From: April-Mae Marshall On Behalf Of applications Sent: Wednesday, 20 September 2017 3:50 pm

To: Withheld under < Withheld under section 9(2)>

Subject: RE: Application to Fund the Abbott Freestyle Libre Interstitial Fluid Glucose Sensor and Reader

Dear Withhe

Thank you for the funding application for Interstitial fluid glucose monitor from Abbott Freestyle Libre for treatment of diabetes we are pleased to have the opportunity to consider this product for funding

We will look to include this application on the next Pharmacology and Therapeutics Advisory Committee (PTAC) agenda or the next meeting of the Diabetes Subcommittee of PTAC. We will be in touch once PHARMAC staff have reviewed the application.

Regards

April Mae April-Mae Marshall | Pharmacology and Therapeutics Advisory Committee Secretary

PHARMAC | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington DDI: Withheld under | P: +64 4 460 4990 | F: +64 4 460 4995 | www.pharmac.govt nz

 From: Nobes, Michael S [mailto:
 Withheld under section 9(2)(a)
]

 Sent: 31 January 2018 14:03
 To: Danae Staples-Moon < Withheld under section 9(2)(a)</td>
 >

 Cc: Chalikias, Peter < Withheld under section 9(2)(a)</td>
 >; Alexander Rodgers

 Withheld under section 9(2)(a)
 >

Subject: Abbott Diabetes Care PTAC Application for FreeStyle Libre

Dear Danae,

As discussed at our meeting last year on the 9th of November, I'd like to confirm that we'll be submitting a PTAC application for FreeStyle Libre

The application will be sent on Friday 2nd of February to arrive at PHARMAC on Monday the 5th of February as originally promised.

In addition, the PTAC Secretary will be sent two New Zealand spec samples of the FreeStyle Libre glucose monitoring system (both sensor and reader kits) as a separate delivery from our current NZ distributor, Mediray

To assist with the evaluation, I'll send a FreeStyle Libre demonstration kit (identical to the one we featured at our November meeting) from our Melbourne office to the PTAC Secretary as another separate delivery.

We look forward to working with you to progress the application for FreeStyle Libre funding on the Pharmaceutical Schedule

Kind regards, Michael



Michael Nobes, Ph.D. Market Access Director ANZ Abbott Diabetes Care 666 Doncaster Rd Doncaster VIC 3108 Australia O: Withheld under F: +61398558020 M: Withheld under Withheld under section 9(2

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From: Danae Staples-Moon Sent: Wednesday, 31 January 2018 2:47 pm To: 'Nobes, Michael S' < Withheld under section 9(2)(a) > Cc: Chalikias, Peter < Withheld under section 9(2)(a) >; Alexander Rodgers < Withheld under section 9(2)(a) >

Subject: RE: Abbott Diabetes Care PTAC Application for FreeStyle Libre

Dear Michael,

Thanks for the update regarding submitting a funding application for the May PTAC deadline and other deliveries to expect I can confirm that the samples from Mediray were received today The PTAC secretary will be able to confirm receipt of your submission and other delivery once received.

Kind regard Danae

Danae Staples-Moon | Therapeutic Group Manager

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PTAC Secretary PHARMAC Level 9 40 Mercer Street WELLINGTON 6011 NEW ZEALAND

2nd February 2018

Dear PTAC Secretary,

Please find attached the submission for FreeStyle Libre on behalf of Abbott Laboratories NZ Limited (trading as Abbott Diabetes Care).

In accordance with your guidelines, please find attached three copies of the submission separated into three volumes as discussed with April-Mae Marshall, within the PTAC Secretary Office. The three volumes are –

- Synopsis of the Submission
- Complete Submission
- Attachments requiring printing

Also included is a USB containing one electronic version of the submission including the above volumes and the additional attachments, endnote files, checklists and WAND information.

If you have any questions regarding the above, please do not hesitate to contact either Withheld under section on Withheld under section (email – Withheld under section 9(2)(a)) or Michael Nobes from Abbott Diabetes Care on Withheld under section (email – Withheld under section 9(2)(a))

Yours sincerely,

Withheld under Soction 9(2)(ba)(i) Withheld under section From: April-Mae Marshall Sent: Monday, 5 February 2018 1:59 pm To: 'Withheld under ' < Withheld under section 9(2)(a) Subject: Freestyle Libre Application

Dear Withheld

Thank you for submitting the funding application for FreeStyle Libre

We are pleased to have the opportunity to consider this product for funding.

We will consider this application for inclusion on the agenda for the May 2018 PTAC meeting and will confirm this closer to the time

Regards April Mae

April-Mae Marshall | Pharmacology and Therapeutics Advisory Committee Secretary

PHARMAC | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington DDI: Withheld under | P: +64 4 460 4990 | F: +64 4 460 4995 | www.pharmac.govt.nz

20 February 2018

Withheld under

Withheld under section

via email: Withheld under section 9(2)(a)

Dear Withheld

Funding Application FreeStyle Libre

Thank you for the funding applications for FreeStyle Libre glucose monitoring system. We are pleased to have the opportunity to consider this product for funding for treatment of type 1 diabetes.

PHARMAC staff have reviewed the application with reference to the Guidelines for Funding Applications to PHARMAC and are planning to initially seek clinical advice Diabetes Subcommittee at their next meeting We will keep you informed regarding the application's progress.

We would like to give you the opportunity to make a presentation of your application to PHARMAC staff. Danae Staples Moon is the therapeutic group manager responsible for the diabetes therapeutic group Danae can be reached at Withheld under or by emailing Withheld under section 9(2)(a)

We look forward to evaluating your application and providing you with the record of the Subcommittee's recommendations to PHARMAC.

