 years old**

Janssen Vaccine	Conditional Marketing Authorisation for active immunisation to prevent COVID-19 caused by SARS-CoV-2 **in individuals 18 years of age and older**

Focus of complaint and subsequent Panel ruling

Pfizer understood the focus of the complaint and the Panel's rulings of breaches of the Code to be the response provided by its CEO to a question asked by the journalist related to vaccination of children aged 5 to 11-years-old. The BBC provided the following transcript in response to Pfizer's request for details of any part of the interview relating to vaccination of children. The transcript obtained indicated that the interviewer asked two questions on this topic within the 45-minute interview which, along with its CEO's responses, were detailed below:

> '**BBC medical editor*:*** In October the FDA, the American regulator approved your vaccine for 5 to 11-year-olds after successful trials. Do you think immunising that age group is likely to happen in the UK and Europe? And if so, why is it a good idea?
>
> **Pfizer CEO*:*** I think it will happen. I don't want to speak about specific candidates I don't want to speak [about] for the health authorities or the regulatory authorities of UK. It's up to them to approve it and use it or not. I believe it's a very good idea. I think that COVID in schools is thriving. I believe that this is disturbing, significantly, the educational system. I think is becoming the pool of infection for the adults. It is becoming a pool of infection for a pool of where the virus keeps replicating and that creates variants. At the end of the day, although the symptoms are not very severe, there is the long COVID. That is very worrisome. And there are kids that will have severe symptoms. So there is no doubt in my mind about the benefits completely are in favour of doing it.
>
> **BBC medical editor:** You're also doing trials in the under-fives. Do you think eventually we'll see the under-fives being immunised?
>
> **Pfizer CEO:** We wait to see the studies. We are using very, very small doses. So we want to make sure that we are perfectly safe. The question is are we going to be effective in those low doses and this is what we are waiting to see. If the studies prove that these very low doses are effective. In this case I think it is a very good way to utilise those vaccines to protect them.'

The specific details of Pfizer's reasons for appeal were set out below.

Clause 5.1

Pfizer strongly disagreed with the Panel's ruling that its CEO's comments were strong and unqualified in nature and, as such, promoted the Pfizer-BioNTech Covid-19 vaccine for use in children aged 5-11 years. The BBC Medical Editor asked Pfizer's CEO a precise question on a topic of national relevance namely, whether he thought immunising 5–11-year-olds was likely to happen in the UK and Europe and, if so, why it would be a good idea.

Pfizer submitted that the Panel had failed to give due consideration to the fact that the published news article included limited elements of Pfizer's CEO's response to a specific question and therefore did not accurately reflect the context of the actual question asked and the full answer provided. Despite the Panel acknowledging that complaints about third party articles in the press must be judged upon the acceptability of the information provided rather than the final published

article, Pfizer was concerned that the Panel's ruling in relation to Clause 5.1 had failed to follow this accepted position. The Panel had, in effect, concluded that Pfizer was responsible for the BBC's editing of the content and had therefore wrongly and unfairly based its ruling of a breach of Clause 5.1 purely on the reported comments 'Immunising that age group [children under the age of 11 in the UK and Europe would be a very good idea' and 'So there is no doubt in my mind that the benefits, completely, are in favour of doing it [vaccinating children against COVID19]'.

Pfizer submitted that, in the Panel's comments relating to the breach of Clause 5.1, it had failed to give due consideration to a number of key facts which demonstrated that the response could not have been designed to promote, or have the effect of, promoting a specific medicine, namely:

- Pfizer's CEO was answering a direct and unsolicited question that asked whether he thought immunising the 5-11 years age group was likely to happen in the UK and Europe having, at that time, recently been approved by the FDA in that age group. And if so, why it was a good idea? Although the interviewer referred to the recent FDA approval of the Pfizer vaccine in that age group prior to asking the question, his actual question referred to immunisation generally and did not specifically ask about use of the Pfizer-BioNTech vaccine in this age group.
- Pfizer's CEO strictly answered the question asked and did not provide any additional information in his response that wasn't required to appropriately answer the question.
- As was clearly evident from the very beginning of his response, he was careful to acknowledge that he was not referring to any specific vaccines or candidates and, moreover, that it was for regulatory agencies to determine whether or not a specific vaccine candidate should be approved and used in a particular age group.
- The closing comment 'So there is no doubt in my mind about the benefits completely are in favour of doing it' was not intended to promote or encourage irrational use of a particular medicine or vaccine but related to the benefits of vaccination in general. Pfizer's CEO simply reflected his opinion that COVID-19 vaccination had been shown to play a leading role in helping protect the public's health and that vaccination of the 5-11 age group was a good idea with evidence-based examples of rising COVID-19 rates and the negative impact that COVID-19 was having on children. By expressing what was clearly articulated as an informed opinion, the audience was being invited to consider the topic for themselves and form their own opinion.
- In line with his briefing on the requirements of the Code, at no point was the Pfizer-BioNTech vaccine promoted either directly by name or indirectly through inference. The response given avoided any discussion of the specific data for the Pfizer-BioNTech vaccine.
- The definition of 'promotion' provided in Clause 1.17 of the Code included activity by a pharmaceutical company that promotes its own medicines. Pfizer's CEO did not specifically promote the Pfizer-BioNTech vaccine, and it was therefore wrong to apply the definition of promotion more broadly to cover discussion of medicines or vaccines generally.

Pfizer submitted that the above facts clearly demonstrated that Pfizer's CEO provided a responsible and considered answer to the question asked which maintained the high standards Pfizer applied to itself and that were expected of the company. The response was neither promotional in tone nor content and such a view could not have been reached if the above facts had been appropriately considered in the Panel's ruling on Clause 5.1.

Pfizer submitted that in the Panel's later comments relating to other alleged breaches of the Code, the Panel itself acknowledged that Pfizer's CEO's response to this question clearly inferred that a risk/benefit analysis would be undertaken by the UK regulator, and they also acknowledged that Pfizer's CEO explained that he was answering the question in the context of COVID-19 vaccination in general, not about specific candidates. The Panel elsewhere in its rulings also accepted that the examples cited by Pfizer's CEO of the negative impact of COVID-19 on this age group, were capable of substantiation and did not mislead and therefore ruled no breaches of Clauses 6.1, 6.2 and 26.2 in relation to these claims.

