Freedom of Information Act 2000 (FOIA)

Decision notice

Date:	**10 August 2023**
Public Authority:	**Medicines and Healthcare products Regulatory Agency**
Address:	**10 South Colonnade** **Canary Wharf** **London E14 4PU**

Decision (including any steps ordered)

1. The Commissioner's decision is that the name that the complainant has requested is exempt from disclosure under section 38(1)(a) and section 40(2) of FOIA. This is because disclosure would be likely to endanger another's mental and physical health and the information is personal data which it would be unlawful to disclose.

2. It isn't necessary for Medicines and Healthcare products Regulatory Agency to take any corrective steps.

Request and response

3. Ethigen Ltd is a pharmaceutical distributor. The complainant made the following information request to Medicines and Healthcare products Regulatory Agency (MHRA) on 10 March 2023:

> "Could you please inform me who the named responsible person for Ethigen Ltd is? Their registration numbers are stated below…
>
> … WDA(H) 18716/M-00259273505
>
> WDA(H) 18716"

4. MHRA's final position was that the information is exempt from disclosure under section 38(1) and 40(2) of FOIA.

5. The Commissioner has discussed with MHRA the circumstances associated with the request. Having considered the matter further, MHRA said that there may be an argument for the request being vexatious under section 14(1). However, MHRA says it's reluctant to apply section 14(1) in cases where the applicant is raising a safety concern.

Reasons for decision

6. As a result of the Commissioner's discussion with MHRA, this reasoning focusses on MHRA's reliance on section 38(1) and section 40(2) of FOIA to withhold the information the complainant has requested. He will discuss vexatious requests under 'Other Matters'.

Section 38 – health and safety

7. Under section 38(1) of FOIA information is exempt information if its disclosure would or would be likely to endanger another person's a) physical or mental health or b) their safety.

8. The Commissioner won't reproduce the complainant's correspondence here but, having received MHRA's refusal notice, in their request for an internal review the complainant raised safety concerns associated with Ethigen, but didn't provide evidence to support those concerns.

9. In its internal review response, MHRA confirmed its reliance on section 38 (and section 40). MHRA said it could recognise from the tone of the complainant's language that this was clearly an issue about which they felt very strongly. As they perceive a risk to patients, MHRA said, it considered that was entirely understandable. However, MHRA advised the complainant that there are other ways in which they could raise concerns about public safety ie through MHRA's 'Yellow Card' website.

10. As noted, the Commissioner has discussed with MHRA the circumstances associated with the request. MHRA has also provided more detail about its reliance on section 38 and section 40 in its submission to the Commissioner, which he doesn't intend to reproduce in this notice.

11. Regarding section 38, MHRA considers this exemption is engaged because disclosing the requested information would, if combined with other information, increase the risk of harm to an individual.

12. It has directed the Commissioner to his decision in FS50633090[1]. This concerned different information, but MHRA considers that the principle is the same. MHRA says that in that case, the Commissioner's investigation focused on whether disclosing the requested information "would be likely to increase the risk" of an attack. It notes that the Commissioner accepted in that case that there was a link between disclosing the information and the increased likelihood of attack.

13. In the present case, MHRA says that in email correspondence to it on 15 March 2023 [before they had received a formal response to their request under FOIA], the complainant said that it was in the public interest to disclose the information "to know who the actual human-being responsible for doing this so that their character can be checked up on".

14. MHRA accepts that an applicant's motive isn't usually relevant to FOIA considerations unless section 14(1) is being considered. But in this case, the complainant themselves has advised MHRA that that they intend to make further inquiries about the person's "character" once the information is disclosed.

15. There's also a wider point around section 38, MHRA says. The Responsible Person (RP) plays a critical role in making sure the medicines supply chain is safe. Given the importance of having a safe and secure medicines supply chain, MHRA says it would want any concerns anyone has with a wholesaler to be shared with MHRA.

16. MHRA says that if there's a safety concern, and MHRA simply provided the name of the RP in response to a person's request, it would not then be able to log and assess the issue that's led to that person seeking to identify the RP ie because the concern hadn't been submitted through an appropriate channel such as the Yellow Card website. That could lead to serious problems further down the line. For that reason, MHRA questions whether directing someone who approaches it with a safety concern to the RP is the right thing to do from a broader regulatory perspective– and ultimately a patient safety standpoint.

17. For example, where someone believes the wholesaler is supplying substandard products (or similar) but is not a customer of the wholesaler, MHRA says it would not want them simply to go to the RP directly. That could expose the RP to risk and would be likely to deprive MHRA of any information as to what the concern is with the wholesaler. In addition, to reiterate on the point of disclosure, MHRA says that this

[1] https://ico.org.uk/media/action-weve-taken/decision-notices/2017/2013536/fs50633090.pdf

would enable the applicant to take action by approaching the RP. MHRA notes again its concerns about whether this action would take some form of harassment or physical approach. However, MHRA re-states that it's also important to remain conscious of the bigger patient safety issue which could be missed if the applicant elected to take up the matter directly with the RP rather than reporting this to the MHRA.

