



Medicines & Healthcare products Regulatory Agency

Dr Kenneth MacArthur
request-819887-5e0a2580@whatdotheyknow.com

MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

www.gov.uk/mhra

22nd June 2022

MHRA reference: FOI 22/049 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 ([22/049]).

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

'a few links are not - in law or in any other way - a substitute for a response to my FOI request. Almost 60 working days have gone by since I made the request without my receiving a response. This is in clear breach of section 10(1) of the Freedom of Information Act 2000. Please can you now reply to my request forthwith.'

2. Consideration of the issues

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

We consider that the Agency, whilst acting in good faith, did not respond to the request adequately and did not directly answer the questions posed. We apologise for this and have now reconsidered as below:

- 1) Who the MHRA needs to seek permission from



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The use of the term 'seek permission' was incorrect. All decisions of the MHRA are taken by the Secretary of State under the Carltona Principle. This includes decisions on matters regarding publication. However, it will be important to ensure that other Government bodies, such as DHSC, are aware of when publication will take place.

- 2) Whether such permission has yet been sought, and, if so, when, or, if not, when you intend to seek it.

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 and therefore, the MHRA does not need to seek permission.

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.

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

Has the Agency fulfilled its general obligation to be helpful?

We consider that the Agency, whilst acting in good faith, did not respond to the request adequately. We apologise and have remedied this above. We now consider that we have fully complied with the request.

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



Medicines & Healthcare products Regulatory Agency

Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

MHRA FOI team

Medicines and Healthcare products Regulatory Agency



Medicines & Healthcare products Regulatory Agency

Annex: background correspondence

Original FOI:

Dear Medicines and Healthcare products Regulatory Agency (MHRA),

It is now almost a year since you first communicated, via responses to FOI requests, your intention to publish interactive drug analysis profiles (iDAPs) for the COVID-19 vaccines. In a number of such responses (eg, <https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fico.org.uk%2Fmedia%2Faction-weve-taken%2Fdecision-notices%2F2022%2F4019679%2Fic-117978-k9g4.pdf&data=04%7C01%7CMHRACustomerServices%40mhra.gov.uk%7C39bb5f8f>), you have spoken of the MHRA "seeking permission" to publish iDAPs.

Please can you confirm:

- 1) Who the MHRA needs to seek permission from.
- 2) Whether such permission has yet been sought, and, if so, when, or, if not, when you intend to seek it.

In responding, I would invite you to take note of the ICO's guidance document "Government policy (section 35)" (<https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fico.org.uk%2Fmedia%2Faction-weve-taken%2Fdecision-notices%2F2022%2F4019679%2Fic-117978-k9g4.pdf&data=04%7C01%7CMHRACustomerServices%40mhra.gov.uk%7C39bb5f8f>), which states:

"In general, arm's-length bodies [which the MHRA, as an executive agency, is] 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."

I would also draw your attention to ICO decision notice FS50420602 on this matter.

Yours faithfully,

Kenneth MacArthur

We responded:

Dear Mr Kenneth MacArthur,

Thank you for your email.

Please see below links to recent decision notices on the Information Commissioner's Office website relating to Interactive Data Analysis Profile and these documents are available in the public domain.

<https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fico.org.uk%2Fmedia%2Faction-weve-taken%2Fdecision-notices%2F2022%2F4019679%2Fic-117978-k9g4.pdf&data=04%7C01%7CMHRACustomerServices%40mhra.gov.uk%7C39bb5f8f>



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[8b8a4ee9641608da10e2e0ab%7Ce527ea5c62584cd2a27f8bd237ec4c26%7C0%7C0%7C637840864255533881%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzliLCJBtil6lk1haWwiLCJXCI6Mn0%3D%7C3000&data=TPUgxiNZxWatUx8N%2BRZsjFYODZp8jTROXiKo%2FHiNa4%3D&reserved=0](https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fico.org.uk%2Fmedia%2Faction-weve-taken%2Fdecision-notices%2F2022%2F4019572%2Fic-119116-g7y5.pdf&data=04%7C01%7CMHRACustomerServices%40mhra.gov.uk%7C39bb5f8f8b8a4ee9641608da10e2e0ab%7Ce527ea5c62584cd2a27f8bd237ec4c26%7C0%7C0%7C637840864255533881%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzliLCJBtil6lk1haWwiLCJXCI6Mn0%3D%7C3000&data=TPUgxiNZxWatUx8N%2BRZsjFYODZp8jTROXiKo%2FHiNa4%3D&reserved=0)

<https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fico.org.uk%2Fmedia%2Faction-weve-taken%2Fdecision-notices%2F2022%2F4019572%2Fic-119116-g7y5.pdf&data=04%7C01%7CMHRACustomerServices%40mhra.gov.uk%7C39bb5f8f8b8a4ee9641608da10e2e0ab%7Ce527ea5c62584cd2a27f8bd237ec4c26%7C0%7C0%7C637840864255533881%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzliLCJBtil6lk1haWwiLCJXCI6Mn0%3D%7C3000&data=EWsW1Vx7acCCqfiNwPmuu%2Bym3R6FXygmm6Ojwc2zM44%3D&reserved=0>

<https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fico.org.uk%2Fmedia%2Faction-weve-taken%2Fdecision-notices%2F2022%2F4019515%2Fic-107706-f9d4.pdf&data=04%7C01%7CMHRACustomerServices%40mhra.gov.uk%7C39bb5f8f8b8a4ee9641608da10e2e0ab%7Ce527ea5c62584cd2a27f8bd237ec4c26%7C0%7C0%7C637840864255533881%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzliLCJBtil6lk1haWwiLCJXCI6Mn0%3D%7C3000&data=u39xbG1or%2FpYMfi8liRrhxlCJgsMUMNI%2Fq8EHx7BQis%3D&reserved=0>

Kind Regards

MHRA Customer Experience Centre

Medicines and Healthcare products Regulatory Agency
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There are then multiple requests from Mr MacArthur for a response