Pfizer submitted, however, that for reasons that were not clear to Pfizer, none of these points had been considered in the Panel's ruling in relation to Clause 5.1. Pfizer therefore strongly disagreed with the Panel's view that its CEO's comments promoted the Pfizer-BioNTech vaccine or that they were of a strong and unqualified nature and appealed the ruling of a breach of Clause 5.1.

Clauses 6.1, 6.2, 26.2 and 14.4

As set out above, Pfizer submitted that that its CEO had not promoted the Pfizer-BioNTech vaccine in his response to the question asked by the BBC medical editor. Through use of the phrases 'I believe' and 'in my mind', Pfizer's CEO made it absolutely clear that he was expressing a personal opinion in answering the question of why vaccinating this age group 'would be a good idea'. He talked about COVID-19 vaccination in general and supported his opinion that vaccination would benefit this age group with evidence-based examples of the negative impact COVID-19 was having on them. He did not make any suggestion or inference that there were no potential side-effects. He also made it completely clear that any use of the vaccine was subject to regulatory assessment before any decision by UK health authorities on administration of a vaccine would be made. Indeed, the Panel itself acknowledged that this clearly inferred that a risk-benefit analysis would be undertaken by the regulator.

Whilst Pfizer submitted that its CEO's answers did not promote or refer specifically to any of the data for the Pfizer-BioNTech vaccine, it was important to note that the opinion expressed by Pfizer's CEO was informed by the independent scientific opinion about vaccination of children aged 5 – 11 years that was available at the time. In the US the FDA and the Centre for Disease Control's (CDC) Advisory Committee on Immunisation Practices (ACPI) had recently completed its assessment of the Pfizer-BioNTech vaccine in 5–11-year-olds. The FDA had concluded that based on the totality of the scientific evidence available, the potential benefits of the Pfizer-BioNTech vaccine in individuals down to the age of 5 years, outweighed the known and potential risks (FDA Authorizes Pfizer-BioNTech COVID-19 [29-Oct-2021]) (copy provided). The ACPI's subsequent systematic review also confirmed that the benefits of vaccination outweighed the risks and they concluded that vaccination was important to protect children against COVID-19 and reduce community transmission of Sars-Cov-2.

Pfizer submitted that its CEO's opinion on the benefits of vaccination in this age group therefore accurately reflected, and could be substantiated by, the publicly available independent benefit – risk assessments conducted on the Pfizer-BioNTech vaccine by both the FDA and ACPI. The FDA had, in fact, noted that no serious adverse events had been detected in the ongoing study for the Pfizer BioNTech vaccine in this age group. Pfizer therefore disagreed that its CEO's response failed to encourage rational use of a medicine (Clause 14.4) and strongly believed that his answer was capable of substantiation (Clause 6.2) and was not misleading with respect to the safety of a medicine (Clauses 6.1 and 26.2) and Pfizer, therefore, appealed the rulings of breaches of Clause 6.1, 6.2, 26.2 and 14.4.

Clauses 6.1 and 26.2

Pfizer disagreed that at the time of the interview there appeared to be differing opinion on the benefit of vaccinating children under 12. In September 2021, Pfizer-BioNTech had reported positive data from the pivotal trial of its COVID-19 vaccine in children 5 – 11 years of age (Pfizer and BioNTech Announce results of study in 5-11-year-olds, copy provided). This was followed by the FDA and ACPI both determining the benefit-risk assessment of the vaccine to be in favour of vaccinating this age group (FDA Authorizes Pfizer-BioNTech COVID-19 [29-Oct-2021] and CDC ACPI recommendations for 5–11-year-olds, copy provided). The UK regulator had not expressed a different opinion, rather at the time of the interview had not yet made its assessment.

Pfizer submitted that whilst the response provided by Pfizer's CEO was not about a specific candidate, at the time of the interview, there was clear alignment across the available clinical study data and opinion from two globally respected independent regulatory and public health bodies that had assessed the Pfizer-BioNTech data and indicated a positive benefit. Pfizer's CEO's personal opinion was therefore fully aligned with leading clinical and scientific opinion. His opinion on the concept of vaccination in children was therefore based on up-to-date scientific evidence (Clause 6.1) and could not be considered to raise unfounded hopes of successful treatment and was not misleading with respect to the safety of a product (Clause 26.2). Pfizer therefore asserted that his comments were fully consistent with the requirements of Clauses 6.1 and 26.2 and appealed the Panel's ruling of breaches of these Clauses.

Clauses 5.1 and 2

Pfizer submitted that the responses provided by its CEO to the journalist's questions about childhood vaccination, in the context of the global public health crisis created by the COVID-19 pandemic, were appropriate and of the high standard expected of its industry.

It was important to note that the section of the interview that was the focus of the complaint actually consisted of two questions. In addition to the question on vaccination of 5 – 11 year olds, the interviewer also asked for Pfizer's CEO's opinion on whether vaccination of the under 5s would eventually happen. At the time of the interview no studies in the youngest age group had reported results and no regulatory assessment had been made in any country. Pfizer's CEO appropriately reflected this in his answer to the question. He stated that we must wait to see the study results and went on to explain that because very low doses of the vaccine were being used in the youngest children to ensure optimal safety, it was not yet known whether the lower doses of the vaccine would be effective at preventing COVID-19. Having explained this in a clear and responsible manner, he went on to confirm that if the benefit risk profile was positive then he thought it would be good to use the vaccines to protect the youngest children.

Pfizer's CEO answered the two questions asked on this topic appropriately and responsibly, with his opinions and responses being accurately aligned to the available evidence at the time. He did not make any claims about the Pfizer-BioNTech vaccine and simply provided accurate and evidence-based responses.

Pfizer submitted that its CEO's answers to these questions maintained the standards expected of its industry and Pfizer appealed the Panel's ruling of a breach of Clause 5.1.

