CASE AUTH/3815/8/23

COMPLAINANT v MODERNA

Complaint regarding tweets, articles and participant information sheets for a Moderna-sponsored clinical trial

CASE SUMMARY

This case was in relation to four tweets and two articles published online, all concerning recruitment of participants for a phase 3 clinical trial evaluating Moderna's COVID-19 vaccine. The tweets and articles had not been subject to the regulatory approval process.

The complainant also made allegations regarding the use of the word "safe" in a participant information sheet and an informed consent form for the same clinical trial.

There was an appeal by the complainant of seven of the Panel's rulings.

In relation to the tweets and articles, the outcome under the 2021 Code was:

Breach of Clause 2 [Panel's no breach ruling overturned at appeal]	**Bringing discredit upon, and reducing confidence in, the pharmaceutical industry**
Breach of Clause 5.1 (x2) [One of Panel's no breach rulings overturned at appeal]	**Failing to maintain high standards**
Breach of Clause 5.5 (x2) [One of Panel's no breach rulings overturned at appeal]	**Failing to be sufficiently clear as to the company's role and involvement**
Breach of Clause 6.1 (x3)	**Making a misleading claim**

No Breach of Clause 5.1 (x4) [One of Panel's no breach rulings upheld at appeal]	**Requirement to maintain high standards at all times**
No Breach of Clause 5.5	**Requirement to be sufficiently clear as to the company's role and involvement**
No Breach of Clause 6.1 (x5) [Two of Panel's no breach rulings upheld at appeal]	**Requirement that claims/information/comparisons must not be misleading**
No Breach of Clause 6.2 [Panel's no breach ruling upheld at appeal]	**Requirement that claims/information/comparisons must be capable of substantiation**

The participant information sheet and informed consent form documents were ruled out of scope of the Code. The outcome under the 2021 Code was:

No Breach of Clause 2	**Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**
No Breach of Clause 5.1	**Requirement to maintain high standards at all times**
No Breach of Clause 6.4	**Requirement that claims must reflect the available evidence regarding possible adverse reactions**

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

FULL CASE REPORT

A complaint was received from a contactable complainant about Moderna.

COMPLAINT

The complaint wording is reproduced below:

> "I am writing to you about the following four Twitter posts and an article on an NHS website, all of which are advertisements for participants in a Moderna-sponsored clinical trial known as NextCOVE
>
> **Tweet A:** [web link provided]
>
> This consists of a photograph of a 12 year old girl in what appears to be a school uniform. The accompanying text is ***'Take part in the new COVID-19 vaccine trial at the [@ account of named patient recruitment centre] now! If you are age 12+ & live in the [named local area], you can take part! P.S. all our junior volunteers get a lovely certificate and a 'be part of research' teddy bear Contact info below'***. This tweet was posted on June 9th 2023 from the account [of named research collaboration] . This group is collaboration between a number of organisations with the aim of encouraging clinical research in the [named location] area.
>
> **Tweet B:** [web link provided]
>
> This can be accessed by a link in tweet A and consists of two photos. Again there is the photo of the child with the teddy and her '*lovely certificate'* and the second photo is of the child with her mother and what would appear to be a clinician involved in the study.
>
> The associated text is ***'A huge thank you to Helen and Evie, who are the first people to take part in the new NextCOVE COVID-19 vaccine trial [@ account of named patient recruitment centre]! Helen joined us at the Patient Recruitment Centre [@ account of named NHS trust] today with her daughter Evie, who were both excited to participate in this important study.'***

The [named patient recruitment centre] have then responded to their own post with the reply ***'If you want to take part and are over the age of 12, please get in touch with us: [email address] or call [phone number] [@ account of named research collaboration] [@ account of named health and care partnership]'***

This tweet was posted on June 9th 2023 from the account of [named patient recruitment centre] which is the NHS Patient Recruitment Centre which is hosted within [named NHS Trust].

Tweet C: [web link provided]

This is a quote retweet of a [@ account of named patient recruitment centre] tweet, which itself is advertising the Moderna NextCove study. Tweet C contains the text: **'*This is a really important study that needs some young Research Volunteers (Hereos)!*** [sic] ***Please share [@ seven local accounts]'***

Tweet C was posted on July 3rd 2023, and is another from the account of [named research collaboration].

Tweet D: [web link provided]

This is a tweet posted by the [named NHS Trust] which links to an article on their website which also promotes recruitment of participants, including healthy children, into this clinical trial. The tweet consists of the same photo of child, parent and paediatrician along with the text: **'*Proud to have recruited our 1st participants to a new [@ account of named patient recruitment centre] #Covid #booster trial. If you're aged 12 - 60+ you can join too. Find out how [@ personal Twitter username] [@ personal Twitter username] [@ personal Twitter username] [@ personal Twitter username] @NIHRresearch*** **[web link to article described below]'**

This tweet was posted on 29th June 2023. [Named NHS trust] is the NHS trust to which the [named patient recruitment centre] belongs.

Article on website of [named NHS trust]: [web link provided]

This article is entitled ***'COVID booster study recruits first participants'*** and consists of an interview with participants and clinical staff involved in this study. It is also an advertisement to recruit participants into the study, including children.

The article is dated 29th June 2023 and there is a link to it in tweet D.

THE REGULATORY CONTEXT TO MY COMPLAINT:

I am writing to you because I believe that each of these interactions between these healthcare organisations, acting on behalf of an ABPI member company, and the general public fall well short of the principles and standards set out in your Code of Practice. I believe that there has been a serious failure to maintain high standards such as to bring discredit on your industry and therefore there have been breaches of Clauses 5.1 and 2 of your Code.

I do realise that advertisements for clinical trial recruitment are not specifically mentioned in your Code but I am unaware of any other regulatory body with responsibility for regulating these communications to which I can complain about this type of malpractice by ABPI members. Knowing that the PMCPA has now provided guidance on the use of social media for clinical trial recruitment, I have assumed that you are willing and able to take action when that guidance has been ignored.

In its Social Media Guidance Document published in January this year, the PMCPA correctly pointed out that when a pharmaceutical company engages with the public on social media ***'Care needs to be taken, particularly when in relation to a new medicine or extension of indications under investigation for a licensed product.'*** In this guidance document the PMCPA also posed some important questions for consideration by pharmaceutical companies when using social media.

These questions included:

- ***'Is the role of the pharmaceutical company clear?***
- ***Has access been limited to the appropriate intended audience? Is interaction with the social media activity limited or controlled, and if not how does this affect the risk of the activity?***
- ***What information is linked to and therefore forms part of the content?'***

There was also some other sound general advice on offer to companies when using social media, including:

'Pharmaceutical companies should always be transparent about the communications, activities and materials they produce, publish, sponsor, fund, or support on social media. Whenever a pharmaceutical company or a third party acting on its behalf publishes content on social media, it should clearly and prominently state the involvement of the pharmaceutical company and users should be aware of such involvement at the outset.

With regards to the ABPI Code, a pharmaceutical company is responsible for all material disseminated/activities carried out by it on any social media channel that comes within the scope of the ABPI Code including by a third party acting on its behalf even if that third party acts beyond the scope of its contract and potentially material/activities sponsored by it.'

'Pharmaceutical companies are strongly advised to preview social media content from their contracted parties in relation to their contracted activities'

It is notable that in the PMCPA Social Media Guidance Document there is included an entire section dedicated to Clinical Trial Recruitment which concludes: ***'When social media is used in relation to recruitment for clinical trials, pharmaceutical companies need to consider all other applicable codes, laws and regulations in this regard'.*** In particular that guidance reminds ABPI members, and other Code adherents, to consider ***'the requirements of the Health Research Authority (HRA).'***

With your guidance about consideration of all other applicable codes, laws and regulations, particularly the requirements of the HRA, in mind, I looked at the general

principles for advertising to, and communication with, the general public set out on the MHRA's website and Blue Guide. I also looked at the rules and processes relating to the ethical approval of clinical trials in the UK, over which the HRA has authority:

The MHRA Website [web link provided]:
It is stated clearly that when advertising medicines to the public you must not direct your advertising at children (under-16s). In this case it refers to the advertising of consumer or over-the-counter medication, but I am sure you will agree that such a principle must equally apply to POMs [(prescription only medicines)] or medicines under investigation. This UK regulatory position is further reiterated by the MHRA in their guidance document of the Medicines Advertising Regulations, the Blue Guide. In section 5.4 of this document it states that ***'Advertising of medicines should not be directed exclusively or principally at children (under-16s). Nor should advertising material aimed at parents and carers be included in non-promotional material aimed at children.'***

The principle that children are not suitable targets for the advertising of medicines thus seems clear and established.

IRAS Guidance: There is also guidance provided to applicants who wish to apply for official permission to conduct a clinical trial in the UK. Such applications are submitted electronically using the government's Integrated Research Application System (IRAS) which includes submission to a Research Ethics Committee (REC). IRAS guidance to applicants can be found at [web link provided]. The guidance is provided in the form of specific questions. Question A28 deals with clinical trial advertisements and states:

- ***'All advertising material designed to recruit participants must be reviewed by the REC. This includes posters, television and radio broadcasts, videos, CDs and web pages. Copies of these (printed material, audio or video tapes, transcripts etc.) should be included with your application and give a version number and date.***
- ***Recruitment material should be restrained in tone. Care should be taken not to over- emphasise potential benefits or make other inducements.'***

Although it is difficult to obtain specific guidance about clinical trial advertising in the UK, other countries are more overt in stating requirements in this regard. For example, in New Zealand, their governmental Health and Disability Ethics Committees [(HDEC)] provide a detailed list of 'Guidelines for [Clinical Trial] Recruitment Material' [web link provided].

'HDEC will review content, as well as the font size and type, and other visual effects, in determining whether materials meet the following guidelines.

1. ***No explicit or implicit claims should be made that the investigational treatment is safe or effective, unless this has been proven in the population and indication under study. Potential therapeutic benefit should not be overstated. Example: "Want to improve your diabetes? Enrol in our trial." would not be approved by HDEC.***
2. ***No explicit or implicit claims should be made that the investigational treatment is equivalent or superior to existing treatments, unless this has been proven in the population and indication under study.***

3. ***Recruitment materials should not use language such as "new treatment," "new medication," "new drug" or "new device" to describe investigational treatments, without explaining that the treatment is investigational. Such phrases may lead potential participants to believe that they will be receiving a treatment that has already been approved by Medsafe. Examples: "investigational medication" or "potential new medication" would be approved, but "new medication" or "new treatment" would not be approved. If the study involves an approved product this may be indicated, and the investigational component of the research outlined.***
4. ***For therapeutic studies where participants will receive investigational treatment or placebo, this should be stated. Potential participants may otherwise assume they will all receive active treatment.***
5. ***Phrases such as "Hurry", "Call now", "Don't miss out", "Places filling fast", "Enrolment limited" should not be used.***
6. ***Recruitment materials should not promote "free medical treatment" or "free specialist care" to refer to study-related care participants will receive.***
7. ***Potential study benefits should not be over-emphasised. The relative size of type used and other visual effects (placement of information, bolding, change in colour, animation, exclamation marks etc.) should not unduly promote compensation or benefits.***
8. ***If the trial is paid, specific compensation may be mentioned, but not emphasized e.g. through prominent placement, larger or bolder type, or other devices (flashing font, exclamation marks, etc.). Specific compensation should in general not be mentioned in recruitment material aimed at paediatric populations.***
9. ***Language, language devices or images that may be perceived as misleading, deceptive, ambiguous, or which play on fear should not be used. Example: "Asthma can be dangerous in kids" would not be approved by HDEC.***
10. ***For commercially sponsored or funded trials, the study funder should be stated.***
11. ***Where a third-party recruitment company is recruiting on behalf of a Sponsor and/or research site, the name and address of the research site and/or Sponsor should be included.***
12. ***A statement that the study has been approved by HDEC, together with HDEC study reference number, should be included.***
13. ***If stock photos of persons are used in recruitment material, efforts should be made to ensure that these are representative of the New Zealand population.***
14. ***Though not required, advertising material may include the following information to help potential participants make the decision to take part in a study:***
    - ***the condition under study***
    - ***the purpose of the research***
    - ***a summary of eligibility criteria in lay language***
    - ***a general description of the time commitment for the study***
    - ***who to contact for more information.'***

Whilst this guidance carries no legal or regulatory authority in the UK, I am sure that you will agree that most of the principles represented within it are sound. Maybe the ABPI and the PMCPA would wish to consider lobbying for some similar detailed official guidance in the UK?

