CASE AUTH/3886/3/24

A COMPLAINT ON BEHALF OF CHILDREN'S COVID VACCINE ADVISORY COUNCIL v MODERNA

Alleged use of social media to solicit the recruitment of children into a clinical trial using unapproved financial incentives

CASE SUMMARY

This case was in relation to an unapproved WhatsApp message used to promote the recruitment of children into a clinical trial which the complainant alleged offered an inappropriate financial inducement.

The outcome under the 2021 Code was:

Breach of Clause 5.1	**Failing to maintain high standards**
Breach of Clause 2	**Bringing discredit upon, and reducing confidence in, the pharmaceutical industry**

No Breach of Clause 3.4	**Requirement that companies must comply with all applicable codes, laws and regulations to which they are subject**

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 on behalf of Children's Covid Vaccines Advisory Council (CCVAC), a group of health professionals and academics who have concerns over the use of COVID-19 vaccines in healthy children, was received about Moderna Biotech UK Ltd. The complainant had consented to disclose their identity to Moderna and to be named within the case report.

COMPLAINT

The complaint wording is reproduced below:

> "I am the convenor of a large group of health professionals and academics who have grave concerns over the use of Covid-19 vaccines in healthy children, initially with enrolment in trials and subsequently through the NHS rollout.
>
> I am writing to complain about an inappropriate financial inducement which was offered by Moderna to children (and their parents) as an incentive for those children to participate in a Moderna-sponsored clinical trial of one of their Covid-19 vaccines. The trial is called NextCOVE and participants (adults and children) aged 12 and over were recruited in a number of centres around the UK (along with the USA and Canada) during 2023.

I have attached a copy of the minutes of the meeting of the research ethics committee (REC) which reviewed and approved this clinical study. You will see that on pages 9 and 11 of these minutes, concerns are expressed by the REC regarding the large amount of money Moderna was proposing to offer trial participants:

"this amount seems much higher than what would be considered a reasonable reimbursement and therefore would contravene clinical trial regulations. The Medicines for Human Use (Clinical Trials) Regulations (2004) explicitly prohibit the giving of incentives or financial inducements to children…..or their parents"

The REC also considered that the amount initially on offer placed the children at risk of coercion. As a result, the REC required Moderna to revise the information given to participants about the payments on offer. This change was required to be made before the REC would approve the study, and thus before recruitment could commence. The necessary changes were subsequently made and the revised leaflet gave a greatly reduced schedule of payments, which amounted to a total of £185, down from the original £1505.

Despite this change, a paediatrician at one of the trial centres, [named NHS trust], posted the unapproved offer of a payment of £1500 in a WhatsApp group (see below).

[Screenshot of WhatsApp message provided, reading:

> "Hi all
>
> I'm [name], a paediatrician at [named hospital research facility] at [named NHS trust].
>
> Were [sic] currently recruiting to the Moderna COVID booster vaccine study and inviting potential participants.
>
> **Who is eligible?**
> Children aged 12-18 years who have had any UK approved vaccine (Moderna, AZ, Pfizer-BionTech) more than 3 months ago, and who don't have COVID now.
>
> **What's involved?**
> - A brief screening visit to the [named hospital]
> - A visit to receive the booster dose of vaccine
> - 3 monthly brief visits to the hospital as follow up
> - Completing a daily e-diary saying how they feel for a year (v simple to do)
>
> **What's in it for them?**
> £1500 on completion of the study.
>
> Let me know here, or email [email address], or call us on [phone number]
>
> We'd love to have you on board!"]

When I wrote to [two senior leaders] of [named NHS trust], I initially received no reply, but then after a Freedom of Information (FOI) request, the Trust replied that the payments were authorised and *"the message was in line with the offer of reimbursement by the sponsor".* On pressing them further, by requesting an FOI "Internal Review", they acknowledged that the offer was based on version 1 of the leaflet, the version which had actually been rejected by the REC.

It is notable that version 1 of the leaflet nowhere mentions that it is still a draft awaiting approval. This unapproved version 1 was clearly circulated to potential recruitment centres either prior to review by the REC or after the REC had rejected it. Whether this unapproved version was distributed by Moderna or by a contract research organisation (CRO) engaged by Moderna, it would appear that there was an assumption on the part of the distributor that version 1 would be approved by the REC without changes. This assumption could potentially have led to children being enrolled after, and therefore possibly as a result of, an inappropriate, and potentially illegal, inducement. Indeed, I am personally aware of a mother of four children who rang the trial centre after seeing this WhatsApp post, but by then the trial had stopped recruiting.

In February 2023, the PMCPA launched a document entitled "PMCPA Social Media Guidance 2023". This guidance contains some useful information about general principles regarding the use of social media by pharmaceutical companies:

"Is it in line with company guidance, is the company guidance clear and consistent with all applicable codes, laws and regulations?"

It also contains some similar useful guidance <u>specifically</u> relating to clinical trial recruitment:

"*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*."

Despite this PMCPA guidance, it now seems clear that the WhatsApp message above, distributed by the member of staff at the [named NHS trust] recruitment centre, was soliciting recruitment of children into the NextCOVE study, using financial incentives which were in breach of The Medicines for Human Use (Clinical Trials) Regulations (2004). Furthermore, Q A46 of the IRAS [(Integrated Research Application System)] guidance document [document link provided] "Payment to Research Participants" requires that any financial inducements or compensation offered for clinical trial participation must be reviewed and approved by a REC. Therefore, on these two counts at the very least, this WhatsApp was seriously inconsistent with the ABPI's Social Media guidance document which requires consideration and consistency with all applicable codes, laws and regulations.

But are Moderna responsible for the actions of staff at the [named NHS trust] recruitment centre? Well the PMCPA Social Media Guidance has something to say about this also:

"Responsibility 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. Contracts with third parties should deal comprehensively with ownership and control including use of and potential withdrawal of materials both during and after the contracted period……Pharmaceutical companies are strongly advised to preview social media content from their contracted parties in relation to their contracted activities "

It would appear therefore that Moderna are indeed responsible for a WhatsApp message about their study posted by a member of staff at a centre contracted to conduct a clinical trial for them. Even if the centre was not finally under contract at the time the WhatsApp was sent, the centre would have been in the process of contracting with Moderna and the only place they could have obtained the offending recruitment materials would have been from Moderna so Moderna would still be responsible. It is possible that Moderna may have outsourced the conduct of this study in the UK to a CRO, who provided [named NHS trust] with the unapproved material. However, as set out in your Social Media Guidance, the responsibility for the behaviour of the CRO still remains with Moderna.

In summary, a clinical trial recruitment centre, for which Moderna is responsible, has used social media to solicit the recruitment of children into a clinical trial using financial incentives which were unapproved, in contravention of the Medicines for Human (Clinical Trials) Regulations (2004) and contrary to the guidance given in IRAS Q A46. As a result Moderna have failed to follow the guidance given in "PMCPA Social Media Guidance 2023". It is therefore my opinion that Moderna is clearly in breach of the following clauses of your Code of Practice:

- Clause 5.1 High standards must be maintained at all times
- Clause 2 Discredit to, and Reduction of Confidence in, the Industry"

Further information from the complainant

The complainant's response following a request by the PMCPA case preparation manager for further information is reproduced below:

"I am aware that the PMCPA is not an investigative body and rather than ask you to "*investigate the conduct of Moderna*" perhaps I should actually have simply said that I wished to "*complain about the conduct of Moderna*."

I would like to make it clear that I am not asking the PMCPA to investigate or rule upon whether Moderna is in contravention of the Medicines for Human (Clinical Trials) Regulations (2004) [the Regulations] or whether Moderna acted contrary to IRAS guidance. The offer of £1500 to child participants, and the status of this offer as unapproved by the REC, are easily verifiable statements of fact:

A. Regarding the clinical trial regulations

- The REC minutes dated 11/4/23 (a copy of which I have previously provided) state clearly on page 9 that *"The AM* [Applications Manager] *noted the PIS* [Patient Information Sheet] *stated the parents of the children involved would be given £1505 if all visits and diaries were completed. The AM stated this amount seemed much higher than what would be considered a reasonable reimbursement and therefore would contravene clinical trial regulations. The*

Medicines for Human Use (Clinical Trial) Regulations 2004 explicitly prohibit the giving of incentives or financial inducements to children (under 16 years of age) or their parents/legal representatives to participate in clinical trials of investigational medicinal products (CTIMPS).”
This REC opinion that the proposed payment was too high is then reiterated later in the minutes, in required Action 1 on Page 13, along with the additional judgement that it was potentially coercive *“The Committee stated the reimbursement for children taking part in the study is too high (£1505 on completion of study visits and diaries). The Committee stated this puts the child at risk of coercion. Please revise this to a more reasonable amount that will cover expenses but not constitute a payment to the child participants. You could consider asking parents to provide an itemised list of expenses.”*

- In addition I would like to draw your attention to the another [sic] document, obtained as a result of FOI requests, as the MHRA [Medicines and Healthcare products Regulatory Agency] have also had an opportunity to comment on this matter. On the final page of their NOTICE OF GROUNDS FOR NON-ACCEPTANCE AND RIGHT TO AMEND REQUEST (GNA) letter to Moderna dated 19/4/23 the MHRA Clinical Trials Unit says that “*The information sheets state that parents will receive £1505 for their child's participation if all visits/diaries etc. However, the Medicines for Human Use (Clinical Trials) Regulations (2004) explicitly prohibit the giving of incentives or financial inducements to children (under 16 years of age) or their parents/legal representatives to participate in clinical trials of investigational medicinal products (CTIMPS). Please provide clarification regarding this*.”

I think that the opinions of the MHRA and the REC clearly indicate that the offer of £1500 was in breach of the Regulations. More importantly, the fact that it was too high was one of the reasons why the clinical trial application was initially rejected by the MHRA and the REC. No investigation by the PMCPA is either needed or requested. This was not disputed by Moderna and on page 12 of their response letter (attached) to the MHRA’s GNA letter, when addressing the MHRA’s concerns about the payments, Moderna simply responded “*The Sponsor has taken the REC assessment and as noted in response to question 6 of this document, the Sponsor has amended the participant reimbursement amounts to reflect only reimburse parent/legal representatives for fees incurred as part of participation such as travel, parking or fuel*.”

B. Regarding IRAS

Whether you agree that the proposed offer of £1505 has been judged by the MHRA and REC to be in breach of the Regulations or whether you just think that the excessive size of this payment was simply a significant reason for the initial rejection of the CTA [(Clinical Trial Authorisation)] by the MHRA and the REC, is actually immaterial to the substance of my complaint. It is an explicit requirement of the IRAS system (Q A28) that “*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.”*

Furthermore Q A46 of IRAS states *that "If you decide to introduce payments after receiving a favourable opinion from the main REC, these must be notified to the REC as a substantial amendment and ethically reviewed before being implemented."*

The offer of £1500 was indeed reviewed by the REC, but it was not approved. The offer of £1500 made on WhatsApp was therefore either:
a. Made in advance of REC review and was therefore unapproved, or…
b. Made after the REC had rejected it and was therefore also unapproved

There are no other possible scenarios. Therefore the requirements of the IRAS system to seek approval for the £1500 payment were unequivocally not followed. Thus no investigation is required, merely the application of some simple logic.

I would like to reiterate here that what I am complaining about is the fact that Moderna permitted the use of social media to promote the recruitment of children into a clinical trial using a social media posting and a financial inducement which had demonstrably not received the required approval from a REC. The reasons why the REC chose not to approve the £1500 payment are actually irrelevant to my complaint. Information relating to the Medicines Regulations was provided for background and context only. The important points are that any payments must be approved by the REC and, as has been clearly demonstrated, the WhatsApp £1500 payment proposal/advertisement never received such approval. It appears that Moderna shared unauthorised materials with potential recruitment sites, with no labelling to show that this was an unapproved draft. When the new documentation was approved, they have made no effort to ensure the original documents were withdrawn.

The PMCPA has published guidance on the use of social media by pharmaceutical companies, including specific guidance on its use for clinical trial recruitment. It would therefore be unusual would it not, if the PMCPA was not then prepared to deal with a complaint about the use of social media for clinical trial recruitment by a pharmaceutical company? Your guidance requires that "*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*." Permitting the unapproved use of social media in order to make unapproved financial inducements, which have been judged by a REC to be potentially coercive, is clearly in breach of this requirement, and hence in breach of Clauses 2 and 5.1 of your Code. It is the use of social media in this way about which I am asking the PMCPA to make a judgement, not on whether or not there have been breaches of the Regulations or the IRAS guidance.

I have also sent a complaint to the HRA [(Health Research Authority)], but have as yet had no response other than an acknowledgement, and more recently an apology for delay in responding."

When writing to Moderna, the PMCPA asked it to consider the requirements of Clauses 5.1 and 2 of the 2021 Code as cited by the complainant. In addition, Moderna was asked to respond in relation to Clause 3.4.

MODERNA'S RESPONSE

The response from Moderna is reproduced below:

> "Moderna engaged [named NHS trust] as a trial site for the NextCOVE clinical trial. A tripartite clinical trial agreement was executed on June 15, 2023, by Moderna's contracted CRO [(clinical research organisation)], [named], involving Moderna TX Inc., and [named NHS trust]. This relationship is ongoing, and the trial is currently in the maintenance phase.
>
> The process of handling and distributing clinical trial documents involves coordination between Moderna (the Sponsor), its Clinical Research Organization (CRO), and the Health Research Authority (HRA). The role of the CRO is crucial as it is responsible for making submissions, on behalf of Moderna, to the HRA, ensuring compliance with regulatory requirements. Typically, after the initial HRA submission is validated by the HRA, the CRO assembles a 'Local Information Pack' (LIP) following guidelines produced by HRA. This LIP is sent via email to the appropriate contact within the NHS Trusts and to Principal Investigators who will be responsible for conducting the trial. The LIP includes documents which have been submitted to the [(Ethics Committee)] EC and MHRA for review as part of the HRA regulatory submission.
>
> On April 5, 2023, trial sites received these Local Information Packs, which included the initial UK versions of the Patient Information Sheet-Informed Consent Form (PIS-ICF) dated March 28, 2023. Once full HRA approval was secured and the site met regulatory requirements to open for enrolment, the CRO provided each site with the final versions of these documents, specifically tailored with contact details relevant to each location. This ensures that each site has the most accurate and up-to-date information required to conduct the trial effectively.
>
> The PIS-ICF documents provided for EC review as part of the HRA regulatory submission are considered final versions at the country level and are intended to receive feedback or approval. If the EC does not request any changes, the document, labelled as version 1.0, is localized with site-specific details, and then distributed to sites. If the EC requests modifications, the document is updated, resulting in version 2.0, and the process continues accordingly. It's crucial to note that the absence of a site-specific version number/date in the footer and the lack of localization (not formatted on hospital-headed paper) on the PIS-ICF documents within the LIP are clear indicators that the document has not yet received final EC approval.
>
> Following HRA regulatory approval, Moderna distributes the final approved versions of both printed and digital centralised recruitment materials (brochures, social media advertising etc.) to trial sites. This distribution is conducted through a secure site portal and via courier shipments, ensuring that all sites receive their materials promptly and securely. Importantly, these recruitment materials do not include any reimbursement amounts, adhering to content guidelines and ensuring clarity and compliance in communication with potential trial participants.
>
> The practice of distributing materials that have not yet been approved by the EC or MHRA in the form of a Local Information Pack aligns with HRA guidelines, which are published online. This procedure is not merely a sponsor or CRO-driven process but follows advice and guidance from the HRA. It's important to clarify that, in the management of clinical trial

documents, Moderna and its CRO do not withdraw documents previously distributed to sites. Instead, they provide the final, approved versions at the appropriate times, adhering closely to HRA guidance to ensure compliance and to maintain the integrity of the trial process. This approach ensures that all participating sites are equipped with the most current and officially sanctioned documents, facilitating a smooth and compliant trial operation.

In this specific case, a paediatrician, formerly employed at the [named hospital] (part of [named NHS trust]), used [their] personal phone to send a WhatsApp message inviting recipients to join the NextCOVE trial, suggesting a payment of £1,500. This amount, detailed in the message, appears to be taken from page 13 out of 24 of a of the **Parent Information Sheet and Informed Consent Form 1.0. version from 28th of March 2023**.

The existence of the WhatsApp message was brought to Moderna's attention on January 19th, 2024, following a meeting with the HRA. A URL was provided to Moderna and the article at the location mentioned the WhatsApp message. The article was published on August 6th, 2023, we assume that the messages must has been sent out prior to this date, however the specific time is not known.

After Moderna became aware of the paediatrician's message, they promptly met with [the Principal Investigator and the Clinical Research Facility Director at named NHS trust] on January 30, 2024. They confirmed that the paediatrician who sent the message was employed by the Trust as a researcher until September 2023. **However, [their] message was not endorsed or approved by the Trust, it is not a method of advertising or standard recruitment procedure for any clinical trial conducted within the Trust, nor was it approved by Moderna.**

After the Research Ethics Committee recommended adjusting the amount to be paid to participants in the minutes from the meeting from April 11th, 2023, Moderna complied by revising the leaflet and removing the amount in the **Parent Information Sheet and Informed Consent Form version 1.1 from 28th of April 2023 accordingly to the recommendation**. Moderna limited the compensation only to reimbursement for expenses, e.g., travel costs. This approach was accepted by the EC, and PIS-ICF version 1.1 dated 28th April 2023 is detailed as an approved document in their approval letter from June 14th, 2023.

[The complainant] claims Moderna is responsible for the misleading spread of information and did not follow standard procedures, including providing unapproved materials to its Clinical Research Organizations (CROs). This is not accurate. Moderna did provide approved, appropriate materials for use during the conduct of the trial; however, the paediatrician in question did not use the approved materials.

Moderna has initiated a Quality Event (QE) to investigate the inappropriate use of non-EC-approved NextCOVE study documentation. The QE will determine any necessary preventative actions to avoid future issues as well as support process improvements that can be implemented by both our CRO strategic partners and Moderna.

Moderna can confirm that no participants were paid the incorrect amounts mentioned in the referenced paediatrician's message. Moderna is committed to maintaining strict

compliance with clinical trial regulations as well as promptly addressing matters that may arise.

We enclose a copy of Moderna [Standard Operating Procedure] SOP-1281 Patient Recruitment & Retention Materials (version 3), outlining the rules for creating and approving materials used in recruiting and retaining trial participants. This SOP emphasizes a structured approach to maintaining high standards of accuracy, compliance, and effectiveness in all materials used.

The provision of the PMCPA Social Media Guidance quoted by the complainant refers to third parties acting on a pharmaceutical company's behalf, to dealing with ownership and control in the company's contracts with such third parties and that companies are strongly advised to preview social media content from their contracted parties in relation to their contracted activities. Considering the fact, that at the time Moderna has entered into the agreement with their employing trust [named NHS trust] the Parent Information Sheet and Informed Consent was not providing the possibility of the renumeration. Hence it is difficult to state, that the paediatrician was acting on Moderna's behalf in sending the message when [they were] using unauthorized version and did so without Moderna's knowledge or consent.