In its ruling of a breach of Clause 2, the Panel considered that Pfizer had not appropriately briefed its CEO prior to the interview. The Panel specifically noted that the briefing inadequately addressed questions on vaccination of children aged 5-11 years and also that the briefing provided key messages on the topic of vaccine hesitancy that contradicted the instructions not to promote nor state messages which could appear to encourage individuals to ask their doctors for a specific prescription medicine. Pfizer strongly disagreed with the Panel's assessment of the briefing document.

Based upon media interest at the time of the interview, Pfizer reasonably considered that the topic of childhood vaccination would not be a specific focus of the interview and that it would primarily focus on access to vaccines across low and middle-income countries, referred to as 'Vaccine Equity'. As stated in the briefing document itself, whilst vaccination of the 5–11-year-olds was considered to be a hot topic within Government, it was not a focus of media attention prior to the interview. Information on the regulatory status of the Pfizer vaccine in children was therefore included in the briefing purely as background context on the UK environment. The key messages provided on the topic of adolescent/paediatric vaccination were of a general nature covering the general principles of vaccination and population immunity as well as highlighting the need for more data to be collected on the long-term impact of the pandemic on children. A briefing point was included highlighting Pfizer's continued work with the regulators around the world to submit data on younger populations for regulatory review. This information, when combined with the specific briefing points on the requirements of the Code, represented an appropriate and responsible briefing.

The Panel also submitted concerns relating to the briefing points on vaccine hesitancy. Specifically, 'I encourage anyone who is on the fence about receiving a vaccine to think again and to look at the science' and 'This is a decision that will not only affect your life but those you spend the most time with including your family and loved ones'.

The Panel suggested that theses briefing points appeared to encourage individuals to ask their doctor for a specific prescription only medicine. Pfizer strongly disagreed with this interpretation. The briefing points highlighted by the Panel represented 2 out of 6 points provided in the briefing on the topic of vaccine hesitancy. As was widely known, under the Government's COVID-19 vaccination deployment strategy, members of the public were not able to request or select a particular vaccine from the three vaccines being used in the UK at the time and, as such, any claim that individuals were being encouraged to ask their doctor for the Pfizer-BioNTech vaccine, was flawed.

Pfizer submitted that the other briefing points on vaccine hesitancy that had not been considered by the Panel included reference to the importance of community protection in a pandemic, highlighting Pfizer's commitment to full transparent communication throughout the vaccine development process and acknowledgement that some people still had questions about the vaccine that it was committed to addressing. The two points highlighted in the Panel's ruling did not refer specifically to the Pfizer vaccine, were intended to encourage people to base their decision making on the scientific evidence and consideration of the impact of the pandemic not just on themselves but also on the people around them. Given the amount of misinformation circulating about COVID-19 vaccines at the time, including the false claim that the Pfizer CEO's wife had died as a result of an adverse event caused by the Pfizer-BioNTech vaccine, the briefing points were designed to encourage people to make evidence-based decisions about vaccination.

Throughout the pandemic Pfizer submitted that it had been committed to making decisions based on the scientific evidence and these briefing points was fully aligned to that principle. The briefing points related to COVID-19 vaccination in general and were consistent with the UK Government's public health campaign that was live at the time. In Autumn 2021, the UK government's pandemic strategy was to encourage everybody eligible for a COVID-19 booster and flu vaccine to take up the offer to 'not only help to protect [themselves] and [their] loved ones, but [also to] help protect the NHS' (Government winter vaccination campaign press release[08-Oct-2021]).

Far from bringing the industry into disrepute, Pfizer submitted that the points included in the briefing, which encouraged people to consider vaccination using the available evidence without promoting the Pfizer-BioNtech vaccine, were entirely appropriate and responsible given the global COVID-19 crisis and UK government's vaccination strategy.

Pfizer submitted that the opinions expressed by its CEO on the benefits of vaccination in children accurately reflected, and could be substantiated, by the publicly available independent benefit – risk assessments available at the time of the interview. Pfizer's CEO clearly acknowledged that use of the vaccine in this age group was subject to the UK regulator and UK health authorities benefit risk assessment. Pfizer therefore considered that the CEO's opinion in no way encouraged irrational use of the vaccine in children aged 5-11 years and for all of the reasons set out above, Pfizer strongly disagreed that the interview and associated briefing brought discredit upon, and reduced confidence in, the industry and Pfizer appealed the Panel's ruling of a breach of Clause 2.

* * * * *

The terms of disclosure of one of Pfizer's enclosures ('a briefing document from Pfizer for an interview with the BBC on November 22, 2021') to the complainant could not be settled with the parties. Pfizer considered the briefing document to be confidential and initially did not want it to be shared with the complainant. The briefing document was not provided to the complainant when notified of the outcome of the Panel's consideration of the case as it was not considered relevant to enable him/her to decide whether or not to appeal the Panel's rulings of no breach of the Code. Upon Pfizer's appeal the issue of confidentiality of this enclosure which Pfizer re-submitted as part of its appeal was reviewed. A redacted version of the briefing document was settled by the Director as set out in Paragraph 7.5 of the PMCPA Constitution and Procedure. The terms of its disclosure to the complainant, however, could not be settled with the parties.

The complainant declined to receive the redacted version of the briefing document based on the terms of confidentiality and was originally sent Pfizer's appeal papers without this redacted Enclosure. The Chair of the Appeal Board was asked to decide how to proceed and decided that:

The procedure that would be followed was:

i) the Enclosure would not form part of the case papers meaning that neither the Appeal Board nor the complainant would see it
ii) the appeal would proceed on the basis that the quotes and summaries in the Panel decision and Pfizer's letter of appeal dated 1 August 2022 are accurate
iii) Pfizer was given an opportunity to identify any other parts of the Enclosure which the company asserts are relevant. The Chair agreed with the relevance of parts which had been identified by Pfizer.

iv) in order for all parties' ease of reference all of the relevant parts of the Enclosure would be extracted (ie the parts referred to in the Panel minute, in Pfizer's letter of 1 August 22, and in Pfizer's recent request) and put onto a single document, which would be part of the case papers.

The Chair decided that the relevant sections, quoted directly from the Enclosure, be included in one document titled 'Relevant extracts from Enclosure 22, a briefing document from Pfizer for an interview with the BBC on November 22, 2021.' and that this was shared with the complainant, Pfizer and the Appeal Board.

