Medicines & Healthcare products
Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

gov.uk/mhra

[redacted]

29 February 2024

FOI 24/103

Dear [redacted]

Thank you for your information request, which we received on 01 February 2024. You asked for:

1. Adverse Reactions: Please provide any reports, studies, or internal documents that detail the adverse reactions, including but not limited to tendon ruptures, peripheral neuropathy, and other serious side effects, associated with the use of fluoroquinolone antibiotics.

2. Safety Assessments: Kindly provide any internal safety assessments, risk evaluations, or risk management plans related to the use of fluoroquinolone antibiotics. This may include any documented analysis of the risks and benefits, as well as any measures taken to mitigate potential harms associated with these medications.

3. Regulatory Actions: Please furnish any information regarding regulatory actions, warnings, or restrictions imposed by regulatory agencies or health authorities concerning the use of fluoroquinolone antibiotics. This may include communications, advisory notices, or any other relevant documentation related to the safety concerns associated with these medications.

4. Overall summary documents: Please provide any overall sumamry reports that influence the decisions around floroquinolone restrictions, including summarised reports of the above information, and data on prescribing of floroquinolones in the UK over recent time periods

We have dealt with your request under the Freedom of Information Act 2000 (FOIA).

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We confirm that we hold the information you have asked for; however, we have also determined that the information cannot be provided as Section 12 of the Freedom of Information Act applies.

Section 12(1) of the FOIA allows public authorities to refuse requests where the cost of dealing with them would exceed the “appropriate limit”, which for central government departments is set at £600. This represents the estimated cost of one person spending 24 working hours in determining whether the department holds the information, locating, retrieving and extracting the information.

We will explain why compliance with your request would exceed the appropriate limit.

The requests for documents concerning adverse drug reactions (ADRs), safety assessments, and overall summary documents associated with fluoroquinolone antibiotics (points 1, 2, and 4 above), are not limited to specific ADRs or to a specific time frame. Responding to these requests would require the MHRA to locate and retrieve records from the systems we use to store documents associated with regulatory procedures for licenced medicines and to store internal documentation relating to MHRA review of potential safety issues.

As an example, there are over 100 fluoroquinolone-containing medicines authorised in the UK, with multiple regulatory submissions for each product over the time it has been authorised – an average of more than 30 submissions per product. Searching each submission for documents and making a preliminary assessment of whether these contain information about ADRs within the scope of this request takes approximately 1 minute, and therefore searching all submissions for all products would take approximately 50 hours. Please note this is an underestimate of the actual time that would be needed, as both the number of products and average number of submissions have been rounded down, and additional time would be needed where detailed review was necessary to determine whether documents included safety information. Additional time beyond these 50 hours would be needed to perform similar searches for internal documentation relating to MHRA review of potential safety issues.

When section 12(1) 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 narrow your request by restricting it to a single ADR or safety issue (for example tendinopathies), and to a time frame relating to a specific regulatory action (for example a specific MHRA safety communication, or specific warnings or other content in the product information for healthcare professionals (the Summary of Product Characteristics, SmPC).

Please note that, as stated in our correspondence dated 02 February 2024 (MHRA reference CEC 174395), the MHRA intends to place information about the recent review of the effectiveness of current measures to reduce the identified risk of

disabling and potentially long-lasting or irreversible side effects in the public domain by publishing a Public Assessment Report.

Regarding point 3, requesting information on regulatory actions, warnings, or restrictions imposed by regulatory agencies or health authorities, when MHRA communicates about regulatory actions taken in relation to medicines this information is in the public domain. MHRA communications relating to fluroquinolone antibiotics can be found in the monthly Drug Safety Update bulletins (https://www.gov.uk/drug-safety-update). Regulatory warnings and restrictions on the use of medicines can be found in the SmPC. SmPCs can be found online on the MHRA website (https://products.mhra.gov.uk/) and on the electronic Medicines Compendium website (https://www.medicines.org.uk/emc#gref).

You may also find the publicly available summaries of suspected ADR reports that MHRA has received via the Yellow Card scheme useful. These are presented in the form of interactive Drug Analysis Prints (iDAPs) online here: https://yellowcard.mhra.gov.uk/idaps. The iDAPs are presented alphabetically by the name of the active ingredient, so reports received for fluoroquinolone medicines are listed under several different substances. The substances for fluoroquinolone medicines currently authorised in the UK are ciprofloxacin, delafloxacin, levofloxacin, moxifloxacin, and ofloxacin. The iDAP for each active ingredient presents a summary of the reported ADRs. Filters can be applied to view the summary for a subset of the data, for example filtering by route of administration, or by the type of ADR (under the “System Organ Class” filter). It is important to note suspected ADRs have not been proven to be related to the medicines they are reported in relation to, and the iDAPs should not be interpreted as a list of known side effects. The MHRA encourages the use of Yellow Card data, however to ensure that these are interpreted in the correct way please refer to the guidance included on the iDAP web pages.

This concludes our response to your request.

If you have a query about this response, please contact us at [FOI email address].

Please remember to quote the reference number at the top of this letter in any future communications. Details of your appeal rights are below.

Yours sincerely,

Benefit Risk Evaluation
Safety and Surveillance group
Medicines and Healthcare products Regulatory Agency

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Appeal rights

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: [FOI email address]

If you remain dissatisfied with the outcome of the internal review, you have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of a request unless the requester has first asked us to conduct an internal review.

The Information Commissioner can be contacted through their online webform at: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

Or in writing to: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5