The Medicines for Human Use (Clinical Trials) Regulations 2004 also explicitly prohibit the giving of incentives or financial inducements to children under the age of 16 to participate in clinical trials of investigational medicinal products.

MY COMPLAINT:

All four of the tweets listed above, and the article published on the NHS website, are clearly in breach of the high standards the British public are entitled to expect of such advertisements. In particular:

Tweet A: This communication is clearly and inappropriately directed specifically at children. The promise of a teddy bear and a ***'lovely certificate'*** as an inducement and reward for their participation is quite shocking. Furthermore, the tweet is highly misleading. The investigational product is described as a ***'new covid vaccine'*** with no indication or suggestion that it is an investigational product still in development, with all the attendant risks and unpredictable benefits (if any) for the children at whom it is directed. It also states that ***'If you are age 12+ & live in the [named local area], you can take part!'***, implying that everyone who applies will be able to participate. There is also no mention of the fact that this study is sponsored by Moderna, or even that it is an industry-sponsored study at all.

Tweet B: Once again there is an image of the 12-year-old girl with her teddy and her ***'lovely certificate'***. Again the tweet is directed at children as the posting account replies to its own post: ***'If you are over the age of 12 and want to take part…'*** This time children (and adults) are invited to participate in ***'the new NextCOVE Covid-19 vaccine trial'*** again with no indication that the 'new' vaccine is unproven, unlicenced and still under investigation. The description of the two participants being ***'excited to participate in this important study'*** does not seem compatible with the IRAS ethical requirement to be ***'restrained in tone'.*** Again there is no mention of Moderna or pharmaceutical industry involvement.

Tweet C: ***'This is a really important study that needs some young Research Volunteers (Hereos)!'*** [sic] This is an appeal to the emotions of the young person which is entirely inappropriate for a clinical trial advertisement and it is certainly not language which is ***'restrained in tone'***.

Tweet D: ***'Proud to have recruited our 1st participants to a new [@ account of named patient recruitment centre] #Covid #booster trial. If you're aged 12 - 60+ you can join too.'*** Another tweet aimed directly at children as well as adults. Again use of the word 'new' without any indication that this is an investigational product, under development, unlicenced with no proven efficacy and with an unknown risk profile. Once again, no mention of industry-sponsorship or of Moderna's involvement. Once again, there is the misleading implication that all who fall within the desired age range will be able to participate in the trial.

In addition Tweet D contains a link to the article on the website of [named NHS Trust] entitled ***'COVID booster study recruits first participants'***, which consists of an interview with people involved in the study and is also an advertisement to recruit participants into the study, including children. As an advertisement for clinical trial recruitment this article falls well short of the standards required:

- The paediatrician interviewed, [named paediatrician], who is also the study's lead investigator in [named location], says: ***'We're really excited to be running this trial here at the PRC because we know that vaccinations do work and they can make a big difference to adults as well as children.'*** This statement fails to exhibit the restrained tone required. It also misleadingly implies that the investigational vaccine is effective and overstates any potential therapeutic benefit that participants can expect.

- [Named paediatrician] then goes on to say: ***'we know vaccinations prevent people from getting unwell. This is a COVID vaccination study that is using a smaller dose than that which has been used in the past. I would encourage adults and children aged over 12 years to take part in this trial.'*** This is misleading and inaccurate. It implies that this is some kind of dose-finding study comparing different doses of the existing licenced product, which it is not. This study will investigate if the investigational vaccine mRNA-1283.222 when given as a booster dose in participants aged 12 years and older is safe and effective in prevention of COVID-19, when compared to the currently authorised vaccine, SPIKEVAX (mRNA-1273.222). It is not simply a test of a smaller dose of an existing product. He then goes on to compound his misleading statement by saying ***'What we are trying to determine is whether, by using a smaller dose of vaccine to the original COVID vaccines, the antibody response is the same, i.e. will the booster offer people the same level of protection against the virus, and is the booster just as effective'***. When people, including children, are being asked to participate in the study of a new investigational product, and not just a lower dose of the existing one, then surely they are entitled to expect that they will not be misled in this way by a lead investigator in an advertisement for that study.

- The article then goes on to say that [named paediatrician] ***'urged people to come forward and take part in the trial in order to help protect themselves as well as others'.*** This statement implies that participation in the study will be certain to help protect the participants. Again no suggestion or indication here that participants may receive the investigational product and therefore may get no protection whatsoever, whilst at the same time exposing themselves to unknown levels of risk from an investigational product. Even if they did receive the licenced product then based on the current recommendations of the UK government it is unlikely that they would be significantly helping to protect themselves. At present, the only children in the UK for whom a Covid vaccine is available are those aged 6 months to 4 years in a high risk category; the offer of a vaccine to all other children has been withdrawn. For the autumn/winter booster program this year it is anticipated that only high risk cohorts will be offered a booster, and indeed healthy young adults are not now recommended to have boosters at all. This approach of course reflects an appreciation of the low risk of illness to which healthy young adults and children are exposed from the virus. The claim by [named paediatrician] that they may also be

helping to protect others is also not supportable. The currently licenced comparator has no data to support that claim and it certainly does not have a licenced indication to that effect. The investigational vaccine is not being investigated for its ability to prevent transmission of infection so how can [named paediatrician] claim that participants will be helping to protect others in this way? These are emotionally loaded and unsupportable claims that do not meet the requirements set out in IRAS guidance that ***'Recruitment materials should be restrained in tone. Care should be taken not to over-emphasise potential benefits or make other inducements.'***

- [The named paediatrician] concludes by saying: ***'It is evolving all the time and we don't know what COVID will look like in the winter of 2023/24 and beyond that for example. It can still be a threat to many people who are vulnerable, there are many people still at risk of the virus being very debilitating for them and causing severe illness. Developing an effective booster is the way forward in protecting ourselves'*** Once again [the] language is emotional, intemperate, inaccurate and misleading. There are indeed people at risk of severe and debilitating respiratory illness, including covid. However, the extensive data now available indicate that healthy children, indeed also the majority of healthy adults within the age range recruited into this study, are very unlikely indeed to be amongst them. Such an egregiously misleading 'play on fear' would, I believe, be unlikely to be approved as a recruitment tactic by the HDEC in New Zealand; why would we expect lower standards to be applied here in the UK?

- The article then goes on to quote a participant in the trial. This participant is a medical secretary in the NHS trust within which the [named patient recruitment centre] is based. She is also the mother of the 12 year old child referred to in the tweets above and so presumably consented for her child to participate as well as herself. This participant is quoted as saying ***'I was reassured by [named paediatrician] regarding the minimal risks associated with the trial…'*** Describing the risks of administering any investigational medicinal product to anyone, let alone a child, as 'minimal' is breathtakingly and dangerously complacent language unworthy of an advertisement for any clinical trial. The trial brochure acknowledges that ***'… we are still researching the product and we do not know if it is effective and safe to use. We do not know if it will prevent SARS-CoV-2 infection or reduce the severity of COVID-19 illness'***. It mentions possible side effects including fever, headache, aches and pains typically lasting between 2 and 3 days. However, there is no mention of myocarditis in the information leaflet, despite the fact that the highest age group for this serious complication is 16–17s according to information presented to the FDA. Many reports of myocarditis only include the Pfizer vaccine which was the predominant mRNA vaccine in use, but a study from Canada shows the incidence of myocarditis after Moderna was significantly higher than after the Pfizer vaccine, especially in young adults aged 18–29. Far from side effects 'typically lasting between 2 and 3 days', the effects of myocarditis may include permanent scarring to heart muscle with increased risk for sudden death. It has been suggested that post-vaccination myocarditis in children is mild and settles quickly, but this is not borne out by the facts. There has been sufficient concern that the FDA is now funding a large study of children with MACiV: Myocarditis After Covid Vaccination. An analysis of the results from the original Pfizer and Moderna mRNA vaccine trials found that 1 in 800 suffered a 'serious adverse event of special

interest', as defined by the WHO- endorsed Brighton Collaboration. Thus, even if one still believes that the risk/benefit calculation remains in favour of their use for everyone, to describe the risks as 'minimal' in a recruitment advertisement for a trial involving an investigational mRNA vaccine is completely unacceptable.

In summary, the tweets and article discussed above have failed on multiple counts to comply with the PMCPA guidance on the use of social media including failing to meet the standards set out in other sets of rules, regulations and guidance.

Overall, and viewed as a group of advertisements for recruitment to a Moderna-sponsored study they have:

- targeted children
- failed to disclose Moderna-sponsorship
- failed to use restrained language
- used inaccurate, not substantiable and misleading claims for efficacy and safety
- used exaggerated and superlative claims of safety
- made misleading claims about the likelihood of applicants being chosen for inclusion
- used inappropriate inducements aimed at children such as toys
- been misleading regarding the investigational and developmental status of the vaccine under investigation
- been misleading as to the design and purpose of the study
- used inappropriate and emotional language to induce fear in order to incentivise recruitment

Whilst none of these items were posted or published by Moderna, they were all posted by the [named patient recruitment centre] contracted to conduct this Moderna-sponsored study, the NHS trust hosting this PRC, or other healthcare groups or individuals closely associated with these two organisations. As you point out in your social media guidance, and as I have mentioned above:

'Pharmaceutical companies should always be transparent about the communications, activities and materials they produce, publish, sponsor, fund, or support on social media. Whenever a pharmaceutical company or a third party acting on its behalf publishes content on social media, it should clearly and prominently state the involvement of the pharmaceutical company and users should be aware of such involvement at the outset.

With regards to the ABPI Code, a pharmaceutical company is responsible for all material disseminated/activities carried out by it on any social media channel that comes within the scope of the ABPI Code including by a third party acting on its behalf even if that third party acts beyond the scope of its contract and potentially material/activities sponsored by it. Pharmaceutical companies are strongly advised to preview social media content from their contracted parties in relation to their contracted activities'

I do not know if either Moderna or the lead investigator sought review and approval for these materials as required by the IRAS guidance: ***'All advertising material designed to recruit participants must be reviewed by the REC'***. I find it difficult to believe that

any REC would approve such recruitment materials, particularly when they are targeting children.

Moderna are paying this NHS organisation to recruit participants into their study and to test their investigational product on those participants, including children. I do not know if Moderna previewed any of this internet material but whether they did or did not, they clearly still remain responsible for the appallingly low standards of ethics, accuracy and honesty displayed within it. That is why I believe that, at a minimum, breaches of Code clauses 5.1 and 2 have taken place here."

In a follow-up email, the complainant provided a link to a website and wrote:

"Please also give consideration to this article which appeared on a local news website and is also an advertisement for recruitment into the NextCOVE study by [named patient recruitment centre], probably as a result of a press release from [named patient recruitment centre] or [named NHS trust]. It contains the same unethical, inaccurate and misleading statements as can be found on the article on the NHS website to which I referred in my previous email."

When writing to Moderna, the PMCPA asked it to consider the requirements of Clauses 2, 5.1, 5.5, 6.1, and 6.2 of the Code.

FURTHER INFORMATION FROM COMPLAINANT (1)

"I have now obtained access to other documents relating to this trial, documents which were obtained using rights under the UK Freedom of Information Act [(FOIA)]. I am afraid that at least two of these documents are also in breach of your Code of Practice [documents attached].

On page 5 of document one, the ICF [(informed consent form)] for the parent of a child to be recruited into this study, the currently licenced Moderna vaccine is described as 'proven to be safe…'. On page 2 of document 2, the 'Main' ICF, the same vaccine is described as 'safe'. Both of these uses of 'safe' are in breach of clause 6.4 of your code. I have not conducted a detailed search of these documents to determine whether there are any other illegitimate, misleading uses of 'safe' within them but I believe that these two examples are enough to demonstrate clear breaches of your code.

In addition, these statements are used to supposedly inform prospective clinical trial participants, including children and their parents, and to enable those participants, or their parents, to give fully informed consent. They are therefore very important documents indeed and the readers must be able to trust the contents. I would also therefore contend that breaches of clause 5.1 (failure to maintain high standards) have also taken place, along with breaches of clause 2 (failing to maintain confidence in, and bringing discredit upon, the pharmaceutical industry)."

