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13 September 2023

s 9(2)(a)

By email: s 9(2)(a)
Ref: H2023031430

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 Manatū Hauora (the Ministry of Health) on 5 September 2023 for information regarding the medicine Cipflox and its datasheet. Each part of your request is responded to below.

1. *Why do the severe warnings about this drug appear on page six section 4.4 and not on the first page of this data sheet to alert consumers to the life changing side effects that this medication can cause. Noting that the Medsafe equivalent in the USA (the FDA) deems it so important that they put it on line 7 of Page one ie. It is the first thing that you read.*
2. *Why has the severe warning "Fluoroquinolones, including ciprofloxacin, have been associated with disabling and potentially persistent adverse reactions……" in the Medsafe data sheet had the word irreversible (from the FDA warning) replaced with persistent?*

Datasheets and the Consumer Medicine Information (CMI) are the property of the company, not Medsafe. The format of the datasheet is dictated by the guidelines and is consistent with the format required by the European Union. The guidelines can be viewed here: www.medsafe.govt.nz/regulatory/current-guidelines.asp.

3. *Why does Medsafe not take the severe and life changing side effects from this medication seriously?*

I do not agree with the premise of your request that Medsafe does not take the side effects of Cipflox seriously. These potential side effects are outlined in the datasheet and warning information has been published on the Medsafe website previously:

- www.medsafe.govt.nz/profs/PUArticles/QuinolonesSept2012.htm.
- www.medsafe.govt.nz/profs/PUArticles/September2023/Reports-persisting-adverse-reactions-fluoroquinolones.html.

While the Act enables people to request official information from the Ministry, there is no obligation for the Ministry to provide an opinion. As such this part of your request is refused under section 18(g)(i) of the Act.

*4. Why does the consumer medicine information sheet NOT contain the serious warning?*

As advised, CMI is the property of the company. The current legislation does not provide Medsafe with authority to regulate the CMI, companies provide these on a voluntary basis.

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 Manatū Hauora website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Nāku noa, nā

Chris James
**Group Manager**
**Medsafe**