Medicines & Healthcare products Regulatory Agency

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

foi.request@mhra.gov.uk.

MHRA Website

[redacted]

Our Ref: **FOI2026/01125**

21 October 2026

Dea[redacted]

Thank you for your Freedom of Information (FoI) request received on 25 July. You wrote:

Under the Freedom of Information Act 2000, I'm writing to request access to specific recorded data, internal communications, and decision-making records held by the MHRA regarding the regulation and safety monitoring of fluoroquinolone antibiotics. Please find my detailed, itemised queries listed below for your review within the statutory 20-working-day timeframe.
Thank you.

1.
Please provide the specific recorded data, epidemiological studies, or statistical models used by the MHRA to calculate and conclude that the minimum frequency of disabling fluoroquinolone side effects is between 1 and 10 per 10,000 patients (the 'rare' classification), as published in the January 2024 Drug Safety Update. Please provide:
a) Any internal assessments, reports, or statistical adjustments held by the MHRA regarding the estimated underreporting rate to the Yellow Card Scheme for fluoroquinolone-associated disability (FQAD).
b) Any recorded risk-benefit evaluations or safety committee papers discussing how the lack of a specific NHS SNOMED or ICD-10 diagnostic code for FQAD impacts the MHRA's ability to capture the true clinical incidence of these adverse events.
c) The official confidence intervals or sensitivity analyses recorded in the MHRA's safety reviews regarding the accuracy of this "rare" statistical incidence.

2. Please share correspondence and shared data between the MHRA and the US Food and Drug Administration (FDA) or European Medicines Agency (EMA) between 2016 and 2024 regarding safety signals for peripheral neuropathy and aortic aneurysm risks in fluoroquinolones.

3. Please provide minutes of meetings, scientific rationales, and internal correspondence from the Commission on Human Medicines (CHM) or MHRA safety committees regarding the decision to update the estimated incidence of disabling side effects from very rare (2019) to a minimum frequency of 1 to 10 per 10,000 patients in the January 2024 update.

4. Please provide copies of all official correspondence, guidance documents, letters, and alerts sent by the MHRA to healthcare professionals, clinical bodies, and NHS organisations

regarding the implementation of safety restrictions on fluoroquinolone antibiotics, regarding both the March 2019 Drug Safety Update and the January 2024 Drug Safety Update. Specifically, any direct alerts, DHPCs, or implementation guidance sent to clinical networks, Royal Colleges, or NHS Trusts regarding the initial introduction and the subsequent tightening of these prescribing restrictions.

5. Please provide the internal documentation, meeting minutes, and scientific rationales concerning the decision-making process to issue the August 2023 Drug Safety Update reminder regarding the March 2019 fluoroquinolone restrictions. Specifically, include:

1. Minutes of meetings held by the Commission on Human Medicines (CHM) or its expert advisory groups where the necessity of an August 2023 safety reminder was discussed
2. Any reports, statistical data summaries, or influxes of Yellow Card adverse drug reaction (ADR) reports reviewed by the MHRA between January 2022 and August 2023 that prompted the decision to issue this specific reminder.

6. Please provide a complete breakdown of all Yellow Card adverse drug reaction (ADR) reports for systemic fluoroquinolones (ciprofloxacin, levofloxacin, moxifloxacin) from 2019 to 2025, specifically broken down by patient age groups, gender, and the duration of the reported disability.

7. Please provide any internal reviews, audits, or data held by the MHRA assessing clinical compliance with the January 2024 Drug Safety Update restrictions on fluoroquinolones, including data on overall UK prescribing volume drops before and after the alert.

8. Please clarify the internal organizational structure of the MHRA by identifying the specific Divisions, Units, or Expert Advisory Groups currently responsible for:

1. The final regulatory decision-making process to restrict fluoroquinolone antibiotics (including the specific expert committees or panels involved in reviewing the benefit-risk profile).
2. The post-marketing surveillance and active collection of data (such as Yellow Card adverse drug reaction reports and real-world data networks) used to identify safety signals and inform these restrictions.
3. The dissemination of updated drug safety advice and restrictions directly to frontline clinicians and professional medical bodies (such as the team responsible for publishing the monthly Drug Safety Update and distributing Direct Healthcare Professional Communications).

9. Please clarify the MHRA's role, policy, and internal process regarding the request or introduction of new clinical diagnostic codes (such as SNOMED CT or ICD-10 terms) within UK clinical practice. Specifically, please provide:

1. Any documentation or standard operating procedures detailing how the MHRA interacts with NHS England's Terminology and Classifications Delivery Service to request new codes following severe drug safety signals.
2. Details of any active or past requests made by the MHRA to NHS England between 2019 and 2024 to establish unique diagnostic codes specifically related to fluoroquinolone-induced toxicity or long-term adverse events.

MHRA Response

Under section 12(1) of the Freedom of Information Act 2000, the MHRA is not obliged to comply with a request where the estimated cost of compliance would exceed the appropriate limit.

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.

Given the breadth of your request and the number of different records, systems and areas of the Agency that would need to be searched, we estimate that the cost of determining whether all of the requested information is held, and locating, retrieving and extracting any information falling within scope, would exceed the appropriate limit of £600.

Your request is wide-ranging and consists of nine substantive areas covering a number of different types of information across a broad timeframe.

The information requested is therefore not limited to a single record, subject area or information source. Relevant information would need to be identified across different types of records and potentially across a number of MHRA functions and systems. The extensive date ranges requested, particularly for correspondence and historical decision-making records, further increase the number of records that would need to be identified and reviewed to establish whether they fall within the scope of the request.

We estimate that the work required to determine what information is held and to locate, retrieve and extract all of the information falling within the scope of the request would exceed 24 staff hours. We are therefore refusing the request under section 12(1) of the Freedom of Information Act 2000.

Section 16: Advice and assistance

Under section 16 of the Freedom of Information Act 2000, we have a duty to provide reasonable advice and assistance.

You may wish to substantially narrow the scope of your request. For example, you could consider:

- selecting one or a small number of the numbered questions;
- limiting your request to a particular type of record, such as committee papers, correspondence or statistical information;
- substantially reducing the time periods covered by requests for correspondence and other records; and/or
- identifying a particular MHRA safety review, regulatory decision or committee whose records you are seeking.

We would consider any revised request afresh. However, we cannot guarantee that a revised request would fall within the appropriate cost limit.

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
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/