* * * * *

COMPLAINANT COMMENTS ON PFIZER'S APPEAL

The complainant stated that its response to Pfizer's appeal had been prepared without having had sight of the briefing document from the original pack of documents supplied to the Panel by Pfizer; if the complainant received that document in sufficient time before the appeal hearing it might be able to update its response, but otherwise the Appeal Board might regard this as its response.

In providing its comments, the complainant had identified thematically the key arguments raised by Pfizer and then explained briefly in each case why those arguments were not credible, not justified or not relevant.

To aid the Appeal Board's review, the complainant had also provided a table which cross-referenced the bold-typed statements in Pfizer's appeal with its most relevant comments.

The complainant identified each of the following arguments raised by Pfizer in its appeal submission, and commented as follows:

1 Argument 1: By prefacing key statements with phrases such as 'I believe' or 'in my mind' Pfizer's CEO was expressing personal opinions and was therefore either not speaking on behalf of Pfizer or otherwise his comments should not have been held to a Code standard as an official Pfizer statement.

A The complainant stated that if Pfizer was suggesting that statements made by its CEO, during an interview with the UK's national broadcaster was neither intended to be, nor would have been construed by any reasonable viewer, as a statement made in his capacity as CEO, this assertion would lack any credibility.

B The complainant stated that Pfizer's CEO was interviewed *because* he was the CEO and was presented as such in the broadcast. Both in common sense and at law it was beyond doubt that a CEO speaking in that public capacity was presumed to speak for his or her company and it was plainly the case that any comment the CEO made in this context should have been regarded, and thus moderated for Code purposes, as a statement made on behalf of Pfizer. The complainant suggested that it would be disingenuous to ask the Appeal Board to consider otherwise.

2 Argument 2: Pfizer's CEO was at key moments talking about vaccinations in general and was thus not promoting Pfizer's vaccine; and/or that his comments were merely factual and therefore not promotional.

A The complainant stated that it would be farcical to suggest that Pfizer's CEO's interview comments were not intended to be, or (more importantly) that they could not have been construed by any reasonable viewer, as promotional of Pfizer's vaccine regardless of whether he named that vaccine in each of his specific comments. Pfizer had not disputed that the Code applied to implied or indirect as well as express references.

B As noted above, the complainant stated that Pfizer's CEO was interviewed and presented not in a personal capacity but as global CEO of Pfizer; a core function of the CEO was undeniably to promote the success of that company and its products. At a time when only two vaccines were available for use with children in the UK (Pfizer and Moderna) and when the complainant understood that the Pfizer vaccine accounted for a significant proportion of those doses acquired by the Government for potential use with children in the UK, it was absurd to imagine that viewers would not have understood that the BBC editor and Pfizer's CEO were discussing the Pfizer vaccine in this context. If Pfizer's CEO expressed a view on the testing, approval, efficacy, merits or appropriateness of a vaccine for a specific age group, absent express words to the contrary it was plain that viewers would assume that his view reflected his sphere of knowledge: namely, that he was talking about Pfizer's vaccine product.

C The complainant stated that the Appeal Board would also have noted that the two questions posed by the BBC medical editor in each case referred to 'your vaccine' and 'you're also doing trials', which could only have meant Pfizer. The transcript affirmed that Pfizer's CEO's responses did not attempt to broaden out the discussion to reference any other vaccines, and indeed seemed clearly to affirm that he similarly assumed that the focus of the questions in each case was Pfizer's vaccine: 'It's up to them to approve it and use it or not' (emphasis added) rather than talking about 'a vaccine' or 'one of the vaccines'; and 'We wait to see the studies. We are using very, very small does. So we want to make sure that we are perfectly safe [etc]…' (emphasis added by the complainant).

D The complainant noted that Pfizer had asked the Appeal Board to accept that Pfizer's CEO's comment that 'I don't want to speak about specific candidates' was a careful acknowledgment that he was not referring to any specific vaccines and, in particular, that he was not referring at any point to Pfizer's vaccine. On the contrary, however, it was far from clear (to any reasonable viewer) whether Pfizer's CEO was using the word 'candidates' here to refer to candidate countries in the UK and Europe region which might decide to vaccinate children, or to vaccines that might be candidates for regulatory approval. Certainly, that ambiguous comment could not and did not have the magical effect suggested by Pfizer of causing all of its CEO's subsequent comments to be generic rather than specific to Pfizer.

E Though the complainant had been unable to verify it because it had not yet had access to the document, in its appeal Pfizer referred to the CEO's briefing document as having explained 'Pfizer's purpose for and desired outcome for the interview'. The complainant alleged that any argument that a 'desired outcome' of giving the interview was not, or did not, at least include, as a significant element, a promotional boost for Pfizer and thus for its vaccine was implausible.

F The complainant understood also that the same briefing document stated that Pfizer 'had no current plans' for 5 to 11-year olds and that it would merely 'submit data to the regulators in the coming weeks', yet Pfizer's CEO chose to go further in his comments by stating that 'If the studies prove that these very low doses are effective [which of course they had not done at this time], in this case I think it was a very good way to utilise those vaccines to protect

[children]'. In other words, Pfizer's CEO chose to go off-script to confirm in advance of those studies being completed (studies which might have revealed particular risks or nuances in the appropriate use of the product with very young children), that already his view was that using his company's vaccine in 5 to 11-year olds would be 'very good'.

3 Argument 3: Pfizer's CEO gave narrow limited responses to specific and unsolicited questions from a journalist which lacked a promotional tone and/or the BBC edited his comments such that the published article did not accurately reflect the context of the full questions and answers.

A From the transcript of the two relevant questions in full, the complainant stated that it was evident that the BBC had not presented either the questions or the answers out of context, nor had it misrepresented the CEO's comments. Indeed, Pfizer had not identified any specific example of its assertion that the response given did not accurately reflect the full answer provided, preferring instead to cite vague generalities. Indeed, on reading the transcript it became ever clearer that Pfizer's CEO's specific answer to the specific questions were promotional or had the effect of promoting benefits of Pfizer's vaccine, including in relation to children.

