

Freedom of Information Act 2000 (FOIA)

Decision notice

Date: 2 March 2022

Public Authority: Department of Health and Social Care
Address: 39 Victoria Street
London
SW1H 0EU

Decision (including any steps ordered)

1. The complainant has requested information relating to the Covid-19 vaccine.
2. The Commissioner's decision is that Department of Health and Social Care (DHSC) does not hold the requested information.
3. The Commissioner does not require DHSC to take any steps as a result of this decision notice.

Request and response

4. On 4 November 2020 the complainant made the following request for information via WDTK for:

"Please provide, from the Govt. negotiation to purchase and/or fund the Covid19 vaccines, e.g. AZ vaccine AZD1222 and NCT04400838, Moderna, Nova [is, etc: the recording or the evidence of that:

- 1) *The negation agreements do these include that the vaccine*
 - a) *is causing an anamnestic response;*
 - b) *is a prophylactic treatment against Covid-19;*
 - c) *will protect against a SARS-00V-2 infection;*

- d) will prevent serious Covid-19 complications;*
- e) will fulfil the criteria to be a Covid-19 vaccine?*
- f) will reduce, for those over the age 60Yrs. Their covid-19' CFR to less than 1.3%;*
- g) will reduce, for those under the age 60Yrs. their covid-19' CFR to less than 0.03%;*
- h) will reduce covid-19 mortality to less than 93 per million (e.g. in Germany);*
- i) will end the 'Covid19 pandemic'.*

2) The safety profile rate of said purchased or funded vaccine e.g. AZ vaccine: its potential adverse health risks -vs - its described health benefits: Has this been recorded and calculated according to the standards for general medications, and does it reach/fulfil these clinical and regulatory milestones?

3) Said above safety profile rate is it such that with scientifically calculated probability said vaccine can be safely enforced as a mass inoculation, and does it justify its Harmless clausula?

4) In case none of the above can be positively answered: Will the Govt then withdraw the funding of said vaccines?"

5. DHSC responded the same day and advised that the correspondence asked for general information and an opinion rather than requesting recorded information or documentation and therefore was an invalid request.
6. The complainant requested an internal review on 7 January 2021. DHSC responded and reiterated that as this was not a valid request therefore no review would be carried out.
7. Following intervention by the Commissioner, DHSC provided a response under FOIA on 22 November 2021 and stated it did not hold the requested information. However, it suggested the Medicines and Healthcare Products regulatory Agency (MHRA) may hold relevant information.

Scope of the case

8. On 5 January 2022 the complainant again contacted the Commissioner as they remained dissatisfied with DHSC's response. Due to the protracted nature of this case, the Commissioner agreed to accept the complaint without an internal review.

9. The scope of this case is to consider whether, on the balance of probabilities, DHSC holds any information within the scope of the request.

Background

10. DHSC explained that MHRA is the UK's independent regulator of medicines and healthcare products, including COVID-19 vaccines. It is an executive agency of DHSC. For COVID-19 vaccine, the MHRA's role is to rigorously assess any vaccine candidate to ensure they meet applicable standards of safety, quality, and efficacy. As part of the approval process, vaccine manufacturers must submit full clinical trial data for review by the MHRA. The MHRA holds full clinical trial data.
11. DHSC does not receive any clinical trial data directly from the vaccine manufacturers. It is sent to the regulator, the MHRA, which as stated above would then review and recommend approving the vaccine if it meets the required standards.
12. The Minister for the Licensing Authority in DHSC holds responsibility for making decisions on UK approvals for COVID-19 vaccines, therapeutics, and antivirals, as well as the terms of these approvals. Most of MHRA's regulatory decisions are taken by officials on behalf of the Secretary of State, but due to the novelty and impact of decisions for the COVID-19 vaccines and other medicines, including additional indemnities the UK Government has given to vaccine manufacturers for COVID-19 vaccines, these decisions are sent to the licensing Minister for approval.
13. The Minister for the Licensing Authority receives a high-level assessment of the product being recommended but does not receive full clinical trial data or other material submitted to the regulator, the MHRA, by the manufacturer in support of their application for approval.
14. This information is not held by DHSC. REG 174 INFORMATION FOR UK HEALTHCARE PROFESSIONALS is an MHRA product which was published by the MHRA on 2 December 2020. This is available in the public domain and can be accessed here:

<https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/information-for-healthcare-professionals-on-pfizerbiontech-covid-19-vaccine>

15. The MHRA is responsible for the regulation and approval of medicines and healthcare products, including any potential vaccine candidates. Vaccine manufacturers must submit their vaccine candidates for approval by the MHRA; this will be accompanied by all relevant trial

data for the MHRA to analyse. The MHRA is responsible for the approval of COVID-19 vaccines for use in the UK. A COVID-19 vaccine will only be authorised once it has met robust standards on safety, effectiveness and quality through clinical trials and authorised for use by the MHRA. The MHRA rigorously assesses the data in the shortest time possible, without compromising the thoroughness of the review. Once it has thoroughly reviewed the data, the MHRA seeks advice from the Government's independent advisory body, the Commission on Human Medicines, which critically assesses the data before advising on the safety, quality, and effectiveness of any potential vaccine. While a vaccine is authorised by the MHRA, the Joint Committee on Vaccination and Immunisation will advise the Government about the use of the vaccine.

