Office of Hon Dr Jonathan Coleman

Minister of Health
Minister for Sport and Recreation
Member of Parliament for Northcote

Ms Pip Keane
Radio New Zealand
Pip.Keane@radionz.co.nz

28 APR 2016

Dear Ms Keane

Response to your request for official information

Thank you for your request received in this office on 9 March 2016 under the Official Information Act 1982 (the Act) for:

- *all correspondence:*
- *Between Health Minister Jonathan Coleman and Merck Sharpe and Dohme and Pharmac regarding Keytruda.*
- *Between Health Minister Jonathan Coleman and Pharmac regarding drug-funding priorities.*
- *Between Health Minister Jonathan Coleman and Bristol-Myers Squibb and Pharmac regarding Opdivo.*
- *Between Health Minister Jonathan Coleman and the Prime Minister's office regarding the funding of a melanoma drug.*
- *Between Health Minister Jonathan Coleman and the Malaghan Institute regarding its trials into an immunotherapy drug.*
- *Between Health Minister Jonathan Coleman and melanoma patients.*

Information relating to your request is attached. We have interpreted your request as being for information in the last 12 months. Note that some information has been withheld under section 9(2)(g)(ii) of the Act.

Your request for all correspondence between the Minister and melanoma patients is refused under section 18(f) of the Act, as this would require a manual search through a large volume of information.

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

Yours sincerely

P. McCardle

Peter McCardle
Senior Ministerial Advisor
Office of Hon Dr Jonathan Coleman

Extracts from Minister's monthly reports – for Pip Keane OIA request - prepared April 2016

Extract from Minister's Report dated October 2015 – sent 2 December 2015

Oncology conference/Melanoma conference

- PHARMAC staff recently attended two key cancer stakeholder meetings; the New Zealand Society of Oncology (NZSO) annual conference and the Melanoma Summit.
- NZSO primarily has a research focus; attendees include Oncology Researchers and Medical Oncologists. There was some focus on the high prices of new cancer medicines and the need for new models for drug discovery, development and commercialisation.
- PHARMAC staff presented the analysis comparing cancer medicines funding in New Zealand with Australia, which was well received. Feedback obtained during the meeting was supportive of PHARMAC and while there was a desire among attendees to see more new cancer medicines funded, the cost of many of them was seen as unreasonable and prohibitive.
- The Melanoma Summit discussed a wide variety of melanoma topics, including prevention, detection diagnosis and surgical/radiation, however, there was a strong focus on access to new melanoma medicines.

Extract from Minister's Report dated January 2016 – sent 10 March 2016

Treatments for advanced melanoma

- As previously advised, PHARMAC is continuing to progress an application for pembrolizumab (Keytruda) for advanced melanoma. No decision has been made.
- We recognise the pressing need for an effective treatment for late stage melanoma and are mindful the lack of treatment options is of significant concern to New Zealanders with the disease and their families.
- In February, PTAC reviewed its earlier advice on another melanoma product, ipilimumab, and their advice is expected to be finalised by the end of April. PTAC had previously recommended this treatment be declined.
- PHARMAC has received a funding application for nivolumab (Opvido), which is not currently registered for use in New Zealand. As part of our process for reviewing funding applications, we will be seeking expert clinical advice on the evidence presented, during April.
- We are continuing to work with the supplier of pembrolizumab, as well as the supplier of nivolumab and ipilimumab on commercial options to address the questions our clinical advisers have already raised regarding data and pricing.

Extract from Minister's Report dated February 2016 – sent 6 April 2016

PD1 inhibitors (including Keytruda)

- As previously advised, PHARMAC has received a funding application for nivolumab (Opvido) from BMS. Nivolumab is currently in the Medsafe registration process for both melanoma and lung cancer indications.
- Anticipating that nivolumab may be approved by Medsafe shortly, PHARMAC will be seeking advice from its Cancer Treatments Subcommittee, in order to make a funding assessment as soon as possible. The Subcommittee will be reviewing the funding application at the end of April and PTAC will consider this at its May 2016 meeting.
- PHARMAC continues to work with both MSD and BMS to reach a commercial agreement that would enable a PD1 inhibitor to be funded for melanoma.