B The complainant was unclear why the Appeal Board was asked by Pfizer to accept that the questions posed to Pfizer's CEO were 'unsolicited'. While he might not have known precisely which questions would be asked, it was evident that the interview was planned and apparently well-prepared; and as the well-briefed CEO of a global pharmaceutical company, Pfizer's CEO should be expected to understand the parameters within which he could responsibly discuss and promote the Pfizer vaccine, including in relation to children, even in response to unscripted questions.

C On the topic of the allegedly narrow responses and absence of promotional tone in Pfizer's CEO's answers, the complainant referred back to its comments at paragraphs 2(A) to (F) above: the responses were plainly promotional of Pfizer's product and strayed beyond the narrow information required to answer the question. The complainant would add that the transcript evidenced that in answering the first question (the question on the merits of vaccinating the 5 to 11-years cohort) Pfizer's CEO had the opportunity, but made no attempt, to limit his answer and to avoid expressing a strong and unqualified view, and so, nevertheless, gave a strong and unqualified endorsement for the roll out of his company's vaccine.

D The complainant stated that the transcript supplied in Pfizer's letter was inaccurate in a significant respect because in the podcast link provided by Pfizer in its letter to the Authority and in the BBC archive copy of the BBC News at One video version of the published interview (https://archive.org/details/BBCNEWS_20211202_130000_BBC_News_at_One/start/360/end/420) Pfizer's CEO was heard to say 'So there is no doubt in my mind that the benefits completely completely are in favour of doing it'. (whereas the transcript erroneously records only one instance of 'completely') Pfizer's CEO's conviction was so strong and unqualified that he ventured to be 'completely completely' convinced.

4 Argument 4: Pfizer's CEO's comments reflected settled clinical/scientific opinion with regard to vaccination of children including 5 to 11-year olds, on which there was a consensus at the time.

A The complainant noted that Pfizer's argument in this area relied heavily on the status of its vaccine at the relevant time in the United States (the FDA, CDC and ACPI) all of which were substantially irrelevant for an interview given to the UK's national broadcaster for a UK audience. At that time, the regulatory position in the US and the UK differed in material respects; and perhaps most importantly, in the UK there had been no regulatory decision approving the use of Pfizer's vaccine for children in the 5 to 11-years cohort, and only a finely balanced, procedurally unorthodox and therefore potentially contentious decision for vaccinating 12 to 15-year olds. The Panel's ruling that in the UK there were differing opinions on the benefits of vaccinating children was plainly correct.

B The complainant stated by way of further background, in the UK:

- the Health Secretary, had in a speech to Parliament in November 2020, initially set a presumptive baseline that the Covid vaccine 'will not be used for children; it hasn't been tested on children … This is an adult vaccine for the adult population.';

- the MHRA in June 2021 approved the Pfizer vaccine for use with 12 to 15-year olds, and in an interview published by the BBC on 4 June 2021 the Health Secretary had stated that any roll-out for that age group would be based on *"clinical advice"* from the JCVI, advice which the UK Government 'would follow'; he stated 'I want to make sure that this is all done on a clinical base following the clinical advice…';

- the JCVI on 3 September 2021 then declined to endorse universal vaccination of otherwise healthy 12 to 15 year olds on clinical grounds, having concluded that 'the margin of benefit, based primarily on a health perspective, is considered too small to support advice on a universal programme of vaccination of otherwise healthy 12 to 15-year old children at this time…';

- on that same date the JCVI however agreed to pass to CMOs the final decision on whether vaccination of that age group should take place taking into account 'wider societal and educational impacts'; and

- by November 2021 neither the JCVI nor the MHRA had published any assessment of the appropriateness of the vaccine for use in the 5 to 11-year old cohort.

C The complainant stated that the fact that Pfizer itself had in September 2021 merely 'reported positive data' from a trial of its vaccine in 5 to 11-year olds, would, by itself, patently be self-serving and therefore insufficient to support Pfizer's argument that there was a clinical/scientific consensus on this topic in the UK and that Pfizer's CEO's comments were aligned with that consensus.

5 Argument 5: Pfizer's CEO mentioned that regulators would need to carry out a risk/benefit assessment and that Pfizer would need to complete its testing in the under-fives, and this was sufficient to discharge the obligation he otherwise had to acknowledge potential adverse events or to present his comments with balance so as to encourage rational use

A The complainant alleged that the Code was very specific about the need for product providers to discuss adverse events and safety in general; specifically, discussion focused exclusively on benefits without any discussion of risks or potential adverse events was, *de facto*,

unbalanced and thus not permitted. Pfizer's assertion that its CEO 'did not make any suggestion or inference that there were no potential side effects' was thus irrelevant; 'neither we nor the Panel stated that this was the case, the issue was that he made no effort to flag the possibility of side effects'.

B The complainant noted that Clause 6.1 referred specifically to information, claims and comparisons being 'accurate, balanced, fair, objective and unambiguous' and must not '… mislead either directly or by … undue emphasis'. Clause 14.4 states that 'Promotion must encourage the rational use of a medicine by presenting it objectively … all-embracing claims must not be made and superlatives must not be used except for those limited circumstances where they relate to a clear fact about a medicine'. Clause 26.2 buttressed these requirements and added that information about prescription medicines must not be 'misleading with respect to the safety of the product'.

C The complainant stated that Pfizer's CEO expressed both superlative and all-embracing promotional opinions about the benefits of vaccinating children with (for the reasons extensively explained above) Pfizer's vaccine, and with undue emphasis on benefits **(emphasis added by the complainant)**. Specifically:

> 'I believe it [vaccinating 5 to 11-year olds] is **a very good idea**.'
>
> 'So there is **no doubt** in my mind about the benefits **completely completely** are in favour of doing it.'
>
> 'If the studies prove these very low does are effective, in this case I think it is **a very good way** to utilise those vaccines to protect [the under-fives].'

