



Medicines & Healthcare products Regulatory Agency

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

Our Ref: **FOI2026/00938**

18 September 2026

Dear [REDACTED]

Thank you for your Freedom of Information (FOI) request received on 21 August 2026. You wrote:

Under the Freedom of Information Act 2000 I request the following information held in connection with the register of persons registered to import, manufacture or distribute active substances under regulation 45N of the Human Medicines Regulations 2012 (the register published at cms.mhra.gov.uk/mhra/api-reg<<http://cms.mhra.gov.uk/mhra/api-reg>>).

- 1. A structured extract (CSV or Excel) of the current register, listing for each registration: registration number, registrant name, activity type (importation, manufacture, distribution), active substance name and code, and for importation entries the name and country of each third-country manufacturer and third-country distributor, as published on the public record pages.*
- 2. For importation entries, a summary table of the number of registered importers and the number of distinct declared third-country manufacturers per active substance, broken down by country of the third-country manufacturer.*
- 3. The number of active substance registrations (by activity type) on the register at 31 December in each year from 2019 to 2025.*
- 4. A list of the third countries for which the MHRA currently accepts "written confirmation" of GMP equivalence for imported active substances, and any country-level waivers in force.*

All of this information is already in the public domain record by record; I am asking for it in aggregated, machine-readable form. If the full extract would exceed the cost limit, please provide items 2 to 4 first and tell me how item 1 could be narrowed to bring it within the limit.

MHRA Response

As the information is reasonably accessible by you, regardless of the format of that information, the information you have requested is exempt from release under Section 21 of the Freedom of Information (FOI) Act (information accessible by other means). As you have stated in your request, this information is accessible online through the MHRA-GMDP database (<https://cms.mhra.gov.uk/mhra/api-reg>). As the information is already publicly accessible, no further action is required by MHRA as a public authority.

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

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