The complainant followed up with a clarification:

"Many apologies, there was an error in my previous email. It is actually on page 5 of both of these documents that the claim is made that the currently licenced Moderna vaccine 'has been proven to be safe…'"

FURTHER INFORMATION FROM COMPLAINANT (2)

"In my original complaint to you about these advertisements I said 'I do not know if either Moderna or the lead investigator sought review and approval for these materials as required by the IRAS guidance' and 'I find it difficult to believe that any REC would approve such recruitment materials, particularly when they are targeting children.'

I am writing to let you know that I have now been finally and officially informed by the NHS's Health Research Agency (the HRA) that these advertisements were indeed never approved by the Research Ethics Committee (REC) as they should have been. In their response letter to me the HRA make the following points which may be of interest to you:

> 'The Sponsor has notified the HRA which has recorded the use of these advertisements without a REC favourable opinion in place as a breach'
>
> 'It is the responsibility of the sponsor to ensure that all study recruitment materials have been appropriately reviewed before they are used. As part of contacting the sponsor in relation to using advertising materials without a REC favourable opinion, we have reminded the sponsor that all advertising materials including social media advertising must be submitted to the Research Ethics Committee for review.'
>
> 'Whilst a breach has been identified in relation to the use of a small number of advertisements for the NextCOVE trial, this by itself would not warrant the REC to reconsider its favourable ethics opinion [for the whole clinical trial] We would instead expect the sponsor to inform us what corrective and preventative action has been taken to ensure that the matter is addressed and that measures are put in place to prevent a reoccurrence.'

I understand that most of the offending materials have now been taken down. However, as this was done only after all UK recruitment into this study had ceased, the effect of this withdrawal on the impact of these unapproved adverts on recruitment will have been zero. The impact of these unapproved advertisements, particularly on children, is difficult to gauge but it is worthy of note that, as a result of Freedom of Information requests, we now know that the [named] centre which produced them recruited far more children than any other centre in the UK. It is also worthy of note that not all the material has actually been withdrawn. Two press articles based on this unapproved and misleading NHS/Moderna material are still accessible to the public: [web links provided].

Whilst I understand that neither the PMCPA nor the HRA have the authority to require the press the [sic] edit or remove articles, I believe it is essential that they are still informed about any important and authoritative decisions and judgements regarding the unapproved, unethical and misleading nature of the materials upon which they were based."

FURTHER INFORMATION FROM COMPLAINANT (3)

"I have now obtained access to further documents relating to this study, again using FOIA rights, which I believe are relevant to this case and in particular to my complaint about the content of the two documents referred to in [my previous] email. I have attached a copy of the minutes of the meeting of the [named] Research Ethics Committee (REC) which reviewed these documents as part of the clinical trial application (CTA) for this study.

In these minutes (dated 11/4/2023), in requirement number 6, on page 12, in the 'Action Required' column, the sponsors/investigator were required to do the following: ***'Revise the unqualified use of the word "safe", e.g., on page 2 of the assent document. Use "acceptable safety profile" or similar.'*** It would appear that the required change was indeed made on page 3 of that document. However, despite the fact that Moderna must have known that the licenced vaccine was described as ***'proven to be safe'*** on page 5 of both of the documents which I have provided to you, they did not also make the same changes to these uses of the word 'safe'. So, despite the fact that the REC had already pointed out to Moderna that use of 'safe' was not acceptable, Moderna still did not see fit to ensure that there were no other such inappropriate uses of the word within the participant-directed documents. This was either because they did not care or because there were unaware that the word 'safe' was being used in these instances. In either case, considering these were documents intended to be read and understood by children and their parents, this represents unacceptable incompetence and/or negligence. I strongly believe therefore that these REC minutes further support findings of breaches of clauses 6.4, 5.1 and 2 of your Code."

MODERNA'S RESPONSE

The response from Moderna is reproduced below:

"We have provided the requested information and our response to the complaint allegations referencing the specific clauses of the ABPI Code highlighted in your letter, below.

1. Moderna UK's affiliate, ModernaTX, Inc., is the sponsor of the NextCOVE clinical trial which is a Phase 3 study evaluating the bivalent COVID-19 investigational vaccine mRNA-1283.222 as a booster dose compared with mRNA-1273.222 in adults and children aged 12 years and over.

2. The NextCOVE trial has been authorised in the UK by the MHRA and approved by the Health Research Authority and Health and Care Research Wales following a favourable opinion from the [named] Research Ethics Committee.

3. Patient Recruitment Centres are research sites funded by the National Institute for Health and Care Research ('NIHR'). The [named patient recruitment centre] is hosted by [named NHS trust]. [Named research collaboration] is a collaboration of research organisations, including [named NHS trust].

4. [Named patient recruitment centre] is one of the UK study sites in the NextCOVE trial. ModernaTX, Inc. has entered into the national model Clinical Trial Agreement with [named NHS trust]. The model CTA includes at Clause 9.3 '*Neither the Trial Site, nor the Principal Investigator, will issue any information or statement to the press or public including but not limited to advertisements for the enrolment of Clinical Trial Subjects without the prior written permission of the Sponsor or CRO* [(contract research organisation)] *as appropriate, not to be unreasonably withheld, and the delivery of research ethics committee approval, where applicable.*'

5. As part of the research ethics committee process and in line with the IRAS guidance, the patient recruitment advertising materials created by ModernaTX, Inc. were submitted to and approved by the [named] Berkshire B Research Ethics Committee. Moderna has only given permission for the site to use these REC-approved patient recruitment advertising materials. Accordingly, under the CTA, [named NHS trust] may only use these materials and may not use any other recruitment advertising materials. *[A] copy of the approved social media patient recruitment advertising materials for the NextCOVE trial [was provided to the Panel]*.

6. Moderna's Corporate Social Media Policy states materials for clinical trial recruitment must be reviewed internally and externally by a research ethics committee (referred in the Policy using the US terminology Institutional Review Board), and that all applicable local requirements must be complied with – Moderna follows the PMCPA Social Media Guidance.

7. Moderna provided the REC-approved patient recruitment advertising materials and social media ads to the site. If a site wants additional materials outside of the already approved patient recruitment advertising materials, Moderna has a process for review and approval of such site-proposed materials.

8. The tweets and article in question do not reflect the REC-approved patient recruitment advertising materials. The content that goes beyond what was contained in the REC-approved materials was created without the knowledge or involvement of Moderna and was not submitted to Moderna for review or approval.

9. [Named research collaboration] and [named NHS trust] were provided with content by [named patient recruitment centre]. Tweets A, B and C were posted by [named research collaboration] on their Twitter account. [Named patient recruitment centre] responded to Tweet B with a post from its account and also posted Tweet D. The article referred to in the complaint was published on the [named NHS trust] website and linked to in Tweet D, and [named patient recruitment centre] also provided content picked up in the local media in the second article referred to in the complaint.

10. The complaint alleges that [named patient recruitment centre], [named NHS trust] and [named research collaboration] were acting on behalf of Moderna. They were not acting on Moderna's behalf. Moderna had no involvement in or awareness of these materials. Through Moderna's contract with the site and approval processes it was made clear that the use of unapproved patient recruitment advertising materials is not appropriate and Moderna's consent is required prior to use of any patient recruitment advertising materials.

11. As quoted by the complainant, the PMCPA's Social Media Guidance states that '*Pharmaceutical companies should always be transparent about the communications, activities, and materials they produce, publish, sponsor, fund, or support on social media. Whenever a pharmaceutical company or a third party acting on its behalf publishes content on social media, it should clearly and prominently state the involvement of the pharmaceutical company and users should be aware of such involvement at the outset.*'

12. Moderna did not produce, publish, sponsor, fund or support the materials at issue and the organisations involved were not acting on ModernaTX, Inc's or Moderna UK's behalf (or on behalf of Moderna's contract research organisation) in publishing the unapproved content.

13. The PMCPA's Social Media Guidance also states, '*With regards to the ABPI Code, a pharmaceutical company is responsible for all material disseminated/activities carried out by it on any social media channel that comes within the scope of the ABPI Code including by a third party acting on its behalf even if that third party acts beyond the scope of its contract and potentially material/activities sponsored by it.*'

14. The materials at issue do not come within the scope of the ABPI Code. Under Clause 4.8 of the Code '*Companies are responsible for information about their products which is issued by their agencies, e.g., communication/advertising etc*.' The organisations in question are not as agencies of Moderna UK and were not acting on behalf of Moderna UK. [Named NHS trust] is engaged by ModernaTX as a clinical trial site, not an agency, and Moderna has no contractual relationship with [named research collaboration] or [named patient recruitment centre].

15. While the organisations involved are not subject to the ABPI Code, we have reminded them that only the approved patient recruitment materials may be used in connection with the NextCOVE trial and requested that they remove the tweets and article in question. We have also provided a summary of the points raised by the complainant for their reference.

16. We have not commented on the New Zealand guidelines quoted by the complainant as they are not applicable in the UK and therefore are not relevant to this complaint under the ABPI Code.

In relation to the clauses of the ABPI Code referred to in your letter:

Clause 5.5: Moderna did not have any involvement in, nor did it sponsor the tweets and article in question. Accordingly, there was no requirement for the materials to indicate the role of Moderna. The complainant has not established on the balance of probabilities that Moderna has breached Clause 5.5 of the Code.

Clause 6.1 and 6.2: The materials in question are not within the scope of the ABPI Code for the reasons provided above. However, if the PMCPA considers Moderna UK to be responsible for the tweets and/or article, while parts of the language used were not well chosen, the information in the materials is accurate and capable of substantiation. In this context, the complainant has not established on the balance of probabilities that Moderna has breached Clause 6.1 or 6.2 of the Code.

Clause 5.1: Moderna has not breached the clauses of the ABPI Code referred to in the complaint, as described above. Moderna provided the REC-approved social media patient advertising materials to the study site and has maintained high standards. The complainant has not established on the balance of probabilities that Moderna has failed to maintain high standards at all times.

Clause 2: Moderna has not breached the ABPI Code and has not brought discredit upon or reduced confidence in the pharmaceutical industry. The complainant has not established on the balance of probabilities that Moderna has breached Clause 2."

MODERNA'S RESPONSE TO FURTHER INFORMATION (1)

"For the reasons explained below, the two additional documents received from the complainant are outside the scope of the ABPI Code. They are therefore not relevant to Case AUTH/3815/8/23 and do not alter our response to the original complaint.

1. The two documents [provided by the complainant] are participant information sheets and informed consent forms from the NextCOVE clinical trial sponsored by ModernaTX, Inc.

2. PIS/ICF 1 and PIS/ICF 2 are not promotional materials, nor do they fall within any of the categories of non-promotional material caught by the ABPI Code. They are akin to the other types of regulated documents excluded from the definition of 'promotion' in Clause 1.17 of the ABPI Code.

3. Specifically, the PIS/ICFs are regulated under the Medicines for Human Use (Clinical Trials) Regulations 2004 ('**CTR**'). Sponsors are required to provide participants in a clinical trial with a PIS/ICF setting out the nature, significance, implications and risks of the trial in order to obtain the patient's informed consent to participate. Sponsors are also required to submit these documents for regulatory and ethical approval.

4. The NextCOVE trial has been authorised in the UK by the MHRA and approved by the Health Research Authority ('HRA') and Health and Care Research Wales ('HCRW'). The PIS/ICFs in question were reviewed by the [named] Research

Ethics Committee, which issued a positive opinion, and approved by the HRA and HCRW. These documents have therefore been approved in line with the CTR requirements as adequately and completely informing participants of the risks involved and as legally compliant.

For the PMCPA to find that such HRA/HCRW approved clinical trial documentation is subject to the ABPI Code would be a material extension of the scope of the ABPI Code and remit of the PMCPA."

MODERNA'S RESPONSE TO FURTHER INFORMATION (2)

"While the organisations involved are not subject to the ABPI Code, we have made the site aware of this further communication and requested that they remove the article in question."

MODERNA'S RESPONSE TO FURTHER INFORMATION (3)

"Thank you for the opportunity to provide additional information regarding the ongoing case. The claimant introduced minutes from the meeting of the [named] Research Ethics Committee (REC) conducted on April 11, 2023, at 10:00 AM (referred to hereafter as 'the Meeting'). According to the minutes of the Meeting, the REC outlined specific actions for Moderna, detailed in a table on page 13. Notably, item 6, bullet 3 directs Moderna to 'Review the unqualified use of the word "safe", e.g., on page 3 of the assent document. Use "acceptable safety profile" or similar terminology.'

