Medicines & Healthcare products
Regulatory Agency

10 South Colonnade
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London
E14 4PU
United Kingdom
gov.uk/mhra

[redacted]

28 February 2024

FOI **24/102**

Dear [redacted]

Thank you for your information request, dated **31 January 2024** where you asked for:

Your request

1. *Who monitors and audits vaccine manufacturers and their products from the UK?*
2. *Do you have any reports from these audits?*
3. *If so can they be supplied for the last five years?*
4. *Can the MHRA request from vaccine manufacturers what animal or human ingredients used in vaccines, including gelatin and any hydrogels, if they are tested for glyphosate contamination? If so can you supply data?*

Our response

With regards to Q1, I can confirm that all sites involved in the manufacture and control of medicinal products are inspected by either MHRA or other regulatory authorities to ensure that they comply with Good Manufacturing Practice (GMP).

With regards to Q2-Q4, I can confirm that the MHRA holds the information that you have requested. However, after detailed consideration of this request, I consider that it is exempted under S14 FOIA; this applies when a single request creates a significant burden on the public authority. On this occasion, a detailed assessment of your request has determined that the scope and breadth of the information you have requested is so great that compliance with this request would create a 'disproportionate burden'.

In cases such as this, a public authority may apply section 14(1) to the request, as the request falls to be termed 'vexatious' under FOIA. We stress that this is solely on the basis of the burden that would be created by compliance, due to the voluminous amount of information that would need to be retrieved and then reviewed in detail in order to comply with your request.

The Information Commissioner's guidance explains that:

> *You cannot claim section 12 for the cost and effort associated with considering exemptions or redacting exempt information.*
>
> *Nonetheless, you may apply section 14(1) where you can make a case that the amount of time required to review and prepare the information for disclosure would impose a grossly oppressive burden on your organisation.*[1]

And:

> *15. The Commissioner's guidance on section 14 states that there is a high threshold for refusing a request on such grounds. It says that a public authority is most likely to have a viable case where:*
>
> *• the requester has asked for a substantial volume of information; and*
>
> *• the authority has real concerns about potentially exempt information, which it will be able to substantiate if asked to do so by the Commissioner; and*
>
> *• any potentially exempt information cannot easily be isolated because it is scattered throughout the requested material.*[2]

The guidance above[3] is particularly relevant to your request and we will explain how this applies below. In the final section, we will also provide some further advice and assistance as to how you could proceed with a significantly narrowed request for information.

We would first need to review all marketing authorisations for the last 5 years to identify which ones were for vaccine products; we would then need to retrieve the inspection reports we hold for each manufacturer associated with each marketing authorisation. Each inspection report would then need to be thoroughly read and

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[1] https://ico.org.uk/for-organisations/foi-eir-and-access-to-information/freedom-of-information-and-environmental-information-regulations/dealing-with-vexatious-requests-section-14/how-do-we-deal-with-a-single-burdensome-request/

[2] https://ico.org.uk/media/action-weve-taken/decision-notices/2023/4025038/ic-197426-f8v9.pdf

[3] https://ico.org.uk/for-organisations/foi-eir-and-access-to-information/freedom-of-information-and-environmental-information-regulations/dealing-with-vexatious-requests-section-14/how-do-we-deal-with-a-single-burdensome-request/

reviewed to identify all personal information (in the form of named individuals) and any commercially confidential information in each report**.** The HMA/EMA guidance on transparency states that the names/addresses of manufacturers/sites in the supply chain for specific medicinal products are exempt from release under S41/S43 of the FOIA (see pages 33 and 34 of the below-linked guidance).

https://www.hma.eu/fileadmin/dateien/HMA_joint/02-_HMA_Strategy_Annual_Reports/07-Transparency/2012_03_HMA_EMA_Guidance_20120309_ComPersInfo.pdf

We would need to identify all such information throughout the documents. Each inspection report would then need to be sent to relevant third parties for their review to ensure that there are no additional concerns that would need to be considered before release. We regularly disclose redacted inspection reports when requested in small numbers, and we are aware that this process takes over 24 working hours for an average 15-20 reports. From initial review of our records, we have identified that in 2023 alone there were 26 authorised vaccines; therefore, reviewing the relevant reports for one year alone creates a significant burden. Your own request asks for the reports for five years.

The ICO identifies that the key consideration in the case of a single burdensome request is whether the value and purpose of the request justifies the distress, disruption or irritation that would be incurred by complying with it. In the First Tier Tribunal, *Independent Police Complaints Commissioner vs The Information Commissioner* (EA/2011/0222, 29 March 2012)[4] the Tribunal found that:

> *"A request may be so grossly oppressive in terms of the resources and time demanded by compliance as to be vexatious, regardless of the intentions or bona fides of the requester." (paragraph 15).*

Similarly, in *Cabinet Office vs Information Commissioner and Ashton* [2018] UKUT 208 (AAC)[5] the Upper Tribunal agreed that even when there may be a public interest in the information, the burden of compliance may still be so great that the request would fall to be considered vexatious:

> *"In some cases, the burden of complying with the request will be sufficient, in itself, to justify characterising that request as vexatious, and such a conclusion is not precluded if there is a clear public interest in the information requested. Rather, the public interest in the subject matter of a request is a consideration that itself needs to be balanced against the resource implications of the request,*

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4 https://informationrights.decisions.tribunals.gov.uk/DBFiles/Decision/i725/20120329%20Decision%20EA20110222.pdf

5 https://assets.publishing.service.gov.uk/media/5b57139a40f0b6339963e8cf/GIA_2782_2017-00.pdf

and any other relevant factors, in a holistic determination of whether a request is vexatious."

In this case, we recognise that there is a public interest in the disclosure of inspection reports, and as noted above, we regularly disclose these in redacted form in response to requests. However, the issue with your request is that it asks for all reports for all vaccine manufacturers for a five-year period; and for this reason, due to the large number requested, we consider that the burden of compliance in this case is therefore disproportionate.

Advice and Assistance

In terms of reducing the scope of your request, the most reasonable advice would be to focus your request on asking for more specific information that you would want to obtain. This could be asking for information on a specific marketing authorisation/medicinal product. Please note that depending on its scope, even a narrowed request may exceed the appropriate limit in the FOIA and, as noted above, will require the consideration of other exemptions.

If you have a query about the information provided, please reply to this email.

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: info@mhra.gov.uk

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely,

MHRA Customer Service Team