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H201503268

Dear Ms Hodson

Response to your request for official information

Thank you for your request dated 31 July 2015, under the Official Information Act 1982, for information relating to which thyroid medicines and bio-identical equivalents qualify to be included on Medsafe's safe medicines list.

Medicines in New Zealand are regulated by the Medicines Act 1981. The Medicines Act describes that the Minister of Health shall grant consent for a new medicine to be distributed in New Zealand when s/he is satisfied:

- that all the necessary information has been supplied; and
- the likely therapeutic value of the medicine outweighs the risk of harm occurring to the patient.

Consent is granted by publication of the Minister's decision in the New Zealand Gazette.

Medsafe is the Government Agency with responsibility for assessing an application for consent to distribute a new medicine and recommending to the Minister of Health the decision s/he should make.

As a public service, Medsafe also publishes information about medicines on its website www.medsafe.govt.nz. By using the product search function at http://www.medsafe.govt.nz/regulatory/DbSearch.asp anyone can find out about medicines with consent.

All medicines have risks and therefore consented medicines published in the New Zealand Gazette and on the Medsafe website are not regarded as a 'safe medicine list'. Rather they should be viewed as a list of medicines where the therapeutic benefit outweighs the risk of harm.

Within the context of Medsafe's role, for your convenience, I have answered your questions in the sequence they are asked:

1. For each of the years 1960, 1970, 1980, 1990, 2000, 2010 and 2015, what of the following have met the criteria to be listed on Med Safe's safe medicines list; and under what criteria. Please provide the breakdown by:
(a) all thyroid medications e.g. Synthroid, Cytomol, Eltroxin, and
(b) all Natural Desiccated Thyroid (NDT) equivalents to these medications (note that NDTs are also called bio-identical hormones) e.g. Whole Thyroid Extract, Extended Release T3.

I am refusing this part of your request under section 18(d) of the Official Information Act because this information is publicly available at http://www.medsafe.govt.nz/regulatory/DbSearch.asp.

By using the 'trade name' search function you can see that Synthroid and Eltroxin have been granted consent. These medicines contain the active ingredient levothyroxine.

You can also search the therapeutic products database using the 'ingredient' option to see any other medicines containing active ingredients you are interested in. The data base uses % as a wild card so you can search using %thyro% to see a range of ingredients such as levothyroxine, thyroid, thyroid extract, triiodothyronine, liothyronine, etc.

The search results will indicate the date of approval. You can also select the product name in the search results to go to the product details. For medicines that are currently marketed you will find a link to the data sheet on the top, right hand of the product details page.

The data sheet is written for healthcare professionals and contains a summary of the safety and efficacy data considered by Medsafe prior to consent being granted. It also contains details of the circumstances in which the medicine can be used safely and effectively.

Some product pages also contain a link to the Consumer Medicine Information (CMI) leaflet. These documents are written for patients to assist in the safe and effective use of their medicines. As for data sheets, CMI summarise the risks and benefits of the medicine based on data reviewed by Medsafe and forms part of the approved details for each medicine.

2. What are the current criteria thyroid medications and/or the NDT equivalents such as Whole Thyroid Extract need to meet to qualify to be included on the Medsafe safe medicines list?

Before any medicine is granted consent in New Zealand, the person wishing to distribute the medicine must make an application to Medsafe. The application must be accompanied by data to demonstrate that the medicine meets the expected standards of safety, quality and efficacy.

Information on the data required to support an application for consent in New Zealand is in the Medicines Act, the Medicines Regulations 1984 and further explained in the Guidelines for the Regulation of Therapeutic Products in New Zealand. Copies of the applicable legislation are available at www.legislation.govt.nz and the Guidelines are available on the Medsafe website http://www.medsafe.govt.nz/regulatory/guidelines.asp.

3. What is the current process (as it applied to thyroid treatment) that is used to set these criteria, specifically:
a. What are the inputs to this process e.g. types of research and source(s); who is consulted e.g. type of medical specialist or medical agency.
b. Who ultimately decides whether a medication/NDT meets the criteria?
c. How are patients' actual experiences of being on these medications/NDTs represented in this process?; and what New Zealand and/or overseas patient data e.g. medical records of patients, are used to substantiate this? And, who provides this information? And who funds this information (as funders and providers may be different entities).

Information about the evaluation and approval process is available here: http://www.medsafe.govt.nz/consumers/Safety-of-Medicines/Medsafe-Evaluation-Process.asp

The legislation describes that consent is granted by the Minister of Health. Typically this function is delegated to the Ministry of Health. Currently the Group Manager Medsafe holds the delegation to grant consent to a new medicine.

The information required for an application is generated by the company who owns the product. Typically they fund the data generation themselves although they may be eligible for a research grant. Funding options depend on the country in which the research will be conducted.

In New Zealand, health research can be funded by the Health Research Council. Further information is available here: http://www.hrc.govt.nz/. Some research may also be eligible for funding administered by the Ministry of Business, Innovation and Employment (http://www.msi.govt.nz/get-funded/research-organisations/types-of-funding/).

Once a medicine is approved, it is still subject to regulatory oversight. You can read about Medsafe's pharmacovigilance programme here http://www.medsafe.govt.nz/Consumers/Safety-of-Medicines/Medicines-Safety-and-Pharmacovigilance.asp

4. Have NDTs ever been up for consideration for inclusion on Med Safe's safe medicines list?
a. If not, then why not? and
b. If they have, then in what year did this happen? Which of the criteria did they meet and which of the criteria did they not meet. What was the outcome of the consideration and on what basis were they declined or accepted?

Medsafe has not received an application for consent from anyone wishing to distribute a medicine containing an NDT.

5. Have thyroid medications containing T3 e.g. Cytomol, ever been up for consideration for inclusion on Med safe's safe medicines list?
a. If not, then why not? and
b. If they have, then in what year did this happen? Which of the criteria did they meet and which of the criteria did they not meet; what was the outcome of the consideration and on what basis were they declined or accepted?

Two medicines containing liothyronine (also known as L-triiodothyronine and the active ingredient in Cytomel) have been approved for use in New Zealand.

These medicines were Tertroxin 20mcg liothyronine tablet and Tri-iodothyronine solution for injection containing 20mcg of liothyronine both distributed by GlaxoSmithKline New Zealand Ltd.

The medicines were assessed against the criteria in the Medicines Act when it came into effect. At that time, companies who had marketed medicines prior to 1 January 1970, and who could provide evidence of supply, were granted a pre-dated approval.

Therefore the approval date of Tertroxin tablets was deemed to be 31 December 1969 and the injection solution was deemed to be approved from 1 January 1965.

The company discontinued supply of the injection solution in 1993 and the tablets in 2003.

I trust this information fulfils your request. You have the right, under section 28 of the Act, to ask the Ombudsman to review my decision to withhold information under this request.

Yours sincerely

Chris James
Acting Group Manager
Medsafe