Medicines & Healthcare products Regulatory Agency

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MHRA Website

[redacted]

Our Ref: **FOI2024/00425**

13 September 2024

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 15 August. You wrote:

> *I was looking into Fluoroquinolone antibiotics and the adverse impacts they can have. According to this government warning, they include - ciprofloxacin, delafloxacin, levofloxacin, moxifloxacin, ofloxacin*
> *https://www.gov.uk/drug-safety-update/fluoroquinolone-antibiotics-reminder-of-the-risk-of-disabling-and-potentially-long-lasting-or-irreversible-side-effects*
> *Would you be able to tell me how many issues have been flagged through the yellow card system in Scotland?*
>
> *Apologies - could you also provide UK STATS.*
> *so: numbers in Scotland and across UK over the last 4 years.*

MHRA Response

We confirm that we hold the information you have requested. A total of **120** UK suspected spontaneous reports were received directly by the MHRA from **01/01/2020** up to and including **12/09/2024**, where a suspect drug was a fluoroquinolone[1], and the reporter postcode was a Scottish postcode[2].

Please see below Table 1, which provides a breakdown of these reports by year. Please be aware that on a Yellow Card report, reporter postcode is not a mandatory field. Therefore, this information may not always be provided. Furthermore, if the postcode is incorrectly provided, the Yellow Card will not be included in this analysis.

Table 1: All UK spontaneous suspected Yellow Card reports received directly by the MHRA from 01/01/2020 up to and including 12/09/2024, for fluoroquinolones[1], where the reporter postcode was a Scottish postcode[2]

Year	Number of UK spontaneous reports from Scottish reporter postcode
2020	15
2021	27

[1]Ciprofloxacin, delafloxacin, levofloxacin, moxifloxacin, and/or ofloxacin
[2]A postcode beginning with one of the following: AB/ DD/ EH/ FK/ G/ HS/ IV/ KA/ KW/ KY/ ML/ PA/ PH/ TD/ ZE

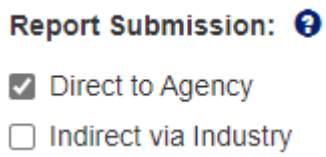
2022	20
2023	27
2024 (up to and including 12/09/2024)	31
Total	**120**

In response to your second question regarding UK-wide data, you can view all our UK adverse drug reaction (ADR) data for fluoroquinolones and other medicines on our Yellow Card website. You can do this by following this link: https://yellowcard.mhra.gov.uk/idaps.

Here, you can use the alphabetical tool to select the drug of interest, which will open an interactive Drug Analysis Profile (iDAP) for this drug. The iDAP displays the data in a variety of tables and graphs. The table at the bottom of the page includes the reactions that have been reported for the drug of interest. You can expand each category of reactions to see the number of reports for individual reactions and also whether any resulted in a fatal outcome. There are also filters down the left-hand side of the webpage that allow you to filter the data by age, sex, seriousness etc, if you wish.

Please be aware that a report may contain more than one fluoroquinolone drug as suspect drug and therefore total number of reports per separate fluoroquinolone cannot be summed.

Please also note that the data we have provided for Scottish reports refers only to reports received directly to the MHRA and excludes reports received indirectly via Industry. If you wish to only view direct reports for the UK, this is also possible on the iDAP website, by filtering the report submission field on the left-hand side:



Please also note that while considering all spontaneous ADR data, it's important to be aware of the following points:

- A reported reaction does not necessarily mean it has been caused by the drug, only that the reporter had a suspicion it may have. The fact that symptoms occur after use of a vaccine or medicine, and are reported via the Yellow Card Scheme, does not in itself mean that they are proven to have been caused by it. Underlying or concurrent illnesses may be responsible and such events can also be coincidental. We continuously review Yellow Card reports, alongside all other sources of safety data, to monitor safety and identify any new risks.

- It is also important to note that the number of reports received via the Yellow Card scheme does not directly equate to the number of people who suffer adverse reactions and therefore cannot be used to determine the incidence of a reaction or compare the safety profile of different medicines. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular drug, and may be stimulated by promotion and publicity about a drug. Reporting tends to be highest for newly introduced medicines during the first one to two years on the market and then falls over time.

You may also find it helpful to view the online Summary of Products Characteristics (SPC) and Patient Information Leaflet (PIL) resources. These resources are freely available to the

public and provide details on the known side effects of medicinal products and vaccines, with their associated frequencies. You can access these resources using this website and searching for the name of the specific products in question:
https://www.medicines.org.uk/emc .

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