IN – CONFIDENCE AUSTRALIAN NATIONAL ADVISORY COUNCIL ON ALCOHOL AND OTHER DRUGS

Monday 6 March 2023 – Tuesday 7 March 2023 Location: Rydges, Canberra

Agenda Item 3

Presentation on Nicotine Vaping Product Reform

RECOMMENDATIONS

That Members:

- NOTE the presentation Deputy Secretary Adjunct Professor John Skerritt and Principal Legal and Policy Adviser Bridget Gilmour-Walsh from the Department's Health Products Regulation Group which includes the Therapeutic Goods Administration (TGA).
- DISCUSS

PURPOSE

To provide a presentation, updating the Council on the TGA's proposed reforms to the regulation of nicotine vaping products.

SUMMARY OF ISSUES OR INFORMATION FOR DISCUSSION

ANACAD members have expressed concern at the public discourse around young people vaping and the potential regulatory reforms proposed by the TGA.

ANACAD have requested this item be added to the agenda.

BACKGROUND

On 30 November 2022, Minister Butler announced that the TGA would be releasing a consultation paper to seek public comment on potential reforms to the regulation of nicotine vaping products (NVPs) in Australia.

These potential reforms are aimed at preventing children and adolescents from accessing NVPs, while supporting access to products of known composition and quality for smoking cessation with a doctor's prescription.

The public consultation was open until 16 January 2023.

From: ANACAD

To: Erin Lalor; Georgie Harman; Jack Nagle (jack@realdrugtalk.com.au); Joe Coyte; Nicky Bath

(nicky.bath@lgbtiqhealth.org.au); Nicole Lee; Rebecca Lang; Robert Ali; Steve Allsop

Cc: ANACAD

Subject: Providing feedback on potential reforms to the regulation of nicotine vaping products [SEC=OFFICIAL]

Date: Friday, 13 January 2023 12:43:29 PM

Attachments: image001.png

Good afternoon ANACAD members

Further to the suggestion from members that the TGA be invited to present to ANACAD on the potential reforms to the regulation of nicotine vaping products, we have followed up and can confirm that the TGA will be available and that this item will be included on the agenda for the 6-7 March ANACAD meeting.

Given the timelines for a public submission on the TGA's consultation paper and the sensitivities of the issues being discussed, we propose that ANACAD members provide feedback directly to the TGA at the March meeting. This feedback can then be formally provided to the Minister as part of the post-meeting summary of advice.

Should individual members wish to provide their own input to the TGA, <u>submissions</u> close at COB on Monday 16 January.

We are in the process of finalising a draft agenda for the 6-7 March ANACAD meeting and we will endeavour to provide this to members as soon as possible. The Secretariat will also be in touch within the coming weeks regarding your travel arrangements.

Kind regards,

S22 (She/Her)

ANACAD Secretariat

Australian Government Department of Health and Aged Care

T: s22 | E: anacad@health.gov.au Location: Level 8, 595 Collins Street, VIC 3000 GPO Box 9848, Canberra ACT 2601, Australia

If you are concerned about your own or someone else's alcohol or other drug use, contact the National Alcohol and Other Drug Hotline on **1800 250 015** or visit <u>drughelp.gov.au</u>. The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

From: <u>Dr. Nicole Lee</u>
To: <u>ANACAD</u>

Cc: Erin Lalor; Georgie Harman; Jack Nagle (jack@realdrugtalk.com.au); Joe Coyte; Nicky Bath

(nicky.bath@lgbtiqhealth.org.au); Rebecca Lang; Robert Ali; Steve Allsop;

Subject: Re: Our latest drug panic (spoiler alert, its about vaping) [SEC=OFFICIAL]

Date: Tuesday, 10 January 2023 4:22:33 PM

Sorry I didn't get to this by yesterday. I underestimated the mountain of things waiting for me after the break!

I agree with Bec's comments below.

My thoughts below, which will undoubtedly need toning down for an ANACAD submission. They are based on the principles of:

- 1. harm reduction we should be taking a harm reduction approach to vaping as with all drugs which aligns to the NDS
- 2. our understanding of black market drivers we know that reducing access to things that are desirable just results in a black market or people using/developing more dangerous substances
- 3. sensibly balancing reduction of access and uptake among children and young people with *increasing* access for adults who want to stop smoking (and in my view adults who want to use nicotine recreationally). Regulation that is too severe risks making smoking more attractive and of the two the evidence is clear that vaping is significantly less harmful than smoking.

I think we should make the point somewhere that we support with regulation of nicotine, but historically the pseudo-regulation of just banning or severely restricting any substance has significant unintended consequences that need to be considered and monitored.

The media and others have exaggerated the prevalence and harms of vaping among young people contrary to the evidence. And I think we should encourage the TGA to ensure an evidence based policy. We want to avoid making policy driven by unsubstantiated anecdotal evidence or selective interpretations of the data.

Nicotine per se is a substance of dependence but beyond that has relatively few harms in comparison to smoking. Smoking harms such as cancer are nearly entirely from the other chemicals in both tobacco and cigarettes, and not nicotine, and that needs to be taken into account in regulation within a harm reduction approach.

I just point out that they are planning to double down on an approach that in the consultation document they have indicated is not working, by only considering the prescription only option: "Nevertheless, it is apparent that the regulations are not achieving their intended purpose. It is clear that a black market of NVPs exists, and that NVPs are being readily accessed unlawfully by children and adolescents, and by adults for 'recreational' purposes (i.e. not for smoking cessation), without a prescription." page 8

We should also make the point that the 'gateway' theory of drug use has been abandoned for other drugs and there's no reason it should be applied to vaping. There's no evidence that vaping results in young people who are not at risk of smoking tobacco to take up smoking.

Any regulation needs to take a harm reduction approach and there is little attention to this in the TGA's briefing document or the options proposed (as in Bec's comment below). The focus should be on safe supply to adults who prefer vaping to smoking, which should be encouraged, rather than on enforcement. There is a legitimate and effective use for

vaping products. Measures to reduce access by young people should not inadvertently put barriers up for adults who want to use nicotine vapes.

Border control

The prescription only approach has already reduced accessibility for people using vaping for tobacco harm reduction which increases the risk of a thriving black market as identified in the briefing paper.

"...anecdotally we have been advised that personal importation is a major source of access to NVPs." page 8. Some estimates are that 95% of vaping is through non prescription routes.

I think worth pointing out here that border control efforts with other illicit drugs is hugely costly with, typically, very little impact on the black market and virtually no impact on use. (There will be a reference of a paper somewhere).

Making vaping products more available for adults is likely to reduce the black market and have little impact on prevalence or incidence of use. The adults currently using to quit smoking who are largely accessing vaping products through 'personal importation' (ie illegally) will access through regulated venues such as pharmacies as with other NRT if more available. Vaping should be treated like any other NRT for regulatory purposes as a general principle.

Quality

There is evidence that flavours that appeal to smokers (e.g. tobacco) encourage uptake of vaping instead of smoking among adults. Flavours would need to be part of the pre market assessment for safety. Again, banning anything tends to increase the black market and possibly even experiments with home mixing of flavours so it is better to make them available and control quality, safety and access.

Having said that... Any hazardous ingredients not required should be banned. There is no reason for smokers trying to quit or reduce smoking to have anything other than palatable nicotine. It's unlikely a black market will arise by banning hazardous ingredients. It's the approach in the UK and they have a banned ingredients list.

There is no obvious need to introduce plain packaging at the moment or provide additional warning labels. If prescription only they should comply with labelling for any other other prescription product. If they are broadened beyond prescription only (for example an over the counter pharmacy product like other NRTs) then packaging and labelling should be in line with other NRT products.

Cheers

Nicole

On 6 Jan 2023, at 3:04 pm, ANACAD wrote:

Good afternoon ANACAD,

Many thanks to Bec for providing initial comments for the ANACAD submission into TGA's

consultation on nicotine vaping products (NVPs). If anyone else would like to provide additional comments this is a reminder to please do so by **COB Monday 9 January 2023.**

I am aware that many of you are on leave and unavailable to contribute at this time, however if you were hoping to contribute and will be unable to meet the deadline above, please be in touch to discuss as soon as possible.

