Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
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Canary Wharf
London
E14 4PU

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MHRA Website

Our Ref: **FOI2025/00471**

3 June 2025

Dear [redacted],

Thank you for your Freedom of Information (FOI) request received on 9 May 2025. You wrote:

> *Can you please share the list of medicines which are unlicensed here in UK. Also, please share database where we can check if a certain medicine in licensed or unlicensed.*

MHRA Response
We confirm that we hold some of the information you have asked for, in that we hold information on unlicensed medicines that UK-based importers have notified MHRA they intend to import. However, we consider that the information is exempt from disclosure because Section 12 of the FOIA applies. Please note that we do not hold information on whether these medicines have actually been imported or not or hold information on unlicensed medicines manufactured in the UK.

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.

Quarterly reports of unlicensed medicines imported into the UK were prepared by MHRA until 2018. A link to these can be found here:
https://www.gov.uk/government/statistics/quarterly-reports-on-the-import-of-unlicensed-medicines

The quarterly summary reports for the importation of unlicensed medicines linked above would take a single member of MHRA staff one week to compile. Therefore, we estimate that to do this work from start of 2019 to now (effectively 26 quarters), would take one staff member 26 weeks to compile.

It should also be noted that 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 notifications from start of 2019 to now 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 should narrow your request by asking if specific medicines are unlicensed. A list of marketing authorisations that have been granted by year is available online, please see the link below:
https://www.gov.uk/government/collections/marketing-authorisations-lists-of-granted-licences

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team
Medicines & Healthcare products Regulatory Agency

Your right to complain under the Freedom of Information Act

If you are not happy with this response you may request an internal review by e-mailing foi.request@mhra.gov.uk or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.
Website: ICO Contact Information or telephone 0303 123 1113.

Re-use of our information
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