Yours sincerely

April-Mae Marshall

April Mae Marshall PTAC Secretary

CC: Michael Nobes, Market Access Director, Abbott Laboratories NZ Limited (trading as Abbott Diabetes Care), Withheld under section 9(2)(a)

From: Nobes, Michael S < Withheld under section 9(2)(a) >

Sent: Tuesday, 13 March 2018 4:33 pm

To: Danae Staples-Moon < Withheld under section 9(2)(a)

Subject: [SPAM]? Offer by PHARMAC for Abbott Diabetes Care to present on the FreeStyle Libre submission

Dear Danae,

Thank you for PHARMAC's correspondence, dated 20 February 2018, offering Abbott Diabetes Care to present on the FreeStyle Libre application.

As outlined in my phone message, I'd like to touch base with you regarding the logistics for the presentation

An understanding of potential dates, audience and format would be helpful for planning purposes.

I look forward to connecting with you on this matter and seeing you again to discuss FreeStyle Libre

Regards, Michael



Michael Nobes, Ph.D. Market Access Director ANZ Abbott Diabetes Care 666 Doncaster Rd Doncaster VIC 3108 Australia O: Withheld under F: +61 3 9855 8020 M: Withheld under Withheld under section 9(2)

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From:

Withheld under section 9(2)(a)

Sent: Thursday, April 5, 2018 7:50 AM

To: Diabetes Feedback < diabetesfeedback@pharmac.govt.nz>

Subject: CGM use could improve HbA1c and reduce distress in adolescents with type 1 diabetes

https://www.diabetes.co.uk/news/2018/apr/cgm-use-could-improve-hba1c-and-reduce-distress-inadolescents-with-type 1 diabetes

98217280.html?utm_source=Communicator&utm_medium=Email&utm_content=Untitled22&utm campaign=Poor+outcomes+spark+urges+for+NHS+foot+care+improvement&utm_dispatch%20ID=6 825252&utm_email%20name=DCUK+NL+-+03%2f04%2f18 As a parent of a now we are old with type 1 and depression, please consider this article in the light of the current application for funding of the libre freestyle blood glucose scanning technology.

Kind regards, Withheld under

 From: Nobes, Michael S [mailto:
 Withheld under section 9(2)(a)
]

 Sent: 26 April 2018 13:26
 To: Danae Staples-Moon < Withheld under section 9(2)(a)</td>
 >

 Cc: Prakash, Deepak < Withheld under section 9(2)(a)</td>
 >; Chalikias, Peter < Withheld under section 9(2)(a)</td>
 >

 Subject: [SPAM]? Request for a progress update on the Diabetes Subcommittee meeting date

Dear Danae,

With respect to our February funding application for FreeStyle Libre, can you please provide an update on whether our application will be reviewed by the Diabetes Subcommittee and, if so, what the meeting date will be?

Also, can you please confirm when applications are added to the PHARMAC application tracker website since FreeStyle Libre is yet to appear on this list as a 'received application' even though the page was updated on 21 March 2018.

Cheers, Michael



Michael Nobes, Ph.D. Market Access Director ANZ Abbott Diabetes Care 666 Doncaster Rd Doncaster VIC 3108 Australia O: Withheld under F: +61 3 9855-8020 M: Withheld under Withheld under section 9(2)

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 From: Danae Staples Moon

 Sent: Tuesday, 1 May 2018 12:12 pm

 To: 'Nobes, Michael S' < Withheld under section 9(2)(a)</td>

 >

 Cc: Prakash, Deepak < Withheld under section 9(2)(a)</td>

 >; Chalikias, Peter < Withheld under section 9(2)(a)</td>

 Subject: RE: Request for a progress update on the Diabetes Subcommittee meeting date

Hi Michael,

Thanks for your email. Yes, I can confirm that the intention is for advice to be sought in the first instance from the Diabetes Subcommittee. While a date has yet to be set, we are currently considering the optimal time for this to be scheduled and I am expecting this will likely be before the end of the year. I will let you know once a date and agenda has been confirmed.

I have updated the Application tracker so it should now show receipt of your application. Apologies for the delay in this happening.

Kind regards Danae

Danae Staples-Moon | Therapeutic Group Manager

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 From: Nobes, Michael S [mailto:
 Withheld under section 9(2)(a)
]

 Sent: 08 June 2018 17:57
 To: Danae Staples Moon < Withheld under section 9(2)(a)</td>
 >

 Cc: Prakash, Deepak < Withheld under section 9(2)(a)</td>
 >; Chalikias, Peter

 < Withheld under section 9(2)(a)</td>
 >; Brockwell, Glenn < Withheld under section 9(2)(a)</td>

Subject: RE: Request for a progress update on the Diabetes Subcommittee meeting date Importance: High

Hi Danae,

Is there any clarity on a date for the Diabetes Subcommittee yet to consider the FreeStyle Libre application – even if Q3 or Q4 2018?

Any update would be useful since we're getting many queries from the public about the anticipated PHARMAC process and timing.

Cheers, Michael



Michael Nobes, Ph.D. Market Access Director ANZ Abbott Diabetes Care 666 Doncaster Rd Doncaster VIC 3108 Australia O: Withheld under F: +61 3 9855-8020 M: Withheld under Withheld under section 9(2)

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From: Danae Staples-Moon Sent: Monday, 11 June 2018 8:14 am To: 'Nobes, Michael S' < Withheld under section 9(2)(a)
 Cc: Prakash, Deepak < Withheld under section 9(2)(a)
 ; Chalikias, Peter
 Withheld under section 9(2)(a)
 ; Brockwell, Glenn < Withheld under section 9(2)(a)
 Subject: RE: Request for a progress update on the Diabetes Subcommittee meeting date

Hi Michael

Apologies for not having replied before now. There is not yet a confirmed date. We are currently considering dates in Q4 however, as there are a number of factors that go into determining meeting dates we may need to consider alternative timings.

Kind regards Danae

Danae Staples-Moon | Therapeutic Group Manager

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 From: Nobes, Michael S [mailto:
 Withheld under section 9(2)(a)
]

 Sent: 12 June 2018 16:30
 To: Danae Staples Moon < Withheld under section 9(2)(a)</td>
 >

 Cc: Prakash, Deepak < Withheld under section 9(2)(a)</td>
 >; Chalikias, Peter

 < Withheld under section 9(2)(a)</td>
 >; Brockwell, Glenn < Withheld under section 9(2)(a)</td>

 Subject: RE: Request for a progress update on the Diabetes Subcommittee meeting date

Thanks for the update, Danae.

