



Medicines & Healthcare products Regulatory Agency

Dr Kenneth MacArthur
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Canary Wharf
London
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www.gov.uk/mhra

22nd June 2022

MHRA reference: FOI 21/794 internal review

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 (**[21/794]**).

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.

You stated in your request for this review that *"In your response to question 1 in my request, you state that the MHRA are still considering the timing of the publication of the COVID-19 vaccine iDAPs and that "therefore" the information I have requested is exempt under section 35 of the Freedom of Information Act (FOIA) 2000 (which you later clarified to me to be section 35(1)(a) FOIA 2000 in particular).*

There are several issues with this."

We have listed and addressed these concerns in detail below in Section 3 points a-e as well as at the Annex.

2. Consideration of the issues

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

Question 1: ***"Which individual or individuals have made the decision to not publish the above-mentioned iDAPs at the present time, whether this individual/these***



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individuals is/are within the MHRA, the wider Department of Health and Social Care, or somewhere else in government, and on what grounds the decision was made”

Response to Q1:

Interactive drug analysis profiles (iDAPs) and the Drug Analysis Prints which they replaced, have never been routinely available for any vaccines. At the beginning of the COVID-19 pandemic, the MHRA employed a similar approach, namely that COVID-19 vaccine data would not be made available in iDAP form.

In January 2021, the MHRA took the decision to publish weekly summaries (along with contextual narrative to avoid to avoid misinterpretation) of Yellow Card reporting for the Coronavirus vaccines, which can be found [here](#). The formal position is that all decisions of the MHRA are taken by the Secretary of State under the Carltona Principle. This includes decisions on matters regarding publication.

Given the Agency's commitment to transparency, we are now looking to provide more information. We are developing a new Information Technology programme, SafetyConnect, to replace the MHRA surveillance system, in line with the Independent Medicines and Medical Devices Safety Review report¹ recommendations. Replacement of iDAPs are a part of this programme, and as part of this, the data contained within iDAPs for COVID-19 vaccines will be published, by the end of 2022.

With reference to your complaint, following consideration, it is now our view that no exemption, including section 35 (*'Formulation of government policy'*) should have been used to respond to this aspect of the FOI request. Given the changed situation regarding forthcoming publication, however, the Agency is currently exempting specific requests for the data contained within iDAPs under s 22 (*'Intention for future publication'*) as highlighted in the ICO decision notice below.

The [ICO decision notice](#) clearly articulates why it is in the public interest to not publish this data ahead of that time.

Question 2) “Which individual or individuals will make the eventual decision about when to go ahead and publish the above-mentioned iDAPs, and whether this individual/these individuals is/are within the MHRA, the wider Department of Health and Social Care, or somewhere else in government”

Response to Question 2:

This decision has been taken. The formal position is that all decisions of the MHRA are taken by the Secretary of State under the Carltona Principle. This includes decisions on matters regarding publication.

The [ICO decision notice](#) clearly articulates why it is in the public interest to not publish this data ahead of that time. Replacement of iDAPs are a part of this programme, and as part of that, the data contained within iDAPs for COVID-19 vaccines will be published by the end of 2022.



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Question 3: *"Whether ministers were involved in the decision not to publish so far, and whether ministers will be involved in the decision to publish in the future, and in each case in what capacity (ie, ultimate decision-maker, consultee, or some other capacity)"*

Response to Question 3:

The MHRA will engage with Ministers as appropriate as we work to publish the data contained within iDAPs as part of the new SafetyConnect System by the end of 2022.

The Carltona principle states that decisions of the MHRA are decisions by the Secretary of State.

Further requests within Internal Review Request:

In the interests of fully assisting you, we have considered in turn each of your further requests where these have not been addressed above.