The Commissioner's view

18. The complainant has stated in their complaint to the Commissioner that they want the Commissioner to order MHRA to tell them who Ethigen's RP is.

19. First, regarding the Commissioner's decision in FS50633090, that case concerned a different public authority, different information and a different exemption – section 24 of FOIA, which concerns national security.

20. That said, the Commissioner accepts that in the circumstances discussed in MHRA's wider submission, disclosing the information in this case would be likely to increase the risk of an individual being subject to, or being fearful of, an unwanted approach, which would be likely to damage that person's mental and physical health.

21. The Commissioner has considered his discussions with MHRA, MHRA's wider submission (which includes its section 40 reasoning) and the tone and language of the complainant's correspondence to MHRA.

22. He notes that the complainant has made unsubstantiated accusations about the RP and has indicated they intend to make further checks about that individual. In the absence of any detail about the nature of those checks – ie whether the complainant intends to simply carry out an internet search about them – there is a risk, albeit perhaps slight, that the complainant or another person may seek to approach the individual directly – either physically or in writing.

23. MHRA has advised the complainant about the route to take if they have a concern about a provider of medicines and healthcare products. Concerns should be submitted through its Yellow Card website and shouldn't be directed to an individual working for that provider. As a result, the Commissioner is satisfied that MHRA is entitled to withhold the requested information under section 38(1)(a) of FOIA. He considers that disclosing the information would be likely to endanger another individual's mental health. Even if a physical approach is unlikely, fear of such an approach can still damage an individual's mental health and poor mental health can also affect a person's physical health.

Public interest test

24. The Commissioner has found that disclosing the requested information would be likely to damage another individual's mental health and, through damage to their mental health, could also damage their physical health. The public interest in disclosing the information would need to be very significant indeed to justify this consequence. The complainant hasn't put forward any such arguments for disclosure.

25. There is, of course a public interest in making sure people's concerns about healthcare companies and products are properly considered by the appropriate bodies. However, there is an appropriate formal route for raising such concerns, to which MHRA directed the complainant.

26. The Commissioner is satisfied that the public interest favours maintaining the section 38(1)(a) exemption in this case.

27. He has found that section 38)1)(a) is engaged and the public interest favours maintaining this exemption. For completeness, however, the Commissioner will also consider MHRA's application of section 40(2) to the same information.

Section 40 – personal data

28. Under section 40(2) of FOIA information is exempt information if it's the personal data of another individual and disclosing it would contravene one of the data protection principles.

29. The Commissioner is satisfied first, that the information in question – a name - is personal data – it relates to a living individual and they can be identified from it. That individual is the 'data subject'.

30. The Commissioner has gone on to consider whether disclosing the information would contravene the data protection principle under Article 5(1)(a) of the UK General Data Protection Regulation (UK GDPR). This says that personal data must be processed lawfully.

31. When considering whether disclosure would be lawful, the Commissioner considers the complainant's legitimate interests and whether disclosure is necessary to meet those legitimate interests. If appropriate he will finally go on to balance the complainant's legitimate interests against the data subject's rights and freedoms.

32. The Commissioner appreciates that the complainant has a concern about, and so an interest in, a particular company and somebody occupied in a role in that company. That's a legitimate interest for them to have. However, MHRA has advised the complainant that the appropriate way to submit such concerns is through its Yellow Card website. The Commissioner doesn't consider that disclosing the

requested information would address the interest that the complainant has.

33. As the Commissioner has decided in this case that disclosure isn't necessary to meet the legitimate interest in disclosure, he hasn't gone on to conduct the balancing test. As disclosure isn't necessary, there's no lawful basis for this processing and it's unlawful. Disclosure would therefore contravene a data protection principle; that set out under Article 5(1)(a) of the UK GDPR.

34. As such, the Commissioner's decision is that MHRA is entitled to withhold the requested information under section 40(2) of FOIA.

Other matters

35. Under section 14(1) of FOIA, a public authority isn't obliged to comply with a request if the request is vexatious.

36. Amongst other factors, a request may be vexatious because of the motive behind it, if it causes harassment to staff, or if the request has little value or serious purpose.

37. MHRA was reluctant to apply section 14(1) on this occasion and so the Commissioner hasn't formally considered whether the request can be categorised as vexatious. The Commissioner doesn't intend to reproduce in this notice some of the complainant's wider correspondence to MHRA, but he considers it to be abusive and aggressive. The complainant also raises unsubstantiated concerns about both Ethigen and MHRA.

38. The Commissioner believes that were the complainant (or anyone else) to submit a request and associated correspondence to MHRA in the future that was expressed in terms similar to those used in this case there would be persuasive case for that request being vexatious. It's not that raising a concern is vexatious in and of itself, but the language in which that concern and associated request is expressed may result in the request being vexatious.

39. With that in mind, the Commissioner advises the complainant in this case that if they intend to submit further requests to MHRA, they first review the Commissioner's published guidance on how to write an effective request for information[2].

[2] https://ico.org.uk/for-the-public/official-information/how-to-write-an-effective-request-for-information/

Right of appeal

40. 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

41. 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.

42. 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

Cressida Woodall
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