Is PHARMAC conducting or planning to conduct any HTA or product evaluations on FreeStyle Libre in the lead up to a future subcommittee meeting?

Cheers, Michael



Abbott Diabetes Care 666 Doncaster Rd Doncaster VIC 3108 Australia O: Withheld under F: +61 3 9855-8020 M: Withheld under Withheld under 9(2)

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From: Danae Staples Moon Sent: Friday, 15 June 2018 3:22 pm To: 'Nobes, Michael S' < Withheld under section 9(2)(a) > Cc: Prakash, Deepak < Withheld under section 9(2)(a) >; Chalikias, Peter Withheld under section 9(2)(a) >; Brockwell, Glenn < Withheld under section 9(2)(a) >; Subject: RE: Request for a progress update on the Diabetes Subcommittee meeting date

Hi Michael,

There may be some HTA work done in order to provide information for clinical advisors However, generally HTA work is undertaken once clinical advice has been received so that the advice can be incorporated into our analysis.

Kind regards Danae

Danae Staples-Moon | Therapeutic Group Manager

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From: Nobes, Michael S Sent: Tuesday, 7 August 2018 3:14 PM To: Danae Staples-Moon < Withheld under section 9(2)(a) > Cc: Prakash, Deepak < Withheld under section 9(2)(a) >; Chalikias, Peter < Withheld under section 9(2)(a) >; Brockwell, Glenn < Withheld under section 9(2)(a) > Subject: RE: Request for a progress update on the Diabetes Subcommittee meeting date

Hi Danae,

Has there been any movement with regards to the Diabetes Subcommittee meeting date?

On another related query, how far in advance do the Diabetes Subcommittee members receive the FreeStyle Libre application?

Cheers, Michael



Michael Nobes, Ph.D. Market Access Director ANZ Abbott Diabetes Care 666 Doncaster Rd Doncaster VIC 3108 Australia O: Withheld under F: +61398558020 M: Withheld under Withheld under section 9(2)

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 From: Nobes, Michael S < Withheld under section 9(2)(a)</td>
 >

 Sent: 21 September 2018 17:32
 To: Danae Staples Moon < Withheld under section 9(2)(a)</td>
 >

 Cc: Prakash, Deepak < Withheld under section 9(2)(a)</td>
 >; Chalikias, Peter < Withheld under section 9(2)(a)</td>
 >

Subject: RE: Request for a progress update on the Diabetes Subcommittee meeting date Importance: High

Hi Danae,

Is a Diabetes Subcommittee meeting still anticipated by year end as previously communicated?

If not, is there another timeframe or date?

On another related query, how far in advance do the Diabetes Subcommittee members receive the FreeStyle Libre application?

Regards, Michael



Michael Nobes, Ph.D. Market Access Director ANZ Abbott Diabetes Care 666 Doncaster Rd Doncaster VIC 3108 Australia 0: Withheld under F: +61 3 9855-8020 M: Withheld under Withheld under section 9(2



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From: Danae Staples-Moon

Sent: Monday, 24 September 2018 9:00 am

To: 'Nobes, Michael S' < Withheld under section 9(2)(a)

Cc: Prakash, Deepak < Withheld under section 9(2)(a) >; Chalikias, Peter < Withheld under section 9(2)(a) : Subject: RE: Request for a progress update on the Diabetes Subcommittee meeting date

Hi Michael

At this stage it is unlikely that a Diabetes Subcommittee meeting will be held before the end of the year. I am currently looking at dates in Q1 next year and will let you know once a date has been confirmed.

Generally, the material for consideration at a meeting (including the applications) is sent about a month in advance to members for their consideration.

Kind regards Danae

Danae Staples-Moon | Senior Therapeutic Group Manager

PHARMAC | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington DDI: Withheld under | F: +64 4 460 4995 | www.pharmac.health.nz From: Nobes, Michael S < Withheld under section 9(2)(a) >
Sent: 18 February 2019 18:57
To: Danae Staples-Moon < Withheld under section 9(2)(a) >
Cc: Prakash, Deepak < Withheld under section 9(2)(a) >; Chalikias, Peter < Withheld under section 9(2)(a)
Subject: RE: Request for a progress update on the Diabetes Subcommittee meeting date
Importance: High

Dear Danae,

Based on your last email in September 2018, a Diabetes Subcommittee meeting was anticipated for Q1 2019

Is this still the timeframe?

We are deeply concerned about the lack of any progress given that the FreeStyle Libre application was now submitted over 12 months ago (on 5th of February 2018)

On this note, the current application tracker only notes that the application was received in Feb '18 rather than also stating that advice is being sought from a sub committee (i.e. "Referred to Committee")

We have received numerous queries from people living with diabetes and HCPs specifically on the progress of the application and why Pharmac has not yet reviewed it.

We trust that our application will be given a level of priority commensurate with the high clinical unmet needs in the New Zealand type 1 population that can be addressed by the FreeStyle Libre system

Regards, Michael



Michael Nobes, Ph.D. Market Access Director ANZ Abbott Diabetes Care 666 Doncaster Rd Doncaster VIC 3108 Australia O: Withheld under F: +613 9855 8020 M: Withheld under Withheld under section 9(2)

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From: Danae Staples Moon
Sent: Tuesday, 19 February 2019 3:48 pm
To: 'Nobes, Michael S' < Withheld under section 9(2)(a) >
Cc: Prakash, Deepak < Withheld under section 9(2)(a) >; Chalikias, Peter < Withheld under section 9(2)(a)

Subject: RE: Request for a progress update on the Diabetes Subcommittee meeting date

Hi Michael

Thanks for your email. I can confirm that the Diabetes Subcommittee is meeting in March 2019 and the funding of Freestyle Libre will be considered at this meeting. I have also updated the App Tracker to reflect that the application has been referred to the subcommittee for advice.

