Freedom of Information Act 2000 (FOIA)

Decision notice

Date: **26 January 2023**

Public Authority: **Medicines and Healthcare products Regulatory Agency (MHRA)**

Address: **10 Colonnade**
London E14 4PU

Decision

1. The Commissioner's decision is that MHRA has correctly applied sections 38(1), 41(1) and 43(2) of FOIA to information about a COVID-19 vaccine as disclosure would be likely to endanger individuals' health, was provided in confidence and is commercially sensitive respectively. It is not necessary for MHRA to take any steps.

Request and response

2. The complainant made the following information request to MHRA on 1 January 2022:

> "I am requesting release of test data and results for each batch of BNT162b2 independently tested prior to deployment by the NIBSC under Regulation 174A.
>
> The MHRA Public Assessment Report for the Authorisation for Temporary Supply of vaccine BNT162b2 under Regulation 174A states in 11.3 and 11.4:
>
> "Independent batch release by the National Institute for Biological Standards and Control (NIBSC) will be performed on all batches to be supplied to the UK."

Characterisation and batch to batch consistency of the active substance BNT162b2 RNA is of clear public interest given that tens of millions of doses have so far been given in the UK. To fully understand RNA synthesis substitution errors, fragmentation errors or strandedness errors in the mRNA synthesis process, robust batch to batch sequencing should be performed and published.

I kindly request the following:

1. The original FastQ files that will confirm the batch to batch sequencing of the vaccines. This will be very valuable as it will either highlight batch to batch consistency or demonstrate batch to batch variation.

2. All data for the batches of BNT162b2 tested by the NIBSC prior to authorising the product batches for deployment. Data includes:

- [2.1] The testing methods, specifications, and limits
- [2.2] The raw test data for every batch tested
- [2.3] The test results for every batch tested
- [2.4] The compliance certificates for every batch tested

As stated above the raw sequencing FastQ files for each batch of vaccine would be ideal."

3. In its response to the request, MHRA applied sections 41 and 43 of FOIA to both parts of the request. The complainant's request for a review discusses the exemptions generally, but MHRA's internal review appears to focus only on part 2 of the request. Its final position with regard to part 2 was to withhold the information requested in part 2.1 under section 41 and to withhold the information requested in parts 2.2 – 2.4 under section 43. MHRA also advised at that point that section 38 was engaged.

4. MHRA subsequently provided the complainant with a fresh response dated 11 January 2023. It explained that part 1 of the request related to work carried out from the Regulatory part of MHRA and part 2 related to the work of the Medicines Control Testing part of MHRA, formerly known as the National Institute for Biological Standards and Control (NIBSC). It acknowledged that its internal review focussed on the work carried out by NIBSC and clarified that NIBSC does not carry out nucleotide sequencing of the vaccine and therefore FastQ files are not produced in any testing by NIBSC. FastQ files related to nucleotide sequencing tests are only relevant to part 1 of the request.

5. MHRA disclosed some information within scope of part 1 of the request, with commercially sensitive information redacted, and acknowledged that it should have provided this when it first responded to the request.

6. MHRA maintained its position regarding part 2 of the request. It confirmed it had applied section 38 of FOIA to part 2 only and addressed questions the complainant had raised about the other exemptions MHRA had applied to this part.

7. On receipt of MHRA's fresh response, the complainant confirmed to the Commissioner that they remained dissatisfied with MHRA's response to part 2 of the request.

Reasons for decision

8. This reasoning focusses on MHRA's application of sections 38, 41 and 43 of FOIA to part 2 of the request.

Section 38 – health and safety

9. Under section 38(1) information is exempt information if its disclosure would or would be likely to a) endanger the physical or mental health of any individual or b) endanger the safety of any individual.

10. Part 2 of the request is for all data for the batches of the BNT162b2 COVID-19 vaccine that NIBSC tested before it authorised the product batches for deployment.

11. In its submission to the Commissioner MHRA has confirmed what it had advised the complainant at internal review. It had acknowledged that the COVID-19 pandemic is the subject of heightened public interest. MHRA considered that disclosing information that might allow comparison between individual types of vaccines could result in loss of confidence in any particular vaccine. This in turn may have a detrimental effect on a vaccination programme that is essential for protecting the UK public.

12. MHRA confirmed that it stood by its view that releasing the data covered by part 2 of the request could lead to a loss of public confidence. For example, if certain results were cherry picked by anti-vaccine proponents this may lead to potentially wide-spread consequences. This includes but is not limited to, risk of lowered public adherence to current and future vaccine programmes. MHRA therefore considers that data about the [COVID-19] vaccines, whether from vaccine manufacturers or data generated by the MHRA itself in relation to those vaccines for control testing, is subject to section 38 for health and safety reasons.

13. With regard to part 2.4 of the request, for "compliance certificates", MHRA has also noted that a release certificate is an official confirmation to the customer (ie the manufacturer) that the vaccine has passed all statutory testing and is fit for release through the recognised regulatory process. MHRA considers it is essential that any risk of fraudulent replication or production of false certificates is reduced in order to avoid potentially untested materials being made available to the public. Mitigating this risk supports the use of section 38, where the public could be put at risk through vaccines that have not been subject to rigorous safety testing.

14. Based on MHRA's submission and correspondence to the complainant and the context of the withheld information, the Commissioner is satisfied that there is a causal link between disclosing the information and endangerment to individuals' health, for the reasons MHRA has given. Furthermore, the Commissioner is satisfied that the likelihood of this occurring is one that is more than hypothetical. The Commissioner has decided that MHRA is entitled to withhold the disputed information under section 38(1) of FOIA as disclosure would be likely to endanger individuals' health. He has gone on to consider the associated public interest test.

15. In a submission to the Commissioner the complainant has re-stated arguments they presented in their request for an internal review. They consider that by releasing the information, MHRA would demonstrate transparency and openness. If batch-to-batch integrity was excellent, as would be expected for any pharmaceutical product, then the requested information would further public confidence and the aims of the Covid vaccine programme and future vaccine programmes for the benefit of the UK public. In the complainant's view MHRA has instead chosen a position where its response will convey, to the lay person, that it is deliberately concealing and withholding information. The complainant argues that this will undermine public confidence and have a detrimental effect on current and future vaccination programs as well as a loss of confidence with MHRA as a regulatory agency.

16. The complainant has also discussed MHRA's introduction at internal review of the idea of "anti-vaccine proponents" cherry picking results. They consider this demonstrates MHRA is seeking to curtail free speech which they consider would contravene the Human Rights Act 1998.

17. MHRA says it has considered the overall public interest in disclosing the information to enable wider public debate about how health authorities ensure the safety of vaccines. However, it has arrived on balance at a position that retains batch analyses data for regulator review and use only, and this position appears aligned with that of other regulators e.g. the European Medicines Agency.

18. The Commissioner agrees with MHRA. He has found that disclosing the requested information would be likely to endanger individuals' health. The public interest in disclosure would have to be extraordinarily great to justify endangering anyone's health. In the Commissioner's view, the complainant has not put forward compelling arguments in their original complaint to him or subsequent correspondence. The Commissioner does not consider the public interest threshold for disclosure is met in this case. The public interest in the COVID-19 vaccines is met to a satisfactory degree through the related information that MHRA and other bodies proactively publish.

19. Although he has found that all the information requested in part 2 of the request is exempt under section 38(1) of FOIA, the Commissioner has also considered MHRA's application of sections 41 and 43 to this information.

Section 41 – information provided in confidence

20. Under section 41(1), a public authority is entitled to withhold information it has confirmed it holds if (a) the information was obtained from another person and (b) disclosure would constitute a breach of confidence. Information has the necessary quality of confidence if it is not trivial or otherwise available; was imparted in circumstances importing an obligation of confidence if disclosing the information would be contrary to the confider's reasonable expectations and therefore cause a detriment to them.

21. MHRA has applied section 41(1) to part 2.1 of the request which is for the testing methods, specifications and limits associated with NIBSC's testing of the BNT162b2 vaccine.

22. Across its correspondence to the complainant and submission to the Commissioner, MHRA has confirmed that it received this information from another person, namely Pfizer-BioNTech, the vaccine's manufacturer.

23. MHRA considers that disclosing this information would constitute a breach of confidence because the manufacturer and MHRA (NIBSC) have a contractual relationship as part of MHRA's statutory functions. The manufacturer provided information to MHRA in confidence and it is not otherwise accessible. The information is more than trivial as it was submitted to allow MHRA to assess if the vaccine was suitable for a product licence to be granted and, in a second stage, to assess if the vaccine is suitable as per its specification to be issued for use on the public.

24. MHRA says that manufacturers provide information to it as the UK Regulator with the understanding that it will be treated in confidence and not shared publicly or with other manufacturers. Disclosing the information could therefore cause detriment to the manufacturer.

25. Section 41 is an absolute exemption not subject to the public interest test. However the common law duty of confidence contains an inherent public interest test. With regard to section 41(1), this test assumes that a public authority should **not** disclose the information unless the public interest in disclosure outweighs the public interest in maintaining the duty of confidence.

26. MHRA has advised that it carries out a regulatory function in approving a licence for a new product, and in the testing of vaccines. As such it ensures independent assurance for the quality and safety of medicines, in this case a specific vaccine. MHRA recognises that there is a strong public interest in allowing access to information where it may help protect the public from unsafe products. In the case of vaccine licencing and testing, the assurance MHRA provides to the public is that it reviews and tests products for all batches of vaccines against agreed specifications to ensure they are safe for the public. Disclosing detailed information about different vaccines could, in MHRA's view, lead to a loss of public confidence. It could result in a risk to current and future adherence to vaccine programmes by the public, and this would not be in the overall public interest.