Question a) *"Firstly, you have responded to a different question than the one I asked. I asked you to confirm which individual or individuals have made the decision to not publish the iDAPs at the present time - ie, thus far. I understand that you may still be considering the timing of the iDAPs' publication, but someone, or some group of people, has made the decision to not publish up until this point. That is clear from the clarification e-mail you sent me on 9 September 2021, in which you said: "we took into account that releasing the information prematurely could impact adversely on the policy around the wider government vaccine campaign as the information may be misused once in the public domain by those who do not agree with vaccination in general". Ie, it is clear from that e-mail that an _active decision_ was taken to not publish yet. I would like to know who made that decision (along with the other pieces of information requested in question 1). Can you please now provide that information?"*

Response to question a) We have addressed these points above and outlined our processes within our response to Question 1 above.

Question b) *"The MHRA's role in the UK's public administration architecture is, inter alia, to license and to provide post-licensing pharmacovigilance for medicinal products. It has a specific statutory role under, inter alia, The Human Medicines Regulations 2012. In exercising that statutory role and broader public administrative function, it is implementing existing government policy around medicines regulation. That point is prima facie clear. However, even if it were not, the ICO, on page 19 of their guidance document "Government policy (section 35)" (<https://ico.org.uk/media/for-organisatio...>), state: "In general, arm's-length bodies are created to deliver specialist services which do not require the day to day engagement of ministers, or which need to be independent of government. As only ministers can approve government policy, it follows that the day to day business of these bodies will not involve government policymaking. By delegating an activity to a body at arm's length from ministers, the government has in effect signalled that the activity is considered operational or otherwise independent of government." (The previous page of the document*



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enumerates the different types of "arm's-length body", with executive agency - which the MHRA is - being one of these.) Can you please now accept that the MHRA's pharmacovigilance function, including the publication of datasets such as iDAPs, is the implementation of existing government policy around medicines regulation, and withdraw your assertion that section 35(1)(a) is relevant to the publication or otherwise of iDAPs for COVID-19 vaccines? Alternatively, if you are unwilling to do this, can you please provide a more robust defence of your reliance on section 35(1)(a) beyond simple assertions like "this information is exempted as per section 35 of the Freedom of Information Act"?

Response to question b)

We have addressed these points above: it is now our view that no exemption, including section 35 (Formulation of government policy) should have been used to respond to this aspect of the FOI request and we apologise for this error.

Question c) *"Further to point (b), could I also ask you to consider the example of iDAPs for HPV vaccines. Given that it is government policy for as many eligible individuals as possible to get an HPV vaccine, is your view that - while you recognise that there is strong interest in seeing iDAPs for HPV vaccines, and accept in principle that they should not be withheld - you could rely on section 35(1)(a) FOIA 2000 to withhold iDAPs for HPV vaccines for many, many years on the basis that their publication "could impact adversely on the policy around the wider government [HPV] vaccine campaign as the information may be misused once in the public domain by those who do not agree with vaccination in general"? (within internal review)"*

Response to question c: We consider that this request is outside the remit of the current request for Internal Review.

Question d) *"In your response to question 2 in my request, you state both that the information is covered by a section 35 FOIA 2000 exemption, and that you do not hold the information "as [it] is a future decision".*

d) Can you please clarify which of the above two statements is true? Specifically, does the information around who will make the eventual decision about when to go ahead and publish the iDAPs (along with the other pieces of information requested in question 2) exist, or does it not exist? (within internal review)

With regards question 3 in my request, part of this question asks whether ministers were involved in the decision not to publish thus far - this part is not about the future. (within internal review)"

Response to question d) Thank you for bringing this to our attention and we apologise for the error. We have addressed these points above.

Question e) *"In light of the various points made above with respect to question 1, can you now please confirm whether ministers were involved in the decision not to publish thus far, and, if so, in what capacity?"*

Response to question e): We have addressed these points within our response to Q3 above.



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Has the Agency fulfilled its general obligation to be helpful?

We aim to be helpful in response to all enquiries and are fully committed to transparency. We do recognise, in considering this further, that the Agency should have provided further information on the decision-making process and should not have applied s35. We have now addressed this as above our responses to questions 1 to 3.

3. Conclusion and recommendations

We have outlined the decision-making process and also referred to information available in the public domain to provide detail where required.