D The complainant stated that Pfizer's CEO chose not to make reference to *any* potential risks or safety considerations in his comments to the BBC interviewer, let alone (for example) to the well-publicised concerns at the time potentially linking the vaccine to elevated instances of myocarditis in adults. Pfizer's CEO did not note 'the need for more data to be collected on the long-term impact of the pandemic on children' which the complainant understood from Pfizer's letter was included as a key message in his briefing. Nor did he mention that a listing of potential adverse events could be found in the SPC.

E The complainant stated that in the context of Pfizer's CEO's strong and superlative statements, and particularly his statement that there was 'no doubt the benefits completely completely are in favour' of vaccinating 5 to 11-year olds, a mere reference to regulators needing to 'approve it and use it or not', and to trials in under-5 year olds needing to be completed, was wholly inadequate and rendered his comments unbalanced and misleading. The Panel's ruling – that Pfizer's CEO's unqualified and superlative comments were incapable of substantiation and did not encourage rational use of a medicine – was correct.

F The complainant also noted that Pfizer's CEO acknowledged in his comments on vaccinating 5 to 11-year olds that Covid-19 symptoms in children were not severe, but also appeared then to suggest, without substantiation, that the Pfizer vaccine might play a role in preventing or mitigating Long Covid in children. To the complainant's knowledge, no such function or effect had been established in November 2021, and nor, to the complainant's knowledge, had it been included either as an indication or as a medicinal property in any Covid-19 vaccine SPC. Thus, any implicit promotion of this function as an unqualified benefit of the Pfizer vaccine

would surely have fallen far short of the requirement to promote rational use of the Pfizer vaccine.

6 Argument 6: The CEO's briefing document encouraged his compliance with the Code, that he/she complied with the briefing document and/or that he responded carefully and thoughtfully.

A As noted above, the complainant had not seen the briefing document so could not comment specifically on its content. The complainant stated that regardless, Pfizer was one of the most well-resourced pharmaceutical groups in the world, and consequently we are all entitled to expect that any briefing document provided to the CEO in this context would, at a minimum, have adequately explained the requirements of the Code, and encouraged Code compliance. Whether the CEO in fact read and understood that document, and whether it performed its intended role effectively, could be judged only by reference to the comments subsequently made, which, in this case, fell short of the Code's requirements.

B The complainant stated that in its original conclusions the Panel noted that the briefing document was inadequate for having failed to instruct the CEO how to respond to questions concerning vaccination of children; and because it was contradictory, insofar, as it included speaking notes at odds with the generic encouragement to avoid promotion and messages that could appear to encourage individuals to ask their doctors for a prescription. For the reasons stated above, and also with reference to the complainant's comments at paragraph 2(E), it remained quite apparent that either the briefing was inadequate on the topic of vaccinating children – as the Panel had already found – and/or that Pfizer's CEO ventured 'off-script' in a manner that he should have known would risk breaching the Code, which in fact it then did.

C The complainant stated that any suggestion made to the Appeal Board that (to paraphrase in the complainant's own words) Pfizer 'tried its best' to comply with the Code was plainly no excuse in these serious circumstances, or at all.

7 Argument 7: Pfizer was committed to maintaining high standards.

A The complainant alleged that as a corporate organisation, Pfizer would state that it was committed to high standards; and individual executives, including the CEO, would doubtless echo that sentiment if asked. But the evidence presently indicated that this aspiration had not been consistently realised, and it must surely be the role of the PMCPA to ensure that product producers in fact achieve those high standards by calling out behaviour that had fallen short.

B In addition to the points the complainant had set out above, and as already referenced in the Panel's original decision, the complainant alleged that Pfizer's recent record with the PMCPA complaints process in connection with the promotion of its Covid-19 vaccine was not unblemished. The complainant noted (potentially not exhaustively) the following other recent adverse findings:

- Case AUTH/3422/11/20, where Pfizer promoted its vaccine prior to the grant of its marketing authorisation in breach of Clauses 3.1, 14.1 and 9.1 of the 2019 Code (when Clause 9.1 dealt with maintaining high standards).

- Case AUTH/3437/12/20, where Pfizer again promoted its vaccine prior to the grant of its marketing authorisation in breach of Clauses 2 and 9.1.

- Case AUTH/3438/12/20, where essentially the same findings were made for similar behaviour.

- Case AUTH/3519/5/21, where Pfizer produced and distributed a press release which misled the general public about the efficacy of its vaccine in breach of Clauses 7.2 and 9.1.

C The complainant alleged that Pfizer might say that it was committed to maintaining high standards, but this claim rang increasingly hollow in light of the above and the facts underlying the present appeal. By upholding the Panel's original decision, the complainant asked the Appeal Board in this case – please – to reaffirm the message that high standards must be maintained and not just claimed.

8 Argument 8: Pfizer's CEO's comments were consistent with the UK Government's messaging on vaccination at the time.

A The complainant alleged that as a commercial pharmaceutical group, Pfizer was held to a special regulated standard in its communications in a way that the UK Government is not. The UK Government's approach to communicating information about Covid-19 and Covid-19 vaccines certainly had not been beyond criticism (as was now starting to emerge in admissions made by former Government ministers and senior civil servants), but it offered no shield to Pfizer that the UK Government might also have failed to meet the standards demanded by the Code had it been subject to it.

B The complainant alleged that as evidenced above, far from merely encouraging people to 'consider [childhood] vaccination using the available evidence' and without promoting the Pfizer vaccine, as Pfizer's appeal submission asserts, Pfizer's CEO made strong, unqualified, superlative, and factually-controversial comments about vaccinating children to promote the success of Pfizer and its vaccine product. For a global CEO to do this might be commercially understandable, but it was not excusable, and it most certainly brought Pfizer and the pharmaceutical industry into disrepute and would reduce confidence in the industry as a result.

The complainant set out a short table of cross-references that might assist in the review of its rebuttal of Pfizer's bold-typed appeal grounds. For all of these reasons, the complainant respectfully asked the Appeal Board to uphold the original Panel's decision in full.

The complainants' rebuttals of Pfizer's appeal statements:

Pfizer's appeal statement	**The most relevant of our rebuttals set out above**
Pfizer therefore strongly disagreed with the Panel's view that its CEO's comments promoted the Pfizer-BioNTech vaccine or that they were of a strong and unqualified nature and appealed the ruling of a breach of Clause 5.1.	Paragraphs 2(A) to (F). Paragraphs 3(C) and (D). Paragraphs 5(C), (D) and (E).

