Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

www.gov.uk/mhra

7th March 2024

Dear [redacted]

FOI 24/134

Thank you for your FOI request dated 8th February 2024, where you requested the following information:

> *"Do you have the incidence rates or reporting rates of the side effects of fluoroquinolones, particularly in relation to*
> - *suicidal thoughts and behaviour*
> - *tendon associated complications*
> - *aortic aneurysm or dissection"*

I can confirm that the MHRA do not hold the information requested beyond data already publicly available. Incidence rates or estimates of the frequency category for the potential adverse reactions requested may be available with the product information for individual medicinal products or within published medical literature, such as those referenced in Drug Safety Updates issued by the MHRA regarding some of these safety concerns[1,2].

You can view all suspected adverse reactions reported to the MHRA, including those for fluoroquinolones, via the Yellow Card scheme on our website as interactive Drug Analysis Profiles (iDAPs). It is important to note that the number of reports received should not be used as a basis for determining the incidence of a reaction as neither the total number of reactions occurring, nor the number of patients using the drug is known. Many factors influence the number of reports that we receive in the UK and we are aware that there is considerable 'under-reporting' of reactions to the Scheme. Reporting rates are influenced by the seriousness of the adverse drug reactions, their ease of recognition, the extent of use of a particular product, and may also be stimulated by promotion and publicity about a product. Reporting rates tend to be highest when a product is first put on the market.

[1] Systemic and inhaled fluoroquinolones: small increased risk of aortic aneurysm and dissection; advice for prescribing in high-risk patients

[2] Systemic and inhaled fluoroquinolones: small risk of heart valve regurgitation; consider other therapeutic options first in patients at risk

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We hope the information provided is helpful, but 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 of this response; and can be addressed to this email address.

Yours sincerely,

FOI Team,
Safety and Surveillance

If you have a query about this email, please contact us. If you are unhappy with our decision, you may ask for it to be reviewed. That review will be undertaken by a senior member of the Agency who has not previously been involved in your request. If you wish to pursue that option please write to the Communications Directorate, 4-T, Medicines and Healthcare products Regulatory Agency, (via this email address). After that, if you remain dissatisfied, you may ask the Information Commissioner at:

The Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF