Freedom of Information Act 2000 (FOIA)

Decision notice

Date:	**10 November 2021**
Public Authority:	**Medicines & Healthcare products Regulatory Agency (Executive Agency of the Department for Health and Social Care)**
Address:	**10 South Colonnade** **London** **E14 4PU**

Decision (including any steps ordered)

1. The complainant has requested copies of the exceptional use authorisations for two Covid-19 testing kits. The Medicines & Healthcare products Regulatory Agency ("the MHRA") refused to provide this information as it considered that the Enterprise Act 2002 prevented it from doing so. It therefore relied on section 44 of the FOIA (statutory prohibition on disclosure) to withhold the information.

2. The Commissioner's decision is that the Enterprise Act only prohibits disclosure of a small quantity of the requested information. The MHRA is therefore not entitled to rely on section 44 of the FOIA to withhold most of the information.

3. The Commissioner requires the MHRA to take the following steps to ensure compliance with the legislation.

    - Disclose copies of both letters that have been withheld, with the exception of:

        - The date of application cited in the first paragraph and the quoted text in italics at the end of that paragraph beginning after the words "The reasons for application cited:"

        - The name and address of the recipient of the letter.

        - The sender's name, job title and signature.

        - In respect of the letter dated 21 December only, paragraph 14

- In respect of the letter dated 22 December only, all five sub-paragraphs (a – e) of numbered paragraph 6.

4. The MHRA 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.

Nomenclature

5. The MHRA is an executive agency sponsored by the Department for Health and Social Care and is therefore not a separate public authority in its own right. However as the MHRA has its own dedicated FOI team and as both the complainant and the Commissioner have communicated with "the MHRA" through the course of this process, the Commissioner will continue referring to the MHRA as the body responding to the request and complaint – although the public authority is, ultimately, the Department for Health and Social Care.

Request and response

6. On 8 March 2021 the complainant requested information of the following description:

> *"I would be grateful if you could arrange to provide me with the following information under the Freedom of Information Act 2000.*
>
> *"1. A copy of the authorisation for emergency use of the 'RT-PCR test' issued by MHRA for the diagnosis of SARS-CoV-2 virus and variants*
>
> *"2. A copy of the authorisation for emergency use of the 'Lateral Flow test' issued by MHRA for the diagnosis of SARS-CoV-2 virus and variants*
>
> *"If you consider it necessary any personal data, or commercially sensitive information, contained in the documentation can be redacted to comply with the data management principles set out in the Data Protection Act 2018 and GDPR."*

7. On 29 March 2021, the MHRA responded. It provided some information within the scope of the request but refused to provide the remainder. It relied upon section 44 of the FOIA as its basis for doing so as it considered that section 237 of the Enterprise Act 2002 prevented it from disclosing such information.

8. The complainant requested an internal review on the same day. The MHRA sent the outcome of its internal review on 13 April 2021. It upheld its original position.

Scope of the case

9. The complainant contacted the Commissioner on 13 April 2021 to complain about the way his request for information had been handled. He considered that there was a strong public interest in disclosure of the information.

10. Section 44 is an absolute exemption, meaning that the Commissioner is not entitled to consider the public interest in disclosure. If the exemption applies, that is the end of the matter.

11. The Commissioner considers that the scope of her investigation is to determine whether section 44 of the FOIA applies to the withheld information.

Reasons for decision

12. Section 44(1) of the FOIA states that:

> *Information is exempt information if its disclosure (otherwise than under this Act) by the public authority holding it—*
>
> *(a) is prohibited by or under any enactment,*

13. This exemption is engaged where a public authority would ordinarily be prohibited from disclosing the particular information by another piece of legislation.

14. In this case, the MHRA has cited the Enterprise Act 2002 as the legislation preventing it from disclosing the information. In order to demonstrate that section 44 is engaged, the Commissioner must carry out a three step test:

a) Does the Enterprise Act 2002 prevent disclosure of any particular category(s) of information under the FOIA? If so;

b) On the facts of the case, does the information being withheld fall within one or more of those categories and, if and to the extent that it does;

c) Is she satisfied that none of the lawful gateways for disclosure, set out in the Enterprise Act, would permit disclosure under FOIA.

15. If the answer to all the above questions is "yes," section 44 will be engaged. If and to the extent that any of the answers is "no", the information in question will not be covered by section 44.

16. Section 237 of the Enterprise Act 2002 states that:

> *(1) This section applies to specified information which relates to—*
>
> *(a) the affairs of an individual;*
>
> *(b) any business of an undertaking.*
>
> *(2) Such information must not be disclosed—*
>
> *(a) during the lifetime of the individual, or*
>
> *(b) while the undertaking continues in existence, unless the disclosure is permitted under this Part.*
>
> *(3) But subsection (2) does not prevent the disclosure of any information if the information has on an earlier occasion been disclosed to the public in circumstances which do not contravene—*
>
> *(a) that subsection;*
>
> *(b) any other enactment or rule of law prohibiting or restricting the disclosure of the information.*
>
> *…*
>
> *(6) This Part (except section 244) does not affect any power or duty to disclose information which exists apart from this Part.*

17. Section 245 of the Enterprise Act states that any disclosure which contravenes section 237 will be a criminal offence.

18. Whilst section 237(6) of the Enterprise Act does refer to duties to disclose information, the construction of section 44 of the FOIA ("otherwise than under this Act") requires the public authority to consider what the position would be if the FOIA did not exist. Clearly, if the FOIA did not exist, it could not impose a duty of disclosure upon the MHRA.

19. The Commissioner therefore accepts that the Enterprise Act does prohibit the disclosure of "specified information" otherwise than under the FOIA. The first part of the test is thus satisfied.

