1. Introduction

Dear Mr MacArthur,

I am writing in response to your request for a review of the Medicines and Healthcare products Regulatory Agency's ('the Agency') reply to your FOI request **[22/1243]**.

The purpose of this review is to determine whether the Agency dealt properly and fairly with your request under the Freedom of Information Act (FOIA). In particular, it will examine the reasons why information was withheld from you.

Your original request and the Agency's response are annexed.

This internal review will focus on the request for emails pertaining to the COVID-19 Pfizer vaccine (request A).

You stated the below in your request for this review:
"And regarding request A:

(v) You have stated that, in order to process my request, you would need to "identify all emails received which referenced the requested words in addition to identifying any emails where these may have been misspelt". I have not asked you to identify e-mails where these words may have been misspelt, and I am hereby explicitly confirming that I do not wish you to do this. Can you confirm that that part of your basis for relying on section 12 FOIA 2000 has now fallen away?

(vi) Given the previous point, you simply need to identify all e-mails sent or received by a single person containing the specified words. It is not clear to me why identifying those e-mails should take anywhere near 24 hours to complete. I would ask you to provide cogent evidence for this estimate, per paragraph 37 of the ICO guidance document on section 12 (https://ico.org.uk/media/for-organisatio...), noting that, while doing so is not a statutory requirement, it will allow me to assess the reasonableness of the estimate, and be required in any case if a complaint is made to the Information Commissioner (per paragraph 38 of the ICO guidance document).

(vii) You have suggested that I narrow my request "by, for example, reducing [my] request to a single product and a single issue/point of interest about that product". This request _is_ for a single product, so can you please explain why you have suggested this? Did this part of your response come from some sort of generic FOI response, included without cognizance being taken of the specifics of the request at hand?

(viii) Further, can you please explain how narrowing my request to cover a single issue/point of interest about the Pfizer-BioNTech COVID-19 vaccine will make it easier for you to comply with my request? Surely devising a search strategy to identify e-mails which are about both (a) the Pfizer-BioNTech COVID-19 vaccine, and (b) specific issues/points of interest about that vaccine, will be more complicated than simply identifying all e-mails about that vaccine. If you don't believe this to be the case, can you please explain why, noting that per paragraph 15 of the aforementioned ICO guidance document, "the staff time taken, or likely to be taken,

in removing any exempt information in order to leave the information that is to be disclosed, often referred to as 'redaction', cannot be included as part of the costs of extracting the requested information."

2. Consideration of the issues

During the process of internal review a sampling exercise was completed and it was noted that we could not be assured of the time that would be taken to locate, extract and retrieve the information would exceed the cost limit for compliance. We have determined that original response, may have incorrectly exempted your request under Section 12 of the FOI Act. Nevertheless, the request was for '*all* emails for 'Pfizer-BioNTech COVID-19 vaccine' and given that this is obviously a very wide parameter, we can see inclination for why Section 12 was considered and applied in the response.

Due to the estimated time taken to locate, retrieve and extract the emails captured by the scope of FOI 22/1243, we believe there is no option within this internal review but to reverse use Section 12, and apply Section 14 (vexatious requests) for the purposes of conserving public health resources, in line with the below guidance.

Our rationale

"The purpose of Section 14…must be to protect the resources (in the broadest sense of that word) of the public authority from being squandered on disproportionate use of FOIA…" (paragraph 10)" Section 14 FOI guidance"

We also considered that the guidance below applies to this request and thus also supports use of Section 14, particularly the first and third bullet points :

"Even where a request is speculative, fishing for information is not, in itself, enough to make a request vexatious. However, some requests might:

- impose a burden by obliging you to sift through a substantial volume of information to isolate and extract the relevant details;
- encompass information which is only of limited value because of the wide scope of the request;
- create a burden by requiring you to spend a considerable amount of time considering any exemptions and redactions; or
- be part of a pattern of persistent fishing expeditions by the same requester."

Sampling exercise
In order to understand the burden that the request for '*all* emails for 'Pfizer-BioNTech COVID-19 vaccine' would place on the Agency, a sampling exercise was undertaken. Initially parts A and B of the request were considered (covering two vaccines), however, given that at the time of the request, part B related to a pending authorisation, we have updated the sampling exercise to focus solely on the Pfizer vaccine (part A). The sampling exercise generated upwards of 1000 emails (1291), and we estimated the time to make the redactions in relation to personal information

at 3 minutes per email, this equates to an estimate of 64.55 hours to complete redactions for personal information*.

Detailed time estimates of necessary redaction activities

The three minute estimate per redacted email is not simply an estimate of redaction, which is in principle a simple click and drag exercise, rather the estimate includes the time to download the email, convert to pdf, mark the redactions, save as a tiff file (redactions irreversible), reconvert to pdf. This estimate does not include time for attachments to be reviewed and redacted of which there are many, for example long form documents, such as ministerial submissions etc. Emails would also need to be read to ensure sensitive information is not included, and to ensure that, amidst the prose, names of external stakeholders and colleagues are not missed.

Public interest

There is obviously a significant public interest in the COVID-19 vaccines, and accessing information related to their regulation is very important, both in terms of organisational transparency and trust building. However, great efforts have been dedicated to the drafting and publishing of the public assessment reports for each of the vaccines i.e. (PARs), in addition the level of safety related monitoring information available online is extensive. Nonetheless, the amount of time and resources that a public authority has to expend in responding to a request should not be out of all proportion to that request's value and purpose, and we do not perceive that providing all emails captured by the scope of your FOI request would surmount the burden on our resources.

As part of the internal review process we tried to confirm if there was a specific piece of information that you were seeking in our email of 28th March, and explained this step was taken to establish if the request could be refined in some manner. We believe your response, which expressed an intention to search through the entire email list is also suggestive of a fishing expedition and critical to the Section 14 decision which as we have set out, would result in an exercise that places a significant burden on our resources.

Has the Agency fulfilled its general obligation to be helpful?

In most circumstances the use of Section 12 should be supported by a form of cost estimation, one that describes how the cost limit was reached. We apologise that this does not appear to have been included in the original response.

Timelines and delays

The original combined FOIs were handled within the recommended period, however, the Internal Review was significantly delayed. The delays were, in part, due to the exceptionally busy period that the MHRA has experienced during the pandemic, and also owing to the time required to consult with senior colleagues and to conduct the sampling exercise.

3. Conclusion and recommendations

We understand that to rescind Section 12 only to subsequently apply Section 14, is unlikely to be well received. We can only stress that the burden that this request would place on already strained resources would be considerable and the benefits to

the public interest are unobvious given the amount of scientific data on the vaccines that is already in the public domain. Also, we would like to again highlight that the opportunity was given for you to refine the request but was not met with a clear approach on how we were to do so.

If you remain dissatisfied, you 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 ICO's address is:

The Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Kind Regards

MHRA Customer Experience Centre
Communications and engagement team
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU
Telephone 020 3080 6000

Annex: background correspondence

Relevant background correspondence is available at the following link:
E-mails relating to Pfizer-BioNTech COVID-19 vaccine - a Freedom of Information request to Medicines and Healthcare Products Regulatory Agency - WhatDoTheyKnow