Freedom of Information Act 2000 (FOIA)

Decision notice

Date: 5 October 2022

Public Authority: Medicines and Healthcare Products Regulatory Agency (MHRA)

Address: 10 South Colonnade
Canary Wharf
London
E14 4PU

Decision (including any steps ordered)

1. The complainant has requested information relating to the identity of individuals responsible for decision making regarding MHRA's intention to publish interactive drug analysis profiles (iDAPs) for the COVID-19 vaccines. MHRA provided the complainant with some information in response to the request.

2. The Commissioner's decision is that, on the balance of probabilities, MHRA does hold further information under section 1(1)(a) FOIA in relation to part 1 of the request and breached section 10(1) FOIA as it failed to provide a response within the statutory time for compliance and failed to respond to an aspect of part 3 of the request.

3. The Commissioner requires the public authority to take the following steps to ensure compliance with the legislation:

    - MHRA must either disclose the further information it holds in relation to part 1 of the request, or issue a refusal notice that complies with section 17 of the FOIA.

    - In relation to part 3 of the request, in particular, "whether Ministers were involved with the decision not to publish so far", MHRA must confirm or deny whether it holds this information. If the MHRA holds information it must either disclose it, or issue a refusal notice that complies with section 17 of the FOIA

4. The public authority must take these steps within 35 calendar days of the date of this decision notice. Failure to comply may result in the Commissioner making written certification of this fact to the High Court

pursuant to section 54 of the Act and may be dealt with as a contempt of court.

Request and response

5. On 9 July 2021 the complainant wrote to MHRA and requested information in the following terms:

> "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."

6. MHRA responded on 25 August 2021. It refused to disclose the information requested at parts 1, 2 and 3 of the request under section 35 FOIA. It also said that it did not hold information in relation to part 2 as this request related to a future decision.

7. On 23 September 2021 the complainant requested an internal review. The complainant also submitted new requests for information within this correspondence.

8. Following an internal review MHRA wrote to the complainant on 22 June 2022. In relation to part 1 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.

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."

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

"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."

In relation to part 3 it explained that:

"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."

9. MHRA also responded to the new requests made within the internal review request correspondence. This falls outside the scope of this Decision Notice. If the Complainant is dissatisfied with MHRA's response to the new requests made, the next step is for the complainant to ask MHRA to carry out an internal review.

Scope of the case

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

11. The Commissioner's investigation has focussed on whether MHRA holds any further 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

12. 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."

13. The Commissioner has sought to determine whether, on the balance of probabilities, MHRA holds further information under section 1(1)(a) FOIA.

Part 1

14. MHRA has explained that the decision is ultimately taken by the Secretary of State. However at paragraph 19 of the previous Decision Notice (IC-107706-F9D4) referred to by MHRA in its internal review response, it confirms that:

> "MHRA has provided the Commissioner with email exchanges covering the period 23 February 2021 to 2 March 2021. In these exchanges members of MHRA staff discuss technical and presentational issues associated with the publication of the requested data."

15. MHRA holds correspondence which discusses decision making surrounding publication of this data. The names of the individuals (either within MHRA or outside MHRA) involved in the decision making and any reasoning will be contained within such correspondence.

16. Based upon this the Commissioner considers that on the balance of probabilities further information is held by MHRA under section 1(1)(a) FOIA.

Part 2

17. At the time of the request it does not appear that a decision had been taken. This request is for future information and would not therefore be

held by MHRA. However MHRA has confirmed that ultimately the decision rests with the Secretary of State.

Part 3

18. At the time of the request a decision to publish had not been taken and therefore as explained above a request for future information would not be held by MHRA. However MHRA has confirmed that it will engage with Ministers as appropriate as it works to publish the data but ultimately the decision rests with the Secretary of State.

19. MHRA has not, however, confirmed whether Ministers were involved with the decision not to publish so far (at the time of the request). The Commissioner therefore considers that MHRA has failed to respond to this aspect of part 3 of the request. This will be addressed under 'Section 10' below.

20. In this case, in relation to part 1 of the request, on the balance of probabilities, the Commissioner considers that further information is held by MHRA under section 1(1)(a) FOIA.

Section 10

21. 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".

22. 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. In relation to part 3 of the request, in particular "whether Ministers were involved with the decision not to publish so far", MHRA has failed to respond to this part of the request at all.

Right of appeal

23. 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

24. 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.

25. 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
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