Kind regards,

S22 (She/Her) ANACAD S22

Australian Government Department of Health and Aged Care

T: s22 | E: anacad@health.gov.au Location: Level 8, 595 Collins Street, VIC 3000 GPO Box 9848, Canberra ACT 2601, Australia

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From: Rebecca Lang < rebecca.lang@qnada.org.au >

Sent: Thursday, 22 December 2022 2:24 PM

To: ANACAD <<u>ANACAD@health.gov.au</u>>; Nicky Bath <<u>nicky.bath@lgbtiqhealth.org.au</u>>; Joe Coyte <<u>joe@theglencentre.org.au</u>>; Steve Allsop <<u>S.Allsop@curtin.edu.au</u>>; Dr. Nicole Lee <<u>nicole@360edge.com.au</u>>

Cc: Jack Nagle < <u>jack@realdrugtalk.com.au</u>>; Georgie Harman

<<u>Georgie.Harman@beyondblue.org.au</u>>; Robert Ali <<u>robert.ali@adelaide.edu.au</u>>; Erin Lalor <<u>Frin.Lalor@adf.org.au</u>>

Subject: RE: Our latest drug panic (spoiler alert, its about vaping) [SEC=OFFICIAL]

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Hi **S22**

Just had a closer look at the TGA consultation and offer the following thoughts for an ANACAD submission:

There is a misalignment between the problem identified by the TGA (ie people accessing nicotine vaping devices without a prescription) and the reform options identified (changes to border controls, pre-market assessment, product standards and the status of NVPs as 'therapeutic goods'. All the options for reform rely more or less on increasing enforcement efforts, with options 3 and 4 looking to widen the net for enforcement (see page 14-15, they even go so far as to suggest option 3 would be 'designed in a way to make the enforcement of the import restrictions more straightforward, and might act as a better deterrent against non-compliance). This is pretty classic prohibitionist framing in so far as the framing highlights the issue as being access to the substance, but the response is not to provide a regulated supply of the substance (noting both tobacco and nicotine replacement products are readily available) but rather a doubling down on regulation and enforcement (despite the problem being a failure of regulation in the first place).

There is an absence of consideration of harm or demand reduction as strategies in the options for reform, in fact page 5 makes explicit that regulation of vaping devices is outside the scope of the consultation (without saying why?). I imagine this relates to the narrow scope of the TGA, but it is astounding to me that despite being part of the drug policy framework in Australia for almost 40 years, our regulatory bodies don't even reference the existence of the National Drug Strategy in the paper, let alone allow for harm or demand reduction efforts in their consideration.....that's a big problem, as my understanding is the harm reduction (in certain

circumstances) potential of vaping is not in dispute – hence the availability for the purposes of smoking cessation. The thinking worth challenging (in my view) is that smoking cessation can only validly occur under the guidance of a medical professional (when the fact is loads of people stop smoking without reference to a medical professional). Why is liquid nicotine different to nicotine lozenges or gum (both of which are available in the medicines isle of the supermarket in Qld, so not even behind a counter). In that same vein, I know a few folks who use NRT as an alternative to smoking (rather than as a means to cessation), and I wonder what the case is for denying adults the choice of vaping instead of smoking?

I'm taking some long service leave from the end of today until the second week of Feb, so won't be around for the submission proper, but I note Nicole will be, so you're in good hands. Have a great festive season everyone, and I look forward to either meeting you or reconnecting in person with you in 2023 ©

Cheers

Rec

Rebecca Lang | CEO

Pronouns: she/her

QNADA | Level 20, 300 Queen Street | Brisbane Qld 4000

(07) 3023 5050 | 0408 669 590

Rebecca.Lang@qnada.org.au | www.qnada.org.au

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From: ANACAD < <u>@health.gov.au</u>>
Sent: Monday, 12 December 2022 3:45 PM

To: Nicky Bath <<u>nicky.bath@lgbtiqhealth.org.au</u>>; Joe Coyte <<u>joe@theglencentre.org.au</u>>; Steve Allsop@curtin.edu.au>; Dr. Nicole Lee <<u>nicole@360edge.com.au</u>>

Cc: ANACAD <<u>ANACAD@health.gov.au</u>>; Rebecca Lang <<u>rebecca.lang@qnada.org.au</u>>; Jack Nagle <<u>jack@realdrugtalk.com.au</u>>; Georgie Harman <<u>Georgie.Harman@beyondblue.org.au</u>>; Robert Ali <<u>robert.ali@adelaide.edu.au</u>>; Erin Lalor <<u>Erin.Lalor@adf.org.au</u>>

Subject: RE: Our latest drug panic (spoiler alert, its about vaping) [SEC=OFFICIAL] Good afternoon everyone,

We are happy for this topic to be added to the next meeting agenda for discussion early next year. We will also see if we can get someone to come along and speak to the topic. I also just wanted to let you know that the Therapeutic Goods Administration (TGA) is now seeking public comment on potential reforms to the regulation of nicotine vaping products (NVPs) in Australia (https://consultations.tga.gov.au/medicines-regulation-division/proposed-reforms-to-the-regulation-of-nicotine-vap/). I have attached the consultation paper for your information.

This consultation will be open until <u>COB 16 January 2023</u>. The Secretariat can support the Council, or a Council Working Group, if you would like to develop a submission.

Input would be needed by **COB Monday 9 January 2023** to allow time for any collation that may be required, and final Council clearance.

Kind regards,

S22 (She/Her) ANACAD S22

Australian Government Department of Health and Aged Care

T: \$22 | E: anacad@health.gov.au Location: Level 8, 595 Collins Street, VIC 3000

GPO Box 9848, Canberra ACT 2601, Australia

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From: Nicky Bath < nicky.bath@lgbtiqhealth.org.au>

Sent: Thursday, 8 December 2022 8:04 AM

To: Joe Coyte <<u>joe@theglencentre.org.au</u>>; Steve Allsop@curtin.edu.au>; Dr. Nicole Lee <<u>nicole@360edge.com.au</u>>

Cc: ANACAD , Rebecca Lang , Jack Nagle , Georgie Harman , Robert Ali , Georgie Harman@beyondblue.org.au>,

Subject: RE: Our latest drug panic (spoiler alert, its about vaping) [SEC=OFFICIAL]

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Hi there

Yes very much in support of this thank you.

Kind regards

Nicky

Nicky Bath, Chief Executive Officer - Pronouns: She/Her/Hers

If you would like to book a meeting, or you have an urgent request, please contact Sharyn Munro, Executive Assistant to Nicky Bath Email: sharyn.munro@lgbtiqhealth.org.au Mobile: 0408 266 795

Switch: 02 7209 6301 | **Mobile**: 0432 328 706 | **Address:** Gadigal Land of the Eora Nation, Suite 2101, Level 21, 233 Castlereagh Street, Sydney NSW, 2000 | **email**:

nicky.bath@lgbtiqhealth.org.au | Website: www.lgbtiqhealth.org.au | Twitter: @LGBTIQHealthAu | Facebook: https://www.facebook.com/LGBTIQHealthAu/

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From: Joe Coyte < joe@theglencentre.org.au > Sent: Thursday, 8 December 2022 4:41 AM

To: Steve Allsop@curtin.edu.au>; Dr. Nicole Lee <<u>nicole@360edge.com.au</u>>

Cc: ANACAD <<u>ANACAD@health.gov.au</u>>; Rebecca Lang <<u>rebecca.lang@qnada.org.au</u>>; Jack Nagle <<u>jack@realdrugtalk.com.au</u>>; Georgie Harman <<u>Georgie.Harman@beyondblue.org.au</u>>; Nicky Bath <<u>nicky.bath@lgbtiqhealth.org.au</u>>; Robert Ali <<u>robert.ali@adelaide.edu.au</u>>

Subject: RE: Our latest drug panic (spoiler alert, its about vaping) [SEC=OFFICIAL]

I agree that it should be added to the Agenda of the next ANACAD meeting and relevant person from the Dept should be invited to attend.

Joe

Kind Regards,

Joe Coyte

Executive Director

The Glen for Men and The Glen for Women Centres

M 0401 673 744

Email - joe@theglencentre.org.au

Please note: We work flexibly at The Glen Group. You may receive emails from me at all times of day or night – I don't expect that you will read, respond to or action my communications outside your usual work pattern. I hope you have a great day.

From: Steve Allsop < S.Allsop@curtin.edu.au > Sent: Wednesday, 7 December 2022 9:20 AM
To: Dr. Nicole Lee < nicole@360edge.com.au >

<<u>nicky.bath@lgbtiqhealth.org.au</u>>; Robert Ali <<u>robert.ali@adelaide.edu.au</u>>

Subject: RE: Our latest drug panic (spoiler alert, its about vaping) [SEC=OFFICIAL]

Of course in Sept was meant to be in Dept!

