Medicines & Healthcare products Regulatory Agency

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Canary Wharf
London
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United Kingdom
gov.uk/mhra

[redacted]

19 February 2024

Dear [redacted],

FOI 24/141

Thank you for your Freedom of Information (FOI) requested dated 9th February 2024 in which you requested *'the data relating to children for the adverse effects of fluoroquinolones to help us edit our guidance'.*

Data concerning the suspected side effects that have been reported to the MHRA for fluoroquinolones is routinely published on our website in the form of interactive Drug Analysis Profiles (iDAPs), which can be accessed here. Each iDAP contains a complete listing of all suspected adverse reactions that have been reported to the MHRA via the Yellow Card scheme. This includes all reports received from healthcare professionals, members of the public, and pharmaceutical companies. You can filter on the data using the options on the left hand to view those reports that concern children.

When using the Interactive Drug Analysis Profile, you should remember that:

- The likelihood of experiencing an adverse drug reaction when taking a medicine cannot be estimated from the data in the Interactive Drug Analysis Profile. This is because we have limited information about how many people have taken the medicine without experiencing a reaction.
- Reporters are asked to submit Yellow Card reports even if they only have a suspicion that the medicine may have caused the adverse drug reaction. The existence of an adverse drug reaction report in the Interactive Drug Analysis Profile does not necessarily mean that the medicine has caused the reaction.
- It may be difficult to tell the difference between something that has occurred naturally and an adverse drug reaction. Sometimes reactions can be part of the condition being treated rather than being caused by a medicine.

- Many factors have to be considered when assessing whether a medicine has caused a reported adverse drug reaction. When monitoring the safety of medicines, MHRA staff carry out careful analysis of these factors.
- It is not possible to compare the safety of different medicines by comparing the numbers presented in the Interactive Drug Analysis Profiles. Reporting rates can be influenced by many factors including the seriousness of the adverse drug reactions, their ease of recognition and the extent of use of a particular product. Reporting can also be stimulated by promotion and publicity about a product.

We hope the information provided is helpful. If you are unable to obtain the information you require from the iDAPs, please submit a new FOI request to MHRACustomerServices@mhra.gov.uk detailing your updated request and we will endeavour to provide you with the data you require.

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
Medicines and Healthcare products Regulatory Agency