Withheld under section 9(2)(g)(i)

Office of Hon Dr Jonathan Coleman

Minister of Health
Minister for Sport and Recreation
Member of Parliament for Northcote

11 FEB 2016

Mr Paul Smith
Director
Merck Sharp & Dohme New Zealand
sheryl_kurte@merck.com

Ref. 1503069

Dear Mr Smith

Thank you for your letters of 13 November and 10 December 2015 about the Melanoma New Zealand Parliamentary Skin Check Day and Merck Sharp & Dohme's application to PHARMAC for funding of Keytruda (pembrolizumab).

I note your comments about the application to PHARMAC to fund pembrolizumab. PHARMAC takes all available evidence into account when making its funding assessments. I am advised that PTAC considered all information provided by Merck Sharpe and Dohme (New Zealand) Limited in its funding submission, and that this was supplemented by additional information sourced by PHARMAC staff. I am advised that the information you refer to is from presentations delivered at clinical conferences and has not yet been subject to peer review. I am also informed that some of the promotional material based on the information you refer to has subsequently been withdrawn and corrected internationally by Merck Sharpe and Dohme.

As you know, on the basis of available clinical data, PHARMAC's expert committees recommended that funding of pembrolizumab be given a lower priority than medicines with greater proven efficacy.

Yours sincerely

Hon Dr Jonathan Coleman
Minister of Health

Private Bag 18041, Parliament Buildings, Wellington 6160, New Zealand. Telephone 64 4 817 6818. Facsimile 64 4 817 6518

MSD
Merck Sharp & Dohme (New Zealand) Limited
Level 3 109 Carlton Gore Road
Newmarket, Auckland 1023
PO Box 99-851 Newmarket Auckland 1149
T 09 523-6000
F 09 523-6001

13 November 2015

Parliament Office
Private Bag 18888
Parliament Buildings
Wellington 6160

Dear Dr Coleman

I would like to thank you for sponsoring the Melanoma New Zealand Parliamentary Skin Check Day on October 15. Your staff, especially Paige Gregg, did an outstanding job of liaising and ensuring the smooth running of the event.

MSD was proud to support the event and the great work of Melanoma New Zealand. Throughout the day 50 people including MPs, Government officials and media received a skin check. The event was successful in raising awareness of the seriousness of melanoma and the importance of early detection, as someone dies from melanoma almost every day in New Zealand.

Since we last wrote to you, there have been a number of developments regarding KEYTRUDA® (pembrolizumab). Pleasingly, both of PHARMAC's clinical advisory committees have now reviewed KEYTRUDA and PHARMAC has the clinical advice it needs to begin negotiations with MSD. We are ready to talk and to make this happen as quickly as possible. **KEYTRUDA could be listed on the New Zealand Pharmaceutical Schedule as early as 1 February 2016,** providing melanoma sufferers with a chance at life.

In addition, KEYTRUDA has been featured in a number of media stories -TVNZ's *Sunday Programme* (Sunday 8 November), and the *New Zealand Herald* (Thursday 12 November) - see links below.

Many media reports have drawn comparisons to KEYTRUDA access in other countries, most notably Australia. KEYTRUDA has been funded in Australia since September and New Zealand can match the 19 week timeframe from medicine registration (Medsafe) to funding.

Listing KEYTRUDA would be a celebration of how the New Zealand Government, PHARMAC, MSD, clinicians, patients and a wide range of patient advocacy groups have jointly collaborated to seize an opportunity to save lives and finally provide a way to beat melanoma – what a great way to start the New Year for many New Zealanders.

I appreciate your support and understanding. Please also feel free to call me.

Yours sincerely

Paul Smith
MSD New Zealand Director
Ph: 09 523 6061
Mob: 027 530 1261

Recent Media Reports

TVNZ Sunday Programme

https://www.tvnz.co.nz/content/tvnz/ondemand/shows/s/sunday/s2015/e41.html

MelNet media release

http://melnet.org.nz/news/2015/summit-calls-for-pharmac-to-fast-track-funding-reviews-for-latest-melanoma-treatments

Melanoma Summit Radio Reports

http://www.newstalkzb.co.nz/news/health/nz-melanoma-treatment-old-and-ineffective-expert/

http://www.radionz.co.nz/news/bites/289158/plea-for-govt-to-fund-latest-skin-cancer-treatment

NZ Herald Cancer Series

http://www.nzherald.co.nz/lifestyle/news/article.cfm?c_id=6&objectid=11543855

ATT00001

MSD
Merck Sharp & Dohme (New Zealand) Limited
Level 3 109 Carlton Gore Road
Newmarket, Auckland 1023
PO Box 99-851 Newmarket Auckland 1149
T 09 523-6000
F 09 523-6001
msd.co.nz

10 December 2015

Parliament Office
Private Bag 18888
Parliament Buildings
Wellington 6160

Dear Minister of Health Hon. Dr. Jonathan Coleman

KEYTRUDA® (pembrolizumab) efficacy clarification

In the recent debate over the efficacy of KEYTRUDA there has been some confusion because the most up-to-date and correct clinical data has not always been referenced in the figures given to the media and the wider public.

This is of significant concern as the use of incorrect data gives a misleading and false impression of how effective this breakthrough drug is, in the treatment of melanoma.

Merck Sharp & Dohme (New Zealand) Limited (MSD) would like to highlight that the latest clinical data given to PHARMAC prior to the CaTSoP/ PTAC meetings was not reviewed or reported in the PHARMAC minutes. We are at a loss as to why this most up to date data was ignored.

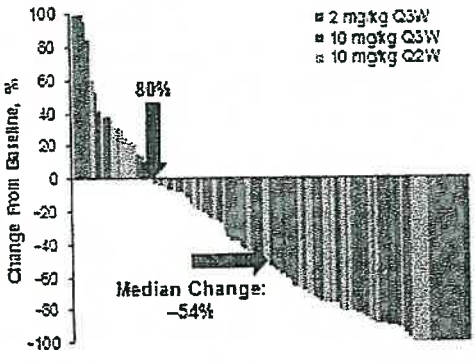
In the latest data presented at the key international oncology meeting (ASCO); patients who had no prior treatment (which matches the New Zealand funding proposal) received much greater benefit from KEYTRUDA compared to the clinical paper that was reviewed by PHARMAC.

In the 2015 ASCO update of Keynote 001, at a median follow up of 15 months:

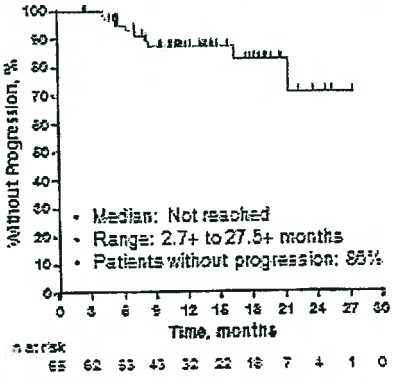
- 80% of patients that received KEYTRUDA as first-line treatment experienced tumour shrinkage
- The median change in tumor size was shrinkage of 54%
- 14% had no identifiable tumour mass left (classified as a complete response)

KEYNOTE 001

Efficacy as First-Line Therapy[a]



Duration of Response in First Line



[a]Excludes patients with ocular melanoma.
Analysis cut-off date: October 16, 2014.

Pr Proprietary

Some of the data reviewed by PHARMAC and published in the minutes, was relating to melanoma patients that had been pre-treated with chemotherapy and other biologics not funded in New Zealand. Pre-treated patients have a poorer prognosis, as they have been sicker for longer than patients who have not received any treatment (first-line patients). MSD is seeking funding for untreated or first-line patients who gain the greatest benefit from KEYTRUDA.

PHARMAC noted that "longer term evidence was needed to be more certain of the benefits and harms of this new class of treatment". KEYTRUDA has been registered by MEDSAFE who assess safety and efficacy of medicines; as well as the TGA in Australia, the FDA, and many other regulatory agencies worldwide.

MSD agrees in an ideal world there would be longer term evidence regarding the duration of benefits. However, the reality is that 2-3 times as many patients are alive at one year when given first-line KEYTRUDA compared to chemotherapy - dacarbazine (dacarbazine 27% Chapman et al, Keytruda 73% KN001 2mg/kg) (not head-to-head) and 60% of KEYTRUDA patients are still alive at 2 years. Given the median life expectancy for an advanced melanoma patient is 8-9 months this is a significant improvement which has not been seen in any previous treatments. Current melanoma patients do not have time to wait for longer term survival data.

MSD submitted a new commerical proposal to PHARMAC on the 2nd of December and we will be meeting with them on December 15. We hope that PHARMAC are willing to engage in good faith and we can reach a positive funding decision for KEYTRUDA; so that melanoma patients and their famiilies can have access to the best treatment possible, and a real chance of survival.

Please feel free to contact me anytime should you have any questions.

Regards,

Paul Smith
Director, MSD New Zealand
Mobile +64 27 530 1261
paul.smith15@merck.com