Medicines & Healthcare products
Regulatory Agency

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

[redacted]
By email: [redacted]

23 March 2024

FOI **24/194**

Dear [redacted]

Thank you for your information request, dated **26 February 2024** where you asked for

Your request
"the 5 organisations that have submitted the highest volume of submissions about their products to the MHRA through the MHRA Submission Portal and European Common Entry Gate (EU-CEG) notification portal for UK wide supply in the calendar year 2023?"

Our response

We would like to explain that in its current form, it would take us over the 24 hours allowed in section 12 of the FOIA to locate, retrieve and extract the information you have asked for, which includes all submissions received by MHRA (initials and variations).

Section 12 allows a public authority to refuse a request if the time needed to determine whether the requested information is held, and then locate retrieve and extract the information, would exceed 24 working hours. We will explain why this is and provide some advice about how you could narrow a new request for a smaller amount of information.

In order to provide the information requested in this case, we would first need to look at each submission that has been made to MHRA in 2023 (both initial applications and subsequent variations) and group these by marketing authorisation holder.

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We would then need to calculate the total size of all the packages received in order to then determine which marketing authorisation holders submitted the highest volume in 2023. For example, 487 marketing authorisations were granted in 2023.

In order to sort through these applications by marketing authorisation holder, calculate the size of submission for each application, and then to total them all by marketing authorisation holder would take longer than the 24 hours allowed under S12 of the FOIA. Time would also need to be included for other marketing authorisation applications received (such as applications that are pending with the agency or that were withdrawn, cancelled or refused) and to include variations submitted to MHRA for existing granted marketing authorisations.

Advice and Assistance

In terms of reducing the scope of your request, the most reasonable advice would be to focus your question on a smaller set of marketing authorisations that you would like to receive information on (for example, the total submissions for a specific product). In this case, you could narrow this to one specific product only.

Please note that retrieval for this may still take us over the cost limit; if retrievable, we will proceed to consider whether the information may be disclosed or if exemptions may apply.

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

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Yours sincerely,

MHRA Customer Experience Centre
Communications and engagement team
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU