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27 May 2025

s 9(2)(a)

Ref: H2025066156

Tēnā koe s 9(2)(a)

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to the Ministry of Health – Manatū Hauora (the Ministry) on 30 April 2025 for:

> *"On September 7th 2023 Medsafe published a prescriber update titled "Reports of persisting serious adverse reactions to fluoroquinolones"*
>
> *Can Medsafe please advise;*
>
> *Why it has taken until September 2023 to publish a prescriber update on the serious adverse reactions to fluoroquinolones including prolonged, disabling and potentially irreversible serious adverse reactions when other modern medicine safety agencies have published similar updates advising the public and the medical community significantly earlier.*
> *FDA published their warnings about permanent injury in 2013 & 2016*
> *EMA published guidance for the public and medical professionals in November 2018 following an extensive review and public hearings*
> *MHRA published a drug safety update in March 2019*
> *In the prescriber update it reports on the number of injuries reported to CARM. Has Medsafe reviewed the number of accepted ACC claims for fluoroquinolone associated injuries?*
> *When will Medsafe issue further warnings about safety and prescriber guidance for Fluoroquinolones in line with the latest drug safety update from MHRA which was issued in January 2024? ; https://www.gov.uk/drug-safety-update/fluoroquinolone-antibiotics-must-now-only-be-prescribed-when-other-commonly-recommended-antibiotics-are-inappropriate"*

The issue of **persisting** adverse reactions to fluoroquinolones was discussed at the Medicines Adverse Reactions Committee (MARC) meeting held in December 2017. Details of this meeting can be accessed through the Medsafe website here: www.medsafe.govt.nz/profs/PUArticles/March2018/MARCRemarks.htm.

The paper regarding fluoroquinolones is publicly available here: www.medsafe.govt.nz/committees/MARC/reports/172-Fluoroquinolones_Redacted.pdf

The minutes for this meeting are also publicly available. Please refer to 3.2.1 for the notes about fluoroquinolones: www.medsafe.govt.nz/profs/adverse/Minutes172.htm.

As detailed in the paper issued to MARC, further communications being required was queried, however the Committee did not recommend wide communication.

The only change at this stage, was that adverse effects could **persist**. Adverse effects have been known and communicated previously. For instance, at: www.medsafe.govt.nz/profs/PUArticles/watchingbriefsNov07.htm#Tendon. And https://www.medsafe.govt.nz/profs/PUArticles/QuinolonesSept2012.htm.

These adverse effects are also detailed on the data sheets for the respective medicines. We would expect that health professionals read the data sheets, and stay informed and educated on known adverse effects, independent of additional communications from Medsafe.

I trust this information fulfils your request. If you wish to discuss any aspect of your request with us, including this decision, please feel free to contact the OIA Services Team on: oiagr@health.govt.nz.

Under section 28(3) of the Act, you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by email at: info@ombudsman.parliament.nz or by calling 0800 802 602.

Please note that this response, with your personal details removed, may be published on the Ministry website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Nāku noa, nā

Chris James
Group Manager
Medsafe