Department of Health & Social Care

Freedom of Information Team
Department of Health and Social Care
39 Victoria Street
London SW1H 0EU

www.gov.uk/dhsc

Ms Carole Waldon
By email to: request-886817-0c98d5f4@whatdotheyknow.com

28 October 2022

Annex A: DHSC response to initial request

Annex B: Request for internal review

Dear Ms Waldon,

FREEDOM OF INFORMATION ACT 2000 (FOIA): INTERNAL REVIEW

CASE REFERENCE: IR-1420039 (FOI-1415351)

You originally wrote to the Department of Health and Social Care (DHSC) on 15 August 2022 requesting information relating to 'Evusheld'. We responded to you on 30 September and a copy of our response, including the full text of your request, can be found in Annex A.

You subsequently emailed DHSC on 30 September requesting an internal review into the handling of your original request. A copy of your email can be found in Annex B.

The purpose of an internal review is to assess how your Freedom of Information (FOI) request was handled in the first instance and to determine whether the original decision given to you was correct. This is an independent review as I was not involved in the original decision.

We have revisited your original FOI enquiry as part of the review and are able to provide the following information in answer to your questions in turn:

1. The decision not to procure Evusheld was based on independent clinical advice by RAPID C-19 (a multi-agency group) and a UK national Expert Policy Working Group. A list of senior RAPID C-19 members, and their job titles, can be found on an Oversight Group Report, which has been published on our website: RAPID C-19 Oversight Group report: review of Evusheld - GOV.UK (www.gov.uk). Any members who have been redacted in the report is because they do not meet the seniority level required.

2. All evidence that was considered by the RAPID C-19 group can also be found on the Oversight Group Report. Following the review of this evidence, the group concluded there was insufficient evidence to recommend deployment of Evusheld at this time.

3. The decision took into account data on the clinical effectiveness of Evusheld to prevent symptomatic COVID-19 caused by the Omicron variant. The decision considered the risk of proceeding to patient access against the risks of not providing this treatment in the current pandemic context. The NICE multi-technology appraisal (MTA) process does take in to account the cost effectiveness of making Evusheld accessible.

4. (also answers Q5) RAPID C-19 provides a streamlined process from horizon scanning of the clinical trial landscape to monitoring for emerging evidence, and when treatments are proven to be clinically effective, enables the system to get them to NHS patients quickly and safely. The Chief Medical Officer for England is content that the correct process for providing clinical advice has been followed and agrees that this should now be referred to NICE for further evaluation.

   The RAPID C-19 process has not been applied differently to Evusheld versus other treatments. When treatments are proven to be effective on the basis of robust data, the RAPID C-19 group works to get them to NHS patients quickly and safely, by providing a streamlined process from horizon scanning to regulatory approval. However, should emerging evidence show that a treatment does not have sufficient evidence of efficacy against a variant, the treatments will be re-evaluated.

   Due to the lack of robust evidence of Evusheld's efficacy against the Omicron variant, it was not recommended by the RAPID C-19 group to issue interim approval for Evusheld until the completion of the NICE MTA review. However, the Department are exploring the possibility of piloting a programme to test antibody levels in immunosuppressed patients to understand future prophylaxis cohort, and whether an individual patient is protected following vaccination.

5. Answered above.

6. The decision not to procure Evusheld was based on the advice from RAPID C-19 and a UK National Expert Policy Working Group. The Independent Advisory Group provided insight into patient cohorts who could benefit from an effective prophylactic, but it was not involved in the decision not to procure Evusheld.

Conclusion

After careful consideration, I have concluded that the response you received to your FOI request was compliant with the requirements of the FOIA.

The review is now complete.

If you are not content with the outcome of your complaint, you may apply directly to the Information Commissioner's Office (ICO) for a decision. Generally, the ICO cannot make a decision unless you have exhausted the complaints procedure provided by DHSC.

Guidance on contacting the ICO can be found at https://ico.org.uk/global/contact-us and information about making a complaint can be found at https://ico.org.uk/make-a-complaint.

Yours sincerely,

Mr E Franklyn
FOI Internal Reviews
freedomofinformation@dhsc.gov.uk

Annex A: DHSC response to initial request

Ms Carole Waldon
By email to: request-886817-0c98d5f4@whatdotheyknow.com

30 September 2022

Dear Ms Waldon,

Freedom of Information Request Reference FOI-1415351

Thank you for your request dated 15 August to the Department of Health and Social Care (DHSC), a copy of which can be found in the accompanying annex.

Your request has been handled under the Freedom of Information Act 2000 (FOIA).

DHSC holds information relevant to your request.

However, we are withholding this information under section 22, which states that public bodies are not obliged to disclose information that is intended for future publication.

Section 22 is a qualified exemption, and we are required to assess as objectively as possible whether the balance of public interest favours disclosing or withholding the information.

We recognise that there is strong public interest in information on the decision to not procure Evusheld being made as freely available as possible, and that disclosure leads to greater transparency in Government. However, there is also very strong public interest in ensuring that information is made available to everyone at the same time, thereby ensuring equity of access. Releasing this information now may also interfere with our established process for publishing information to ensure that only accurate and validated data is released.

Therefore, DHSC concludes that the public interest in withholding this information outweighs the public interest in its release at this time. DHSC takes the view that the public interest in the disclosure of this information will be satisfied by its publication. The information will be available on the Antivirals and Therapeutics Taskforce webpage: The COVID-19 Antivirals and Therapeutics Taskforce - GOV.UK (www.gov.uk).

With regard to your question about the names of panel members, a list of the RAPID C-19 decision makers can be found here RAPID-C19-oversight-group-membership.docx (live.com).

Please also find attached a list of the names of the UK National Expert Policy Working Group membership in the document 'UK National Expert Policy Working Group menbership_redacted.pdf'. However, please note that some of this information has been redacted under section 40(2) of the FOIA, which provides for the protection of personal information. Section 40 prohibits a public body from disclosing personally identifiable information, as doing so would contravene data protection principles.

If you are not satisfied with the handling of your request, you have the right to appeal by asking for an internal review. This should be sent to freedomofinformation@dhsc.gov.uk or to the address at the top of this letter and be submitted within two months of the date of this letter.

Please remember to quote the reference number above in any future communication.

If you are not content with the outcome of your internal review, you may complain directly to the Information Commissioner's Office (ICO). Generally, the ICO cannot make a decision unless you have already appealed our original response and received our internal review decision. You should raise your concerns with the ICO within three months of your last meaningful contact with us.

Guidance on contacting the ICO can be found at https://ico.org.uk/global/contact-us and information about making a complaint can be found at https://ico.org.uk/make-a-complaint.

Yours sincerely,

Freedom of Information Team
freedomofinformation@dhsc.gov.uk

Annex

From: Carole Waldon <request-886817-0c98d5f4@whatdotheyknow.com>
Sent: 15 August 2022 08:59
To: FreedomofInformation <freedomofinformation@dhsc.gov.uk>
Subject: Freedom of Information request - Decision process re Evusheld preventative treatment

Dear Department of Health and Social Care,

Following last week's announcement by Stephen Barclay that DHSC has decided not to rollout Evusheld treatment for the immunocompromised and immunosuppressed communities in Autumn 2022 (it being required to go through the lengthy NICE stages which mean spring/summer 2023 at the earliest), I would like to know the following regarding the decision making process used to come to this decision:

1 - who within DHSC made the decision? Was there a panel of members? If so please provide their names and areas if clinical/medical expertise.

2 - please provide details of the evidence /studies/tests considered in determining that the long term efficacy of Evusheld against the Omicron variant is not yet proven. (There are lab studies and long terms real life studies available that show it's efficacy against Omicron which 32 other countries have chosen to follow)

3 - what factors were used in making the decision? Was economic cost one of the factors?

4 - why has Evusheld gone through a different process/order of events to all other Covid treatments ? Who made the decision for this?

5 - was consideration given to issuing immediate interim approval for Evusheld pending the full NICE review? Who was involved in this decision and what was their clinical/medical expertise ?

6 - I am aware that the COVID-19 Neutralising Monoclonal Antibodies (nMABs) and Antivirals Access Independent Advisory Group had generated the patient groups at highest clinical risk from Covid. I believe this group had no involvement in the decision not to rollout Evusheld for Autumn 2022. Please confirm.

I look forward to your response

Carole Waldon

Annex B: Request for internal review

From: Carole Waldon <request-886817-0c98d5f4@whatdotheyknow.com>
Sent: 30 September 2022 10:32
To: FreedomofInformation <freedomofinformation@dhsc.gov.uk>
Subject: Internal review of Freedom of Information request - Decision process re Evusheld preventative treatment

[You don't often get email from request-886817-0c98d5f4@whatdotheyknow.com. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear Department of Health and Social Care,

Please pass this on to the person who conducts Freedom of Information reviews.

I am writing to request an internal review of Department of Health and Social Care's handling of my FOI request 'Decision process re Evusheld preventative treatment'.

I note that you claim a s22 exemption to providing the information. You do not give any indication of the timing of when additional information is to be released to the public (your Department has already been stating for weeks that additional information/evidence will be released but nothing has been issued yet).

My main concern is that you need to satisfy that a s22 exemption is applicable to each of my separate questions in my FOI request. I do not believe you can apply a s 22 exemption for each of the points and you should be able to provide answers to some of them currently. Please explain in detail why a blanket s22 exemption should apply to the entirety of my request.

I sent a complaint to ICO on 28 Sep 2022 regarding your handling of my request and that complaint still stands in my view.

A full history of my FOI request and all correspondence is available on the Internet at this address:
https://eur03.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.whatdotheyknow.com%2Frequest%2Fdecision_process_re_evusheld_pre&data=05%7C01%7Cdhmail%40dhsc.gov.uk%7C47a99fa4fd51493f6b2c08daa2ca424f%7C61278c3091a84c318c1fef4de8973a1c%7C1%7C0%7C638001286815264592%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=OfbqF6PViyKyK%2FQuIlWUlDbsRTkAeDs1b4kuKmE%2FpPU%3D&reserved=0

Yours faithfully,

Carole Waldon