Medicines & Healthcare products Regulatory Agency

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[redacted]
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25 April 2024

MHRA reference: FOI2024/00013

Dear [redacted]

Thank you for your information request, which we received on 26 March. You asked the following:

> *Dear Medicines and Healthcare Products Regulatory Agency, Please provide GMP inspection report of parenterals product manufacturing sites conducted after 23 august 2023 in the UK*

We have dealt with your request under the Freedom of Information Act 2000 (FOIA).

We confirm that we hold the information you have asked for; however, we consider that the information is exempt from disclosure because Section 12 of the FOIA applies.

Section 12 allows public authorities to refuse requests where the cost of dealing with them would exceed the "appropriate limit" in the FOIA; for central government departments this is set at £600. This represents the estimated cost of one person spending 24 working hours to determine if the requested information is held, and then to locate, retrieve and extract it.

We will explain how compliance with your request would exceed the appropriate limit and why section 12 applies in this case.

We have conducted a search of our records and have identified that 181 GMP inspections have been conducted since 23 August 2023. As 'parenterals' isn't a

separate classification on a licence, we cannot easily identify from our records which of the sites that have been inspected manufactures parenteral products. In order to identify the correct inspection reports, we would have to open each inspection case folder to confirm if an inspection report is available and to confirm if the case has been closed. For those where inspection reports are available, we would have to conduct a search of a separate database system to identify the licence numbers of products manufactured by each particular inspected site. We would then need to look up each product licence number to see what type of product it is. Some sites will have multiple product numbers that need to be checked.

We therefore estimate that the time needed would be approximately 30 minutes per inspected site, giving a total time of 5430 minutes or 90.5 hours.

When section 12 of the FOIA applies, we also provide advice to assist you in making a new, narrowed request for a smaller amount of information.

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 inspection reports for specific sites that have been inspected. We would suggest asking for no more than 20 reports.

A list of inspected sites can be found on our website: GMP | MHRA

Please note that 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).
Microsoft Word - HMA_EMA_Guidance_Document_20120309_adopted_clean.doc

Please also note that depending on its scope, even a narrowed request may exceed the appropriate limit in the FOIA and will require the consideration of other exemptions.

This concludes our response to your request.

If you have a query about this response, please contact us at FOILicensing@mhra.gov.uk.

Please remember to quote the reference number at the top of this letter in any future communications. Details of your appeal rights are below.

Yours sincerely,

Healthcare, Quality and Access Group
Medicines and Healthcare products Regulatory Agency

Medicines & Healthcare products
Regulatory Agency

Appeal rights

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

If you remain dissatisfied with the outcome of the internal review, you 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 a request unless the requester has first asked us to conduct an internal review.

The Information Commissioner can be contacted through their online webform at: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

Or in writing to: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF

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