Mr Alex Fell, Director,
Prescription Medicines Code of Practice Authority
2nd Floor Goldings House Hay's Galleria
2 Hay's Lane
London
SE1 2HB

Dr Rosamond Jones
Convenor, Children's Covid Vaccines Advisory Council

2nd March 2024

Dear Mr Fell,

Re: NextCOVE trial - A randomized, observer-blind, active-controlled Phase 3 study to investigate the safety, immunogenicity, and relative vaccine efficacy of mRNA-1283.222 administered as a booster dose compared with mRNA-1272.222 in participants aged 12 years and older for the prevention of COVID-19.

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.

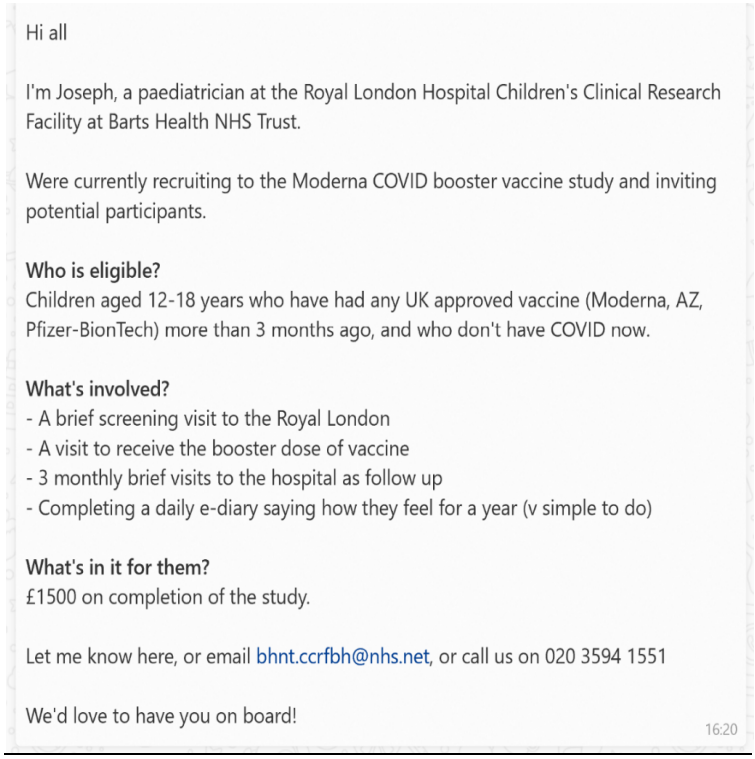
I have attached a copy of the minutes of the meeting of the research ethics committee (REC) which reviewed and approved this clinical study. You will see that on pages 9 and 11 of these minutes, concerns are expressed by the REC regarding the large amount of money Moderna was proposing to offer trial 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, Barts Health NHS Trust, posted the unapproved offer of a payment of £1500 in a WhatsApp group (see below).



Hi all

I'm Joseph, a paediatrician at the Royal London Hospital Children's Clinical Research Facility at Barts Health NHS Trust.

Were 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 Royal London
- 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 bhnt.ccrfbh@nhs.net, or call us on 020 3594 1551

We'd love to have you on board!

16:20

When I wrote to the CEO and chairman of Barts Health 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 specifically 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 Bart’s 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 guidance document “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 Barts 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 Barts 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

After reading a recent article in the BMJ I understand that the PMCPA are currently taking an extraordinarily, and many would say unacceptably, long time (often well over a year) to deal with complaints. However, I also understand that several other complaints have already been made about materials and activities relating to this study. Therefore, if it would make things easier, and quicker, I would be happy for these matters to be considered alongside any other complaints about this study which may already have been made.

Yours sincerely,

Dr Rosamond Jones, MBBS (Hons), MD, FRCPCH, retired consultant paediatrician

Convenor of Children's Covid Vaccines Advisory Council (www.childrensunion.org/ccvac)