Kind regards Danae

Danae Staples-Moon | Senior Therapeutic Group Manager

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From: Nobes, Michael S < Withheld under section 9(2)(a) > Sent: Tuesday, 19 February 2019 4:03 pm To: Danae Staples Moon < Withheld under section 9(2)(a) > Cc: Prakash, Deepak < Withheld under section 9(2)(a) >; Chalikias, Peter < Withheld under section 9(2)(a) > Subject: RE: Request for a progress update on the Diabetes Subcommittee meeting date Attachments: 2018-02-20 Freestyle Libre Supplier May PTAC.PDF

Thank you, Danae.

That is good news.

Has a specific date been set for the March meeting?

PHARMAC has previously offered Abbott the opportunity to make a presentation of our application to PHARMAC staff, as attached.

As such, we'd suggest that this presentation be best scheduled prior to the Diabetes subcommittee meeting and time may be short if early March.

Regards, Michael



Michael Nobes, Ph.D. Market Access Director ANZ Abbott Diabetes Care 666 Doncaster Rd Doncaster VIC 3108 Australia O: Withheld under F: +61 3 9855 8020 M: Withheld under Withheld under section 9(2)



From: Danae Staples-Moon Sent: Wednesday, 27 February 2019 4:02 pm To: 'Nobes, Michael S' Withheld under section 9(2)(a) > Cc: Prakash, Deepak < Withheld under section 9(2)(a) >; Chalikias, Peter < Withheld under section 9(2)(a) > Subject: RE: Request for a progress update on the Diabetes Subcommittee meeting date

Hi Michael,

Yes, the meeting will be on March 19 and I agree it would be best for your presentation to occur prior to the Subcommittee meeting. Therefore, would need to look at a date either next week or in the week starting the 11th?

Let me know if there is a date/time that would suit you and I will see what fits in diaries.

Kind regards Danae

Danae Staples-Moon | Senior Therapeutic Group Manager

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 From: Nobes, Michael S < Withheld under section 9(2)(a)</td>

 Sent: 27 February 2019 17:45

 To: Danae Staples Moon < Withheld under section 9(2)(a)</td>

 Cc: Prakash, Deepak < Withheld under section 9(2)(a)</td>

 Subject: RE: Request for a progress update on the Diabetes Subcommittee meeting date

Thank you, Danae

Can you please advise on available dates for Wed 13th or Thur 14th?

The preference would be morning or early afternoon.

Cheers, Michael



Michael Nobes, Ph.D. Market Access Director ANZ Abbott Diabetes Care 666 Doncaster Rd Doncaster VIC 3108 Australia O: Withheld under F: +613 9855-8020 M: Withheld under Withheld under section 9(2)

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 From: Danae Staples-Moon [mailto:
 Withheld under section 9(2)(a)
]

 Sent: Wednesday, 27 February 2019 4:27 PM

 To: Nobes, Michael S
 Withheld under section 9(2)(a)
 >

 Cc: Prakash, Deepak
 Withheld under section 9(2)(a)
 >

 Subject: RE: Request for a progress update on the Diabetes Subcommittee meeting date

Hi Michael

Wednesday 1.30pm 2.30 Thursday – 9am-10, 1pm-2 or 2-3pm

Hopefully one of these is suitable, if not let me know alternatives.

Kind regards Danae

Danae Staples-Moon | Senior Therapeutic Group Manager

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 From: Nobes, Michael S

 Sent: Friday, 1 March 2019 1:41 PM

 To: 'Danae Staples Moon' < Withheld under section 9(2)(a)</td>

 Cc: Prakash, Deepak < Withheld under section 9(2)(a)</td>

 >; Chalikias, Peter

 < Withheld under section 9(2)(a)</td>

 >; Brockwell, Glenn < Withheld under section 9(2)(a)</td>

Subject: RE: Request for a progress update on the Diabetes Subcommittee meeting date

Hi Danae,

Please book us in for Wednesday 13th 1.30pm-2.30pm.

We look forward to presenting FreeStyle Libre evidence base and a productive discussion.

Cheers, Michael



Michael Nobes, Ph.D. Market Access Director ANZ Abbott Diabetes Care 666 Doncaster Rd Doncaster VIC 3108 Australia O: Withheld under F: +6139855-8020 M: Withheld under Withheld under section 9(2

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From: Nobes, Michael S < Withheld under section 9(2)(a) >
Sent: 01 March 2019 16:32
To: Danae Staples-Moon < Withheld under section 9(2)(a) >
Cc: Chalikias, Peter < Withheld under section 9(2)(a) >
Subject: RE: Request for a progress update on the Diabetes Subcommittee meeting date

Hi Danae,

We've just booked flights - the only option is a 3:50pm departure for Melbourne.

Is there any possibility to start earlier on Wednesday?

If not, we'll need to ensure a stop at or close to 2:30pm just in case

Cheers, Michael



Michael Nobes, Ph.D. Market Access Director ANZ Abbott Diabetes Care 666 Doncaster Rd Doncaster VIC 3108 Australia 0: Withheld under F: +61.3.9855-8020 M: Withheld under Withheld under section 9(2)



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From: Danae Staples Moon [mailto: Withheld under section 9(2)(a)] Sent: Monday, 4 March 2019 6:36 AM To: Nobes, Michael S < Withheld under section 9(2)(a) > Cc: Chalikias, Peter < Withheld under section 9(2)(a) > Subject: RE: Request for a progress update on the Diabetes Subcommittee meeting date

Hi Michael

Our diaries are pretty tight that day However, I think that we could juggle things to start at 1pm but would need to finish up at 2pm. One hour should be sufficient time to cover the key points and this would give you a bit more breathing space to make the flight.