In response, Moderna amended the language, thus adhering to the directives explicitly stated in the Actions Required by the REC.

Moderna was not prohibited from using the term 'safe'; instead, it was instructed to refine its unqualified usage in the document, which Moderna did in fact do. The REC did not specify each instance where the modification was necessary, but did provide an example, leaving it to Moderna's discretion to assess the other uses of 'safe' in the document.

The claimant contends that Moderna failed to remove the word 'safe' where it was deemed unacceptable, specifically noting that the phrase found on page: 'mRNA-1273.222 has been proven to be safe and effective for the prevention of COVID-19' demonstrates non-compliance with the REC's requirements. This is not the case.

The directive to update the wording was specifically tied to the clinical trial context ('…study vaccine is safe for children'), whereas the statement on page 5 pertains to the broader context of Moderna's vaccine. The assertion 'mRNA-1273.222 has been proven to be safe and effective for the prevention of COVID-19' is justified based on extensive data and objective studies demonstrating its safety throughout the pandemic. Therefore, Moderna was not required to and did not revise this particular usage of 'safe' on page 5.

In conclusion, Moderna adhered to the REC guidance. The retained phrasing on page 5 was appropriate and does not constitute non-compliance with the REC's mandated actions."

PANEL RULING

The complainant's allegations related to four unapproved tweets and two articles published online, all concerning recruitment of participants for the NextCOVE phase 3 clinical trial evaluating Moderna's COVID-19 vaccine. The complainant also made allegations regarding participant information sheets and informed consent forms for the clinical trial.

The Panel noted that only certain aspects of clinical trial activities came within the scope of the Code.

Tweets and online articles

The Panel noted the social media platform now named X was known as Twitter at the time of the complaint and would therefore use the terminology associated with Twitter, such as 'tweet', for the purpose of this complaint.

In relation to the tweets and the first of the online articles, the Panel noted that the complainant made a number of allegations, citing breaches of Clauses 5.1 and 2 of the Code, which they summarised at the end of their original complaint letter. The complainant alleged that the second online article contained the same "unethical, inaccurate and misleading statements" as could be found in the first online article. In addition to Clauses 5.1 and 2, the case preparation manager had also asked Moderna to respond to the complaint in relation to Clauses 5.5, 6.1 and 6.2.

The Panel noted Moderna's submission that the tweets were created without the knowledge or involvement of Moderna and were not submitted to Moderna for review or approval. The Panel further noted Moderna's submission that the organisations involved are not subject to the ABPI Code. In this regard the Panel noted that it had to decide whether Moderna was responsible for any acts or omissions of each organisation that came within the scope of the Code. That the materials were created without Moderna's knowledge did not automatically mean that it was not responsible for them. Moderna had further submitted that the materials at issue did not come within the scope of the ABPI Code.

The Panel noted that only certain aspects of clinical trial activities came within the scope of the Code. The Panel noted that the PMCPA's social media guidance, published in 2023, included guidance about the use of social media for clinical trial recruitment – in particular the need to ensure careful targeting, appropriate message content and the need to consider all other applicable codes, laws and regulations.

The Panel noted that the materials at issue had not been subject to the regulatory approval process and that the complainant referred to a letter that they had received from the NHS Health Research Agency about the use of unapproved recruitment materials which, according to the complainant, stated 'It is the responsibility of the sponsor to ensure that all study recruitment materials have been appropriately reviewed before they are used' and, further, 'We would instead expect the sponsor to inform us what corrective and preventative action has been taken to ensure that the matter is addressed and that measures are put in place to prevent a reoccurrence.' The Panel had not been provided with a copy of this letter and noted that the NHS Health Research Agency was, of course, not assessing the matter in relation to the Code.

Clause 1.24 of the Code states that companies are responsible under the Code for the acts and omissions of their third parties which come within the scope of the Code, even if they act contrary to the instructions which they have been given. In this regard, the Panel noted that the relevant contract was between [named NHS trust] and Moderna. The Panel did not have a copy of the contract but noted that, on the balance of probabilities, other organisations would be involved in the delivery of the trial arrangements including as sub-contractors.

The Panel considered the allegations relating to each item in turn.

Tweet A and Tweet C

Tweets A and C were both posted by the [named research collaboration] account. The Panel noted that Tweet C was a retweet of a post originally made by [named patient recruitment centre], with additional wording added by [named research collaboration]. It was this additional wording from [named research collaboration] ("This is a really important study that needs some young Research Volunteers (Hereos)!" [sic]) that was the subject of the complainant's allegations in relation to Tweet C, not the content from [named patient recruitment centre].

The Panel noted that the original tweet from [named patient recruitment centre] included a Moderna logo.

The Panel considered that its comments above were relevant here. The Panel noted that Moderna described [named research collaboration] as a collaboration of research organisations, including [named NHS trust]. The Panel noted Moderna's submission that it had no contractual relationship with [named research collaboration]. The Panel considered that, while [named NHS trust] (with whom Moderna had a contractual relationship) was involved in the [named research collaboration], there was no evidence before the Panel that [named research collaboration] could be seen as a sub-contractor or an extension of a third party contracted by Moderna. In the Panel's view, there was no evidence before it of any relationship between Moderna and the [named research collaboration] such that Moderna would be responsible for its acts or omissions that came within the scope of the Code. The Panel noted that the complainant bore the burden of proof in this regard. The Panel therefore ruled **no breaches of Clauses 5.1, 5.5 and 6.1** in relation to the allegations about Tweet A and **no breach of Clause 5.1** in relation to the allegations about Tweet C.

Tweet B

The Panel considered its comments above were relevant here. From the information before it, the Panel understood that the complainant provided a link to a response by [named patient recruitment centre] to a tweet but made no allegation about that response. The complainant stated that the tweet was posted by [named patient recruitment centre], which also responded to its own post. The complainant provided a brief description of the tweet but did not provide a copy of it. The Panel noted that, according to Moderna, the tweet was posted by [named research collaboration] and responded to by [named patient recruitment centre]. Moderna made no comment on the content of the original tweet to which [named patient recruitment centre] had responded. The Panel considered that, overall, and on balance, the subject matter of the complaint was unclear. The Panel therefore ruled **no breaches of Clauses 5.1, 5.5 and 6.1**.

Tweet D

Tweet D was posted by the [named NHS trust] account. The Panel considered that its comments above about the tweets applied here.

Clause 1.24 of the Code states that companies are responsible under the Code for the acts and omissions of their third parties which come within the scope of the Code, even if they act contrary to the instructions which they have been given. The Panel noted Moderna's submission that [named NHS trust] was engaged by ModernaTX as a clinical trial site and that the two parties had entered into the national model Clinical Trial Agreement. In the Panel's view, [named NHS trust] could, therefore, be considered a third party as defined by Clause 1.24, and so Moderna bore responsibility under the Code for Tweet D.

The Panel noted Moderna's submission that patient advertising materials that had been created by ModernaTX and approved by the research ethics committee were provided to [named NHS trust] for use, and that any additional materials should have been sent to Moderna for review and approval. The Panel noted that Tweet D was unapproved and noted Moderna's submission that it was created without its knowledge or involvement.

Tweet D consisted of a photograph of three people – a child in school uniform (appearing to be of secondary school age, i.e. 12 years or older), a woman assumed to be the child's mother, and a man who appeared to be a health professional – seated in a healthcare setting. This was accompanied by the words "Proud to have recruited our 1st participants to a new [@ account of named patient recruitment centre] #Covid #booster trial. If you're aged 12 – 60+ you can join too. Find out how", with an '@ mention' tagging the Twitter accounts of four individuals and the NIHR research account, and a link to an article on the [named NHS trust] website.

The complainant alleged that Tweet D was inappropriately aimed directly at children, as well as adults. In the Panel's view, while children were included in the relevant age bracket ("12 – 60+"), neither the method of communication, nor the language and imagery of the tweet appeared directed specifically towards children. The Panel noted the complainant's comments about the principle that children are not suitable targets for the advertising of medicines and noted that it is not permitted to advertise prescription only medicines (including vaccines) to the general public, regardless of age. In the Panel's view, Tweet D did not promote Moderna's vaccine to the public but was intended to drive recruitment to a clinical trial. The Panel noted that the complainant bore the burden of proof; it did not consider that the complainant had demonstrated, on the balance of probabilities, that the tweet was targeted towards children. The Panel therefore ruled **no breach of Clause 5.1** in this regard.

The complainant alleged that Tweet D included "no mention of industry-sponsorship or of Moderna's involvement". Clause 5.5 requires that material relating to medicines and their uses, whether promotional or not, and information relating to human health or diseases which is sponsored by a pharmaceutical company or in which a pharmaceutical company has any other involvement, must clearly indicate the role of that pharmaceutical company. The Panel noted Moderna's submission that there was no requirement for Tweet D to indicate the role of Moderna because Moderna had no involvement in and did not sponsor the tweet. In this regard, the Panel noted its view above that Moderna was responsible for the Tweet. In addition, the Panel considered the importance of companies and their third parties ensuring that all materials are appropriately approved. Given the tweet had not been subjected to regulatory approval, the Panel's view was that it ought to comply with the relevant requirements of the Code. While the

Panel noted that the news article that could be accessed via a direct link from the tweet, "COVID booster study recruits first participants", stated that the trial used a Moderna vaccine, the tweet had to stand alone with respect to the requirements of the Code. Tweet D did not contain any mention of Moderna's role, contrary to the requirements of Clause 5.5, and so the Panel ruled **a breach of Clause 5.5**.

The complainant alleged that Tweet D made misleading claims about the likelihood of applicants being chosen for inclusion and also regarding the investigational and developmental status of the vaccine under investigation. The Panel noted that the application of Clause 6.1, which required that information, claims and comparisons must not mislead, was not limited to information or claims of a medical or scientific nature.

In relation to the likelihood of applicants being chosen for inclusion, the Panel noted that the approved social media advertisements for recruitment to the NextCOVE trial included language such as "See if you or your child may qualify". The unapproved Tweet D read "If you're aged 12 - 60+ you can join too." The Panel considered that the language in the unapproved Tweet D was not sufficiently cautious. Applicants would have to be screened to see whether they were eligible. The Panel noted that the intended audience was unlikely to be familiar with the process. The Panel noted that the PMCPA Social Media Guidance 2023, Clinical Trial Recruitment stated, "Any information shared must not raise unfounded hopes of entry into the trial or successful treatment outcomes". The Panel therefore considered that the statement ''If you're aged 12 - 60+ you can join too." was, on balance, not accurate or a fair reflection of the clinical trial recruitment process and therefore ruled **a breach of Clause 6.1**.

In relation to the allegation that the Tweet D did not make clear that this was for an "investigational product, under development, unlicenced with no proven efficacy and with an unknown risk profile", the Panel noted that the approved social media copy used language such as "investigational vaccine that may help protect against multiple variants of COVID-19" and referred to research. The Panel considered that, while the approved language should have been used in any social media communication, the reference to recruiting participants and the inclusion of the words "#Covid #booster trial" in Tweet D meant on balance that it was clear that it referred to a clinical trial and the term 'booster' would be understood by the public in the context of vaccinations to prevent COVID-19. The Panel whilst noting that the Tweet should stand alone in relation to the requirements of the Code understood that further, more detailed information would be provided to those readers that expressed an interest. The Panel did not consider that the complainant had demonstrated, on the balance of probabilities, that Tweet D was misleading on this narrow point as alleged. The Panel ruled **no breach of Clause 6.1** in this regard.

Article linked to from Tweet D

Tweet D contained a link to an article published on the [named NHS trust] website entitled "COVID booster study recruits first participants". The Panel noted its determination, above, that [named NHS trust] could be considered a third party to Moderna in relation to the NextCOVE trial, as defined by Clause 1.24, and so considered that Moderna bore responsibility under the Code for this article.

The article consisted of an interview with an adult participant in the NextCOVE study and a paediatrician involved in the study. The article also referred to the child of the adult participant also being a participant in the study. The article was accompanied by the same photograph as

used in Tweet D, assumed to be the three people referred to in the article. The article ended with links and contact details for the reader to find out more about taking part in the trial. The Panel considered the intention of the article was to encourage people to find out about, and potentially participate in, the NextCOVE trial. The Panel noted it was an established principle that any material linked to within a social media post would normally be regarded as being part of that post. The Panel therefore considered that such patient recruitment material was potentially within the scope of the Code. The Panel noted that the article contained implied benefits and positive statements relating to Moderna's vaccine, and considered that such information should be correct and balanced and fell within the scope of the Code.