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

MHRA FOI Team

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Annex: background correspondence

Non-publication of COVID-19 vaccine iDAPs – Decision-makers:

Original FOI:

Dear Medicines and Healthcare products Regulatory Agency (MHRA),

I am writing to make a request for information under section 1 of the Freedom of Information Act (FOIA) 2000.

In response to a number of freedom of information (FOI) requests over the last several months (including my own: <https://www.whatdotheyknow.com/request/s...> ; others are linked at the end of this message), you have stated that you plan to publish interactive drug analysis profiles (iDAPs) for the COVID-19 vaccines at some point in the future, without committing to a particular publication date (or even suggesting a likely publication date). You have cited section 22 FOIA 2000 as exempting the publication of the iDAPs data, on the basis that you intend to publish it in the future.

In a subsequent response to me, you say that you "recognise that there is strong interest in seeing this data and accept it should not be withheld."

Yet more than 6 weeks after writing that, you continue to withhold the data.

In your response to my request for internal review, you have additionally cited section 35 FOIA 2000 as exempting the publication of the data on the basis that the data is linked to the formulation or development of government policy.

You are not of course required by law to make use of any exemptions provided for in sections 22 and 35 FOIA 2000. You have made a decision to do so.

Please can you confirm:

1) Which individual or individuals have made the decision to not publish the above-mentioned iDAPs at the present time, whether this individual/these individuals is/are within the MHRA, the wider Department of Health and Social Care, or somewhere else in government, and on what grounds the decision was made

2) Which individual or individuals will make the eventual decision about when to go ahead and publish the above-mentioned iDAPs, and whether this individual/these individuals is/are within the MHRA, the wider Department of Health and Social Care, or somewhere else in government

3) Whether ministers were involved in the decision not to publish so far, and whether ministers will be involved in the decision to publish in the future, and in each case in what capacity (ie, ultimate decision-maker, consultee, or some other capacity)



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NB: While the names of individuals are clearly personal data, you will be familiar with the ICO guidance on section 40 FOIA 2000 (<https://ico.org.uk/media/for-organisatio...>), which states:

"Disclosure of personal data will always involve some intrusion into privacy, but intrusion may be warranted. For example, disclosure may be acceptable if the information relates to the performance of public duties ... by senior officials."

Yours faithfully,

Kenneth MacArthur

[then links to other FOIs where we have committed to publication]

We responded:

Thank you for your FOI request dated July 9th where you requested the below regarding the publication of the vaccine iDAPs. Additionally, please accept our apologies for the late response to your request.

- 1) Which individual or individuals have made the decision to not publish the above-mentioned iDAPs at the present time, whether this individual/these individuals is/are within the MHRA, the wider Department of Health and Social Care, or somewhere else in government, and on what grounds the decision was made
- 2) Which individual or individuals will make the eventual decision about when to go ahead and publish the above-mentioned iDAPs, and whether this individual/these individuals is/are within the MHRA, the wider Department of Health and Social Care, or somewhere else in government
- 3) Whether ministers were involved in the decision not to publish so far, and whether ministers will be involved in the decision to publish in the future, and in each case in what capacity (ie, ultimate decision-maker, consultee, or some other capacity)

With regards to question one, the MHRA are still considering the timing of the publication of the vaccine iDAPs and therefore this information is exempted as per section 35 of the Freedom of Information Act. Section 35 is a qualified exemption, which means that we have considered whether the public interest in releasing the information is outweighed by the public interest in not giving the information. The purpose of section 35 is to protect good government. It reflects and protects some longstanding constitutional conventions of government and preserves a safe space to consider policy options in private.

Questions two and three are also exempt as per section 35 as the MHRA do not hold the information on which individuals will be involved as this is a future decision and cannot provide information on this decision from a policy perspective.

I hope the information provided is helpful, but if you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date of this response; and can be addressed to this email address.

Yours sincerely



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Claimants Request for Internal Review:

Dear Medicines and Healthcare products Regulatory Agency (MHRA),

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

I am writing to request an internal review of the MHRA's handling of my FOI request 'Non-publication of COVID-19 vaccine iDAPs - Decision-makers'.