Kind regards Danae

Danae Staples-Moon | Senior Therapeutic Group Manager

PHARMAC | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington DDI: Withheld under | F: +64 4 460 4995 | www.pharmac.health.nz

 From: Nobes, Michael S < Withheld under section 9(2)(a)</td>
 >

 Sent: Monday, 4 March 2019 10:45 am
 To: Danae Staples-Moon < Withheld under section 9(2)(a)</td>
 >

 Cc: Chalikias, Peter < Withheld under section 9(2)(a)</td>
 >; Mitchell, Melissa

 <melissa.mitchell@abbott.com>
 Subject: RE: Request for a progress update on the Diabetes Subcommittee meeting date

Thanks Danae,

That would be perfect and we'll ensure a 2pm hard stop.

Cheers, Michael

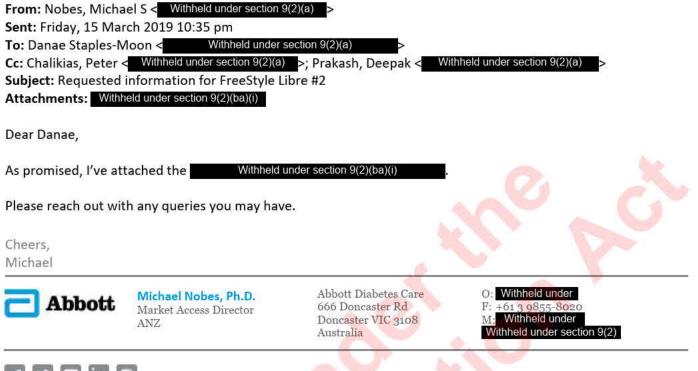


Michael Nobes, Ph.D. Market Access Director ANZ Abbott Diabetes Care 666 Doncaster Rd Doncaster VIC 3108 Australia 0: Withheld under F: +6139855-8020 M: Withheld under Withheld under section 90



From: Nobes, Micha	el S < Withheld under section 9	(2)(a) >		
Sent: Friday, 15 Mai				
To: Danae Staples-N	N CARACTER CONTRACTOR CONTRA	section 9(2)(a) >		
Cc: Chalikias, Peter	Withheld under section 9(2)(a)	>; Prakash, Deepak < Wit	nheld under section 9(2)(a) >	
Subject: Requested	information for FreeStyle Li	bre #1		
Attachments:	and a second billion	d under section 9(2)(ba)(i)		
	Withheld unde	r section 9(2)(ba)(i)		
Withheld under			-51°	
Dear Danae,				X
Please find attached	I the requested information	on the Withheld under sec	tion 9(2)(ba)(i)	
Withheld under section	since the FreeStyle Libre a	application was lodged 🛛 📐		
Also attached is the	Withhe	ld under section 9(2)(ba)(i)		
Withheld u	inder section 9(2)(ba)(i)			
	17 17 17 17 17 17 17 17			
I will also send all of	the Withheld under section	n 9(2)(ba)(i) as a 2 nd email		
Cheers,				
Michael				
—	Michael Nobes, Ph.D.	Abbott Diabetes Care	O: Withheld under	
C Abbott	Market Access Director	666 Doncaster Rd	F: +61 3 9855 8020	
	ANZ	Doncaster VIC 3108 Australia	M: Withheld under Withheld under section 9(2)	

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AGENDA DIABETES SUBCOMMITTEE OF PTAC

Tuesday 19 March 2019 9.00 am – 3.30 pm

PHARMAC, Tait Room, Level 9, 40 Mercer Street, Wellington

Time	Agenda item	Discussion leade
9:00 am	Arrival (coffee/tea provided)	NO
9.05 am	Welcome and introductions	Chair
9.10 am	Declarations of conflicts of interest	Chair /All
9 15 am	Action points	Chair /All
9.20 am	 Minutes review Record of the previous Diabetes Subcommittee meeting, 10 October 2016 Review of relevant diabetes minutes from PTAC since previous Diabetes Subcommittee meeting 	Chair /All
9:35 am	Correspondence and Matters Arising Letter from NZSSD Insulin priming Insulin glargine long acting (Toujeo) 	Chair /All
9 45 am	1. Therapeutic Group Review	Chair /All
10.30 am	Morning tea (provided)	
11.00 am	Therapeutic Group Review continued	Chair /All
12.00 pm	Lunch (provided)	
12.30 pm	CGM and FGM technology overview and Freestyle Libre Flash Glucose Monitoring application	Main: Nic Crook 2 nd : Esko Wiltshire (paediatric view)
1 15 pm	Antidiabetic Agents Discussion including updated data for cardiovascular benefit and access criteria discussion	Bruce Small
2 00 pm	Afternoon tea (provided)	
2.30 pm	Glucose solution (Hypopak)	Helen Lunt
3.15 pm	Any other business	Chair /All
3 30 pm	Meeting ends	

From: Withheld under section 9(2)(a)

Sent: Monday, 1 April 2019 11:48 AM To: applications <<u>applications@Pharmac.govt.nz</u>> Subject: Application for funding of Freestyle Libreville and Dexcom CGM

To whom it may concern

Please refer to the relevant Pharmac Application Manager.

I would like to make a consumer funding application for both devices listed above.

I understand there has been a pharmaceutical and clinician application made in respect of the Freestyle Libre CGM is this on the programme for discussion at the forthcoming (23/24 May) PTAC meeting?

I would like to lodge a funding application for both Can you advise what information you require given there is already an application under consideration for the Freestyle Libre?

Sincerely,

Withheld under section

Withheld under

Sent from Yahoo Mail on Android

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This footnote also confirms that this email message has been swept by MIMEsweeper for the presence of computer viruses.

www.clearswift.com

On Fri, Apr 12, 2019 at 12:00, Elena Saunders

Withheld under section 9(2)(a) > wrote:

Dear Withheld

Thanks for getting in touch with PHARMAC

As you are aware, we have received a funding application from the supplier of the Freestyle Libre Flash Glucose Monitoring System and this was considered by the Diabetes Subcommittee of PTAC at its March meeting. We have recorded your email as being in support to the supplier application.

With regards to the Dexcom G5 CGM system, we are in discussions with a number of suppliers to ensure we have the right information to support consideration of CGM systems more broadly CGM technology more generally was also reviewed by the Diabetes Subcommittee at its March meeting. Dexcom is one of the devices that was noted as part of this review. Again, we have recorded your email in support of the information we have received from the supplier of Dexcom.

The record of the Diabetes Subcommittee meeting will be made publicly available once it is finalised, this will likely be in early May. You will be able to find the record of the clinical advice we received

and keep track of the applications progress <u>here</u>. I am happy to notify you directly once it has been published if you would like?

In general, if you did wish to submit a formal funding application then the form outlining the information required is available on the PHARMAC website <u>here</u>. Please note that the information provided by the supplier includes a detailed summary of the product and available evidence, so I would encourage you to instead provide a letter or email regarding the product(s) you are interested in seeing funded by PHARMAC if you do wish to provide a submission in support of Freestyle and/or Dexcom. If you send it through to me then I would be more than happy to add it in further support to the information we have received from the relevant supplier.

Please let me know if I can provide you any further clarity.

Ngā mihi,

Elena

Elena Saunders | Therapeutic Group Manager

PHARMAC | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington Cell: Withheld under | DDI: Withheld under | P: +64 4 460 4990 | F: +64 4 460 4995 | www.pharmac.govt.nz

From: Withheld under section 9(2)(a)

Sent: Friday, 12 April 2019 12:09 pm To: Elena Saunders < Withheld under section 9(2)(a) >

Subject: Re: Application for funding of Freestyle Libreville and Dexcom CGM

Dear Elena,

Thank you for your reply. I would appreciate if you could let me know when the information becomes publicly available. I'll endeavor to keep up with the link you posted also.

I look forward to a positive outcome.

Sincerely, Withheld under section

Sent from Yahoo Mail on Android

From: Nobes, Michael S < Wi	nheld under section 9(2)(a) >	
Sent: Wednesday, 3 April 2019	7:07 pm	
To: Danae Staples-Moon <	Withheld under section 9(2)(a)	
Cc: Chalikias, Peter < Withheld	under section 9(2)(a) >; Prakash, Deepak < Withheld under section 9(2)(a)	>
Subject: RE: Requested inform	ation for FreeStyle Libre #2	19
Attachments:	Withheld under section 9(2)(ba)(i)	
Withheld under section 9(2)(ba)(i)		
Importance: High		

Dear Danae,

As previously discussed, we have provided relevant articles recently published and further real world data, including for New Zealand, for your and PTAC's interest

Please let me know if you require the Withheld under and this information in one consolidated package or have any questions

Also, could you please let us know whether there is any correspondence or outcomes from the Diabetes Sub Committee meeting held on the 19th of March and whether our application will be considered at the 23rd 24th of May PTAC meeting

Regards, Michael



Michael Nobes, Ph.D. Market Access Director ANZ Abbott Diabetes Care 666 Doncaster Rd Doncaster VIC 3108 Australia O: Withheld under F: +61398558020 M: Withheld under Withheld under section 9(2)

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 From: Nobes, Michael S < Withheld under section 9(2)(a)</td>

 Sent: Wednesday, 10 April 2019 11:47 am

 To: Danae Staples-Moon < Withheld under section 9(2)(a)</td>

 Cc: Prakash, Deepak < Withheld under section 9(2)(a)</td>

 Subject: RE: Requested information for FreeStyle Libre #2

Dear Danae,

I wanted to touch base to confirm that you received my email on the 3rd of April with relevant articles recently published and further real-world data, including for New Zealand.

Also, could you please let us know whether there is any correspondence or outcomes from the Diabetes Sub Committee meeting held on the 19th of March and whether our application will be considered at the 23rd 24th of May PTAC meeting.

If you have already handed over diabetes responsibilities, it would be great to know Eleanor's contact details.

Regards, Michael



Michael Nobes, Ph.D. Market Access Director ANZ Abbott Diabetes Care 666 Doncaster Rd Doncaster VIC 3108 Australia O: Withheld under F: +6139855-8020 M: Withheld under Withheld under section 9(2)

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Original Message From: April-Mae Marshall [mailto: Withheld under section 9(2)(a)] Sent: Wednesday, 1 May 2019 8:36 AM To: Nobes, Michael S < Withheld under section 9(2)(a) > Subject: 2019-05-01 Abbott Diagnostics Diabetes March 2019 Minutes (A1261282)

Dear Michael

Please see the attached in regards to the funding application for FreeStyle Libre Flash Glucose Monitoring system for the measurement of interstitial fluid glucose levels in individuals with type 1 diabetes advisory committee review

Regards April Mae April-Mae Marshall | Pharmacology and Therapeutics Advisory Committee Secretary

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-----Original Message-----From: Nobes, Michael S < Withheld under section 9(2)(a) > Sent: Wednesday, 1 May 2019 2:27 PM To: Elena Saunders < Withheld under section 9(2)(a) > Cc: April-Mae Marshall < Withheld under section 9(2)(a) >; Prakash, Deepak < Withheld under section 9(2)(a) > Subject: RE: 2019 05-01 Abbott Diagnostics Diabetes March 2019 Minutes (A1261282)

Dear Elena,

Thank you for provision of the 19 March 2019 PTAC Diabetes Subcommittee Minutes

As outlined in my phone message, I'm hoping to clarify 2 aspects

First, in the PTAC Diabetes Subcommittee Minutes, Pharmac indicates in 'Application Status' that the Minutes will be reviewed by PTAC at its May 2019 meeting

Is this the current status, given that in your last email to me dated 18 April, you mentioned "we have not been successful in getting the item on the agenda for the May PTAC meeting"?

Second, do you have an indicative date for when the PTAC Diabetes Subcommittee Minutes will be posted on the Pharmac website?

Kind regards, Michael

Michael Nobes, Ph.D. Market Access Director ANZ

Abbott Diabetes Care 666 Doncaster Rd Doncaster VIC 3108 Australia

O: Withheld under F: +61 3 9855 8020 M: Withheld under

Withheld under section 9(2)(a)

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Original Message From: Elena Saunders Sent: Wednesday, 1 May 2019 3:12 pm To: 'Nobes, Michael S' < Withheld under section 9(2)(a) > Cc: April-Mae Marshall < Withheld under section 9(2)(a) >; Prakash, Deepak < Withheld under section 9(2)(a) >

Subject: RE: 2019 05-01 Abbott Diagnostics Diabetes March 2019 Minutes (A1261282)

Hi Michael,

Further to our call just now, confirming the Diabetes Subcommittee minutes are now scheduled to be considered by PTAC at its May meeting. This supersedes the information I provided previously.

