Medicines & Healthcare products Regulatory Agency

MHRA

Mr Wynne Jones
Via email:
cj-editor@biggeesblog.cymru

13/04/2021

Medicines & Healthcare products Regulatory Agency

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Internal Review of FOI Request FOI 21/238

Review completed on 13/04/2021

1. Purpose of Internal Review

The purpose of this internal review is to determine whether the Medicines and Healthcare Products Regulatory Agency ('the Agency') dealt properly with the applicant's request under the Freedom of Information Act (FOIA).

The terms of reference of this review are:

- To read all correspondence between the applicant and the Agency, and other relevant correspondence;
- To form an opinion on the handling of the correspondence by the Agency;
- To advise whether the actions taken by the Agency in reaching their decisions is justified under the FOIA;
- To make recommendations for further action by the Agency if appropriate; and
- To prepare a report of the review for the Agency and the requester.

2. Introduction

Mr Wynne Jones, the Requester, sent an email on 08 March 2021, which included a request for the following information:

A copy of the authorisation for emergency use of the "RT-PCR test" issued by M H R A for the diagnosis of SARS-CoV-2 virus and variants

A copy of the authorisation for emergency use of the "Lateral Flow test" issued by M H R A for the diagnosis of SARS-CoV-2 virus and variants

The Agency treated this request under the FOIA and replied on 29 March 2021 (which was within the 20 working-day target). The Agency declined to provide the information requested, as it was exempted under the FOIA.

A copy of the Agency's response is at Annex A.

The Requester sent an email on 29 March 2021, which included a request for an Internal Review. A copy of this request is at Annex B.

3. Consideration of the issues

The issues under consideration are:

- Has the Agency answered the request and have any exemptions been properly applied?
- Has the Agency fulfilled its general obligation to be helpful?

Has the Agency answered the request and have any exemptions been properly applied?

The Agency declined to provide the requested information, as it was exempted under Section 44(1)(a) of the FOIA, which is an absolute exemption and, as such, not subject to a public interest test.

Also, as stated in the MHRA's reply, section 237 of the Enterprise Act 2002 prohibits a public authority from releasing information which came to it in connection with the exercise of its functions, and which relates to the affairs of an individual or business.

Following review, it is considered that the Agency's refusal to release the requested information was correct, as the subject matter of the requested information was obtained in connection with the Agency's role as the Competent Authority for medical devices in the UK.

In your email you listed five points as justification for your request for a review. I have added comments to each of these points below:

1. *Authorisation provided by MHRA [a public body] is considered to be a public document. Disclosure is in the wider public interest. An exemption under S.44 of the Act is not considered appropriate.*

   Please see the paragraphs above, which explain that the Section 44(1)(a) exemption is not subject to a public interest test.

2. *Any sensitive information [including the name and address of any test kit manufacturer] contained in the authorisation document can be redacted if you consider it necessary to comply with the data management principles set out in the Data Protection Act 2018 and G D P R.*

   All aspects of the information supplied to MHRA in connection with its role as the UK Competent Authority are exempted under Section 44(1)(a) of the FOIA, not just the details of the manufacturer.

3. *The information is required in connection with an ongoing investigation into the validity of the "RT-PCR test" and "Lateral Flow test" for diagnosis of Covid 19: an infection purportedly caused by the SARS-CoV-2 virus. Withholding the information hinders progress in that investigation.*

   The purpose of the request for this information has no influence on MHRA's decision to refuse the request for its release.

4. *The validity of the RT-PCR test is currently subject to challenge, with lawsuits now pending in various countries.*

   Again, this has no influence on MHRA's decision to decline to release the requested information.

5. *An external peer review undertaken by a highly respected group of 22 international virologists, microbiologists and related scientists has identified 10 major scientific flaws at molecular and methodological level in the RT-PCR test.*

   This, too, does not influence MHRA's decision to decline to release the requested information.

Has the Agency fulfilled its general obligation to be helpful?

Yes. The request was clear and did not require further advice and assistance under section 16. The Agency does not consider that there is another way that the request could be framed to bring it outside the scope of the exemption.

In an attempt to provide the Requester with some useful information, the reply sent on 29 March 2021 included a link to the list of all exceptional use authorisations issued by MHRA, including devices associated with COVID-19 testing.

