Freedom of Information Act 2000 (FOIA)

Decision notice

Date: 14 October 2022

Public Authority: Medicines and Healthcare products Regulatory Agency

Address: 10 South Colonnade
Canary Wharf
London E14 4 PU

Decision (including any steps ordered)

1. The complainant has requested information about the COVD-19 vaccines. The Medicines and Healthcare products Regulatory Agency (MHRA) directed the complainant to relevant information published on its website and also provided other more general information. MHRA's position is that it does not hold any further relevant information.

2. The Commissioner's decision is as follows:

    - On the balance of probabilities, MHRA does not hold any further information within scope of the complainant's request and has complied with section 1(1) of FOIA.

3. The Commissioner does not require MHRA to take any corrective steps.

Request and response

4. On 16 August 2021 the complainant wrote to MHRA and requested information in the following terms:

> "I would like to find out what health and safety risk assessments exist to ensure safe roll out of the vaccine. - If there is one, where should I submit an FOI request?

I am specifically wanting to find if there is a set number of fatalities or injuries to occur as shown on the yellow card government system before any reassessment of the rollout is taken? …"

5. On 14 September 2021 MHRA responded. It directed the complainant to where relevant information about civil liability and conflicts of interest is published on its website. MHRA also advised the complainant to contact the Department of Health and Social Care if they had any further questions about liabilities. MHRA provide general information about its Yellow Card scheme and vaccination.

6. The complainant requested an internal review on 14 September 2021. They confirmed that their request was as follows:

"How many lives should be lost before there is a health and safety review of the national rollout ?

Also I have not been shown or supplied with any health and safety risk assessments regarding the rollout as originally requested, do they exist? yes or no, can they be forwarded?

I doubt and question the algorithm used to produce imagined numbers of lives saved thrown up by the media .

I prefer to take note of the real lives lost."

7. MHRA provided an internal review on 12 November 2021. It provided the complainant with links to its Yellow Card website and its monitoring strategy. Regarding risks, MHRA directed the complainant to its published Public Assessment Reports. MHRA advised that it does not hold health and safety assessments that apply to physical spaces where vaccines are administered (such as vaccine centres and GP practices).

Scope of the case

8. The complainant contacted the Commissioner on 5 January 2022 to complain about the way their request for information had been handled.

9. MHRA reconsidered the request as a result of the complaint and provided a further response to the complainant on 11 October 2022. This will be included in the discussion below.

10. The Commissioner's investigation has focussed on whether MHRA holds any further recorded information within scope of the complainant's request.

Reasons for decision

11. Under section 1(1) of FOIA anyone who requests recorded information from a public authority is entitled under subsection (a) to be told if the authority holds the information and, under subsection (b), to have the information communicated to them if it is held and is not subject to an exemption.

12. In this case, the recorded information the complainant has requested is COVID-19 vaccination health and safety risk assessments. In correspondence to the Commissioner, the complainant said first, that MHRA had informed them that there is a monitoring strategy but had not provided any detail, such as how this monitoring strategy works using the Yellow Card system. Second, they expected the assessments they have requested would show the level of fatality or injury from the vaccinations at which point the roll out of the vaccination programme would be reconsidered. The complainant considered that 'flags' or 'markers' associated with the Yellow Card system must exist in order to halt further vaccinations using the "4 experimental brands".

13. MHRA had directed the complainant to relevant information on its website including its monitoring strategy and Public Assessment Reports.

14. In its further response to the complainant of 11 October 2022, with regard to their second point MHRA explained that there is currently no defined threshold or number of Adverse Drug Reaction (ADR) reports at which a medicine or a vaccine would be removed from use or in this case before a reassessment of the national COVID-19 vaccine campaign was taken. This is because many factors must be taken into account as indicated below.

15. Yellow Card reports of suspected ADRs are evaluated, together with additional sources of evidence, by a team of safety experts to identify any new safety issues or side effects. MHRA applies statistical techniques that can tell it if it is seeing more events than it would expect to see, based on what is known about background rates of illness in the absence of vaccination. This aims to account for factors such as coincidental illness. MHRA also looks at the clinical characteristics to see if new patterns of illness are emerging that could indicate a new safety concern.

16. MHRA said it supplements this form of safety monitoring with other epidemiology studies including analysis of data on national vaccine usage, anonymised GP-based electronic healthcare records and other healthcare data to proactively monitor safety. This combined safety data

enables the MHRA to detect side effects or safety issues associated with COVID-19 vaccines.

17. In its submission to the Commissioner, MHRA also addressed the complainants first point, about its monitoring strategy. It confirmed that it has provided the complainant with that document (the monitoring strategy) that sets out MHRAs vigilance activities. This includes how the Yellow Card scheme is used to detect safety signals. There are four strands to the MHRA's strategy, which combine to address the relative strengths and weaknesses of each form of vigilance:

    - **Enhanced passive surveillance** - observed vs expected analysis. This involves the collection and scientific and clinical assessment of Yellow Card reports in the context of near-real-time information on the number of doses administered at the relevant time point, stratified by age and gender, and the background rate of the event of interest in the absence of vaccination.

    - **Rapid Cycle Analysis and Ecological analysis**. This involves analysing anonymised electronic healthcare records that are routinely collected in clinical practice using pre-defined events within given population cohorts to rapidly identify safety signals.

    - **Target active monitoring** - Yellow Card Vaccine Monitor. This involves targeted active monitoring of certain groups of vaccinees through the Yellow Card scheme, focused particularly on those who may have been excluded or under-represented in clinical trials.

    - **Formal epidemiological studies**. These are undertaken on an ad-hoc basis to specifically test a given hypothesis and is usually necessary to confirm and quantify a suspected rare side effect.

18. MHRA concludes its submission by confirming that it does not hold any other recorded information within scope of the complainant's request.

The Commissioner's conclusion

19. As noted above, FOIA concerns recorded information that a public authority holds. Although a public authority has a duty under section 16 of FOIA to provide advice and assistance in certain circumstances, FOIA does not place an obligation on a public authority to explain any information it discloses. The Commissioner considers that MHRA's response and internal review were satisfactory in terms of the level of detail and explanation it provided. MHRA has now provided further detail through its submission to the Commissioner.

20. The Commissioner also considers that MHRA has provided a satisfactory explanation as to why it does not hold the specific information the complainant has requested. His decision is therefore that, on the balance of probabilities, MHRA does not hold the requested information and its response complied with section 1(1) of FOIA.

Right of appeal

21. 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

22. 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.

23. 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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