In your response to question 1 in my request, you state that the MHRA are still considering the timing of the publication of the COVID-19 vaccine iDAPs and that "therefore" the information I have requested is exempt under section 35 of the Freedom of Information Act (FOIA) 2000 (which you later clarified to me to be section 35(1)(a) FOIA 2000 in particular).

There are several issues with this.

a) Firstly, you have responded to a different question than the one I asked. I asked you to confirm which individual or individuals have made the decision to not publish the iDAPs at the present time - ie, thus far. I understand that you may still be considering the timing of the iDAPs' publication, but someone, or some group of people, has made the decision to not publish up until this point. That is clear from the clarification e-mail you sent me on 9 September 2021, in which you said: "we took into account that releasing the information prematurely could impact adversely on the policy around the wider government vaccine campaign as the information may be misused once in the public domain by those who do not agree with vaccination in general". Ie, it is clear from that e-mail that an active decision was taken to not publish yet. I would like to know who made that decision (along with the other pieces of information requested in question 1). Can you please now provide that information?

b) The MHRA's role in the UK's public administration architecture is, inter alia, to license and to provide post-licensing pharmacovigilance for medicinal products. It has a specific statutory role under, inter alia, The Human Medicines Regulations 2012. In exercising that statutory role and broader public administrative function, it is implementing existing government policy around medicines regulation. That point is prima facie clear. However, even if it were not, the ICO, on page 19 of their guidance document "Government policy (section 35)" (<https://ico.org.uk/media/for-organisatio...>), state: "In general, arm's-length bodies are created to deliver specialist services which do not require the day to day engagement of ministers, or which need to be independent of government. As only ministers can approve government policy, it follows that the day to day business of these bodies will not involve government policymaking. By delegating an activity to a body at arm's length from ministers, the government has in effect signalled that the activity is considered operational or otherwise independent of government." (The previous page of the document enumerates the different types of "arm's-length body", with executive agency - which the MHRA is - being one of these.) Can you please now accept that the MHRA's pharmacovigilance function, including the publication of datasets such as iDAPs, is the implementation of existing government policy around medicines regulation, and withdraw your assertion that section 35(1)(a) is relevant to the publication or otherwise of iDAPs for COVID-19 vaccines? Alternatively, if you are unwilling to do this, can you please provide a more robust defence of your reliance on section 35(1)(a) beyond simple assertions like "this information is exempted as per section 35 of the Freedom of Information Act"?



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c) Further to point (b), could I also ask you to consider the example of iDAPs for HPV vaccines. Given that it is government policy for as many eligible individuals as possible to get an HPV vaccine, is your view that - while you recognise that there is strong interest in seeing iDAPs for HPV vaccines, and accept in principle that they should not be withheld - you could rely on section 35(1)(a) FOIA 2000 to withhold iDAPs for HPV vaccines for many, many years on the basis that their publication "could impact adversely on the policy around the wider government [HPV] vaccine campaign as the information may be misused once in the public domain by those who do not agree with vaccination in general"?

In your response to question 2 in my request, you state both that the information is covered by a section 35 FOIA 2000 exemption, and that you do not hold the information "as [it] is a future decision".

d) Can you please clarify which of the above two statements is true? Specifically, does the information around who will make the eventual decision about when to go ahead and publish the iDAPs (along with the other pieces of information requested in question 2) exist, or does it not exist?

With regards question 3 in my request, part of this question asks whether ministers were involved in the decision not to publish thus far - this part is not about the future.

e) In light of the various points made above with respect to question 1, can you now please confirm whether ministers were involved in the decision not to publish thus far, and, if so, in what capacity?

Can I kindly ask you to respond individually to each of points (a), (b), (c), (d) and (e).

A full history of my FOI request and all correspondence is available on the Internet at this address: <https://www.whatdotheyknow.com/request/n...>

Yours faithfully,

Kenneth MacArthur