The complainant alleged that the claim that taking part in the trial would "help protect themselves as well as others" could not be substantiated because the currently licensed comparator had no data to support that claim, there was no licensed indication to the effect that the vaccine would protect others, and the investigational vaccine was not being investigated for its ability to prevent transmission. The Panel noted that this wording was part of an indirect quotation from the paediatrician: "[They] urged people to come forward and take part in the trial in order to help protect themselves as well as others." The Panel considered this wording in the context of vaccination. In the Panel's view, it was not unreasonable to make a general reference to one of the potential benefits of vaccination being to reduce the risk of infection in the wider population – because as more people are vaccinated, it could be expected that fewer people will come into contact with the virus. The Panel noted in general terms that it was not unacceptable to refer to secondary benefits that flowed from using a medicine for its licensed indication so long as the licensed indication was clear.

The Panel noted that the complainant bore the burden of proof; it did not consider that the complainant had provided evidence to demonstrate, on the balance of probabilities, that this quotation constituted a claim about Moderna's vaccine and that it could not be substantiated. The Panel ruled **no breach of Clause 6.2** in this regard.

The Panel considered the following allegations in relation to the requirements of Clause 6.1 of the Code:

- that the article was misleading as to the design and purpose of the study
- that the article used inaccurate and misleading claims for efficacy
- that the article made exaggerated and superlative claims relating to safety.

The Panel noted the complainant's comments in relation to the language used to describe the design and purpose of the study. The complainant cited two quotations from the paediatrician: "This is a COVID vaccination study that is using a smaller dose than that which has been used in the past." and "What we are trying to determine is whether, by using a smaller dose of vaccine to the original COVID vaccines, the antibody response is the same, i.e. will the booster offer people the same level of protection against the virus, and is the booster just as effective?". The complainant alleged that this implied that the NextCOVE study was a dose-finding study, comparing different doses of the existing licensed product. The Panel considered that the wording of the article following that second quote ("The type of vaccine differs from previous COVID vaccines in that it has a longer shelf life, it does not need to be refrigerated, …") made it clear to the reader that this study was investigating a new vaccine, and not a different dose of the existing product. The Panel also noted that the wording was "by using a smaller dose of vaccine" and not "by using a smaller dose of **the** vaccine" (emphasis added). On balance the Panel was satisfied that the article was not misleading in terms of the design or purpose of the study as alleged and ruled **no breach of Clause 6.1** on this point.

The complainant cited a quotation from the paediatrician in relation to the allegation of misleading claims for efficacy: "… we know that vaccinations do work and they can make a big difference to adults as well as children". The complainant alleged that this statement misleadingly implied that the investigational vaccine is effective, and overstated any potential therapeutic benefit that participants could expect. The Panel noted that the complete quotation in question read "We are excited to be running this trial here at PRC as we know that vaccinations do work and can make a big difference to adults as well as children." The Panel considered, on balance, that in linking the phrase "make a big difference" to the excitement at 'running this trial', this statement from a health professional (a trusted source) was misleading in terms of the potential efficacy of Moderna's investigational vaccine. The Panel therefore ruled **a breach of Clause 6.1** on this point.

The Panel noted that the complainant cited a quotation from the adult participant, "I was reassured by [named paediatrician] regarding the minimal risks associated with the trial", in relation to the allegation about safety claims. The Panel noted that, among other things, Clause 6.1 required information to be accurate, balanced and objective and that it must not be misleading. The Panel considered that the quote from the adult participant, which included the phrase "the minimal risks associated with the trial" did not provide an accurate reflection of the safety profile of the investigational vaccine or the safety considerations associated with the clinical trial. Particularly in the context of the intended audience of the article, the Panel considered that the phrase in question, "I was reassured by [named paediatrician] regarding the minimal risks associated with the trial", was unbalanced and inappropriate and ruled **a breach of Clause 6.1**.

The Panel considered the following allegations in relation to the requirement of Clause 5.1 to maintain high standards:

- that the article failed to use restrained language
- that the article used inappropriate and emotional language to induce fear in order to incentivise recruitment.

The complainant cited two quotations from the paediatrician in terms of use of inappropriate language: "We're really excited to be running this trial here at the PRC because we know that vaccinations do work and they can make a big difference to adults as well as children" and "It is evolving all the time and we don't know what COVID will look like in the winter of 2023/24 and beyond that for example. It can still be a threat to many people who are vulnerable, there are many people still at risk of the virus being very debilitating for them and causing severe illness. Developing an effective booster is the way forward in protecting ourselves".

The Panel reviewed the wording of the article. The Panel noted Moderna's submission that patient advertising materials that had been created by ModernaTX and approved by the research ethics committee were provided to [named NHS trust] for use, and that any additional materials should have been sent to Moderna for review and approval. The Panel noted Moderna's submission that the article did not reflect the approved materials and was created without the knowledge or involvement of Moderna. In the Panel's view, it appeared that Moderna was let down by a third party who had not followed the agreed processes and had used unapproved materials. The Panel considered that, on occasion, the language used in the article was not suitably "restrained" – particularly the direct quotations attributed to the paediatrician in the article (as cited by the complainant), for example, "… they can make a big difference …" and the quotation from the trial participant, "… the minimal risks associated with

the trial …". The Panel considered that, while Moderna appeared to have set standards for what could and could not be said in patient recruitment materials, these standards had not been adhered to and the processes by which materials should have been reviewed and approved had not been followed. The Panel considered that the article had failed to use restrained language as alleged and therefore high standards had not been maintained and therefore ruled **a breach of Clause 5.1**.

Article on local news website

The second article referred to by the complainant was published on a local independent news website and was titled "[Named location] launches COVID-19 vaccine trial with first participants enrolled". The complainant stated that the article was probably as a result of a press release and alleged that it was an advertisement for recruitment into the NextCOVE clinical trial and contained "the same unethical, inaccurate and misleading statements as can be found on the article on the NHS website". The Panel noted Moderna's submission, in relation to the article in question, that [named patient recruitment centre] had provided content that was picked up in the local media.

The Panel noted that complaints about articles in the press were judged on the information provided to that publication by the pharmaceutical company, such as a press release, rather than the content of the news item. The Panel had no locus over journalists or news publications. The Panel had to decide whether Moderna was responsible for any acts or omissions of [named patient recruitment centre] that came within the scope of the Code and, if so, was obliged to make its rulings based on the information provided to the independent news website by [named patient recruitment centre], rather than the published article.

The Panel noted that [named patient recruitment centre] was funded through the National Institute for Health Research and managed and operated by [named NHS trust], with whom Moderna had a contractual relationship. In the Panel's view, [named patient recruitment centre was used by the NHS Trust to deliver its contractual obligations to Moderna and could, therefore, and on balance, be considered an extension of a third party contracted to Moderna as defined by Clause 1.24, or a subcontractor, and so Moderna bore responsibility under the Code for information provided to the independent news website.

The Panel noted that the published article was different to, but bore certain similarities to, the article published on the [named NHS trust] website entitled "COVID booster study recruits first participants", for which Moderna was responsible and on which the Panel had ruled above. The Panel noted that, in general terms, any rulings of breaches of the Code in relation to the article published on the [named NHS trust] website would apply not only to that article but also to closely similar material for which Moderna was responsible.

Turning to the article in question published on the local independent news website, the Panel noted that it did not have a copy of any information provided to the independent news website on which to base its ruling and it was not for the Panel to speculate in this regard, bearing in mind that there were differences between the article at issue published by the news website and that published on the [named NHS trust] website. On this narrow basis, the Panel ruled **no breaches of Clauses 6.1 and 5.1**.

Tweets and online articles – overall

Clause 2 was a sign of particular censure and reserved for such use. The Panel considered that the failure to use approved material was concerning but also noted that Moderna appeared to have been let down by the third party, who had used materials that had not been reviewed and approved by Moderna or the research ethics committee. The Panel considered that its rulings of breaches of Clauses 5.1 and 6.1 of the Code were sufficient, and ruled **no breach of Clause 2**.

Participant information sheet and informed consent form documents

The Panel noted that the complainant provided further information following the submission of their original letter of complaint. Within this, the complainant made allegations around the use of the word 'safe' in two 'informed consent forms', citing breaches of Clauses 6.4, 5.1 and 2. The Panel noted that the case preparation manager had not raised Clause 6.4 in their original letter to Moderna; however the clause was explicitly cited by the complainant in their letter, which was sent to Moderna for its response. The Panel therefore determined that it should rule on Clause 6.4 in relation to this aspect of the complaint.

The complainant provided two 'participant information sheet and informed consent form' documents and the minutes of the meeting of the research ethics committee that reviewed them. The complainant alleged that the use of the word "safe" to describe the currently licensed vaccine, SPIKEVAX (mRNA-1273.222), breached Clause 6.4 of the Code. The Panel noted that Clause 6.4 required that the word 'safe' must not be used without qualification.

The Panel noted Moderna's submission that the two documents were not promotional materials and did not fall within any of the categories of non-promotional material within the scope of the Code. They were regulated under the Medicines for Human Use (Clinical Trials) Regulations (2004) and were required to be submitted for regulatory and ethical approval.

The Panel considered that these documents were very different to the public-facing patient recruitment advertising materials. Participant information sheet and informed consent form documents are intended to provide full details about what is involved in the clinical trial for anyone who is considering taking part, and to obtain their written formal consent. The reader will have already expressed interest in participating in the trial and had discussions about the trial. The documents form an integral part of the clinical trial materials for patients and, as such, require regulatory and ethical approval.

The Panel noted that it had no precedent before it to establish whether such materials came within the scope of the Code. The Panel noted Moderna's submission that the NextCOVE trial had been authorised in the UK by the MHRA and approved by the Health Research Authority (HRA) and Health and Care Research Wales (HCRW). While the Panel was concerned about the unqualified use of the word 'safe' within these documents, it considered that the PMCPA was not the appropriate body to consider the acceptability of, or adjudicate on informed consent forms or participation information sheets for clinical trials. In the Panel's view, the complainant had not demonstrated why the materials in question fell within the scope of the Code and, therefore, the Panel ruled **no breach of Clauses 2, 5.1 and 6.4**.

APPEAL FROM THE COMPLAINANT

The complainant's written basis for appealing is reproduced below.

> "Dear PMCPA Appeal Board Members,
> I am writing to appeal several of the findings of your Panel for Case AUTH/3815/8/23.
>
> **Findings Relating to Tweet D**
>
> 1. The Panel said that I had complained that
>
> ***"Tweet D was inappropriately aimed directly at children, as well as adults"***
>
> However, they found no breach of clause 5.1 because they said that the Tweet was not directed "specifically" at children. Although they agreed that the Tweet was indeed directed at children as well as adults, they said
>
> ***"neither the method of communication, nor the language and imagery of the tweet appeared directed specifically towards children." "it did not consider that the complainant had demonstrated, on the balance of probabilities, that the tweet was targeted towards children."***
>
> The content of Tweet D which about which I complained was
>
> ***"If you're aged 12 – 60+ you can join too. Find out how"***
>
> I believe this finding by the Panel to be wrong and that it is a misunderstanding of both my complaint and the intention of the regulations governing such communications. I note that your code makes no comment about communications directed at children, perhaps because it is clearly illegal to advertise POMs to children. Fortunately, the MHRA does provide guidance on the subject of advertising to children. Its advice relates to advertising of medicines but I can think of no reason why it should not in principle be applied to other healthcare interventions which also have risks to be considered as well as potential benefits. On its website Advertise your medicines - GOV.UK (www.gov.uk) the MHRA says explicitly that when advertising medicines you must not "direct your advertising at children". Please note that the MHRA do not say here that one must not "direct your advertising **specifically** at children" or that one must not "direct your advertising **only** at children". The intention here, as with any healthcare advertising, whether for medical products, services or clinical trials, must surely be to prohibit the advertising of any healthcare interventions directly to children. Whether or not such advertising is simultaneously also directed at adults must therefore surely be irrelevant. I am afraid that the impression given by the Panel's decision is that it is acceptable for children to become collateral damage of healthcare advertising so long as it is also aimed at adults too?
>
> The section of the statement in Tweet D which says "If you are aged 12…" is clearly material which is directed at children. If you are aged 12, you are a child.
>
> I repeat, I do not think that the appropriate offence to be considered here is whether the advertisement has been directed ***specifically*** or ***only*** at children but rather whether the

advertisement should have been directed at children at all. Had their considerations been properly addressed in this direction I do not think that the Panel would have concluded that a statement such as…

"If you're aged 12 - 60+ you can join too."

…was not directed at children. Indeed, if this statement was not deliberately intended to be directed at children would it not have been expressed something like this? …

"If you are over the age of 16 you can join too. And, if you are the parent or guardian of a child over the age of 12 who may want to take part, they can also join."

Therefore, I believe that Tweet D contained material that was indeed intentionally directed at children and as such represents a breach of Clause 5.1. The fact that it was not directed **specifically** at children, but at children **along with** adults should not affect this decision.

2. I complained that Tweet D did not make it clear that this was a clinical trial for an

"investigational product, under development, unlicenced with no proven efficacy and with an unknown risk profile"

The Panel found no breach of Clause 6.1. The reasons they gave for this finding were

"The Panel considered that, while the approved language should have been used in any social media communication, the reference to recruiting participants and the inclusion of the words "#Covid #booster trial" in Tweet D meant on balance that it was clear that it referred to a clinical trial and the term 'booster' would be understood by the public in the context of vaccinations to prevent COVID-19. The Panel whilst noting that the Tweet should stand alone in relation to the requirements of the Code understood that further, more detailed information would be provided to those readers that expressed an interest. The Panel did not consider that the complainant had demonstrated, on the balance of probabilities, that Tweet D was misleading on this narrow point as alleged."

The statements that ***"the Tweet should stand alone in relation to the requirements of the Code" and*** that ***"further, more detailed information would be provided to those readers that expressed an interest."*** are somewhat contradictory. If further information needs to be provided in order for someone to properly understand the Tweet then clearly the Tweet is unable to "stand alone". If the people doing the Tweeting are unable to use Twitter to properly represent the nature of what they are advertising, or asking people to do, without breaching your Code, then surely one must question whether Twitter is the appropriate vehicle for them to be placing this type of advertising in the first place.

The Panel were satisfied that

"the reference to recruiting participants and the inclusion of the words "#Covid #booster trial" means that "it was clear that it referred to a clinical trial and the

term 'booster' would be understood by the public in the context of vaccinations to prevent COVID-19."

However, I am afraid that this explanation does not actually deal with the substance of my complaint. I did not say that the public would not understand that this was a clinical trial of a booster vaccine with the intention of preventing covid. My complaint was that nowhere in the Tweet was it made clear that this was a clinical trial involving an investigational product, under development, unlicenced with no proven efficacy and with an unknown risk profile. There are many sorts of clinical trials, most of which will be "recruiting patients" but many of which can involve medicines that are not investigational in nature, are not under development, whose efficacy has been demonstrated to the regulators and whose tolerability profile has been judged by the regulators to be acceptable. Clinical trials which investigate the health economic characteristics of an approved medicine, or the effectiveness of different Public Health delivery approaches in using an approved medicine, are examples of such studies. The public will be familiar with covid vaccines, there are several now approved and available, and the concept of a booster is now also established and will be familiar to them. It is important therefore that it is made clear that they are not being asked to participate in a new study of an existing and licenced covid booster, but that they will be actually be participating in the development of a booster which is currently unproven in terms of efficacy and safety. I think that this should particularly be the case in recruitment advertisements that are directed at children.

Therefore, I consider that Tweet D was misleading about the nature of this clinical trial and represent a breach of Clause 6.1.

<u>Findings related to article linked to in Tweet D</u>

I complained that [named paediatrician] had

"urged people to come forward and take part in the trial in order to help protect themselves as well as others".

The Panel interpreted this as a complaint that this statement was not capable of substantiation which would be a breach of Clause 6.2. However, they then decided that there had been no breach of Clause 6.2. The reasons given for this finding are

"In the Panel's view, it was not unreasonable to make a general reference to one of the potential benefits of vaccination being to reduce the risk of infection in the wider population – because as more people are vaccinated, it could be expected that fewer people will come into contact with the virus. The Panel noted in general terms that it was not unacceptable to refer to secondary benefits that flowed from using a medicine for its licensed indication so long as the licensed indication was clear.

The Panel noted that the complainant bore the burden of proof; it did not consider that the complainant had provided evidence to demonstrate, on the balance of probabilities, that this quotation constituted a claim about Moderna's vaccine and that it could not be substantiated. The Panel ruled no breach of Clause 6.2 in this regard."

I disagree with this finding for the following reasons

- By the time [named paediatrician] makes this statement in the article [they have] already been quoted at length about the Moderna NextCOVE study specifically. For example, [name paediatrician] talks at length about the dose reduction and cold storage aspects of the study and asks for people to participate in NextCOVE. Therefore, when [they make] the statement which is the subject of this complaint it is very clear that [they are] referring to the NextCOVE study specifically, rather than referring to vaccination in general.

- Community benefits of vaccination are not generalisable and vary depending upon the infection, the vaccine and the population concerned. Therefore, contrary to the assertion of the Panel, it is not reasonable for [named paediatrician], in an article specifically about the NextCOVE study, to make a bold general reference to one of the potential benefits of covid vaccination as being a reduction in the risk of infection in the wider population, when this has never been conclusively demonstrated with covid vaccination. Similarly, with regard to the covid vaccines it is not true for the Panel to assert that ***"because as more people are vaccinated, it could be expected that fewer people will come into contact with the virus."***

- At the time [named paediatrician] was making these comments there was no generally accepted agreement that any covid vaccines had any effect on reducing transmission. Not only were there data suggesting that covid vaccination had little or no effect on helping to "protect others" but there were data which suggested the opposite was true. There were also data suggesting that vaccinated people who become infected have similar viral loads to unvaccinated but having fewer and less severe symptoms they may be less likely to self-isolate, potentially increasing the risk of transmission to others. There were also data to suggest that vaccination might even promote infection and that narrow vaccine induced immunity might favour variant selection
  In July 2021, SAGE reported on ONS findings about covid vaccination and transmissibility, saying,

  "ONS data suggest that for those who have been vaccinated who do get infected with the delta variant, PCR cycle threshold (Ct) values are generally lower [meaning a stronger test result] than for those infected with alpha, suggesting that vaccinated people may still have a high viral load with delta infection (medium confidence). This may mean that there is limited vaccine effect against onward transmission for the delta variant."

  Whether or not you personally agree or disagree with any of this, and whether or not you think that any of this has been proven or disproven since [named paediatrician] made his comments, is immaterial. The key point is that at the time he made his comments there was no settled scientific or clinical agreement on whether or not an individual getting vaccinated against covid did in fact help to "protect others". It was therefore wrong for him, as a lead investigator, in a

Moderna-sponsored study, to assert that it did, in order to encourage people (including children) to participate in that study.

- In the supplementary information to Clause 6.1 of your Code it states that:

  "emerging clinical or scientific opinions which have not been resolved in favour of one generally accepted viewpoint must be referred to in a balanced manner"

  I have provided above some links to papers published before [named paediatrician] made [their] statement.

  These publications suggest that covid vaccination, though it may reduce the severity of symptoms and signs of the condition for the vaccinated individual, does not necessarily help to "protect others".

  Encouraging children to participate in a clinical trial to "protect others" when there was continuing dispute about whether this was true or not, is not balanced. It is also unethical and potentially coercive.

  Similarly, if there was clinical and scientific dispute about whether "protecting others" is or is not actually a benefit of covid vaccination, then it cannot be treated as a "secondary benefit", rendering the following assertion by the Panel, in defence of their finding, irrelevant

  "The Panel noted in general terms that it was not unacceptable to refer to secondary benefits that flowed from using a medicine for its licensed indication so long as the licensed indication was clear."

  Clinical or scientific opinions had not been resolved in favour of one generally accepted viewpoint regarding effects on transmission by covid vaccination at the time [named paediatrician] made these comments. I have provided you with information suggesting that [their] claim that getting vaccinated against covid helps to "protect others" was not established at the time it was made. I accept that advocates of covid vaccination may wish to provide you with contemporary data suggesting the opposite. However, your Code requires that these opposing views be treated in a "balanced manner" and [named paediatrician] did not do so. Whilst this debate was taking place it was inappropriate to encourage people (including children) to participate in a covid vaccine trial by saying that one of the benefits of participation was helping to "protect others". Especially when the reduction in transmission was not being investigated in the study and the licenced comparator does not have reduction in transmission either as a licenced indication or even a "secondary indication".

[Named paediatrician's] statement therefore represents breaches of Clause 6.2 of your Code.

Findings Relating to Tweet B

Firstly, I would like to say that I am surprised by the Panel's assertion that they

"understood that the complainant provided a link to a response by [named patient recruitment centre] to a tweet but made no allegation about that response." And that….

"The complainant provided a brief description of the tweet but did not provide a copy of it."

As the panel noted, I did provide a link to the tweet, which, if the Panel had used it, would have enabled them to see the Tweet for themselves rather than just relying on my description. If the tweet had been deleted by the time the Panel got round to using link then they could still easily have contacted me to find out if I had a copy which I could give to them. They did not do this, but instead appear to have been happy to simply believe Moderna's assertion that

"the tweet was posted by [named research collaboration] and responded to by [named patient recruitment centre]"

The Panel may not have bothered to ask me to provide them with a copy of Tweet B but I am happy to be able to provide the Appeal Board with a copy here.

As you can see, my description of this tweet in my original complaint is completely accurate and the Moderna assertion that the tweet was posted by [named research collaboration] (for whom Moderna apparently bear no contractual responsibility) is entirely false. In fact, and as I stated in my original complaint, both the original tweet and the response to it were posted by [named patient recruitment centre], with whom Moderna do have a contractual relationship. I am bound to ask, why did Moderna mislead the Panel in this way?

The reason given by the Panel for finding no breaches for Tweet B was as follows

"The Panel considered that, overall, and on balance, the subject matter of the complaint was unclear. The Panel therefore ruled no breaches of Clauses 5.1, 5.5 and 6.1"

I would say that the subject matter of my complaints about tweet B was actually very clear. In fact, a number of my complaints about Tweet B were also repeated for Tweet D (see details below) and yet the Panel apparently had no difficulty identifying and dealing with them for that Tweet. So why did they have a problem identifying and dealing with them for Tweet B?

My specific complaints about Tweet B were as follows

1. I complained that

   "Once again there is an image of the 12-year-old girl with her teddy and her 'lovely certificate'. Again, the tweet is directed at children as the posting

account replies to its own post: 'If you want to take part and are over the age of 12, please get in touch with us'

It should therefore be clear to any reasonable person that the subject matter of this part of my complaint about Tweet B is that the tweet contains material that is clearly and inappropriately directed at children. This is a breach of Clause 5.1. There are two reasons why I believe this to be the case

- One of the photographs in Tweet B consists of a child in school uniform holding a teddy bear and a certificate, both apparently offered as rewards for participation. This is the same photograph used in Tweet A which was offering a teddy bear and a "lovely certificate". It is difficult to imagine how anyone could interpret this photograph as anything other than being directed at children.

- The [named patient recruitment centre] response tweet states "If you want to take part and are over the age of 12, please get in touch with us".

It is for these reasons that my complaint about Tweet B said

"Again, the tweet is directed at children"

Please note that I did not complain that Tweet B was directed **specifically** or **only** at children.

I have explained above why I believe a similar decision by the Panel about Tweet D was incorrect and why I wish to appeal it. I would wish to use the same argument here to explain why I believe that Tweet B similarly contains material inappropriately directed at children. Please refer to the Tweet D material above for the detailed explanation.

In fact, it seems to me that Tweet B contains material which is even more obviously and inappropriately directed at children than Tweet D because

a) It contains the photograph of the schoolgirl holding her rewards/inducements of the teddy bear and the "lovely certificate". And….

b) It contains the statement ***"If you want to take part and are over the age of 12, please get in touch with us"***. According to clinical trial regulations, if you are 12, 13, 14 or 15, you are a child.

   Also, as I explain for Tweet D above, if this statement had not been intentionally and deliberately directed at children, would it not have been more appropriately worded as something like

   "If you want to take part and are over the age of 16, or if you are the parent or guardian of a child over the age of 12 who may want to take part, please get in touch with us"

[I accept that the inappropriate use of the teddy bear and the "lovely certificate" as inducements and rewards offered for the participation of children occurred in Tweet

A rather than Tweet B. The Panel did not deal with any of my complaints with regard to tweet A because they judged that Moderna could not be held responsible for material posted by [named research collaboration].