Is the withheld information "specified information"?

20. Section 238 of the Enterprise Act defines specified information as information that "comes to a public authority" in the course of that public authority exercising functions that have been delegated to it – either by the Enterprise Act directly or by another piece of legislation listed in Schedule 14 of that Act.

21. The Consumer Protection Act 1987 delegates, to the MHRA, a duty to protect consumers – and this is one of the pieces of legislation listed in schedule 14 of the Enterprise Act. In particular, the MHRA is required to enforce the Medical Devices Regulations 2002, which are safety regulations as defined in the Consumer Protection Act.

22. Therefore the Commissioner accepts that any information that comes to the MHRA in connection with its consumer protection functions will be "specified information" for the purposes of Enterprise Act – and thus exempt from disclosure.

23. The withheld information in this case comprises of two letters that the MHRA sent to the organisations concerned, authorising the exceptional use of two products which had not (at that point) received the "CE" quality marking.

24. Having viewed the withheld information, the Commissioner is not satisfied that either letter is, in its entirety, specified information. Section 238 is very clear that information will only be specified information if it "comes to" the public authority in connection with its functions.

25. During the course of her investigation, the Commissioner noted that the withheld information appeared to be information that the MHRA had created itself and therefore asked for an explanation as to why it was considered that this information had "come to" the MHRA.

26. The MHRA responded to say that:

> *"These Exceptional Use Authorisation letters have been generated by MHRA following an assessment of the data supplied to the Agency by the manufacturer of the products in question, as an integral part of the application process."*

27. The ordinary meaning of the phrase "comes to" implies that specified information is information that has either been communicated to the

MHRA by another party or reflects other information that has been communicated. The legislation does not refer to information that "comes to or is created by" the MHRA, nor does it refer to information simply "held" or "possessed" by the MHRA. It is not enough for the information to be merely connected with or relating to the MHRA's functions (although this information clearly is): the information must also have "come to" the MHRA. That would appear to exclude information that the MHRA has created itself.

28. Many regulators, in order to discharge their functions efficiently, often require those that they regulate to provide information that would ordinarily be commercially or otherwise sensitive. Statutory prohibitions allow regulated entities to share information with the regulator, secure in the knowledge that this is a confidential process and that the regulator and its staff will not share the information more widely. However, this will usually only relate to the information a regulator receives, not the information it generates itself – unless that information refers in turn to information which has been received.

29. Such a definition is also consistent with the wording of the EU Directives which the Medical Devices Regulations incorporate into UK law. Article 15 of Directive 90/385, Article 20 of Directive 93/42 and Article 19 of Directive 98/79 all state:

> *"Member States shall ensure that all the parties involved in the application of this Directive are bound to observe confidentiality with regard to all information* ***obtained*** *in carrying out their tasks"* [emphasis added]

30. Dictionary.com defines the word "obtain" as

> *"to come into possession of; get, acquire, or procure, as through an effort or by a request."*[1]

31. Given the similarities between the content of the two letters, the Commissioner considers it likely that the MHRA has some form of template wording that it uses to construct such letters. This further supports the position that this is information the MHRA has created itself for its own purposes – rather than information which has "come to" the MHRA.

[1] https://www.dictionary.com/browse/obtained

32. The Commissioner therefore considers that, taken as a whole, these letters have not "come to" the MHRA, they are letters created by the MHRA, which would therefore not be classed as "specified information."

33. However, the Commissioner recognises that the FOIA applies to information, not to documents themselves. A document created by the MHRA may still contain specified information if it reflects or discusses information that has "come to" the MHRA. She has therefore looked closely at each letter to determine whether any parts of the letter reflect or discuss information that has come to the MHRA.

34. The names of the recipients of the letter and the date of the application will be information that has come to the MHRA, as will the section of each letter which quotes from the original application. This will therefore be specified information. In the case of both letters, one paragraph in each appears to be discussing or commenting on information previously provided to the MHRA so this would also be specified information.

35. This specified information has clearly come to (or reflects information which has come to) the MHRA in connection with its functions. The MHRA has confirmed that the undertakings in question continued in existence at the time the request was responded to. Therefore the statutory bar is engaged in respect of this information.

36. However, the remainder of the letter does not reflect information that has "come to" the MHRA. As such, the Commissioner does not consider that such information is "specified information" and thus does not engage the statutory bar from disclosure set out in section 237 of the Enterprise Act 2002. As the statutory bar does not apply, it follows that section 44 of the FOIA is not engaged and, as the MHRA has not indicated that any other exemption would apply, it must disclose this information.

Is there a lawful gateway to disclosure?

37. In relation to the information which the Commissioner does consider to be specified information, she has gone on to consider whether a lawful gateway exists that would permit the information to be disclosed.

38. Section 239 of the Enterprise Act allows for the disclosure of specified information if it is done with the consent of the party(s) who is the subject of that information. The MHRA confirmed that it did not have the required consent and the Commissioner notes that the MHRA is not obliged to seek it.

39. Sections 241, 241A, 242 and 243 refer to specific scenarios in which specified information can be shared. These relate to disclosures for the purpose of the carrying out of other statutory functions or for judicial

proceedings. None of these permit the unrestricted disclosure that FOIA requires.

40. The Commissioner is therefore satisfied that no lawful gateway exists that would allow for the disclosure of the specified information she has identified. This information is therefore prohibited from disclosure by the Enterprise Act and, as such, engages section 44 of the FOIA.

41. As section 44 is an absolute exemption, the Commissioner is not required to consider the balance of the public interest.

Right of appeal

42. 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

43. 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.

44. 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 .....

Roger Cawthorne
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