

16 February 2023

s 9(2)(a)

By email: s 9(2)(a)
Ref: H2023019058

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 Haoura (the Ministry of Health) on 28 December 2022 for information regarding metformin. You requested:

“Can you inform what steps you have taken re the Nitrosamine contamination of Metformin. Please respond with detailed information.”

Medsafe first became aware of the potential for metformin products to contain a nitrosamine impurity above the internationally acceptable limit on 5 December 2019. The New Zealand companies responsible for marketing the seven product ranges (15 products) likely to be available for supply in New Zealand containing metformin (either alone or in combination) were contacted and were asked to advise what actions were being taken to ensure the medicines supplied in New Zealand did not contain higher than acceptable levels of N-nitroso dimethylamine (NDMA is a type of nitrosamine compound). All companies responded with a risk assessment demonstrating their products were within acceptable levels or indicated their products were no longer supplied in New Zealand.

Please note these risk assessments are withheld under section 9(2)(ba)(i) of the Act to protect information that is subject to an obligation of confidence and making it available would likely prejudice the supply of similar information, or information from the same source. I have considered the countervailing public interest in releasing this information and consider that it does not outweigh the need to withhold at this time

Further Information about Medsafe’s approach to the nitrosamine issue can be found at: www.medsafe.govt.nz/medicines/policy-statements/NitrosamineImpurities.asp.

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, na

A handwritten signature in blue ink, appearing to be 'Chris James', written in a cursive style.

Chris James
Group Manager
Medsafe