We hope to have the minutes posted on the PHARMAC website early next week

Ngā mihi,

Elena

Elena Saunders | Therapeutic Group Manager

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 From: Nobes, Michael S <</td>
 Withheld under section 9(2)(a)
 >

 Sent: Friday, 3 May 2019 5:29 PM
 To: Elena Saunders <</td>
 Withheld under section 9(2)(a)
 >

 Cc: April Mae Marshall
 Withheld under section 9(2)(a)
 >
 >

 Cwitcheld under section 9(2)(a)
 >
 >
 >

 Subject: RE: 2019 05-01 Abbott Diagnostics Diabetes March 2019 Minutes (A1261282)
 Importance: High

Dear Elena,

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

If possible, could you please revert with the expected date for publication of the Minutes on the PHARMAC website.

Also, could you please update your filing nomenclature and contact details to reflect <u>Abbott</u> <u>Diabetes Care</u> as the business for ongoing reference to FreeStyle Libre rather than Abbott Diagnostics, since these are separate business units within the global Abbott Laboratories company

Regards, Michael



Michael Nobes, Ph.D. Market Access Director ANZ Abbott Diabetes Care 666 Doncaster Rd Doncaster VIC 3108 Australia O: Withheld under F: +613 9855 8020 M: Withheld under Withheld under section 9(2)

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From: April-Mae Marshall

Sent: Monday, 6 May 2019 2:23 pm

To: Withheld under section 9(2)(a) < Withheld under section 9(2)(a) >

Cc: Elena Saunders < Withheld under section 9(2)(a) >; Withheld under section 9(2)(a)

< Withheld under section 9(2)(a) >; ' Withheld under section 9(2)(a) ' < Withheld under section 9(2)(a)

Subject: RE: 2019-05-01 Abbott Diagnostics (Abbott Diabetes Care) Diabetes March 2019 Minutes (A1261282)

Dear Michael

Thank you for your response to our email regarding the Diabetes Subcommittee March 2019 Minutes.

As we noted in our letter of 1 May, we provided these minutes in order for you to advise us of any specific content that you felt should be withheld from publication. As also noted, in deciding whether to withhold any sections of this minute from public release, we follow the rules for withholding information specified in the Official Information Act 1982 (OIA).

Minutes are a reflection of what is discussed at a meeting by our members and are approved by the Chair as a record of the meeting, and as such it is not possible to amend them.

After considering Abbott's requests and discussing these with our legal advisors we have concluded that there are no grounds to withhold relevant sections under the OIA.

As we mentioned in our letter, your comments in relation to the public release of this minute do not prevent you from commenting on it or providing further information for consideration by PHARMAC at a later date.

We will notify you once the minute is published.

We have noted the change from Abbott Diagnostics to Abbott Diabetes Care for further communications.

Kind regards April Mae Marshall

April-Mae Marshall | Pharmacology and Therapeutics Advisory Committee Secretary

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 From: Nobes, Michael S < Withheld under section 9(2)(a)</td>
 >

 Sent: Monday, 13 May 2019 12:14 PM
 To: Elena Saunders < Withheld under section 9(2)(a)</td>
 >

 Cc: April-Mae Marshall < Withheld under section 9(2)(a)</td>
 >
 >

 Kithheld under section 9(2)(a)
 >
 >

 Withheld under section 9(2)(a)
 >; Chalikias, Peter < Withheld under section 9(2)(a)</td>
 >

Subject: RE: 2019-05-01 Abbott Diagnostics Diabetes March 2019 Minutes (A1261282)

Hi Elena,

Can I please confirm that the Diabetes Subcommittee minutes are still scheduled to be considered by PTAC at its May meeting?

I've noted the posted agenda below and assume this is only the list of applications rather than other agenda items such as consideration of subcommittee minutes

Applications

The **May 2019** PTAC meeting will review the applications below. Note this is draft and subject to change:

- Buprenorphine transdermal patches (persistent moderate/severe pain)
- CDK4/6 inhibitors (HR positive HER-2 negative advanced breast cancer 1st & 2nd endocrine agent)
- Everolimus (HR positive, HER-2 negative advanced breast cancer)
- Nab-Paclitaxel (metastatic breast cancer)
- Capsaicin Cream 0.075% (cannabinoid hyperemesis syndrome)
- · Baclofen oral solution (muscle relaxant)
- Prucalopride succinate (chronic constipation)
- Methylnaltrexone, subcutaneous injection (Opioid-induced constipation in patients - outside of palliative care)
- Glycomacropeptide (PKU phenylketonuria)
- Fluticasone foroate/umeclidinium/vilanterol (COPD)
- · Fomepizole (Methanol and ethylene glycol poisoning)

Regards, Michael

Michael Nobes, Ph D. Market Access Director ANZ

Abbott Diabetes Care 666 Doncaster Rd Doncaster VIC 3108 Australia

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From: Elena Saunders

Sent: Monday, 13 May 2019 12:18 pm

To: 'Nobes, Michael S' < Withheld under section 9(2)(a)

 Cc: April-Mae Marshall
 Withheld under section 9(2)(a)
 >; Prakash, Deepak

 Withheld under section 9(2)(a)
 >; Chalikias, Peter
 Withheld under section 9(2)(a)

Subject: RE: 2019 05-01 Abbott Diagnostics Diabetes March 2019 Minutes (A1261282)

Hi Michael,

Yes, your understanding is correct. The Subcommittee minutes will be considered by PTAC at its May meeting.