From: Dr. Nicole Lee <nicole@360edge.com.au>
Sent: Tuesday, 6 December 2022 9:41 AM
To: Steve Allsop@curtin.edu.au>

Cc: ANACAD <<u>ANACAD@health.gov.au</u>>; Rebecca Lang <<u>rebecca.lang@qnada.org.au</u>>; Jack Nagle <<u>jack@realdrugtalk.com.au</u>>; Georgie Harman <<u>Georgie.Harman@beyondblue.org.au</u>>; Joe Coyte <<u>joe@theglencentre.org.au</u>>; Nicky Bath (<u>nicky.bath@lgbtiqhealth.org.au</u>) <<u>nicky.bath@lgbtiqhealth.org.au</u>>; Robert Ali <<u>robert.ali@adelaide.edu.au</u>>

Subject: Re: Our latest drug panic (spoiler alert, its about vaping) [SEC=OFFICIAL] that is a very good idea

On 6 Dec 2022, at 12:40 pm, Steve Allsop@curtin.edu.au> wrote:

I wonder if those involved in the development of related strategy in sept could come to meeting ${\sf S}$

On 6 Dec 2022, at 9:34 am, Dr. Nicole Lee < nicole@360edge.com.au > wrote:

I think we should be providing advice on this area to the Minister, so I would be in favour of discussing it at a meeting. There is a lot of misinformation and the federal and state Ministers and decision makers are taking much of it on without good advice or consideration of the evidence.

Nicole

On 6 Dec 2022, at 12:05 pm, ANACAD <<u>ANACAD@health.gov.au</u>> wrote: Hi Bec

Thanks for sharing and starting this conversation. If this is something ANACAD would like to discuss at the next meeting we can look at adding it to the agenda once meeting details have been established.

Otherwise if ANACAD would like to provide advice to the Minister out of session this can also be done.

Kind regards,

S22 (She/Her)
ANACAD S22

Australian Government Department of Health and Aged Care

T: s22 | E: anacad@health.gov.au Location: Level 8, 595 Collins Street, VIC 3000 GPO Box 9848, Canberra ACT 2601, Australia

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From: Rebecca Lang < rebecca.lang@qnada.org.au >

Sent: Friday, 2 December 2022 1:46 PM

To: Steve Allsop <<u>s.allsop@curtin.edu.au</u>>; Jack Nagle <<u>jack@realdrugtalk.com.au</u>>; Georgie Harman <<u>Georgie.Harman@beyondblue.org.au</u>>; Joe Coyte <<u>joe@theglencentre.org.au</u>>; Nicky Bath (<u>nicky.bath@lgbtiqhealth.org.au</u>) <<u>nicky.bath@lgbtiqhealth.org.au</u>>; Nicole Lee <<u>Nicole@360edge.com.au</u>>; Robert Ali <<u>robert.ali@adelaide.edu.au</u>>

Cc: ANACAD < ANACAD@health.gov.au >

Subject: Our latest drug panic (spoiler alert, its about vaping)

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe. Hi all

I read the article (link below) with some alarm this morning on guardian australia. I don't want to minimise the concern around young people vaping, but this article, along with a few others I've read recently on the ABC website are definitely trending towards a drug panic kind of coverage that leans towards the 'won't someone think of the children' tone.

In this one, dad's a GP who is now 'giving' his son '2 cigarettes a day' as supposed harm reduction for his vaping dependence. Mum throws in some classic internalised stigma – talking about how great her son did before he vaped and talking about his attempts to stop as him being 'clean from vaping' (ps, clean from anything is not a thing anymore).

The reality is that at least part of the blame for the relative ease with which young people can access sweet flavoured vapes that contain nicotine can be attributed to the prohibitionist choice of the last Health Minister to limit nicotine liquids to prescription only. This decision provided space for the unregulated market to meet the demand from adults who prefer to vape (or are trying to stop smoking), and unregulated markets are less discerning than regulated ones, with the entirely predictable result that the nicotine on the unregulated market is now more available and potent than that in the regulated one and is being sold to people who should not have access.