I am therefore not appealing the Panel's findings regarding Tweet A. However, it should be noted that Tweet A contained a link to Tweet B so we know that this photograph of the schoolgirl and her teddy bear and "lovely certificate" was in fact used and posted by [named patient recruitment centre] in Tweet B before it was eventually posted by [named research collaboration] in Tweet A.]

2. I complained that

   "This time children (and adults) are invited to participate in 'the new NextCOVE Covid-19 vaccine trial' again with no indication that the 'new' vaccine is unproven, unlicenced and still under investigation."

   It seems clear that I was complaining about the fact that the tweet was misleading about the nature of the clinical trial. I made a similar complaint about Tweet D and the Panel appear to have had no difficulty in identifying and dealing with my complaint there. For Tweet D they found no breach of Clause 6.1. I have appealed that finding too. The details of that appeal can be found above and I wish to use the same rationale here to explain why I think that Tweet B also represents a breach of Clause 6.1. Please refer to the Tweet D explanation above.

3. I complained

   "Again, there is no mention of Moderna or pharmaceutical industry involvement"

   Thus, once again, the particular subject matter of my complaint was and is clear.

   I made a similar complaint about Tweet D and I note that for Tweet D the Panel found that

   "Tweet D did not contain any mention of Moderna's role, contrary to the requirements of Clause 5.5, and so the Panel ruled a breach of Clause 5.5."

   I believe that if the Panel had properly dealt with my complaint about Tweet B, as they did with Tweet D, then they would have similarly concluded that Tweet B was also in breach of clause 5.5, for the same reasons.

4. I complained

   "The description of the two participants being "excited to participate in this important study" does not seem compatible with the IRAS ethical requirement to be "restrained in tone".

   This is inappropriate emotive language, especially when directed at children. The Panel clearly identified issues with the use of unrestrained language in the article linked to Tweet D (again including language such as "excitement") and indeed

found breaches of clause 5.1 for Tweet D. So why did they have difficulty identifying that the "subject matter" of my complaint about Tweet B was of a similar nature? Do the Panel now require that members of the public, with no specialist knowledge of your code of practice, should actually quote specific clauses of your code that they think have been breached before they will consider their complaints?

For the same reasons given by the Panel for their decision about Tweet D, I believe that the description in Tweet B of the two participants being ***"excited to participate in this important study"*** represents a further breach of Clause 5.1 of your Code.

In summary, with regard to Tweet B

- I believe that the Panel made insufficient effort to understand the subject matter of my complaints about Tweet B, which I believe were quite clear. They also failed to ask me for a copy of the Tweet, which I could have easily provided.
- As a result, they did not properly address the substance of my complaints about Tweet B
- The Panel, and Moderna, have made factually incorrect statements about Tweet B. Specifically they said that the original tweet was posted by [named research collaboration] and replied to by [named patient recruitment centre]. In fact, both the original tweet and the response were posted by [named patient recruitment centre] and so Moderna has responsibility, and is accountable, for them under your Code.
- For clarity, here are my specific complaints about Tweet B, with further explanation of why I think they should be upheld. To avoid any further confusion regarding the "subject matter" I have attempted to identify here the clauses which I believe have been breached:
    - Failure to disclose involvement of a pharmaceutical company. Breach of clause 5.5
    - Failure to use restrained language. Breach of clause 5.1.
    - Material inappropriately directed at children. Breach of Clause 5.1.
    - Misleading information about the nature of the clinical trial. Breach of clause 6.1.

Finally, the Panel decided that there had been no breach of Clause 2 because

"The Panel considered that the failure to use approved material was concerning but also noted that Moderna appeared to have been let down by the third party, who had used materials that had not been reviewed and approved by Moderna or the research ethics committee."

I would ask the Appeal Board to reconsider this finding by the Panel, whether or not any of my other appeals are upheld. [Named patient recruitment centre] may legally be considered to be a third party but they are an integral and important part of the Moderna NextCOVE clinical research team. The levels of training and knowledge regarding clinical research regulations and practices expected should be no less than those expected of a Moderna employee. If a group of Moderna employees had been involved in posting these advertisements, with multiple counts of failure to maintain high standards, then would the Panel have found a breach of Clause 2 or would they have simply said that "Moderna appeared to have been let down by a group of employees". An experienced group of highly trained clinical research professionals

contracted by Moderna, even if they are technically a third-party, should be treated no differently in this respect to a group of employees. It is Moderna's responsibility to ensure that they are carefully selected, properly trained and that their performance is appropriately monitored. Moderna clearly failed in one or more of these responsibilities and should be properly held to account for that. A finding of a breach of Clause 2 would be entirely appropriate.

Thank you for dealing with this matter for me."

RESPONSE FROM MODERNA

Moderna's written response to the appeal is reproduced below.

"Thank you for your letter regarding the appeal lodged by the complainant in the above case. We have reviewed the appeal and submit our comments as requested.

We note that the complainant's appeal challenges the Panel's decisions regarding Tweet B and D, as well as elements of the article linked to Tweet D. The complainant raises concerns that both Tweets were directed at children and have failed to make clear the investigational nature of the vaccine involved in the clinical trial.

We respectfully maintain our position as outlined in our previous response. Our response below includes comments on the points raised by the complainant in his/her appeal letter, in the same order as presented in that letter.

1. Tweet D (Clause 5.1, 6.1 and 6.2)

Targeting of Children (Clause 5.1) The complainant has appealed the Panel's ruling that Tweet D, which includes the statement, "If you're aged 12 – 60+ you can join too", was not specifically targeted at children. The complainant argues that that it is sufficient that the material was "directed at children" and that it does not need to have been directed "specifically or only" at children.

The complainant refers to the MHRA website which states that you must not "direct your advertising at children". The complainant has omitted to note that this statement on the MHRA website is followed by the wording "See chapter 5 of the Blue Guide for more information". As the complainant noted in his/her original complaint, section 5.4 of the MHRA's Blue Guide provides further commentary on this requirement and states "Advertising of medicines should not be directed exclusively or principally at children (under-16s)".

Therefore the correct test under the MHRA Blue Guide is not as the complainant claims whether the material was directed at children but whether it was directed "exclusively or principally" at children.

As noted in the Panel's ruling, the Tweet D was directed at both adults and children, and there was no language or imagery that was specifically directed toward children. The fact that children are within the age range eligible for the clinical trial does not mean that the tweet was targeted "exclusively or principally" towards children. The tweet provided accurate recruitment information without any content that was

specifically directed at children. The Panel therefore rightly concluded that the complainant had not demonstrated, on the balance of probabilities, that the tweet was specifically targeted at children and Tweet D did not promote Moderna's vaccine to the public but rather was intended to drive recruitment to a clinical trial.

Misrepresentation of the Clinical Trial (Clause 6.1) The complainant also contests the Panel's decision regarding the clarity of Tweet D about the investigational nature of the vaccine. The Panel found that while the term "#Covid #booster trial" made it clear that the trial related to a COVID-19 vaccine, the phrase "investigational product" was not required at that stage of the recruitment message.

We support the Panel's findings in this regard. The tweet was intended as a first step to generate interest, with full trial details including the unlicensed status and risk profile of the product being provided later to those interested before making any decision as to whether to participate in the trial. While we acknowledge the complainant's statement that there are many sorts of clinical trial, the average reader of the tweet in isolation would likely understand a "trial" as involving an investigational product under development. We maintain that the level of detail in the tweet was appropriate for a social media post about recruitment for a clinical trial and on a standalone basis was consistent with the ABPI Code.

Statement in the Linked Article Regarding Protection (Clause 6.2) Regarding the complainant's objection to the statement in the article that the trial might help protect participants and others, we agree with the Panel's finding that it was reasonable to make general reference to the potential public health benefit of vaccination. The Panel's interpretation was balanced, considering that vaccines have the potential to reduce transmission in the population. This was a fair and justifiable statement and was not misleading.

Even if this statement is interpreted, as the complainant alleges, as referring to the NextCOVE study, the reference to "help protect themselves as well as others" does not specifically claim "a reduction of risk of infection in the wider population" or any "effect on reducing transmission" as stated by the claimant. Participating in the development of a booster is also of potential public health benefit in terms of contributing to a booster product potentially becoming available not only to participants but to other patients more widely.

2. Tweet B (Clauses 5.1 and 6.1)

The copy of "Tweet B" provided to Moderna by the PMCPA as an attachment to the complaint differs from the copy of "Tweet B" in the complainant's appeal letter. The copy provided by the PMCPA appears to be the response tweet referred to in the complainant's appeal letter rather than the initial post. Our response to the original complaint was based on the copy of "Tweet B" provided by the PMCPA.

The copy of "Tweet B" in the complainant's appeal letter was posted by [named patient recruitment centre], which is Patient Recruitment Centre sites funded by the National Institute for Health and Care Research ("NIHR") and hosted by [named NHS trust].

Again for the reasons explained above we disagree with the complainant's assertion that the correct test is whether the tweet was directed at children and instead the standard to be applied is whether the tweet was directed "exclusively or principally" at children.

The tweet used language that was neutral and appropriate for recruiting a wide age group. The text and the two equally sized images in the tweet reference both an adult and a child over 12 participating in the study. The complainant has not provided evidence on the balance of probabilities that the tweet was directed "exclusively or principally" at children.

In relation to the complainant's allegation that the tweet failed to disclose involvement of a pharmaceutical company, as noted in our original response we were not involved in the tweet, rather it was posted by a third party in breach of the contractual arrangements in place.

Clarity of the Clinical Trial's Nature (Clause 6.1) As explained in relation to Tweet D above, the complainant has not proved on the balance of probabilities that the tweet was misleading as to the nature of the clinical trial. As above, the average reader of the tweet would likely understand a "trial" as involving an investigational product under development. We maintain, as the Panel concluded, that this tweet was a first- step communication designed to spark interest in the trial. Full details regarding the investigational nature of the vaccine and other specifics were provided to interested individuals later in the recruitment process. The tweet was consistent with the general practice of using social media for initial engagement and was not misleading. Thus, we agree with the Panel's ruling of no breach of Clause 6.1.

3. High Standards and Third-Party Responsibility (Clause 5.1, Clause 2)

We acknowledge the Panel's ruling that Tweet D breached Clause 5.5 for failing to disclose Moderna's involvement and Clause 6.1 for not adequately reflecting the clinical trial's recruitment process.

However, as the Panel noted the tweets in question were posted by a third party contrary to the clear contractual restrictions that Moderna had in place prohibiting the third party from using unapproved recruitment materials. While Moderna accepts that under the Code companies are held responsible for the acts and omissions of their third parties even where they act contrary to the instructions given, we reiterate that Moderna had no involvement in the tweets and article in question. The third party involved is one of a number of sites that have conducted clinical research involving Moderna's vaccine products and is not, as the complainant alleges, akin to an employee. Moderna acted appropriately in provided REC-approved materials, and the third party that did not follow the contractually agreed processes. We have since taken steps to further reduce the likelihood of any such future occurrences of a third party site acting contrary to its contractual obligations.

Given these circumstance, we respectfully request that the PMCPA Appeal Board uphold the original ruling of the Panel in relation to no breach of Clause 2.

Thank you for considering our comments."

FURTHER APPEAL FROM THE COMPLAINANT

The complainant's further written comments are reproduced below.

