Freedom of Information Act 2000 (Section 51)

Information notice

Date: **25 March 2022**

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

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

Section 51

Under section 51 of the Freedom of Information Act 2000 (FOIA), which is set out below, the Information Commissioner (the Commissioner) has the power to serve a notice on a public authority requiring it to furnish him with any information he requires to enforce the requirements of FOIA.

51. – (1) If the Commissioner –

(a) has received an application under section 50, …

he may serve the authority with a notice (in FOIA referred to as "an information notice") requiring it, within such time as is specified in the notice, to furnish the Commissioner, in such form as may be so specified, with such information relating to the application, to compliance with Part I or to conformity with the code of practice as is so specified.

Application under section 50

1. The Commissioner has received an application under section 50, reference [IC-111457-W7C5], for a decision whether a request for information made by the complainant to Medicines and Healthcare products Regulatory Agency (MHRA) on 14 April 2021, has been dealt with in accordance with the requirements of Part I of FOIA.

Nature of complaint

2. On 14 April 2021 the complainant requested information of the following description:

> "I am writing to make a request for information under section 1 of the Freedom of Information Act 2000.
>
> Please can you confirm whether the MHRA holds any information produced since 2020 which relates to the matters of:
>
> a) Potential safety signals identified with any COVID-19 vaccine
> b) Whether and how to publicly communicate about these potential safety signals
> c) Whether and how to publicly communicate about any communication or collaboration on these potential safety signals that has taken place with the European Medicines Agency (EMA), including, but not limited to, with the EMA's Committee for Medicinal Products for Human Use (CHMP) and Pharmacovigilance Risk Assessment Committee (PRAC), or members thereof, and with national medicines regulators and vaccination/immunization advisory bodies in EU/EEA countries.
>
> If any such information exists, please can you provide it to me."

On 14 May 2021 MHRA responded. You directed him to where information you considered relevant is published.

MHRA provided an internal review on 8 June 2021. You again directed the complainant to where information you consider is relevant to the request is published. MHRA also advised that some information you hold is exempt from disclosure under sections 40(2) and 41(1) of FOIA. Finally, MHRA noted the complainant's use of the term "any information" in his request and request for a review. You advised that this was too general and advised him to clarify the specific additional information he is seeking.

The Commissioner has been asked to consider MHRA's reliance on section 40(2) and section 41(1) of FOIA to withhold specific information MHRA has identified that it holds and which the complainant has requested.

Having now reviewed MHRA's correspondence with the complainant again, the Commissioner will also consider the terms of the complainant's request for "any information" and whether MHRA could have reasonably been expected to fully comply with this request, as framed.

On 18 November 2021 the Commissioner wrote to MHRA. The letter included instructing MHRA to provide a submission justifying its reliance on the above two exemptions. MHRA was asked to provide its submission by Thursday 16 December 2021.

MHRA requested an extension for its submission to 21 January 2022 which the Commissioner agreed.

When he did not receive a submission from MHRA, the Commissioner requested updates from MHRA on 4 February 2022 and 16 March 2022. In the latter correspondence he advised that he would consider serving an information notice if he did not receive MHRA's submission by Wednesday 23 March 2022. The Commissioner did not receive MHRA's submission by that date.

Information required

3. In view of the matters described above the Commissioner hereby gives notice that in the exercise of his powers under section 51 of FOIA he requires that MHRA shall, within 30 calendar days of the date of this notice, furnish the Commissioner with a copy of the following information:

- A submission that fully addresses the questions on MHRA's reliance on section 41(1) of FOIA, that the Commissioner asked in his correspondence to MHRA of 18 November 2021.

- As requested in the Commissioner's correspondence of 18 November 2021, the submission should also provide more detail on whose personal data MHRA is withholding under section 40(2). MHRA's submission should also explain how those specific individuals could be identified from the information and address the questions under 'Section 40 – personal information' on the ICO's website: https://ico.org.uk/for-organisations/key-questions-for-public-authorities-foi-act-2000/#40

- If, since 18 November 2021 and having reconsidered the request as a result of the complaint to the Commissioner, MHRA's position has changed, MHRA should advise the Commissioner and its submission should address the appropriate 'Key Questions' published on the ICO's website: https://ico.org.uk/for-organisations/key-questions-for-public-authorities-foi-act-2000/#introduction

Failure to comply

4. Failure to comply with the steps described above may result in the Commissioner making written certification of this fact to the High Court (or the Court of Session in Scotland) pursuant to section 54 of FOIA and may be dealt with as a contempt of court.

Right of appeal

5. There is a right of appeal against this information notice to the First-tier Tribunal (Information Rights). Information about the appeals process can 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

6. Any Notice of Appeal should be served on the Tribunal within 28 (calendar) days of the date on which this information notice is sent. If Notice of Appeal is served late the Tribunal will not accept it unless it is of the opinion that it is just and right to do so by reason of special circumstances.

Signed

Cressida Woodall
Senior Case Officer
Information Commissioner's Office
Wycliffe House
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Wilmslow
Cheshire
SK9 5AF