PHARMAC
Pharmaceutical Management Agency

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Ms Belinda Hodson
Via email: fyi-request-3000-77bbef80@requests.fyi.org.nz

Dear Ms Hodson

REQUEST FOR INFORMATION

Thank you for your request dated 31 July 2015 under the Official Information Act 1982 (OIA) for information relating to thyroid medications. You have asked for information relating to the criteria for subsidisation by the government.

As you are aware, part of the information you have requested in part one of your request, relating to the years 1960, 1970, 1980 and 1990, is believed to be more closely associated to the functions and responsibilities of the Ministry of Health as these predate the establishment of PHARMAC. Your request was transferred to the Ministry of Health under Section 14(b)(ii) of the OIA on 14 August 2015.

For ease in responding to your requests for information, we have responded separately to each section of your request.

1. *For each of the years 1960, 1970, 1980, 1990, 2000, 2010 and 2015, what of the following have met the criteria for subsidisation by the government; 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 .

The thyroid and antithyroid agents that were subsidised by PHARMAC for the years you have stipulated are:

- 2000: carbimazole, levothyroxine, liothyronine and propylthiouracil.
- 2010: carbimazole and levothyroxine.
- 2015: carbimazole, levothyroxine and propylthiouracil.

Natural Desiccated Thyroid (NDT) medications have never been funded by PHARMAC and we have not received any funding applications for these medications. We note that NDT medications are not registered by Medsafe for use in New Zealand. Medsafe is the New Zealand Medicines and Medical Devices Safety Authority responsible for the regulation of medicines, ensuring they are acceptably safe. Generally, a pharmaceutical is unlikely to be funded by PHARMAC if it is not registered with Medsafe and registered alternatives exist.

2. *What are the current criteria thyroid medications and/or the NDT equivalents such as Whole Thyroid Extract need to meet to attract government funding so that the cost of these are lower for patients?*

In deciding which medicines to fund, and to ensure our decisions are as fair and robust as possible, we use nine Decision Criteria along with expert clinical advice. We analyse clinical, economic and commercial issues, and seek the views of users and the wider community through consultation. The processes we generally use, as well as the nine Decision Criteria, are outlined in our Operating Policies and Procedures. The Operating Policies and Procedures can be found on our website here: http://www.pharmac.health.nz/assets/opp-2006-01-3rd-ed.pdf

You may be interested to know that PHARMAC is changing the way it makes decisions by introducing the Factors for Consideration which will replace the Decision Criteria. PHARMAC will begin utilising the Factors for Consideration for decision making from 1 July 2016. We're making this change to reflect feedback we've received about how we make decisions, and also to ensure our process fits all our work, including medicines, vaccines and medical devices. The long lead-in time is to help us and our stakeholders adapt to the change, and we'll be communicating with our stakeholders throughout the implementation process. You may wish to read more about the Factors for Consideration on our website here: http://www.pharmac.health.nz/medicines/how-medicines-are-funded/factors-for-consideration/

Anyone – a patient, a health professional or a pharmaceutical supplier – can make a funding application to PHARMAC. Most applications are made by pharmaceutical companies, who have access to the full range of information PHARMAC requires to assess applications. You can find more information about new funding applications, including application forms on the following link: http://www.pharmac.health.nz/medicines/how-medicines-are-funded/new-funding-applications/

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).

As noted in our response to part two of your request for information, PHARMAC currently uses nine Decision Criteria. These assist us in deciding which medicines to fund as we follow the processes outlined in our Operating Policies and Procedures.

PHARMAC requires good advice from clinicians to make decisions on medicines funding. This advice is received in a number of ways, including through expert committees. PHARMAC also keeps up-to-date with the latest clinical information through ongoing professional development, monitoring of trials and medical journal articles. We

also take other research and data into consideration that is provided to us in new funding application submissions.

Our main clinical advice comes from an expert committee of medical practitioners, called the Pharmacology and Therapeutics Advisory Committee (PTAC). PTAC considers clinical evidence around funding applications, and takes into account PHARMAC's nine Decision Criteria before making recommendations to PHARMAC on medicines funding. The Committee has 10 members who have expertise in examining clinical studies and broad experience and knowledge of medicines and the conditions they treat. PTAC operates under defined Terms of Reference which are available on our website, along with minutes of their meetings, here: http://www.pharmac.health.nz/about/committees/

PTAC also has a number of expert subcommittees which provide clinical evaluations in specialist areas. The subcommittees and the minutes of their meetings can be viewed on our website here: http://www.pharmac.health.nz/about/committees/ptac/ptac-subcommittees/

PHARMAC has a procedure for listing a pharmaceutical on the Pharmaceutical Schedule. This diagram can be found in our Operating Policies and Procedures (Procedure 4.5). Ultimately the PHARMAC Board is responsible for all listing decisions PHARMAC makes, and in the case of major decisions the Board makes the decision itself. In other cases, the Board delegates decision making to the Chief Executive who may further delegate to other PHARMAC staff.

Our work directly affects the lives of New Zealanders so we need to consider the views of consumers and patients. We keep in touch with communities and consumers to hear their views on pharmaceutical-related issues and involve them in our work.

PHARMAC consults with the public, when we consider it appropriate, about our activities and the decisions we make. We carefully exercise this discretion to decide when we seek public comment; both in relation to individual funding decisions and other activities. When developing a new policy or considering a funding decision or a change to existing funding, it will often be desirable to carry out a formal, time-bound, public, written consultation exercise. More often than not we formally consult before making our funding decisions.

Consultation can take many forms, and the approach we take may differ from proposal to proposal, depending on the type of work underway. For example, some consultations will be shorter than others, and involve a single round of written submissions to a proposal. Consultation may be targeted to particular groups with a specific interest or specialty.

In addition, the Consumer Advisory Committee (CAC) provides advice to PHARMAC from a consumer and patient perspective on matters related to PHARMAC's activities. Its role is to provide advice to PHARMAC on appropriate processes and plans to better understand consumer and patient perspectives. The Committee is made up of people from a range of backgrounds and interests including the health of Māori people, Pacific peoples, older people and patients with chronic disease, to name a few. The advice we seek from the CAC covers many different areas including:

- How PHARMAC can obtain and consider consumers' views on our funding and policy decisions
- PHARMAC's strategy, policy and operational activities related to funding decisions, and access to and optimal use of medicines.

- How PHARMAC can best communicate its decisions, policies and strategies.
- How the CAC can engage with consumers to ensure it can provide quality advice to PHARMAC.
- Educational information to assist patients.

CAC members are not employed by PHARMAC, although they are reimbursed for the time they give to serving on the Committee. CAC is guided by its Terms of Reference, which you can view on our website here: http://www.pharmac.health.nz/assets/cac-terms-of-reference-april-2010.pdf

4. *Have NDTs ever been up for consideration for government funding?*

   (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?

As noted in our response to part one of your request, PHARMAC has not received any funding applications for NDT medications, therefore they have not been considered for funding. While PHARMAC does have the ability to consider a product for funding in the absence of an application from an external party, this has not occurred.

5. *Have thyroid medications containing T3 e.g. Cytomol, ever been up for consideration for government funding?*

   (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?

PHARMAC has not received any funding applications for thyroid medications containing T3, therefore they have not been considered for funding. While PHARMAC does have the ability to consider a product for funding in the absence of an application from an external party, this has not occurred.

Please note you have the right, by way of complaint under Section 28(3) of the OIA to an Ombudsman, to seek an investigation and review of our decision.

We trust that this information answers your queries, if you have any further questions please feel free to contact us again.

Yours sincerely

Jude Urlich
Director of Engagement and Implementation