Pfizer's appeal statement	The most relevant of our rebuttals set out above
Pfizer therefore disagreed that its CEO's response failed to encourage rational use of a medicine (Clause 14.4) and strongly believed that his answer was capable of substantiation (Clause 6.2) and was not misleading with respect to the safety of a medicine (Clauses 6.1 and 26.2) and Pfizer, therefore, appealed the rulings of breaches of Clause 6.1, 6.2, 26.2 and 14.4.	Paragraphs 4 and 5.
Pfizer's CEO's opinion on the concept of vaccination in children was therefore based on up-to-date scientific evidence (Clause 6.1) and could not be considered to raise unfounded hopes of successful treatment and was not misleading with respect to the safety of a product (Clause 26.2). Pfizer therefore asserted that his comments were fully consistent with Clauses 6.1 and 26.2 and appealed the Panel's ruling of breaches of these Clauses.	Paragraphs 4(A) to (C).
Pfizer submitted that its CEO's answers to these questions maintained the standards expected of its industry and Pfizer appealed the Panel's ruling of a breach of Clause 5.1.	Paragraphs 5 and 7.
Pfizer submitted that the opinions expressed by its CEO on the benefits of vaccination in children accurately reflected, and could be substantiated, by the publicly available independent benefit – risk assessments available at the time of the interview. Pfizer's CEO clearly acknowledged that use of the vaccine in this age group was subject to the UK regulator and UK health authorities benefit risk assessment. Pfizer therefore considered that the CEO's opinion in no way encouraged irrational use of the vaccine in children aged 5-11 years and for all of the reasons set out above, Pfizer strongly disagreed that the interview and associated briefing brought discredit upon, and reduced confidence in, the industry and Pfizer appealed the Panel's ruling of a breach of Clause 2.	Paragraphs 4(A). Paragraphs 5(A) to (F). Paragraphs 7 and 8.

COMPLAINANT FURTHER RESPONSE TO THE APPEAL

In relation to the extracts from Enclosure 22, the complainant had the following comments to supplement earlier comments at paragraph 6(B) above:

1 The complainant alleged that it was now clear that the briefing document was flawed for having failed adequately to instruct Pfizer's CEO how to respond to questions concerning the vaccination of children; and it was also now clear that Pfizer's CEO chose to speak 'off script' when commenting on the vaccination of children. The complainant alleged a failure of the briefing note and a failure by the CEO.

2 The complainant alleged that it was evident, even just from these limited extracts, that while the section of the briefing dealing with the Code accurately noted the requirement for the Pfizer CEO to (a) avoid promotion, (b) present information in a balanced way and (c) avoid messages that could appeared to encourage individuals

to ask their doctors for a prescription medicine, the speaking notes included comments plainly at odds with that guidance because they attempted to promote uptake of the Pfizer vaccine and to encourage unvaccinated listeners/viewers to seek out the vaccine.

3 The complainant stated that specifically, the speaking notes encouraged the Pfizer CEO to leverage emotions of fear, guilt and shame to promote uptake ('you are only as protected as your neighbour' and 'this is a decision that will not only affect your life but those you spend the most time with including your family and loved ones') but without any recognition of the potential for risks or side effects, or indeed the possibility that an individual's personal circumstances might differentiate their situation. Worse still, the notes did this despite elsewhere acknowledging that, certainly in relation to children, critical data on the balance of benefits and risk of harms remained incomplete. The briefing notes made no effort to reflect nuance in this important topic, and thus perhaps it was unsurprising that the CEO's 's comments to the BBC also lacked balance and objectivity.

4 Regardless, the complainant stated that nothing in the briefing paper could anyway have served to exculpate Pfizer's CEO's comments in the interview. The issues at stake here turned on what he said in that interview, not on what he should have said, or what his communications team encouraged him to say; and the appeal must surely be judged on this basis.

APPEAL BOARD RULING

The Appeal Board noted Pfizer's submission that it had been approached by the BBC for an interview with its CEO which was held on 22 November 2021. The news article and associated video interview, which were referred to in the complaint, were published by the BBC on 2 December 2021. The Appeal Board noted Pfizer's submission that the 45-minute interview was intended to cover news topics identified by the broadcaster about Pfizer's commitment to the global Covid-19 vaccine rollout and ongoing innovation to fight the pandemic. Pfizer submitted that its objective for the interview was to reiterate its continued commitment to delivering equitable access to its COVID-19 vaccine across low- and middle-income countries which was a topic of particular media interest at the time. Pfizer submitted that it had reasonably considered that the topic of childhood vaccination would not be a specific focus of the interview. The Appeal Board acknowledged that Pfizer at the appeal stated that its CEO who was based in the USA had been given the briefing document and verbally briefed by an experienced media relations team and senior staff. Pfizer UK had briefed the CEO about the regulatory status of Covid-19 vaccines in the UK and the requirements of the ABPI Code. In response to a question at the appeal, Pfizer however acknowledged that perhaps additional wording could have been added to the briefing to help the CEO navigate the more complicated areas.

The Appeal Board agreed with the Panel that complaints about third party articles in the press etc were judged upon the acceptability of the information provided to that third party by the pharmaceutical company. The Appeal Board noted Pfizer's submission that it had no editorial control or right to review the excerpts of the interview chosen by the BBC for inclusion in its news articles and no press briefing was issued to the BBC in association with the interview. The Appeal Board also noted Pfizer's submission that it had not been able to obtain a full transcript of the interview from the BBC as the BBC's own policies did not allow this; it had, however, obtained some limited expanded excerpts from the interview. Pfizer at the appeal stated that

whilst the topic of vaccination in children appeared to be a focus in the online article, it formed only a small part of the complete 45 minute interview. The Appeal Board agreed with the Panel that it was obliged to make its rulings based on what Pfizer's CEO had actually stated rather than the edited published article and video. The Appeal Board noted that whilst it did not have the full unedited transcript of the interview, it had before it two questions and answers in relation to vaccination in children. One was not included within the online article and was not the subject of the complaint. The other was:

> **BBC medical editor**: 'In October the FDA, the American regulator approved your vaccine for 5 to 11-year-olds after successful trials. Do you think immunising that age group is likely to happen in the UK and Europe? And if so, why is it a good idea?
>
> **Pfizer CEO**: 'I think it will happen. I don't want to speak about specific candidates I don't want to speak about for the health authorities or the regulatory authorities of UK. It's up to them to approve it and use it or not. I believe it's a very good idea. I think that COVID in schools is thriving. I believe that this is disturbing, significantly, the educational system. I think is becoming the pool of infection for the adults. It is becoming a pool of infection for a pool of where the virus keeps replicating and that creates variants. At the end of the day, although the symptoms are not very severe, there is the long COVID. That is very worrisome. And there are kids that will have severe symptoms. So there is no doubt in my mind about the benefits completely [completely] are in favour of doing it.'

It was accepted that the Pfizer-BioNTech vaccine was not approved by the MHRA for use in children aged 5 to 11 years until 22 December 2021, after this interview.

The Appeal Board noted Pfizer's submission that its CEO was asked a specific question by the journalist about vaccinating 5 to 11-year-old children against SARS-CoV-2 infection. Pfizer at the appeal submitted that it was not unreasonable to talk about the principles of vaccination in this age group in general and that at the time, there were two other vaccine candidates being investigated in children under 12.

The Appeal Board noted that Clause 1.17 of the 2021 Code defined promotion broadly as any activity undertaken by a pharmaceutical company or with its authority which promotes the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicine. The Appeal Board considered the comments by Pfizer's CEO particularly 'Immunising that age group [children under the age of 11] in the UK and Europe would be a very good idea' and 'So, there is no doubt in my mind that the benefits, completely [completely], are in favour of doing it [vaccinating children against Covid-19]'. The Appeal Board determined that the strong unqualified nature of the comments were such that they promoted the use of Covid-19 vaccines in the 5-11 age group in general, but in the context of the whole answer the Appeal Board considered that those comments did not promote the Pfizer-BioNTech Covid-19 vaccine in isolation.

Clause 11.2 had not been raised in relation to the allegation that the Pfizer-BioNTech vaccine had been promoted for use in 5 to 11 year olds for which it was not approved at the time of the interview and so the Panel had considered the matter under Clause 5.1. The Appeal Board noted that Clause 11.2 stated that the promotion of a medicine must be in accordance with the terms of its marketing authorisation and must not be inconsistent with the particulars listed in its SPC. The Appeal Board, noting its comments above, did not therefore consider that Pfizer's

CEO had specifically promoted Pfizer's Covid-19 vaccine for use in the 5-11 age group and no breach of Clause 5.1 was ruled in this regard. The appeal on this point was successful.

The Appeal Board noted Pfizer's submission that the CEO made it clear that the decision on whether to authorize the vaccines in the 5 to 11 year group was the responsibility of the MHRA and that he was not speaking on its behalf; he also explained that he was answering the question in the context of Covid-19 vaccination in general rather than specifically in relation to the Pfizer-BioNTech vaccine and then went on to express his opinion that the wider benefits of vaccinating the 5 to 11 year age group were in favour of vaccination.

The Appeal Board noted that Clause 6.1 stated, *inter alia*, 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.'

and Clause 6.2 stated, *inter alia*, that:

> 'Any information, claim or comparison must be capable of substantiation.'

The Appeal Board further noted that Clause 26.2 stated, *inter alia*, that:

> 'Information about prescription only medicines which is made available to the public either directly or indirectly must be factual and presented in a balanced way. It must not raise unfounded hopes of successful treatment or be misleading with respect to the safety of the product.'

In the Appeal Board's view, the above clauses would apply if classes of medicines were referred to and not only a specific medicine.

The Appeal Board considered that the subsequent strong opinion statements, including 'So, there was no doubt in my mind that the benefits completely [completely] were in favour of doing it [vaccinating children against Covid-19]' and 'I believe it's a very good idea' might infer to the ultimate audience, including members of the public, that there was no need to be concerned about potential side-effects of vaccination in healthy children aged 5-11 which was not so. The Appeal Board considered that this implication was misleading and incapable of substantiation. The Appeal Board therefore upheld the Panels rulings of breaches of Clauses 6.1, 6.2 and 26.2. The appeal on this point was unsuccessful.

The Appeal Board noted that Clause 14.4 stated:

> 'Promotion must encourage the rational use of a medicine by presenting it objectively and without exaggerating its properties. Exaggerated or all-embracing claims must not be made, and superlatives must not be used except for those limited circumstances where they relate to a clear fact about a medicine. Claims should not imply that a medicine or an active ingredient has some special merit, quality or property unless this can be substantiated.'

The Appeal Board did not consider the claim failed to 'encourage the rational use' of a particular medicine and it therefore ruled no breach of Clause 14.4. The appeal on this point was successful.

Whilst the Appeal Board noted the Pfizer CEO's statement that he/she 'did not want to speak for the health authorities or the regulatory authorities of UK, it was up to them to approve it and use it or not', the Appeal Board considered that the CEO's opinion statements, including 'So there is no doubt in my mind about the benefits completely are in favour of doing it' might infer to the ultimate audience, including members of the public, that the benefits outweighed the risks when the UK regulatory authorities had not yet made any conclusions in relation to the vaccination of 5 to 11 year olds; no Covid-19 vaccine was licensed in the UK in that age group when the article at issue was published and the Appeal Board therefore upheld the Panel's ruling of a breach of Clauses 6.1 and 26.2. The appeal on this point was unsuccessful.

The Appeal Board noted the unique circumstances of the Covid-19 pandemic and noting its comments above including that Pfizer UK had briefed the Pfizer CEO about the regulatory status of Covid-19 vaccines in the UK and the requirements of the ABPI Code, it considered that in the particular circumstances of this case its concerns were covered by its rulings above, and a further ruling of a breach of Clauses 5.1 and 2 was not warranted. The Appeal Board ruled no breach of Clauses 5.1 and 2. The appeal on this point was successful.

Complaint received	**11 December 2021**
Case completed	**6 December 2022**