Elena

Elena Saunders | Therapeutic Group Manager

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From: Nobes, Michael S < Withheld under section 9(2)(a) >
Sent: Monday, 27 May 2019 3:10 PM
To: Elena Saunders < Withheld under section 9(2)(a) >
Cc: April-Mae Marshall < Withheld under section 9(2)(a) >; Prakash, Deepak
< Withheld under section 9(2)(a) >; Chalikias, Peter < Withheld under section 9(2)(a) >
Subject: RE: 2019-05-01 Abbott Diagnostics Diabetes March 2019 Minutes (A1261282)

Hi Elena,

Can you advise when we'll be informed of last week's PTAC meeting outcome?

Is this provided to sponsors prior to circulation of meeting minutes?

Many thanks for your guidance on this matter

Kind regards, Michael



Michael Nobes, Ph.D. Market Access Director ANZ Abbott Diabetes Care 666 Doncaster Rd Doncaster VIC 3108 Australia O: Withheld under F: +61 3 9855 8020 M: Withheld under Withheld under section 9(2)



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From: April Mae Marshall	< Withheld under sectio	n 9(2)(a) >
Sent: Monday, 27 May 20	19 2:26 PM	
To: Nobes, Michael S <	Vithheld under section 9(2)(a)	× 4
Cc: Elena Saunders <	Withheld under section 9(2)(a)	>; Prakash, Deepak
< Withheld under section 9(2)	(a) >; Chalikias, Peter <	Withheld under section 9(2)(a) >
Subject: RE: 2010.05.01 A	hhatt Diagnostics Diabate	March 2010 Minutos (A1261

Subject: RE: 2019-05-01 Abbott Diagnostics Diabetes March 2019 Minutes (A1261282)

Hi Michael

We do not usually share the PTAC record in regards subcommittee meeting recommendation discussions prior to publication. This would only be done if the record of the PTAC meeting held commercially sensitive information that required an applicant consideration. Once the PTAC minute is written we will consider if this is necessary.

Letters to applicants will be sent out the end of July with publication of the minutes scheduled for 16 August 2019.

Kind regards April-Mae Marshall

April Mae Marshall | Pharmacology and Therapeutics Advisory Committee Secretary

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From: Nobes, Michael S < Withheld under section 9(2)(a) >
Sent: Monday, 27 May 2019 4:31 pm
To: April-Mae Marshall < Withheld under section 9(2)(a) >
Cc: Elena Saunders < Withheld under section 9(2)(a) >; Prakash, Deepak
Withheld under section 9(2)(a) >; Chalikias, Peter < Withheld under section 9(2)(a) >
Subject: RE: 2019 05-01 Abbott Diagnostics Diabetes March 2019 Minutes (A1261282)

Thank you, April Mae

We'll look forward to the letter end of July.

Cheers, Michael



Michael Nobes, Ph.D. Market Access Director ANZ Abbott Diabetes Care 666 Doncaster Rd Doncaster VIC 3108 Australia O: Withheld under

F: +61 3 9855 8020

M: Withheld under Withheld under 9(2)



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From: April Mae Marshall < Withheld under section 9(2)(a)

Sent: Thursday, 1 August 2019 1:55 PM

To: Nobes, Michael S < Withheld under section 9(2)(a)

Cc: Elena Saunders < Withheld under section 9(2)(a) >; Prakash, Deepak

< Withheld under section 9(2)(a) >; Chalikias, Peter < Withheld under section 9(2)(a)

Subject: RE: 2019-05-01 Abbott Diagnostics Diabetes March 2019 Minutes (A1261282)

Dear Michael

Please note the May 2019 PTAC record of the meeting (minutes) has been published. It can be seen @ https://www.pharmac.govt.nz/assets/ptac-minutes-2019-05.pdf.

Kind regards April Mae

April Mae

April-Mae Marshall | Pharmacology and Therapeutics Advisory Committee Secretary

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From: Nobes, Michael S < Withheld under section 9(2)(a) > Sent: Thursday, 29 August 2019 4:09 PM To: Elena Saunders < Withheld under section 9(2)(a) > Cc: Prakash, Deepak < Withheld under section 9(2)(a) > Subject: RE: 2019 05-01 Abbott Diagnostics Diabetes March 2019 Minutes (A1261282)

Hi Elena,

I wanted to reach out to you to understand the next steps for review of FreeStyle Libre given the PTAC minutes regarding the Diabetes Subcommittee advice

"The Committee considered that PTAC and its Subcommittee's may not have the technical expertise to appropriately assess these devices and recommended that PHARMAC consider aligning its assessment of community devices such as continuous glucose monitoring technology and insulin pumps with the assessment framework currently being developed for hospital devices, particularly to ensure patient safety, usability, lifespan and technology upgrades were appropriately considered and managed."

Kind regards, Michael



Michael Nobes, Ph.D. Market Access Director ANZ Abbott Diabetes Care 666 Doncaster Rd Doncaster VIC 3108 Australia O: Withheld under F: +61398558020 M: Withheld under Withheld under section 9(2)



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From: Elena Saunders < Withheld under section 9(2)(a) > Sent: Thursday, 29 August 2019 3:03 PM To: Nobes, Michael S < Withheld under section 9(2)(a) > Cc: Prakash, Deepak < Withheld under section 9(2)(a) > Subject: RE: 2019 05-01 Abbott Diagnostics Diabetes March 2019 Minutes (A1261282)

Subject. NE. 2019 05 01 Abbott Diagnostics Diabetes March 2015 Min

Hi Michael,

Thanks for getting in touch.

We're evaluating options at the moment, so I can't give any guarantees. At this point the next stage in the process would be for the system to be ranked alongside the other options we have for investment within our fixed combined pharmaceutical budget (CPB). I am also looking at the possibility of seeking specialist advice in addition to that which we have received from PTAC and its Subcommittee to address some of the points noted below. If we do proceed with that approach I will let you know

Ngā mihi,

Elena

Elena Saunders | Therapeutic Group Manager

PHARMAC PO Box	10 254 Level 9, 40 Mercer Street, Wellington	
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Keep in touch! If you would like to receive consults and communications from PHARMAC please sign up here