Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
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MHRA Website

[redacted]

Our Ref: **FOI2026/00917**

16 September 2026

Dear [redacted]

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

I am writing to request information under the Freedom of Information Act 2000 regarding the MHRA Drug Safety Update published on 22 January 2024 titled:

"Fluoroquinolone antibiotics: must now only be prescribed when other commonly recommended antibiotics are inappropriate."

https://www.gov.uk/drug-safety-update/fluoroquinolone-antibiotics-must-now-only-be-prescribed-when-other-commonly-recommended-antibiotics-are-inappropriate

The published update states that MHRA reviewed the effectiveness of previous measures to reduce the risk of disabling, long-lasting or potentially irreversible side effects from systemic fluoroquinolones, sought advice from the Commission on Human Medicines, and then took additional regulatory action to update the indications for systemic fluoroquinolones.

Please provide the following recorded information.

1. The MHRA review referred to in the Drug Safety Update

Please provide the full review, report, briefing paper, evidence assessment, safety assessment, or equivalent document that supported the January 2024 regulatory action.

2. Terms of reference, scope and methodology

Please provide any documents setting out the scope, terms of reference, methodology, inclusion/exclusion criteria, data sources, date ranges, analytical methods, or review questions used for the MHRA review.

3. Evidence on the effectiveness of the 2019 restrictions

Please provide the evidence used to assess whether the 2019 restrictions had been effective. This should include, where held, prescribing data, trend analyses, audit data, Yellow Card reporting trends, healthcare-professional awareness data, compliance assessments, or any other evidence used to judge the effectiveness of the 2019 measures.

4. Commission on Human Medicines advice

Please provide the CHM papers, minutes, recommendations, advice, briefing notes, slides, annexes or decision records relating to fluoroquinolone safety and the January 2024 restriction. I am happy for personal data to be redacted.

5. Basis for the estimated frequency of serious reactions

The update states that disabling and potentially long-lasting or irreversible adverse reactions are estimated to occur in at least between 1 and 10 people per 10,000 patients, while also stating that the frequency cannot be estimated precisely. Please provide the analysis, data sources, calculations, assumptions and denominator information used to derive this estimate.

6. Case definitions and classification criteria

Please provide any documents defining or classifying terms such as "disabling," "long-lasting," "potentially irreversible," "serious adverse reaction," "multi-system," and "fluoroquinolone-associated disability," if such terms were used in the review.

7. Drug-specific and route-specific analyses

Please provide any analyses, tables or summaries comparing risks across individual fluoroquinolones, including ciprofloxacin, levofloxacin, moxifloxacin, ofloxacin and delafloxacin, and across routes of administration, including oral, injection and inhaled use.

8. Risk-factor analysis

Please provide any evidence or analyses used to support the warnings relating to older age, renal impairment, solid-organ transplantation, corticosteroid coadministration, prior serious adverse reactions, treatment duration, dose, indication, or other patient-level risk factors.

9. Mechanistic evidence

Please provide any literature reviews, briefing notes or evidence summaries considered by MHRA relating to proposed mechanisms of fluoroquinolone toxicity, including tendon injury, mitochondrial dysfunction, oxidative stress, neuropathy, psychiatric effects, sensory effects, connective-tissue injury or delayed adverse reactions.

10. Patient evidence and stakeholder input

Please provide any summaries of patient reports, patient-group submissions, stakeholder consultation, expert submissions, qualitative evidence, meeting notes or correspondence that informed the review, particularly evidence relating to long-lasting disability and patient reports of not being adequately acknowledged by healthcare professionals.

11. Decision rationale and benefit-risk assessment

Please provide the documents explaining the rationale for the final wording that systemic fluoroquinolones must now only be used when other commonly recommended antibiotics are inappropriate. Please include any benefit-risk assessment, options appraisal, regulatory impact assessment or implementation assessment.

12. Implementation and communication planning

Please provide any documents relating to the implementation of the January 2024 restrictions, including communication plans, updates to product information, Dear Healthcare Professional communications, engagement with NICE, NHS England, professional bodies, GP prescribing systems, antimicrobial stewardship teams, patient-facing materials, or monitoring plans.

13. Correspondence with marketing authorisation holders

Please provide correspondence, instructions, assessment reports or variation documents sent to or received from marketing authorisation holders concerning the January 2024 fluoroquinolone indication changes and safety information updates.

14. Conflicts of interest

Please provide any declarations of interest, conflict-of-interest summaries or management plans for committee members, experts or external contributors involved in the review and decision-making process.

Please provide the information electronically, preferably in PDF, Word, CSV or Excel format where appropriate. For numerical data, I would prefer machine-readable tables rather than scanned documents.

I am not requesting personal data of patients or members of the public. Please redact personal data where necessary and disclose the remaining information.

If any information is withheld, please identify the exemption relied upon and provide the reasoning and public-interest test where applicable. Please also provide a schedule of

withheld documents where possible.

I would be grateful if you could acknowledge receipt of this request. I understand that public authorities normally respond to FOI requests within 20 working days.

MHRA Response

We can confirm we hold information requested, but it is exempt from disclosure under section 12(1) of the Freedom of Information 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 question 13 of your requests includes a considerable amount of data that would require manual reviewing to determine if it is within scope.

We conducted a search inbox across the agency using the term fluoroquinolone in conjunction with 42 registered market authorisation holders between September 2024 and April 2024 to allow for consideration of any potential communications in the lead up to and soon after the issuance of 22 January DSU. This has identified 11,930 emails that we estimate conservatively would take 45 seconds an email to review which in conjunction with the time taken to conduct the searches would take over 150 hours.

Under Section 16 of the FoI Act we should help you narrow your request so that it may fall beneath the cost limit and as such we recommend any new request excludes question 13. We have not conducted further assessment of the remaining elements of the requests once it was clear this element was considerably over the cost limit and as such any new request would be assessed on its own merits.

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/