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AUTH/3591/12/21 - A complaint on behalf of UsForThem v Pfizer

Concerns about a Pfizer BBC news article

Received 11 December 2021

Case number AUTH/3591/12/21

Applicable Code year 2021

Completed 06 December 2022

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No breach Clause(s)	2	3.1	3.3	5.1	6.1
	6.2	11.3	14.4	26.1	26.2
	26.4				
Breach Clause(s)	6.1	6.2	26.2		
Sanctions applied	Undertaking received				
Additional sanctions					
Appeal	Appeal by the respondent				

Case summary

Full report

Case Summary

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 jobs 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

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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 ar [Back to top](#)

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

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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 inte

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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

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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 [Back to top](#)

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 in [Back to top](#)

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 whe [Back to top](#)

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 Pane'

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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 un-

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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

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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

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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

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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 inter

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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

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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-Bi

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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 [Back to top](#)

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

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