> "I have been reading the recently published case report AUTH/3886/3/24 with some interest as it has a great deal in common with my own ongoing case AUTH/3815/8/23. They both relate to the Moderna-sponsored clinical trial NextCOVE and the recruitment of healthy children in the UK. However, I have noticed some inconsistency between the way that 3886 was handled by the Panel and the way that 3815 was handled. I wish to draw this to your attention because I think that it has implications for the conduct of my appeal of several of the Panel's decisions about 3815.
>
> In 3886 the complainant reminded the Panel of the fact that the PMCPA guidance on the use of social media in clinical trials says "When social media is used in relation to recruitment for clinical trials, pharmaceutical companies need to consider all other applicable codes, laws and regulations in this regard". However, the complainant appears only to have complained about breaches of clauses 5.1 and 2., presumably because they were unaware that the guidance quoted above was also reflected in the requirements of clause 3.4 of your code. The Panel, however, interpreted the complaint such that they also asked Moderna to respond in relation to clause 3.4. Having then asked for a response in relation to 3.4, and despite the fact that the complainant appears to me to have provided ample evidence of a breach of 3.4, the Panel finally decided that 3.4 had not been breached because "there was no evidence of a formal finding of infringement under the Regulations or IRAS guidance."
>
> In my complaint letter for 3815 I too referred to the same wording from your social media guidance. However, I too was unaware of the requirements of clause 3.4 of your code and therefore did not include this as a specific clause breach in my complaint. Contrary to 3886 however, the Panel did not interpret my reference to the quote from the social media guidance as requiring Moderna to respond in relation to clause 3.4 so a potential breach of clause 3.4 was not considered in my case. I think that I am entitled to ask why two such similar cases were treated in entirely different ways by the Panel? As I point out above, the reason given for the Panel's eventual rejection of a 3.4 breach for 3886 was because of a lack of a "formal finding of infringement". Yet as part of my complaint I provided information on a formal complaint to the HRA about use of these same adverts without the required REC approval, which was contrary to the conditions for the ethical approval of the study. The HRA found in my favour in this complaint and judged that these adverts had indeed been used without seeking the required REC approvals. Thus, had the PMCPA Panel considered 3.4 as part of my complaint, their requirement for "a formal finding of infringement" could and would have been met. Although the Panel said in their judgement that they had not been provided with a copy of my letter from the HRA, they did not ask for one. I have attached here a copy of that letter. I have removed sections of the letter relating to other aspects of this study which I also discussed with the HRA. These are not relevant to this case and I do not wish Moderna to see them. As you can see, the HRA state clearly that "The sponsor has notified the HRA which has recorded the use of these advertisements without a REC favourable opinion in place as a breach"

In summary, if the Panel had treated my complaint in the same way as 3886 and required Moderna to respond in relation to clause 3.4 then I believe that I would have been able to provide the necessary documentary evidence to demonstrate that clause 3.4 has been breached. I do however realise that it is too late now in the process for this complaint to include consideration of a breach of 3.4. However, I would like to ask that this note, and my enclosed response letter from the HRA, be forwarded to the Appeal Board as I believe that it should be relevant to their consideration of breaches of clauses 5.1 and 2. If this is not going to be possible then please let me know and I will sent it in as an enclosure with a fresh complaint about this breach of clause 3.4.

I have no objection to any of this information being sent to Moderna (suitably redacted to remove personal information, names, emails etc)"

NOTE – The PMCPA advised the parties that Clause 3.4 was not at issue in this case.

FURTHER RESPONSE FROM MODERNA

Moderna's further written response to the appeal is reproduced below.

"Thank you for the opportunity to address the concerns raised by the complainant. We understand that the complainant seeks to include the Health Research Authority letter dated 8 December 2023 (the "HRA Letter") and their own supplementary e-mail correspondence dated 28 October 2024 (the "Email") in the appeal proceedings for this Case AUTH/3815/8/23.

As outlined in our previous response, whilst Moderna accepts that under the Code companies are held responsible for the acts and omissions of their third parties even where they act contrary to the instructions given, we reiterate that Moderna had no involvement in the materials in question. Upon learning of the use of unapproved materials, we promptly contacted the parties involved to ensure their removal and reminded them of our compliance requirements under the Clinical Trial Agreement (CTA). This is confirmed in the HRA Letter, where the HRA notes its understanding that Moderna was unaware of the materials' publication and has acknowledged our corrective actions. We accept the inclusion of the HRA Letter in these appeal proceedings, as it is directly relevant to the matters under review.

However, we respectfully disagree with the complainant's assertion that the Email is relevant to these appeal proceedings. As noted, Clause 3.4 is not under consideration in this case. Furthermore, the complainant references Case AUTH/3886/3/24, in which the Panel found no breach of Clause 3.4 and in circumstances where unapproved materials were provided in draft by Moderna. In the present case, Moderna had no involvement in the materials at issue, rendering any comparison to Case AUTH/3886/3/24 unfounded."

FINAL COMMENTS FROM THE COMPLAINANT

The complainant's final written comments are reproduced below.

"I would like to make some final observations on Moderna's response to my appeal and their response to my HRA letter.

Both in their appeal response and in their response to my HRA letter Moderna are saying “Moderna had no involvement in the materials in question.” However they are also saying “Moderna accepts that under the Code companies are held responsible for the acts and omissions of their third parties even where they act contrary to the instructions given”. I am afraid that I am still struggling to understand how these two positions are consistent with each other and compatible with both the letter and spirit of your code.

As I have pointed out before in this case, the staff at the [named] centre dealing with these children are key members of the team for this Moderna study in exactly the same way as if they were employees rather than contracted staff. Moderna are fully responsible for the recruitment, training and monitoring of all their staff (contracted and employed) and are also fully responsible for their actions as admitted by Moderna above. It is for this reason that I believe that Moderna’s assertion of “no involvement” to be unsustainable. It is also the basis of my appeal of the Panel’s finding of no breach of Clause 2. The Panel’s reason for this finding was “The Panel considered that the failure to use approved material was concerning but also noted that Moderna appeared to have been let down by the third party, who had used materials that had not been reviewed and approved by Moderna or the research ethics committee.”

If one were to replace the phrase “third party” with “employee” in the above rationale would the appeal board also consider that to be a supportable rationale for no-breach of Clause 2? If not then I think that if my appeal is not upheld then everyone needs to understand that an important precedent would be being set here. That precedent would be an acceptance by the PMCPA that, in terms of bringing discredit on your industry, the standards expected of individuals and organisations contracted by UK pharma companies are lower than those expected of the pharma companies themselves. I doubt that the general public and the media would find such a position to be either acceptable or credible.

Finally I would like to respond to Moderna’s comments about the HRA letter. They say that they “disagree with the complainant’s assertion that the Email is relevant to these appeal proceedings.”

I would like to remind everyone that I have accepted that it was too late now to include a breach of clause 3.4 as part of this case. (I do however think that it should have at least been considered by the panel in the same way as for the llegal [sic] offer of payments in Case AUTH/3886/3/24). No, I clearly stated that my specific reason for asking for this formal decision document to be included was to support my complaint of breaches of clauses 5.1 and 2. I clearly said:

“However, I would like to ask that this note, and my enclosed response letter from the HRA, be forwarded to the Appeal Board as I believe that it should be relevant to their consideration of breaches of clauses 5.1 and 2.”

The HRA response helps to demonstrate that Moderna had failed to ensure compliance with the rules and regulations required by the HRA and hence failed to follow the guidance issued by the PMCPA in their Social Media Guidance document. The results of this failure, adversely affecting as is it did the communication of

healthcare information to children, are sufficient, indeed require, findings of breach of clause 2."

APPEAL BOARD RULING

Tweet B

The Appeal Board observed that the complainant in their appeal had provided a copy of the original tweet, posted by the [named patient recruitment centre] account, that had not been before the Panel. The Panel had only reviewed the response to the tweet (also from the [named patient recruitment centre] account) and the complainant's description of the original tweet.

The original tweet included two photographs. One photograph featured a young girl in school uniform (appearing to be of secondary school age, i.e. 12 years or older) holding a teddy bear and a certificate. The other photograph consisted of a photograph of three people – the same child in school uniform, a woman assumed to be the child's mother/caregiver, and a man who appeared to be a health professional – seated in a healthcare setting.

In response to a question, representatives from Moderna stated that they accepted responsibility for the actions of [named patient recruitment centre] in the context of this case. It was acknowledged that as part of its agreement with [named NHS trust] Moderna encouraged the use of social media for clinical trial recruitment. At the appeal, the representatives from Moderna confirmed that they were unaware of Tweet B or the response to it and that the company would not have approved this tweet had it been aware of it.

The Appeal Board considered that in accordance with Clause 1.24 of the Code, which states that companies are responsible under the Code for the acts and omissions of their third parties, even if they act contrary to the instructions which they have been given, Moderna bore responsibility under the Code for Tweet B.

The Appeal Board considered that Tweet B referred to a new COVID-19 vaccine trial and that to the intended audience it was clear that this tweet concerned involvement with a clinical trial. The Appeal Board did not consider that there was any evidence put forward by the complainant to show that the tweet was misleading in that the trial was for a product under development and it ruled **no breach of Clause 6.1**. The appeal on this point was not successful.

The Appeal Board considered that neither Tweet B or the reply to it clearly indicated the involvement of the pharmaceutical company and this was contrary to the requirements of Clause 5.5. The Appeal Board ruled **a breach of Clause 5.5**. The appeal on this point was successful.

The Appeal Board observed that the response to Tweet B stated "If you want to take part and are over the age of 12, please get in touch.." The Appeal Board considered that the combination of the wording of the response to the tweet – with emphasis on "you" being "over the age of 12" with the image of the girl holding a teddy bear and certificate meant that the post was inappropriately directed at children and therefore high standards had not been maintained and it ruled **a breach of Clause 5.1**. The appeal on this point was successful.

Tweet D

The Appeal Board considered that Moderna's acceptance of responsibility equally extended to Tweet D and the linked article at issue. The Appeal Board observed that Tweet D consisted of a photograph of three people – a child in school uniform (appearing to be of secondary school age, i.e. 12 years or older), a woman assumed to be the child's mother/caregiver, and a man who appeared to be a health professional – seated in a healthcare setting. This was accompanied by the words "Proud to have recruited our 1st participants to a new [@ account of named patient recruitment centre] #Covid #booster trial. If you're aged 12 – 60+ you can join too. Find out how", with an '@ mention' tagging the Twitter accounts of four individuals and the NIHR research account, and a link to an article on the [named NHS trust] website.

The Appeal Board considered the complainant's allegation that Tweet D was inappropriately directed at children. The Appeal Board noted particularly the reference to an age bracket in relation to the relevant age range for the trial "12 – 60+") and the image of trial participants within a healthcare setting. The Appeal Board considered that neither the method of communication, nor the image used within the tweet appeared directed towards children. The Appeal Board therefore upheld the Panel's ruling of **no breach of Clause 5.1**. The appeal on this point was not successful.

In relation to the allegation that Tweet D did not make clear that this was for an "investigational product, under development, unlicenced with no proven efficacy and with an unknown risk profile", the Appeal Board agreed with the Panel's observations that the reference to recruiting participants and the inclusion of the words "#Covid #booster trial" in Tweet D meant that it was clear that it referred to a clinical trial and the term 'booster' would be understood by the public in the context of vaccinations to prevent COVID-19. The Appeal Board also took into account that anyone who expressed any interest would receive further information and screening before taking part in any trial. The Appeal Board did not consider that the complainant had demonstrated that Tweet D was misleading on this narrow point as alleged. The Appeal Board therefore upheld the Panel's ruling of **no breach of Clause 6.1**. The appeal on this point was not successful.

Article linked to from Tweet D

The Appeal Board considered the complainant's allegation that the statements made by the paediatrician in the linked article where "[they] urged people to come forward and take part in the trial in order to help protect themselves as well as others." could not be substantiated.

The Appeal Board considered that this was a general statement in support of vaccination. The Appeal Board considered that it was not unreasonable to make a general reference to one of the potential benefits of vaccination being to reduce the risk of infection in the wider population. The Appeal Board noted in general terms that it was not unacceptable to refer to secondary benefits that flowed from using a medicine for its licensed indication so long as the licensed indication was clear.

The Appeal Board did not agree with the complainant's allegation that the quotation constituted a claim about Moderna's vaccine which could not be substantiated. The Appeal Board therefore upheld the Panel's ruling of **no breach of Clause 6.2**. The appeal on this point was not successful.

Tweets and online articles – overall

The Appeal Board considered the Panel's rulings of breaches of the Code in addition to its own rulings. The Appeal Board was concerned about the level of oversight that Moderna was able to demonstrate in relation to third parties. The use of the photograph of the schoolgirl with a teddy bear and certificate, along with the language encouraging children to take part in the vaccine trial were unacceptable (Tweet B) and reflected poorly on the industry. Taking into account the rulings of breaches across Tweet B, Tweet D and the linked article, the Appeal Board considered, on balance, that Moderna had brought discredit upon and reduced confidence in the pharmaceutical industry. The Appeal Board ruled **a breach of Clause 2**. The appeal on this point was successful.

Complaint received **30 August 2023**

Case completed **13 January 2025**