I note this article says the current Health Minister is intending to refer this back to the TGA for further consideration — I think we need to provide advice to the effect that further restrictions will likely only make the problem worse and we'll end up criminalising more people.

https://www.theguardian.com/australia-news/2022/dec/02/ive-lost-my-children-to-vaping-the-tragic-stories-behind-the-soaring-rates-of-youth-addiction

Not sure about the TGA timeframes, so maybe this can wait until our meeting in early 2023, or write to the Minister to flag our interest in helping on this one? Cheers

Bec

Rebecca Lang | CEO

Pronouns: she/her

QNADA | Level 20, 300 Queen Street | Brisbane Qld 4000

(07) 3023 5050 | 0408 669 590

Rebecca.Lang@gnada.org.au | www.gnada.org.au

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From: GILMOUR-WALSH Bridget

To: Scott Rudkin

 Cc:
 \$22
 ; \$22

 Subject:
 RE: SAABI [SEC=OFFICIAL]

 Date:
 Friday, 16 December 2022 6:38:44 PM

Attachments: <u>image005.png</u> <u>image006.png</u>

image002.png

Hi Scott

In relation to a possible webinar re the consultation, we were not intending to hold one given proximity with the holiday period. Note that no decision has been made to implement any reforms and the details of how any option might be implemented have not been fully worked through. We would welcome you making a formal submission on the consultation paper, including your views as to what will be workable and effective. However, if you have questions that need to be answered to submit a consultation response, we would be happy try to answer them. It would be best if you could send any questions through to the consultation email box (NVP@Health.gov.au). However, for transparency reasons, we would want your agreement to be able to publish the questions and answers.

s22

Kind regards

Bridget

Dr Bridget Gilmour-Walsh Principal Legal and Policy Adviser

Regulatory Legal Services | Health Products Regulation Group Australian Government, Department of Health and Aged Care T: 02 6289 4290 | E: bridget gilmour-walsh@health.gov au

Location: Scherger Drive 2.N.119

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: Scott Rudkin <scott@mysaabi.com>
Sent: Thursday, 8 December 2022 1:32 PM

To: GILMOUR-WALSH, Bridget < Bridget.GILMOUR-WALSH@Health.gov.au>

Subject: Re: SAABI [SEC=OFFICIAL]

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Thank you.

Sent from my iPhone

On 8 Dec 2022, at 12:01 pm, GILMOUR-WALSH, Bridget < Bridget.GILMOUR-WALSH@health.gov.au> wrote:

Hi Scott

A quick note to acknowledge that I've received your email and will be back in touch about this sometime next week.

Kind regards

Bridget

Dr Bridget Gilmour-Walsh Principal Legal and Policy Adviser

Regulatory Legal Services | Health Products Regulation Group Australian Government, Department of Health and Aged Care T: 02 6289 4290 | E: bridget.gilmour-walsh@health.gov.au

Location: Scherger Drive 2 N.119

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From: Scott Rudkin < scott@mysaabi.com>
Sent: Monday, 5 December 2022 3:46 PM

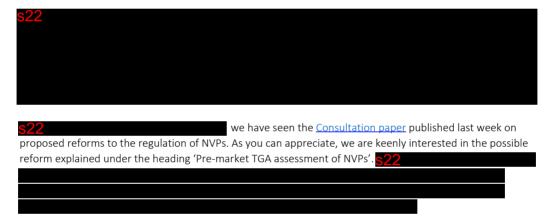
To: GILMOUR-WALSH, Bridget < Bridget.GILMOUR-WALSH@Health.gov.au >

Subject: SAABI

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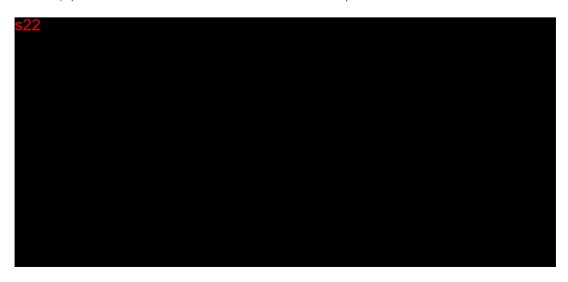
Dear Dr Gilmour-Walsh,

I hope this finds you well.



Given the clear significance of this proposed reform for Saabi we, as I am sure many others, would very much appreciate an opportunity to participate in a web seminar/other open forum including with the option for questions and answers. There are aspects of the proposed reforms which would benefit from further clarification and discussion.

We would therefore be most grateful if you could please advise whether the TGA is hosting such a seminar/open discussion forum before the close of the consultation period.





Kind Regards Scott Rudkin Director



scott@mysaabi.com +61 0408 952 016 WWW.MYSAABI.COM

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