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Megs

Via Email: fyi-request-12688-913afaa1@requests.fyi.org.nz

Dear Megs

REQUEST FOR INFORMATION: DISCONTINUATION OF PHENELZINE SULPHATE

Thank you for your email of 23 April 2020 requesting information about the discontinuation of phenelzine sulphate. Specifically, you have asked for:

…all information and documentation, including email or other correspondence documents with both internal and external parties, for the following:

1. *What other alternative suppliers have been contacted or considered, what was the outcome?*
2. *Is the discontinuation of phenelzine related to the current cost of alternatives?*
3. *Has phenelzine been permanently discontinued in NZ? Or will it be available when the supply has stabilised?*
4. *Any estimations around the suicide risk (and management) of these 100 New Zealanders (who are currently using phenelzine sulphate), the potential cost to the health and welfare system given the extremely high likelihood of relapse.*
5. *All information related to the suggestion of using tranylcypromine sulphate (Parnate) as "appropriate alternative MAOI for patients", including …. a list detailing the qualifications and professional experience regarding MAOI and treatment resistant depression of those on the Mental Health Subcommittee of the Pharmacology and Therapeutics Advisory Committee. Please also include any studies cited or external professionals who were consulted.*

Your request for this information has been considered under the Official Information Act 1982 (OIA). Each of your points are addressed below.

What other alternative suppliers have been contacted or considered, what was the outcome? Please provide documentation relating to the attempt to find an alternative supplier. Australia's supplier has switched from Link Medical to Medsurge who are currently attempting to confirm an ongoing supply of phenelzine for Australians; why is NZ not doing the same?

Nardil is the only Medsafe registered brand of phenelzine tablets in New Zealand. It has been supplied to the New Zealand market by Link Healthcare. Link Healthcare is the contracted supplier of phenelzine and there are no other registered suppliers that can supply the New Zealand market at this time. In situations where there is a disruption to supply, we would usually approach other registered suppliers. PHARMAC has requested both Link Healthcare and Medsurge to seek alternatives and neither was successful.

There have been ongoing supply issues with Nardil, with Link Healthcare supplying two alternative, unregistered brands, Nardil S29 and Lupin, to meet the needs of the New Zealand market. A search for a reliable, alternative source of Nardil has not been successful and Link Healthcare has now advised that it has no option but to discontinue supply. Documents in relation to this are attached to this response.

We are aware that the supply issue for phenelzine is global and there are difficulties sourcing alternatives worldwide. With regards to your comment about the supply of phenelzine in Australia, PHARMAC has not been made aware of any potential alternative suppliers that could guarantee long-term supply.

Is the discontinuation of phenelzine related to the current cost of alternatives? Currently, the only brand available in Australia under the special access scheme is $398+GST for a bottle. Please provide all information and documentation regarding the cost for supply of phenelzine, especially relating to decisions by those within PHARMAC.

As advised above, the discontinuation of phenelzine is a decision resulting from lack of reliable supplies of the medicine globally. This includes manufacturing difficulties.

Information about the cost of phenelzine sulphate is available on PHARMAC's website at: www.pharmac.govt.nz/wwwtrs/ScheduleOnline.php?osq=phenelzine+sulphate

Has phenelzine been permanently discontinued in NZ? Or will it be available when the supply has stabilised? Please provide anything related to future of phenelzine in NZ.

Link Healthcare informed PHARMAC that it expected all remaining stock of Nardil, Nardil S29 and Lupin to be depleted by mid-late May 2020. After these stocks are exhausted, the discontinuation of phenelzine is expected to be permanent as it is unlikely that a reliable, registered, long-term supply will be found.

Phenelzine is a last resort for everyone who takes it. Given there are currently 100 people in NZ on it, what sort of risk analysis and discussion has taken place regarding the ongoing management of these New Zealanders? Please provide all available documentation, including but not limited to reports, briefing, correspondence, transcripts of meetings or phone calls with all internal and external parties, including but not limited to Mental Health Subcommittee of the Pharmacology, Therapeutics Advisory Committee, Department of Health, Local DHBs, MPs. Specifically, I am interested in any estimations around the suicide risk (and management) of these 100 New Zealanders, the potential cost to the health and welfare system given the extremely high likelihood of relapse.

The need for careful management of patients transitioning off phenelzine is recognised and this has been discussed by PHARMAC. Information and advice provided by the Mental Health Subcommittee of the Pharmacology and Therapeutics Advisory Committee is provided with this response.

It is the role of general practitioners and specialist physicians to provide clinical analysis and management of medical conditions in individual patients. They have been informed about the discontinuation of phenelzine and will take responsibility for assessing and identifying suitable alternative treatments for their patients. Information about the potential suicide risk and management of individual patients, and cost analysis should relapse occur, is not held by PHARMAC and is unable to be supplied pursuant to section 18(g) of the OIA.

Please provide all information related to the suggestion of using tranylcypromine sulphate (Parnate) as "appropriate alternative MAOI for patients", including all reports, correspondence, transcripts, and a list detailing the qualifications and professional experience regarding MAOI and treatment resistant depression of those on the Mental Health Subcommittee of the Pharmacology and Therapeutics Advisory Committee. I would specifically expect to see discussion and acknowledgement from these members that the two MAOI are not interchangeable. Please also include any studies cited or external professionals who were consulted.

As advised above, it is the responsibility of the prescribing doctor to manage the patient's condition, including assessing and prescribing any medicines that are required. Advice from the Mental Health Subcommittee of the Pharmacology and Therapeutics Advisory Committee suggesting that tranylcypromine sulphate would be an appropriate alternative medicine is provided with this response. This suggestion is made because it is of the same class of medicine (a Monoamine Oxidase Inhibitor) as phenelzine, however PHARMAC recognises that treatment changes need to be individualised for each patient.

Information and advice relevant to questions 1, 4 and 5, provided by the Mental Health Subcommittee and Pharmacology and Therapeutics Advisory Committee, is included with this response.

In addition, a journal article titled *MAOIs – Does the evidence warrant their resurrection?* (by Menkes, Bosanak, Castle), published in the Australian Psychiatry Journal 1-3 was circulated. This journal was published by the Royal Australian and New Zealand College of Psychiatrists in 2016. This article has been refused under section 18(d) of the OIA, on the grounds that it is already publicly available.

We have redacted information from the documents we are releasing to you, where:

- this is necessary to protect the privacy of natural persons (section 9(2)(a)); and
- this is necessary to maintain the effective conduct of public affairs through the free and frank expression of opinions by or between officers and employees of an organization in the course of their duty (section 9(2)(g)(i).

As required under the OIA, we also considered whether, in the circumstances, the withholding of this information was outweighed by other considerations which render it desirable, in the public interest, to make this information available. In this case we did not consider that the public interest outweighed the reasons for withholding the information.

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. We are making our information more freely available, so we will now publish selected OIA responses (excluding personal details) on our website. Please get in touch with us if you have any questions about this.

Ngā Mihi

Rachel Read

Manager, Policy and Government Services