4. Conclusion and recommendations

In conclusion, the MHRA's decision to withhold the requested information was correct.

If the Requester remains dissatisfied, they may ask the Information Commissioner (ICO) to make a decision on whether or not we have interpreted the FOIA correctly in dealing with the request and subsequent internal review. The Information Commissioner's Office may be contacted through their website: https://ico.org.uk/

Review completed by Philip Grohmann, Group Manager, Devices Division.

Medicines and Healthcare Products Regulatory Agency.

Annex A

MHRA reference FOI 21/238

Dear Wynne Jones,

Thank you for your information request, dated 8 March where you asked for:

- A copy of the authorisation for emergency use of the "RT-PCR test" issued by MHRA for the diagnosis of SARS-CoV-2 virus and variants

- A copy of the authorisation for emergency use of the "Lateral Flow test" issued by MHRA for the diagnosis of SARS-CoV-2 virus and variants

Unfortunately we cannot share information that is specific to named manufacturers. This includes makes and models that would identify the manufacturer.

The information you have asked for is exempt from disclosure under Section 44 of the Freedom of Information Act 2000 (FOIA).

Section 44 – Prohibitions on disclosure: the release of information is exempt as its disclosure is prohibited by other legislation. In this case, section 237 of the Enterprise Act 2002 prohibits a public authority from releasing information which came to it in connection with the exercise of its functions, and which relates to the affairs of an individual or business.

The MHRA is satisfied that the information you have requested:

- constitutes information which came to us in connection with the exercise of the Agency's functions. The MHRA has a duty of consumer protection under the Consumer Protection Act 1987 which is listed as a specified function under Schedule 14 of the Enterprise Act 2002, and receives information while exercising consumer protection functions in its role as the regulator of medicines and healthcare products.

- relates to the affairs of businesses which continue to exist.

On that basis we are satisfied that section 44 of FOI Act apply, and the information is exempt from release.

However, below is a link to the list of all exceptional use authorisations issued by MHRA, which includes any devices associated with COVID-19 testing.

https://www.gov.uk/government/publications/medical-devices-given-exceptional-use-authorisations-during-the-covid-19-pandemic/list-of-medical-devices-given-exceptional-use-authorisations

If you disagree with how we have interpreted the Freedom of Information Act 2000 with regards to your request, you can ask for an internal review. It will be carried out by a senior member of the Agency who was not involved with the original decision. Internal review requests should be submitted within two months of the date you receive this response and addressed to: info@mhra.gov.uk.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review.

The Information Commissioner can be contacted online: https://ico.org.uk/make-a-complaint/official-information-concerns-report/official-information-concern/

Yours sincerely

Annex B

Date: 29 03 2021

Dear Customer Services Team

Subject: C J 122: R T - P C R test for Covid 19 diagnosis

Thank you for your letter dated 29 March. I am disappointed to learn that you consider the information requested to be exempt under S.44 of the Freedom of Information Act 2000. I respectfully disagree with your interpretation of the legislation. Accordingly, I would be grateful if you would arrange to progress to the next stage: an **internal review** of your decision to withhold the information requested. Justification for the review is set out below in point format.

1. Authorisation provided by MHRA [a public body] is considered to be a public document. Disclosure is in the wider public interest. An exemption under S.44 of the Act is not considered appropriate.
2. Any sensitive information [including the name and address of any test kit manufacturer] contained in the authorisation document can be redacted if you consider it necessary to comply with the data management principles set out in the Data Protection Act 2018 and G D P R.
3. The information is required in connection with an ongoing investigation into the validity of the "RT-PCR test" and "Lateral Flow test" for diagnosis of Covid 19: an infection purportedly caused by the SARS-CoV-2 virus. Withholding the information hinders progress in that investigation.
4. The validity of the RT-PCR test is currently subject to challenge, with lawsuits now pending in various countries.
5. An external peer review undertaken by a highly respected group of 22 international virologists, microbiologists and related scientists has identified 10 major scientific flaws at molecular and methodological level in the RT-PCR test.

I look forward to the outcome of your internal review at your earliest convenience. The review timeframe is not prescribed in statute. The Information Commissioner's Office has previously advised that 20 working days is considered a "reasonable" timeframe for review. I would therefore hope to receive the outcome of your review within that timeframe. Thank you.

Yours sincerely

Wynne Jones