16. Clinical trial results for the Pfizer vaccine, including information on participants and results relating to effectiveness and adverse events has been published for peer review in the New England Journal of Medicine and a summary can be found on the MHRA website here:

New England Journal of Medicine:

<https://www.nejm.org/doi/full/10.1056/nejmoa2034577>

MHRA: <https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/information-for-healthcare-professionals-on-pfizerbiontech-covid-19-vaccine>

17. Publishing trial results for peer review is standard practice.
18. The 90% effectiveness figure refers to immunisation rather than suppressing COVID-19 symptoms. While the DHSC has material that records the headline results for COVID-19 vaccines it does not hold full clinical trial data.
19. Any consideration of adverse events or allergies would be a matter for the regulator and would be expanded upon in the precautions or contraindications summary included in any authorisation.

Reasons for decision

20. Section 1(1) of the FOIA states that:

Any person making a request for information to a public authority is entitled –

- (a) to be informed in writing by the public authority whether it holds information of the description specified in the request, and*

(b) if that is the case, to have that information communicated to him.

21. Where there is a dispute between the information located by a public authority, and the information a complainant believes should be held, the Commissioner follows the lead of a number of First-tier Tribunal (Information Rights) decisions in applying the civil standard of the balance of probabilities.
22. In cases where a dispute arises over the extent of the recorded information that was held by a public authority at the time of a request, the Commissioner will consider the complainant's evidence and arguments. He will also consider the actions taken by the authority to check that the information is not held and any other reasons offered by the public authority to explain why the information is not held. Finally, he will consider any reason why it is inherently likely or unlikely that information is not held.
23. For clarity, the Commissioner is not expected to prove categorically whether the information is held, she is only required to make a judgement on whether the information is held on the civil standard of the balance of probabilities.

The Complainant's position

24. In correspondence to the Commissioner the complainant stated:

"Since said FOI request date, ±51 million British citizens have been inoculated with a 'covid19 vaccine' which is in a trial phase until 2023 of which trail data, content, contract and risks have not been fully disclosed to the public.

After said inoculation ±740,562 were injured of which ±50,000 are permanently disabled and 1,822 citizens have died mostly (± 80%) within 2 weeks of the inoculation.

It is therefore not creditable that the DHSC authorised said inoculations without having the data regarding said risk, and without being able to inform citizens that said risk is about 1% (which is higher than the risk of the 'Covid19 virus infection'.

Said inoculations being in a trial phase, being insufficiently investigated and having caused an unacceptable number of injuries; means that the DHSC has violated the Nuremberg codes and the Declaration of Helsinki."

DHSC's position

25. As is his usual practice in cases such as this, the Commissioner asked DHSC for further details relating what searches it had carried out to locate the requested information.
26. DHSC explained that searches were conducted using appropriate and reasonable terms in file management systems held by the DHSC deployment vaccines directorate.
27. It further explained that searches were made using key terms "Pfizer", "Trial" "BNT162b2". Each of these terms returned thousands of results. When used together, "BNT162b2 Trial" and "Pfizer Trial" returned thousands of email results but 0 files on the file management system.
28. The nature of the request makes it difficult to refine the search any further. Any external searches would have been disproportionate as DHSC is not the regulator.
29. DHSC stated that it knows the MHRA and the New England Journal of Medicine published the full clinical trial data online (linked above) and so some information is available in the public domain.
30. It considered adequate searches were carried out as above. The information is held by the MHRA, a DHSC arm's length body. Any records would have been held and retained electronically.
31. The DHSC retention and destruction policy states that standard administration records are retained for three years and then deleted. A record is kept of any deletions and those have been checked.
32. There is no business purpose, or statutory requirement for which the requested information should be held or retained.

The Commissioner's decision

33. The Commissioner's view is that the DHSC does not hold the requested information.
34. Based on a balance of probability test, the Commissioner is satisfied that the DHSC does not hold any information falling within the scope of the complainant's request.

Right of appeal

35. 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

36. 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.
37. 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

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