Freedom of Information Act 2000 (FOIA)

Decision notice

Date:	**12 February 2024**
Public Authority:	**Health Research Authority**
Address:	**2 Redman Place** **Stratford E20 1 JQ**

Decision (including any steps ordered)

1. The Commissioner's decision is that the requested information about the NextCOVE trial is exempt from disclosure under section 43(2) of FOIA, which concerns commercial interests. No corrective steps are necessary.

Request and response

2. Information on the Health Research Agency's website dated 3 November 2023[1] indicates that the NextCOVE trial is a clinical trial of a new COVID-19 vaccine for adults and children over the age of 12. Concerns were raised about the trial and the Health Research Agency's article discusses those concerns.

3. In relation to the NextCOVE trial, the complainant made the following information request to the Health Research Agency (HRA) on 21 August 2023:

[1] https://www.hra.nhs.uk/about-us/news-updates/nextcove-how-hra-handles-complaints-and-concerns-raised/

"1. The full study application submitted to the REC, including the ethical rational for the conduct of the study in children, particularly with regard to the issues identified in the Declaration of Helsinki about the inclusion of children in clinical research

2. The study protocol

3. A copy of the minutes of the REC meeting which discussed the application

4. A copy of correspondence between the REC and sponsor/study team which relates to concerns or questions raised by the REC about the design or conduct of the study."

4. HRA disclosed information within scope of Q1, Q3 and Q4 and advised that the information requested in Q2 is exempt information under section 43(1) and 43(2) of FOIA. HRA also advised that it had withheld a section of the Amendment Tool and cover letter and the Investigator's Brochures under sections 43(1) and 43(2).

5. In their request for an internal review, the complainant disputed HRA's application of section 43 to the Study Protocol and Investigator's Brochures.

6. HRA maintained its position following its internal review.

Reasons for decision

7. In their request for an internal review the complainant said that they were only interested in the sections of the Brochure and Protocol documents that concern the ethics of including healthy children in the study. They considered that HRA should be able to redact any commercially sensitive information from those documents.

8. In its internal review response, HRA noted that it had written to the complainant on 19 October 2023. In that correspondence it had advised that there are no sections in either document which specifically outline the ethical rationale for including healthy children in the study.

9. As such, this reasoning covers HRA's application of both section 43(1) and 43(2) of FOIA to the entirety of the requested Study Protocol and Investigator's Brochures. Section 43(1) concerns trade secrets and section 43(2) concerns commercial interests. Since it's more usual for section 43(2) to be engaged than section 43(1), the Commissioner will consider that exemption first. But, if necessary, he'll also consider HRA's reliance on section 43(1).

10. HRA has provided the Commissioner with copies of the information it held at the time of the request and which it's withholding under section 43. The information comprises two Investigator's Brochures (one for each of the two different COVID-19 vaccines the NextCOVE study was investigating at the time) and the Study Protocol. Both are highly technical documents.

11. Under section 43(2) information is exempt information if its disclosure would, or would be likely to, prejudice the commercial interests of any person (including the public authority holding it).

12. When he's deciding whether section 43(2) is engaged, the Commissioner considers whether the envisioned harm relates to commercial interests, why disclosing the information would or could prejudice those commercial interests and how likely it is that the envisioned prejudice will happen.

13. In its submission to the Commissioner, HRA has first confirmed that it considers that it's the pharmaceutical company Moderna whose commercial interests would or could be prejudiced if the information were to be disclosed.

14. HRA has told the Commissioner that a third party (ie Moderna) provided the information to it as part of its application for HRA approval, and it's information which HRA doesn't own. HRA therefore consulted with Moderna at an early stage of the request to understand the implications of releasing the information and why disclosure would prejudice Moderna's commercial interests.

15. Moderna advised that the information contained "commercially sensitive information which … would be more likely than not to significantly prejudice … commercial interests." It said that publishing the information would lead to a harmful impact on its business.

16. HRA has described the information detailed within the Study Protocol as containing specific and detailed information and insight into Moderna's product development plans for this vaccine. This includes unpublished elements of study design, supporting data and regulatory strategy that Moderna has advised HRA are proprietary, such as:

    - Detailed study dose information and immunogenicity information.
    - Benefit assessment of the vaccine in comparison with other vaccines.
    - Detailed study design information including the scientific rationale for the study and scientific justification for the dose.

17. HRA says that because this information isn't currently in the public domain, disclosing the documents could provide potential competitors with an insight into Moderna's product development plans. This would grant those competitors an unfair commercial advantage and could compromise over 10 years of research and development investment into Moderna's platform. Disclosing this information could also impact on the commercial viability of "the launch of a pipeline of future products."

18. HRA has gone on to explain that during the COVID pandemic, the competitive nature of the pharmaceutical industry was evident more than ever, with companies working hard to test and release their own vaccines ahead of competitors. The importance of developing vaccines to combat the deadly nature of the disease and save lives is evident. But the environment these organisations operate within is extremely competitive and is a multi-billion-pound industry. Therefore, the risk of significant harm to commercial interests is real.

19. The specific study to which the information relates concerns the need for updated vaccination strategies to deal with COVID variants. Notably to enable longer shelf life at refrigerated temperatures while providing a safe and tolerable vaccine with potent immune responses at lower doses compared to the original Moderna vaccine. The length of time a vaccine can be stored for, and so be used for longer, is a factor when healthcare providers consider which vaccine to purchase. So, releasing this information could have a detrimental effect on Moderna.

20. First, the Commissioner is satisfied that the interests that would or could be prejudiced are the commercial interests that section 43 of FOIA is designed to protect.

21. Second, the Commissioner accepts that disclosing the information would or could prejudice Moderna's commercial interests. This is because it would give Moderna's competitors an insight into Moderna's product development plans. This would give those competitors an unfair competitive advantage over Moderna and compromise its investment into research and development over the last decade.

22. Regarding the level of likelihood, HRA says it's satisfied that the level of likelihood of the envisioned prejudice occurring is more probable than not if the information were to be disclosed. This is because, "in the competitive world of the pharmaceutical industry, the ability of the third party to participate competitively would be impacted, with significant and real harm to their commercial interests, if the information were to be released."

23. Finally, because of the highly competitive environment in which Moderna operates, the Commissioner will accept that disclosing the information

would prejudice Moderna's commercial interests. It meets the higher threshold ie the envisioned prejudice is more likely to occur than not, although it isn't certain to occur.

24. Because the conditions at paragraph 12 are met, the Commissioner finds that the withheld information engages section 43(2) of FOIA. He's gone on to consider the associated public interest test.

Public interest test

25. In their request for an internal review, the complainant advised that they wanted to interrogate and potentially challenge why the Research Ethics Committee (REC) thought it was acceptable to include healthy children in the NextCOVE study. They said that they considered that the Investigator's Brochures and Study Protocol will have been key to the REC's decision.

26. In their complaint to the Commissioner, the complainant has argued that there's much public interest in this information. In the spirit of openness and transparency, they would expect HRA to provide the documents without any further delay.

27. As arguments in favour of disclosure, HRA says it promotes transparency surrounding research and publishing this information would support openness and transparency about the study.

28. HRA notes that there has been a "constrained but concentrated" interest in this study by certain groups (paediatricians and child campaigning groups) because children are included as participants. Disclosing study documents may help promote public understanding of the study.

29. HRA also acknowledges that there have been safeguarding concerns raised about including children therefore disclosing this information may allay some of these concerns.

30. HRA has presented the following public interest arguments against disclosure:

    - The requested documents contain information about a newly modified vaccine which is a trade secret and contains commercially sensitive information. Releasing the information would impact the commercial interests of the third party.

    - This information isn't currently in the public domain and is classed by the third party as confidential.

    - The information contained within the requested documents contains very specific, technical, and commercially sensitive

information specific to the study vaccine. Such information may be unlikely to contribute much to public understanding of the study.

- Disclosing this information would prejudice the third party's ability to participate competitively in a commercial activity.

- HRA relies on sponsors to submit confidential information to enable the HRA to carry out its regulatory functions. Disclosing information which relates to trade secrets, or which is commercially sensitive could impact on the HRA's ability to carry out these functions through damage to trust or relationships.

31. Finally, HRA has discussed the balance between disclosing the information and maintaining the exemption.

32. In its view the factors pro-disclosure don't outweigh the factors against disclosure. The exempted documents aren't in the public domain at present, and this is a new study, approved by the REC on 4 May 2023.

