Freedom of Information Act 2000 (FOIA)

Decision notice

Date: **5 October 2022**

Public Authority: **Medicines and Healthcare Products Regulatory Agency**

Address: **10 South Colonnade**
Canary Wharf
London
E14 4PU

Decision (including any steps ordered)

1. The complainant has requested information relating to MHRA's intention to publish interactive drug analysis profiles (iDAPs) for the COVID-19 vaccines. In particular the complainant asked who the MHRA needs to seek permission from and whether such permission has yet been sought, and, if so, when, or, if not, when it intends to seek it. MHRA explained that the use of the term 'seek permission' in the request was incorrect, it explained that decisions of the MHRA are taken by the Secretary of State however it makes relevant bodies such as DHSC aware of when publication will take place. It also explained when publication will take place.

2. The Commissioner's decision is that MHRA does not hold the information requested under section 1(1)(a) FOIA but breached section 10(1) FOIA as it failed to provide a response within the statutory time for compliance.

3. The Commissioner does not require MHRA to take any remedial steps.

Request and response

4. On 5 January 2022 the complainant wrote to MHRA and requested information in the following terms:

"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://www.whatdotheyknow.com/request/1...), 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."

5. MHRA responded on 28 March 2022 providing links to previous ICO Decision Notices relating to requests regarding iDAPs. The complainant requested an internal review on the same date as MHRA had not addressed the actual FOIA request made.

6. Following an internal review MHRA wrote to the complainant on 22 June 2022. It acknowledged that it had not addressed the request made. In relation to part 1 of the request it explained that:

"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."

In relation to part 2 of the request it explained that:

"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."

Scope of the case

7. The complainant contacted the Commissioner to complain about the way his request for information had been handled.

8. The Commissioner's investigation has focussed on whether MHRA holds the requested information under section 1(1)(a) FOIA and whether it complied with section 10 FOIA in the handling of this request.

Reasons for decision

Section 1

9. Section 1 (1) FOIA provides that:

> "Any person making a request for information to a public authority is entitled –
>
> (a) to be informed in writing by the public authority whether it holds information of the description specified in the request, and
> (b) if that is the case, to have that information communicated to him."

10. The Commissioner has sought to determine whether, on the balance of probabilities, MHRA holds the information requested.

11. The Commissioner notes that in his request, the complainant directed the MHRA to a previous FOI response it had provided to a request relating to iDAPs in which it had said:

> "It remains our intention to seek permission to publish interactive drug analysis prints (iDAPs)…"

12. The Commissioner therefore understands why the complainant may have understood that MHRA required permission to publish this data and as such why this request was made.

13. However MHRA has been clear in its response that it does not need to seek permission to publish this data. The decision rests with the Secretary of State however MHRA will make relevant bodies, such as DHSC, aware of when publication will take place.

14. Based upon MHRA's response, that it is not required to seek permission to publish this data, the Commissioner considers that, on the balance of probabilities, the information requested is not held under section 1(1)(a) FOIA.

Section 10

15. Section 10(1) of FOIA states that a public authority must respond to a request promptly and "not later than the twentieth working day following the date of receipt".

16. In this case MHRA did not provide a response with the statutory time for compliance and therefore it breached section 10(1) FOIA in the handling of this request.

Right of appeal

17. Either party has the right to appeal against this decision notice to the First-tier Tribunal (Information Rights). Information about the appeals process may be obtained from:

    First-tier Tribunal (Information Rights)
    GRC & GRP Tribunals
    PO Box 9300
    LEICESTER
    LE1 8DJ

    Tel: 0203 936 8963
    Fax: 0870 739 5836
    Email: grc@justice.gov.uk
    Website: www.justice.gov.uk/tribunals/general-regulatory-chamber

18. If you wish to appeal against a decision notice, you can obtain information on how to appeal along with the relevant forms from the Information Tribunal website.

19. Any Notice of Appeal should be served on the Tribunal within 28 (calendar) days of the date on which this decision notice is sent.

Signed……

Gemma Garvey
Senior Case Officer
Information Commissioner's Office
Wycliffe House
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Wilmslow
Cheshire
SK9 5AF