Freedom of Information Act 2000 (Section 51)

Information notice

Date: **4 April 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-117930-T6R1], for a decision whether a request for information made by the complainant to Medicines and Healthcare products Regulatory Agency (MHRA) on 3 April 2021, has been dealt with in accordance with the requirements of Part I of FOIA.

Nature of complaint

2. On 3 April 2021 the complainant requested information of the following description:

> "Please can you provide the list of suspected adverse reactions to COVID-19 vaccines received by the MHRA since December 2020 broken down by the following attributes:
>
> i) Vaccine type
> ii) Patient age (or age band of a maximum of 5 years)
> iii) Patient sex
> iv) Patient ethnicity
>
> For clarity:
>
> - This request is for the above attributes to be provided simultaneously for each reaction type - ie, so that it is possible to determine, for example, the number of White British female recipients of COVID-19 Vaccine AstraZeneca in the 35-39 age band who have suffered from an infected dermal cyst following
> receipt of this vaccine (and not simply the number of White British people, or the number of females, or the number of 35-39 year olds).
>
> - The "list of suspected adverse reactions to COVID-19 vaccines received by the MHRA since December2020" is those enumerated in the most recent analysis prints published at
> https://www.gov.uk/government/publicatio..."

On 5 May 2021 MHRA responded to the request. You refused the request under section 22 of FOIA and said you would advise him when the data was published.

MHRA provided an internal review on 9 July 2021. You maintained your reliance on section 22 to withhold the information the complainant has requested, and also discussed the exemption under section 35 of FOIA.

On 25 January 2022 the Commissioner wrote to MHRA. In his email the Commissioner asked MHRA to clarify its position with regard to an element of the requested information, namely the information on 'patient ethnicity'.

When he did not receive a response to his question, the Commissioner wrote to MHRA on 1 February 2022, 16 February 2022, 16 March 2022 and 24 March 2022, requesting a response to the 25 January 2022 email. In his email of 24 March 2022 the Commissioner advised that he

would consider serving an information notice if he did not receive a response to his email of 25 January 2022 by Thursday 31 March 2022. The Commissioner did not receive any response from MHRA 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 response that fully addresses the Commissioner's questions in his email to MHRA dated 25 January 2022.

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
Water Lane
Wilmslow
Cheshire
SK9 5AF