33. As a general rule, HRA says it doesn't usually disclose the sort of information that was requested in this case as the information is likely to contain commercially sensitive information. However, HRA considers requests on a case-by-case basis. In this instance, HRA considers that there's likely to be minimal benefit to public understanding or scrutiny of the study if the documents were released. This is because of the scientific and technical nature of the information contained in them. However, the impact on Moderna's commercial interests would be significant and real.

34. HRA has acknowledged that a number of concerns have been raised in relation to this study, largely around including healthy adolescents in the research, with safeguarding concerns raised. This has led to the complainant submitting this FOIA request. HRA says that although it has given allaying safeguarding concerns as an argument in favour in releasing this information, it's important to highlight the important role the REC plays in reviewing the research. The REC is appointed by HRA, and it's made up of independent expert and lay members. The REC must weigh up the participation of healthy adolescents in research (with consent in place from their parents) and the non-inclusion of children. This would mean that potentially lifesaving treatments and vaccines given to any of that population, healthy or sick, were untested.

35. HRA says that it's also important to highlight that the safety of a product in the population concerned is the remit of the Medicines Health products Regulatory Agency (MHRA). The combined review process involving the REC and MHRA involves reviews being undertaken in parallel. This ensures that there's an opportunity for any overlapping

concerns to be addressed between the REC and MHRA. As part of this process, the REC receives assurance from the MHRA that the safety aspects of a trial have been considered. In the case of the NextCOVE trial, the REC and the MHRA didn't need to reconcile any such issues.

36. The REC's primary concern is to ensure that children (where appropriate) and their parents/carers have the relevant information, so they understand the purpose of the study and what is being asked of them, including the risks. It's particularly important that the children don't feel coerced by anyone to take part, nor are they or their parents offered financial or other inducements that might persuade them to do so against their better judgement. They also need to understand and be reassured that they are free to make a choice about participating. During the ethics review of the NextCOVE trial, the REC requested several changes to the information being provided to potential participants and their parents/carers. This was so that the children and their families could make an informed decision about whether to participate.

37. HRA concludes by noting that RECs recognise that not everyone will agree with their ethics opinion. However, they review applications very carefully and draw on the expertise and life experience of all their members to reach their opinion. In a combined review this is shared with the MHRA who will also make its assessment and give approval, or not, to the study.

38. HRA says that it aims to promote transparency around research. However, in this instance disclosing confidential information, which has been approved in line with regulation, would be unlikely to allay the fundamental concerns of those who don't believe that research should go ahead on healthy adolescents. Disclosure would however impact significantly on Moderna's commercial interests. HRA therefore found that, on balance, the public interest favoured maintaining the exemption.

The Commissioner's conclusion

39. The final of the bullet points at paragraph 30 appears to the Commissioner to be key. The Commissioner considers that in this case there's greater public interest in HRA having a good relationship with sponsors – one built on trust – so that sponsors are prepared to submit confidential commercial information to HRA. This enables HRA to carry out its regulatory functions.

40. The public interest in transparency about the NextCOVE study, and the ethical and safety aspects of it, is met to a satisfactory degree, in the Commissioner's view, through the relevant information HRA has published and through the involvement of the REC and MHRA. The Commissioner is therefore satisfied that the public interest favours withholding the information.

41. Because the Commissioner has found that section 43(2) is engaged and the public interest favours maintaining this exemption, it hasn't been necessary for him to consider HRA's application of section 43(1) to the same information.

Right of appeal

42. Either party has the right to appeal against this decision notice to the First-tier Tribunal (Information Rights). Information about the appeals process may be obtained from:

    First-tier Tribunal (Information Rights)
    GRC & GRP Tribunals
    PO Box 9300
    LEICESTER
    LE1 8DJ

    Tel: 0203 936 8963
    Fax: 0870 739 5836
    Email: grc@justice.gov.uk
    Website: www.justice.gov.uk/tribunals/general-regulatory-chamber

43. If you wish to appeal against a decision notice, you can obtain information on how to appeal along with the relevant forms from the Information Tribunal website.

44. Any Notice of Appeal should be served on the Tribunal within 28 (calendar) days of the date on which this decision notice is sent.

Signed

Cressida Woodall
Senior Case Officer
Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF