Freedom of Information Act 2000 (FOIA)

Decision notice

Date: 26 April 2022

Public Authority: Medicines & Healthcare Products Regulatory Agency (Executive Agency of the Department for Health and Social Care)

Address: 10 South Colonnade
Canary Wharf London
E14 4PU

Decision (including any steps ordered)

1. The complainant has requested information relating to Non-Disclosure Agreements (NDAs) entered into by the Medicines & Healthcare Products Regulatory Agency (MHRA).

2. The Commissioner's decision is that MHRA correctly cited section 12(2) in response to the request.

3. However, the Commissioner considers that MHRA breached section 16 FOIA (advice and assistance) as it did not offer to consider a refined request. As MHRA has now contacted the complainant to advise of this, no further steps are required as a result of this decision notice

Request and response

4. On 18 May 2021 the complainant requested information in the following terms:

   "I am requesting the following data items:

   1. Full unredacted T&Cs of the MHRA
   2. # of NDAs signed by the MHRA with private companies and individuals as part of all MHRA services over the last 2 years
   3. All specific T&C and legal clauses relating to confidentiality of company and private information (i.e. protection of confidential information such as trade secrets/intellectual property shared by companies or individuals) as part of the MHRA's T&C
   4. Full, unredacted T&Cs of the MHRA Borderline Advice Form
   5. # of NDAs signed by the MHRA with private companies and individuals as part of the MHRA Borderline Advice Form service over the last 2 years
   6. All specific T&C and legal clauses relating to confidentiality of company and private information (i.e. protection of confidential information such as trade secrets/intellectual property shared by companies or individuals) as part of the MHRA Borderline Advice Form
   7. The specific clauses in the MHRA's T&Cs stating NDAs cannot be signed for the MHRA Borderline Advice Form
   8. The specific clauses guaranteeing confidentiality of company specific information (i.e. company trade secrets, company confidential information, intellectual property) under the MHRA Medicines and Healthcare products Regulatory Agency Privacy Notice."

5. MHRA responded on 15 June 2021 and stated it did not hold some of the information requested. It further stated that some information was already in the public domain and provided a number of links, citing section 21 FOIA.

6. Following an internal review MHRA wrote to the complainant on 15 July 2021. It maintained its reliance on section 21, stating T&Cs published online are the full and unredacted versions. It further explained it does not have specific T&Cs that cover the use of NDAs. MHRA explained that other T&Cs are published which were not considered relevant to the

request however, it also provided links to these as part of its review. It also acknowledged it had not answered part 5 of the request.

"# of NDAs signed by the MHRA with private companies and individuals as part of all MHRA services over the last 2 years"

7. It explained it does not maintain a central register of all NDAs so this information is not readily available.

8. MHRA provided further explanations with regard to part 6 and stated it does not maintain its own T&Cs and/or legal clauses to cover this point specifically. MHRA referred to this part of its response for the remainder of the request.

Scope of the case

9. The complainant contacted the Commissioner on 29 August 2021 to complain about the way their request for information had been handled. In their complaint to the Commissioner the complainant stated that MHRA should:

"Provide the outstanding data element, namely "# of NDAs (Non-disclosure agreements) signed by the MHRA with private companies and individuals as part of all MHRA services over the last 2 years" and a clarification as to why the elements provided after internal review were not provided in the first instance."

10. The Commissioner wrote to the complainant on 21 February 2022 providing a preliminary view that MHRA had not provided a response to part 5 of the request in accordance with the requirements of the FOIA. It simply stated it does not *"maintain a central register of all NDAs".*

11. He also advised that MHRA may potentially consider section 12 (costs) applies. This was based on the fact that MHRA stated it does not record all NDAs in a central register. Consequently, it may need to carry out searches in a variety of areas which could exceed the cost limit.

12. In its submission to the Commissioner MHRA explained it had reconsidered its handling of this request and the internal review. It acknowledged that it had not been clear with regard to which exemption it considered was applicable.

13. The Commissioner considers the scope of this investigation to be to determine if MHRA was entitled to rely on section 12 FOIA to refuse the request.

Reasons for decision

Section 12 - cost of compliance exceeds appropriate limit.

14. Section 1(1) does not oblige a public authority to comply with a request for information if the authority estimates that the cost of complying with the request would exceed the appropriate limit.

    (2) Subsection (1) does not exempt the public authority from its obligation to comply with paragraph (a) of section 1(1) unless the estimated cost of complying with that paragraph alone would exceed the appropriate limit.

15. Section 12(2) provides that a public authority is not obliged to confirm or deny whether requested information is held if it estimates that to do so would incur costs in excess of the appropriate limit. In other words, if the cost of establishing whether information of the description specified in the request is held would be excessive, the public authority is not required to do so.

16. When considering whether section 12(1) applies, the authority can only take into account certain costs, as set out in The Freedom of Information and Data Protection (Appropriate Limit and Fees) Regulations 2004 ('the Regulations'). These are:

    (a) determining whether it holds the information,
    (b) locating the information, or a document which may contain the information,
    (c) retrieving the information, or a document which may contain the information, and
    (d) extracting the information from a document containing it.

17. The Regulations state that the appropriate cost limit is £600 for central government, legislative bodies and the armed forces, and £450 for all other public authorities. The cost limit in this case is £600, which is equivalent to 20 hours' work.

18. The fees regulations cited above also apply to section 12(2). Section 12(2) requires a public authority to estimate the cost of confirmation or denial, rather than to formulate an exact calculation. The question for the Commissioner here is whether the estimate provided by MHRA was reasonable. If it was, then section 12(2) was engaged and MHRA was not obliged to confirm or deny whether the requested information was held.

19. MHRA also clarified that, at the time of the original reply and the internal review it could not confirm whether the MHRA had signed any NDAs, as it does not hold a central record of these.

20. The time and cost it would have taken to firstly establish if MHRA had signed any such agreements and, if it had, to then identify what these were, was estimated in two different ways as follows:

21. Firstly, at the time of the request the MHRA was structured in several divisions, each of which contained groups within them, as follows:
IE&S Division; 4 Groups
Licensing Division; 4 groups
Devices Division; 5 groups
VRMM Division; 4 groups
CPRD Division; 4 groups
NIBSC Division; 6 groups
Corporate Division; 7 groups
Total; 34 groups

22. Each group also contains sub-teams, so to cascade a call for NDAs across the agency (to cover "all services" as requested), for teams to search records and respond, it estimated between 30 to 60 minutes per group, depending on its' size. Taking an average of 45 minutes per group; 34 x 45 = 1530 minutes or 25.5 hours (£638 at £25 per hour).

23. Secondly, at the time of the request there were approx. 1300 staff, and MHRA estimated that perhaps 500 of them were in a role/at a grade where they might sign an NDA.

24. MHRA explained it also operates generic mailboxes and for completeness it should include these (500 personal mailboxes and 50 generic mailboxes). To run a couple of keyword searches in outlook advanced search it estimated at 3-5 minutes per mailbox.

25. This gives a total search time of 550 x 3 = 1,650 minutes or 27.5 hours (£687 at £25 per hour).

26. The two estimates obtained by the two different approaches were close to each other (25.5 and 27.5 hours), which MHRA consider supports the "reasonableness" of the estimate. Taking the lower value, the cost incurred would exceed the cost threshold of £600.

27. MHRA confirmed it considered the quickest method (electronic searches rather than manual files). It further confirmed that a sampling exercise has not been undertaken in this case.

28. On this basis MHRA was relying on Section 12(2) – it can neither confirm or deny whether it holds this information without exceeding the cost of compliance threshold.

29. MHRA acknowledged that it did not give the complainant the opportunity to refine their request, and advised it would contact them to provide an opportunity to do so.

30. MHRA noted that the initial enquiry to MHRA was about its borderline advice service. In this respect, it did answer the other question about the number of NDAs signed by MHRA specifically in relation to this service as part of its response to, and internal review of the FOI request.

31. Having considered the estimate above, the Commissioner considers it to be a reasonable one and therefore concludes that section 12(2) is engaged and MHRA was not obliged to confirm or deny holding any of the information.

Other matters

Section 16 – advice and assistance

32. Section 16(1) of FOIA provides that a public authority is required to provide advice and assistance to any individual making an information request. In general, where section 12 is cited, in order to comply with this duty a public authority should advise the requester as to how their request could be refined to bring it within the cost limit, albeit that the Commissioner does recognise that where a request is far in excess of the limit, it may not be practical to provide any useful advice.

33. In this case the Commissioner notes that the estimate is not too far in excess of the cost limit. He is also aware that, as referred to in paragraph 29 above, MHRA wrote to the complainant on 24 April 2022.

Right of appeal

34. 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: 0300 1234504
    Fax: 0870 739 5836
    Email: grc@justice.gov.uk
    Website: www.justice.gov.uk/tribunals/general-regulatory-chamber

35. 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.

36. 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

Susan Duffy
Senior Case Officer
Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
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SK9 5AF