# Freedom of Information Act 2000 (FOIA)

# Decision notice

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| **Date:** | **8 November 2023** |
| **Public Authority:** | **Medicines & Healthcare products Regulatory Agency (MHRA)** |
| **Address:** | **10 South Colonnade**<br>**Canary Wharf**<br>**London**<br>**E14 4PU** |

## Decision (including any steps ordered)

1. The complainant has requested MHRA to disclose information relating to section 3 of its 2021 Annual Report entitled "Delivering High Standards in Medicines Advertising Regulation". MHRA advised the complainant that it does not hold any recorded information falling within the scope of their request.

2. The Commissioner's decision is that on the balance of probabilities MHRA does not hold any recorded information falling within the scope of the complainant's request. He does not require any further steps to be taken.

## Request and response

3. On 19 April 2023, the complainant wrote to MHRA and requested information in the following terms:

> "I refer you to the 2021 Annual Report of your Advertising Standards & Outreach Unit, Vigilance and Risk Management of Medicines Division,

Published 17th March 2022 and entitled "Delivering High Standards in Medicines Advertising Regulations".

In section 3. Of this document, which is headed "Vetting advertising before issue" it says :

" We also reviewed information disseminated on COVID-19 vaccines given a temporary supply and conditional authorisations,"

Under the requirements of the Freedom of Information Act 2000 I am requesting that you send me copies of, or specific and direct electronic links to, each such item of information which has been reviewed by the MHRA Advertising Standards Unit in 2019, 2020, 2021, 2022 and 2023

I am also asking for the MHRA to tell me exactly why the MHRA Advertising Standards and Outreach Unit reviewed each item of information and what sets of regulations, standards or guidelines the Unit used to review each item of information and assess its suitability for dissemination.

Please note that this FOIA request does not apply to the review of materials produced by pharmaceutical companies. However, it applies to all information reviewed which was produced by the UK Government, all UK devolved governments and all governmental departments or agencies ( including, but not restricted to, the NHS, the UKHSA, the MHRA, the DHSC)."

4. MHRA responded on 26 April 2023. It stated that it does not hold the requested information.

5. The complainant requested an internal review on 2 May 2023. They confirmed that they did not feel MHRA had responded appropriately to the information request they made. They listed various reasons why.

6. MHRA did not respond to the internal review request on time so the complainant referred the matter to the Commissioner on 23 June 2023.

7. The Commissioner wrote to MHRA on 3 July 2023 and requested that it completes the internal review within 10 working days.

## Scope of the case

8. The complainant contacted the Commissioner again on 17 July 2023 to complain about the way their request for information had been handled. Despite the Commissioner's intervention MHRA still failed to respond to

the complainant's request for an internal review. He therefore accepted the complaint for full investigation.

9. The Commissioner considers that the scope of his investigation is to establish whether or not, on the balance of probabilities, MHRA holds the requested information.

## Reasons for decision

### Section 1 – general right of access

10. Section 1 of the FOIA states that any person making a request for information is entitled to be informed in writing by the public authority whether it holds information of the description specified in the request and, if that is the case, to have that information communicated to them.

11. In cases where a dispute arises over whether recorded information is held by a public authority at the time of the request, the Commissioner - following the lead of a number of First-tier Tribunal decisions – applies the civil standard of the balance of probabilities. In essence, the Commissioner will determine whether it is likely, or unlikely, that the public authority holds information relevant to the complainant's request.

12. MHRA has provided the Commissioner with detailed submissions, explaining why it does not hold the requested information. It said that the request specifically references section 3 of the 2021 annual report and a quote that is made in that section, which says:

    "… reviewed information disseminated on COVID-19 vaccines given a temporary supply and conditional authorisations."

    The request asked for each such item reviewed by the Advertising Standards and Outreach Unit (the unit) from 2019 to 2023, why and what regulations, standards and guidelines used to review each item.

    The request specifically excludes the review of materials produced by pharmaceutical companies.

13. MHRA confirmed that section 3 of the 2021 annual report is about the targeted, proactive review or vetting process of pharmaceutical companies that its unit carry out under the legislative framework of Part 14 ("Advertising") of the Human Medicines Regulations 2012. It explained that it only approaches pharmaceutical companies and asked those companies to submit advertising of their medicinal products. Although section 3 of the report is implicit in this, it does just refer to the pharmaceutical companies the unit approached and nothing more.

14. It confirmed that information is held by the unit which corresponds to "information disseminated on COVID-19 vaccines given a temporary supply and conditional authorisations", which was reviewed by that unit. A 'vetting request' was sent to each of the pharmaceutical companies applying for temporary and conditional marketing authorisation for their specific product, in each case a specific Covid-19 vaccine, and advertising material was provided to the unit by each of the pharmaceutical companies for each of their respective products.

15. However, MHRA said that the request itself specifically excludes pharmaceutical companies and therefore this information from the scope of the request and this is why it gave a 'not held' response.

16. It noted that the request covered information reviewed, which was produced by the UK Government, but again stated that section 3 of the report does not cover government material. It went on to explain that any information reviewed, which was produced by the UK Government would not meet the legal definition for an advertisement for a medicine and therefore would not be within the scope of the work of the unit to oversee Part 14 of the Regulations.

17. To highlight this further MHRA allowed the Commissioner to view during a call the files held by the unit for all materials submitted for the individual products. MHRA shared the relevant folders for Covid-19 vaccines with the Commissioner and demonstrated how these contain separate submissions from each of the pharmaceutical companies for their respective product. There are no other submissions from any other parties.

18. MHRA referred to the complainant's own interpretation of the advertising regulations and how from their perspective on this, the requested information must be held. But it is MHRA's position that the recorded information it holds is simply that and the section of the report referred to in the request addresses only the review of pharmaceutical companies and their products. For these reasons it is firmly of the view that the requested information is not held.

19. The Commissioner is satisfied that on the balance of probabilities MHRA does not hold the requested information. It has explained how the section of the report referred to in the request only concerns the review of pharmaceutical companies and their products and how the complainant specifically excluded such information from the scope of the request. MHRA shared the files held by the unit for Covid-19 vaccines with the Commissioner and demonstrated how these only contain the relevant submissions from pharmaceutical companies about their product.

20. The Commissioner notes that the complainant may have a different interpretation of the advertising regulations and on this basis feel recorded information is held. But this does not alter MHRA's interpretation and the recorded information it does hold relating to section 3 of the report falling outside the scope of the request. If the complainant wishes to challenge the interpretation of the advertising regulations, this should be pursued via other means.

## Other matters

21. The Commissioner notes that MHRA failed to carry out an internal review within the recommended timeframe outlined in the Section 45 Code of Practice. This advises public authorities to carry out internal reviews within 20 working days of receipt and certainly no later than 40 working days. MHRA is reminded of the requirements of the code and of the importance of carrying out internal reviews within a timely manner.

## Right of appeal

22. 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

23. 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.

24. 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**

**Samantha Coward**
**Senior Case Officer**
**Information Commissioner's Office**
**Wycliffe House**
**Water Lane**
**Wilmslow**
**Cheshire**
**SK9 5AF**