27. The complainant argues that the use of novel mRNA technology has tremendous potential for public health, but the technology is just beginning to be developed. They consider that the public has a right to know and understand everything about this new technology. Transparency, both for the public at large and the broader scientific community, would, in their view, undoubtedly further the aims of developing and utilising mRNA technology for future generations. By "hiding scientific data behind a wall of secrecy", MHRA could create the very loss in public confidence to which it alludes.

28. The Commissioner appreciates that there is much public interest in COVID-19 and the vaccines associated with this virus. However, he does not consider that the public interest in the specific information in this case is such that it would warrant MHRA breaking its obligation of confidence to Pfizer-BioNTech by disclosing the information. To ensure vaccines are suitable for use on the public, it is in the public interest that MHRA has a strong and efficient working relationship with that manufacturer, and others. As noted above, the Commissioner considers that the related information that is proactively published satisfactorily addresses the public interest in the COVID-19 vaccines. And as MHRA has noted, one of its roles is to review and test batches of vaccines,

which also addresses the public interest in ensuring vaccines are suitable for public use.

29. The Commissioner is therefore satisfied that the information requested in part 2.1 of the request meets the conditions under section 41(1) and that the MHRA is entitled to withhold this information under that exemption.

Section 43 – commercial interests

30. Section 43(2) of FOIA states that information is exempt if its disclosure would, or would be likely to, prejudice the commercial interests of any person, including the public authority holding it.

31. MHRA has applied section 43(2) to part 2.2 – 2.4 of the request which is for raw test data, test results and compliance certificates, specifications for batches of the BNT162b2 vaccine tested.

32. Across its correspondence to the complainant and submission to the Commissioner, MHRA has confirmed that disclosure would be likely to prejudice Pfizer-BioNTech's (and other manufacturers') commercial interests, and its own.

33. MHRA has explained that the licencing and testing of vaccines is a regulatory requirement that MHRA carries out for the UK. This is a commercial activity. Any detailed information or correspondence from the manufacturer, and testing data received or generated through this activity, is confidential data relevant to a particular customer. This information, if released, could be used by competitors for their commercial advantage. For example, to inform research and development into rival products that could result in other manufacturers overcoming many regulatory hurdles in their product's development. As well as undermining the relationship with the particular manufacturer in this case, MHRA says that disclosing data received or generated would not only prejudice or harm its commercial interests with that company, but also with other vaccine manufacturing companies. This is because the envisioned harm could ultimately undermine manufacturers' confidence in sending materials for licencing and testing to MHRA.

34. The Commissioner is satisfied first, that the harm MHRA envisages relates to commercial interests; those of Pfizer-BioNTech, other manufacturers' and its own. Second, the Commissioner accepts that a causal link exists between disclosure and commercial prejudice; those that MHRA has explained above. Finally, the Commissioner accepts MHRA's position that the envisioned prejudice is more than a hypothetical possibility. The Commissioner's decision is therefore that

MHRA is entitled to apply section 43(2) to the withheld information and he will go on to consider the associated public interest test.

35. The complainant has advised that their public interest arguments are those discussed in the section 38 analysis of this notice.

36. MHRA considers that protecting the UK public relies on a robust process for regulating medicines, and in this situation, vaccines. This is the case during the first stage of assessing a new vaccine and authorising a licence for that vaccine to be marketed in the UK. It is also necessary for the independent testing of the vaccines from manufacturers to ensure the quality and efficacy of those vaccines before they are issued for use on the UK public. MHRA has again argued that any potential risk to this process is likely to lead to a loss of public confidence and result in a risk to current and future adherence to vaccine programmes by the public. MHRA says that in this particular example where the COVID-19 pandemic is the subject of heightened public interest, disclosing information that might allow comparison between individual types of vaccines could result in loss of confidence in any particular vaccine. This may have a detrimental effect on a vaccination programme that is essential for the protection of the UK public.

37. MHRA's public interest arguments are again more relevant to the section 38 exemption. However, the Commissioner is satisfied that the public interest in the information in this case is outweighed by the greater public interest in vaccine manufacturers' commercial interests not being undermined and there being a range of manufacturers carrying out this work. This helps to foster the development of new vaccines. There is also greater public interest in MHRA being able to maintain strong and efficient commercial relationships with those manufacturers, which ensures vaccines are robustly tested and appropriately licenced.

Right of appeal

38. 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: 0300 1234504
    Fax: 0870 739 5836
    Email: grc@justice.gov.uk
    Website: www.justice.gov.uk/tribunals/general-regulatory-chamber

39. 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.

40. 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
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