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

Clause 3.4: Moderna has complied with all applicable codes, laws, and regulations in relation to the trial in question, in accordance with Clause 3.4 of the Code, including the Medicines for Human Use (Clinical Trials) Regulations 2004 and the IRAS guidance. Moderna has followed the required MHRA and REC processes and only approved use of the final materials which stated the reduced, compliant amount.

Clause 5.1: Moderna has maintained high standards at all times in accordance with Clause 5.1 of the Code. The decision by a paediatrician to send an unapproved WhatsApp message with incorrect information does not constitute Moderna failing to maintain high standards.

Clause 2: As Moderna has not breached Clause 5.1 or 3.4 of the Code, Moderna has not brought discredit upon, or reduced confidence in, the pharmaceutical industry under Clause 2."

PANEL RULING

The Panel noted the complainant's allegation that Moderna permitted the use of social media to promote the recruitment of children into the NextCOVE clinical trial using an unapproved WhatsApp message and financial inducement that had not received the required approval.

The Panel noted from the screenshot provided by the complainant that the WhatsApp message appeared to have been sent by an individual – a paediatrician working at a named NHS trust. While the Panel had no evidence before it about the recipients, the complainant referred to the posting of the message in a WhatsApp group. In the Panel's view, the intention of the message was clearly to recruit participants aged 12–18 years for the NextCOVE trial, described in the message as "the Moderna COVID booster vaccine study". The Panel noted that the message included the wording "**What's in it for them?** £1500 on completion of the study."

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.

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 it had engaged the NHS trust as a trial site for the NextCOVE clinical trial, with a tripartite clinical trial agreement in place between Moderna, the NHS trust, and Moderna's contracted clinical research organisation. In the Panel's view, the NHS trust could, therefore, be considered a third party as defined by Clause 1.24, and so Moderna bore responsibility under the Code for the message sent by an employee of that contracted third party.

The Panel noted Moderna's submission that the WhatsApp message was sent from the personal phone of a paediatrician employed (at the time) by a named hospital (part of the named NHS trust). The Panel noted Moderna's submission that the message was not part of the approved recruitment materials provided by Moderna for use during the NextCOVE trial and that Moderna had been unaware of the message until several months after it had been sent.

The Panel considered the complainant's allegations that the offer of £1,500 for participation in the trial was in breach of the Medicines for Human Use (Clinical Trials) Regulations (2004) and that, contrary to the requirements of the integrated research application system (IRAS), the content of the WhatsApp message had not been reviewed by the research ethics committee. The Medicines for Human Use (Clinical Trials) Regulations (2004) state that "No incentives or financial inducements" may be given to a "minor" (a person under the age of 16 years) or "to a person with parental responsibility for that minor or, as the case may be, the minor's legal representative". The Panel noted that the WhatsApp message was specifically aiming to recruit "children aged 12–18 years" and that it implied that participants would receive £1,500 on completion of the study. The Panel considered that the level of payment represented an offer of a financial incentive. Regarding the requirement for the content of the WhatsApp message to have been approved by the research ethics committee, the Panel noted Moderna's submission that it had "initiated a Quality Event (QE) to investigate the inappropriate use of non-EC [(ethics committee)]-approved NextCOVE study documentation".

In relation to the alleged breach of Clause 3.4, the Panel noted that it could only make rulings in relation to the ABPI Code. While Clause 3.4 of the ABPI Code states that companies must comply with all applicable codes, laws and regulations to which they are subject, it is important to note that the PMCPA is not a body formally charged with determining matters in relation to the Medicines for Human (Clinical Trials) Regulations (2004) or IRAS guidance which includes materials for clinical trials. While the minutes of the Research Ethics Committee meeting dated 11 April 2023 stated that the level of payment would contravene clinical trial regulations and an MHRA notice of grounds for non-acceptance and right to amend request (GNA) letter to Moderna dated 19 April 2023 noted that the Medicines for Human Use (Clinical Trials) Regulations (2004) explicitly prohibit the giving of incentives or financial inducements to children (under 16 years of age) or their parents/legal representatives to participate in clinical trials of investigational medicinal products and asked for clarification, there was no evidence of a formal finding of infringement under the Regulations or IRAS guidance. While the Panel was

concerned about the level of payment to be offered, it considered that, in the absence of such a formal finding, the complainant, who bore the burden of proof, had not established that Moderna had failed to comply with all applicable codes, laws and regulations to which it was subject. Accordingly, the Panel ruled **no breach of Clause 3.4**.

Moderna submitted that the £1,500 referred to in the WhatsApp message for participation in the trial appeared to have come from an early draft of the 'Parent Information Sheet and Informed Consent Form' and that the final approved version contained a reduced figure for compensation for reimbursement of expenses, which had been accepted by the ethics committee. While the Panel considered that Moderna had been let down as the approved recruitment materials had not been used, the Panel queried whether Moderna had made it sufficiently clear that the early draft of the Parent Information Sheet and Informed Consent Form was not the final version and that substantive changes could be made to it before approval.

The Panel considered that the process of approving and distributing the 'Local Information Pack', which included the 'Parent Information Sheet and Informed Consent Form', as described in Moderna's response was confusing, with the potential for errors in relation to version control. From Moderna's submission, the Panel understood that a version of the document would be distributed to NHS Trusts and the researchers conducting the trial prior to its approval by the ethics committee. If the ethics committee requested changes to the document, a new version would be distributed. The Panel noted Moderna's submission that there were "clear indicators" that a document had not yet received final approval by the ethics committee – the absence of a site-specific version number/date in the footer and the lack of localisation (not formatted on hospital-headed paper). The Panel reviewed the two versions of the document provided as part of Moderna's submission and could see no indication on the document that there might be substantive changes made to it before approval for use.

The Panel was concerned about the use of a clinical trial recruitment message that had not been appropriately reviewed, which offered an inappropriate financial incentive to encourage participation in a clinical trial. The Panel considered that its observations on the approval and distribution process for the 'Parent Information Sheet and Informed Consent Form' and Moderna's failure to clearly communicate the 'draft' status of the document, which led to the offer of an inappropriate financial incentive, indicated that high standards had not been maintained. The Panel ruled a **breach of Clause 5.1**.

Clause 2 was a sign of particular censure and reserved for such use. The Panel noted that the offer of £1,500 for participation in the trial referred to in the WhatsApp message was described in the minutes of the ethics committee meeting as an amount that "seemed much higher than what would be considered a reasonable reimbursement and therefore would contravene clinical trial regulations". A reduced figure was subsequently accepted by the ethics committee. The Panel noted the circumstances of this case and considered that, while it had been let down, Moderna nonetheless bore responsibility under the Code for the acts of the contracted third party. The Panel noted that unacceptable payments was listed in the supplementary information to Clause 2 as an example of an activity likely to be in breach of that clause. The Panel noted that the financial incentive offered within the unapproved WhatsApp message was never paid but considered that it might have encouraged participants to apply to take part. The Panel also noted the section on clinical trial recruitment in the PMCPA's social media guidance and noted its emphasis on the need for care to be taken. The Panel considered that the unique circumstances of the COVID-19 pandemic, and the particular circumstances of this trial, which involved the recruitment of children, meant that Moderna should have been especially cautious.

The Panel considered that Moderna's failure to ensure only approved recruitment materials were used had led to a WhatsApp message being sent by a third party that contained an unapproved and inappropriately high financial incentive to encourage the recruitment of children. On balance, the Panel considered that this brought discredit upon and reduced confidence in the pharmaceutical industry. A **breach of Clause 2** was ruled.

Complaint received **2 March 2024**

Case completed **6 August 2024**