Medicines & Healthcare products
Regulatory Agency

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

[redacted]

24 May 2024

MHRA reference: FOI2024/00066

Dear [redacted],

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

We're reaching out to you to request for below information:

1. *List of products imported under MS license in the past year for named patient business*
2. *Also, if possible, please share volume imported or notification granted to import against each of the products*

We understand some of the information might not be available, hence request to please share the information readily available with you.

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.

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

Currently, we have 160,000 notifications that could be relevant to your request. Each of these would need to be manually compiled onto a list and checked to see if it was imported under a Wholesale Distributor Authorisation (WDA) or Manufacturing Specials Licence (MSL). We estimate that it will take 10 mins on average to compile 10 notifications. So, to complete all 160,000 notifications would take us over the 24 working hours that is set as the “appropriate limit” in the FOIA.

There is also a check required of each notification to ensure that there is no commercially sensitive information or information that would contravene the General Data Protection Regulation (GDPR), and so be exempt under other sections of the FOIA. To do this check for all 160,000 notifications would also trigger Section 14 of the FOIA, which concerns vexatious requests.

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 this case, we advise that you could narrow your request by picking a smaller data set of notifications, such as notifications for a specific medicinal product. However, as we have advised above, other sections of the FOIA may also apply to any new, narrowed request.

This concludes our response to your request.

If you have a query about this response, please contact us at foi.request@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

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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.

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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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