



Medicines & Healthcare products
Regulatory Agency

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[MHRA Website](https://www.mhra.gov.uk)

Our Ref: **FOI2026/00987**

22 September 2026

Dea [REDACTED]

Thank you for your Freedom of Information (FOI) request received on 4 September 2026.
You wrote:

Under the Freedom of Information Act 2000, I would like to request aggregated product-level information from the MHRA Import Notification System relating to unlicensed human medicinal products notified for import into Great Britain.

Please provide data for the calendar years 2024 and 2025, together with 2026 year-to-date, containing the following fields where held:

- 1. Active ingredient or generic product name*
- 2. Brand name, where recorded*
- 3. Strength*
- 4. Pharmaceutical form*
- 5. Pack size*
- 6. Source country*
- 7. Number of import notifications for each product*
- 8. Total number of packs or units notified for import, where recorded*
- 9. Notification outcome, including accepted, no objection, objected to, withdrawn or any equivalent classification*
- 10. The clinical speciality or broad therapeutic category, where recorded*
- 11. Whether the product was imported from within the EEA or from outside the EEA*
- 12. Whether the import arose in connection with a recognised UK supply shortage, where recorded.*

Please provide the information in Excel or CSV format, with one row for each product, strength, pharmaceutical form, source country and reporting period combination.

I am not requesting:

- * patient-identifiable information;*
- * individual prescriber information;*
- * commercially confidential pricing information; or*
- * any information that would compromise patient confidentiality.*

If the identities of importers or suppliers are considered commercially sensitive, please

omit those identities and provide the remaining aggregated product-level information.

If pack or unit quantities cannot be disclosed, please provide the number of notifications for each product. If exact figures are considered sensitive, I would be grateful for volume bands, for example:

- * 1–10 notifications*
- * 11–50 notifications*
- * 51–100 notifications*
- * More than 100 notifications.*

Please also let me know if an existing report, dataset or previous FOI response contains substantially equivalent information.

MHRA Response

We can confirm we hold the information requested, but it is exempt from disclosure under Section 12(1) of the FOI Act.

This is because we estimate the cost of searching for and identifying the requested information would exceed the cost limit of £600 specified in the Freedom of Information and Data Protection (Appropriate Limit and Fees) Regulations 2004. This represents the estimated cost of at least one person spending 3½ working days (equivalent to 24 staff-hours) in determining whether the Agency holds the information, and locating, retrieving and extracting it.

Under Section 12(1) of the FOI Act, the Agency is not therefore obliged to comply with your request and we will not be processing it further. The reason being to provide the information you seek would require us to open every Notification of Intent (NOI) since 01 January 2024 and then manually compile any relevant to your request with the fields you have requested. Based on the number of NOIs submitted to MHRA since 01 January 2024, this would engage Section 12 of the FOI Act.

We suggest that you refine your request to include a smaller set of active substances and also a smaller number of fields.

Please note, MHRA periodically publishes its Import Notification System annual report, typically by the last quarter of the following year:

<https://www.gov.uk/government/statistics/quarterly-reports-on-the-import-of-unlicensed-medicines>

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 FOI and EIR complaints](#) or telephone 0303 123 1113.

Re-use of our information

The MHRA information supplied in response to your request is subject to Crown copyright. Information created by the MHRA which is disclosed under the Freedom of Information Act is made available for re-use under the Open Government Licence (OGL) v3.0, except where this is otherwise stated. There are some restrictions on re-use under the OGL and these can be viewed here:

<https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/>