

11 FEB 2020

Ref: H202000146

Dear [REDACTED]

Response to your request for official information

Thank you for your email of 14 January 2020, requesting under the Official Information Act 1982 (the Act):

Part A.

- 1. The citation lists (clinical research studies, other clinical papers and publications including randomised control trials and guidelines) that support all currently Medsafe approved funded thyroid medications. Citations are to include those on safety, benefits, efficacy and risk, and risk management; and*
- 2. The citation list of all NZ or international patient survey data that supports these treatments.*

Part B. Please provide

- 1. The citation lists (clinical research studies, other clinical papers and publications including randomised control trials and guidelines) that say that Desiccated Thyroid Extract or other forms of combination T3/T4 treatment for hypothyroidism and Liothyronine are NOT safe, beneficial, effective and risks cannot be managed safely. Citations are to include those on safety, benefits, efficacy and risk, and risk management.*
- 2. The citation lists of all NZ or international patient survey data that show they are NOT safe, beneficial or effective.*

Please note that for Part A and B, copies of the actual studies themselves are not required, just the citation (also known as an APA reference e.g. Elizabeth A. McAninch and Antonio C. Bianco (July, 2019). The Swinging Pendulum in Treatment for Hypothyroidism: From (and Toward?) Combination Therapy. Frontiers in Endocrinology. published: 09 July 2019. doi: 10.3389/fendo.2019.00446

In response to part A (one and two) of your request, there are three funded thyroid medications in New Zealand. These are: Eltroxin, Levothyroxine and Synthroid.

Eltroxin is the innovator medicine and was approved before 1969. The Ministry of Health (the Ministry) does not hold individual medicine information from before that time.

The other two products are generics of Eltroxin and therefore did not need clinical data to be approved. They provided bioequivalence data to show they act the same way in the body as the original product. You can find out more about generic medicines and bioequivalence here: <https://www.medsafe.govt.nz/profs/PUArticles/Mar2013GenericMedBioequivalence.htm>

Part A (one and two) of your request is refused under section 18(e) of the Act, as the information requested does not exist.

In response to Part B (one and two) of your request, there are currently no approved products in New Zealand with "*desiccated thyroid extract and other forms of T3/T4 treatments and liothyronine*". Moreover, the Ministry does not hold any New Zealand or international patient survey data on whether these medicines are not safe, as there have been no applications for these products for approval.

Therefore, Part B (one and two) of your request is refused under section 18(e) of the Act, as the information requested does not exist.

You have the right, under section 28 of the Act, to ask the Ombudsman to review any decisions made under this request.

Please note that the Ministry may publish this response (with your personal details removed) and any attachments on the Ministry of Health website.

Yours sincerely

A handwritten signature in blue ink, appearing to be 'Chris James', written over a faint circular stamp.

Chris James
Group Manager
Medsafe