s 22(1) [redacted]

From: [redacted]
Sent: Tuesday, 27 June 2017 5:28 PM
To: [redacted]
Cc: [redacted]
Subject: RE: Low risk ERIC paper [SEC=UNCLASSIFIED]
Attachments: ERIC paper - Consultation analysis - Low risk products (2) - June 2017 JS.docx

Importance: High

Looks good – there is only one part under homeopathy where more explanation is needed – see attached.

[redacted]
Department of Health

(The Health Products Regulation Group comprises the Therapeutic Goods Administration and the Office of Drug Control)

PO Box 100 Woden ACT 2606 Australia
Phone: [redacted]
Email: [redacted]

From: [redacted]
Sent: Tuesday, 27 June 2017 2:41 PM
To: [redacted]
Cc: [redacted]
Subject: RE: Low risk ERIC paper [SEC=UNCLASSIFIED]
Importance: High

[redacted]

Please find attached the reworked paper. I have incorporated your changes and added the additional material you requested. I too am cognisant of appearing to go with the most "popular" option. While this is not the case, it is inevitable of course that some of the intended directions will also have received the most external support, and so I have attempted strike a balance of measures and rationales. More detail can of course be covered verbally at the meeting, bearing in mind that the "next steps" discussion groups are happening in parallel.

I am a little concerned about targeting late July for coming back to ERIC with firm policy proposals. This is the new timeframe for informing the Minster of the consultation outcomes and I'm not sure the timing reflects the necessary order of events. But in any case, I would like a little flexibility since some will be more straightforward than others and we might be able to pursue them independently. There may be one or two firm proposals that will be ready in late July, and I have added comments to this effect in the paper.

For your comment/clearance please.

Thanks

[redacted]

From: [redacted]
Sent: Monday, 26 June 2017 1:09 PM
To: [redacted]

Cc: [redacted]
Subject: RE: Low risk ERIC paper [SEC=UNCLASSIFIED]
Importance: High

[redacted]

I think this one needs a bit more work.

It can still make the Friday meeting if you lodge it by COB tomorrow, please.

[redacted]

[redacted]

[redacted]

Department of Health

(The Health Products Regulation Group comprises the Therapeutic Goods Administration and the Office of Drug Control)

PO Box 100 Woden ACT 2606 Australia
Phone [redacted]
Email: [redacted]

From: [redacted]
Sent: Monday, 26 June 2017 12:19 PM
To: [redacted]
Cc: [redacted]
Subject: Low risk ERIC paper [SEC=UNCLASSIFIED]

Hi [redacted]

Please find attached the draft ERIC low risk paper for your comment/clearance.

[redacted]

Expert Review Implementation Committee (ERIC)

Meeting: 30 June 2017

Agenda Item X: Consultation analysis – Options for the future regulation of 'low risk' products.

Sponsor: [redacted] Regulatory reforms

Recommendations:

That ERIC:

1. **NOTES** the summary of public consultation
2. **NOTES** the next steps for Options for the future regulation of 'low risk' products.

Purpose:

To provide ERIC with both the preliminary analysis of submissions to the public consultation 'Options for the future regulation of 'low risk' products' and the proposed next steps for this project.

Background:

The Government accepted the recommendations from the Expert Panel Review of Medicines and Medical Devices Regulation (MMDR) to carry out further reviews of the regulation of 'low risk' products (MMDR recommendations 14, 23 and 48).

In conducting these further reviews and developing the public consultation paper 'Options for the future regulation of 'low risk' products', the TGA Regulatory reforms team engaged TGA stakeholders as well as conducted external meetings with other APS agencies (ACCC, APVMA and FSANZ).

A facilitated internal workshop was held on 26 October 2016 to demonstrate and validate a tool to help objectively define 'low risk' products which allowed the scope of the review into low risk products to be defined.

Targeted industry consultation was conducted in November and December 2016 with ADIA, MTAA, Accord Australasia, ASMI, CMA and representative sunscreen manufacturers.

Consultation details:

COMB, MDB, MQB and PSAB have been consulted on the proposed options for products in their respective areas.

The public consultation paper was published on the TGA website for six weeks (31 March – 12 May). In addition, key stakeholders were also specifically invited to comment. These stakeholders include peak industry bodies (e.g. MTAA, ACCORD, ASMI, CMA, ADIA and Australia sunscreen manufacturers) and health professional interest groups (e.g. the Australian Medical Association, Royal Australasian College of General Practitioners and the Australasian College of Dermatologists).

Submissions received:

Total number of submissions received:

- 1028 submissions
- 963 submissions from individuals (predominantly relating to homoeopathy using various versions of a 'form' letter[1])
- 65 submissions from organisations
- 201 submissions were marked as confidential. The vast majority of these were individuals commenting on the potential reforms to homoeopathic products.

A list of organisations that responded is included in **Attachment A.**

A list of the responses from individuals has not been provided due to the large number and frequent repetitive nature of these submissions.

Analysis of consultation responses and proposed regulatory directions by category

A table of organisations that provided a submission (with key organisations highlighted) is in Attachment **A.**
A tally of responses by option for each 'low risk' product type is included in **Attachment B.**
A summary of key stakeholder submissions is included in **Attachment C.**

Broadly speaking, the key stakeholders were identified as the major industry groups, sponsors/manufacturers, healthcare professional bodies and individuals with a significant interest in the product types discussed in the consultation document.

Note that in many cases the options proposed were not mutually exclusive and several options could be implemented simultaneously for a particular product type. Despite this, many stakeholders simply indicated support for one option. This analysis needs to be read in conjunction with Attachment C.

Other than for homoeopathy, an interesting observation out of this consultation is that there was reasonable consensus between professional healthcare associations and sponsors/manufacturers of the various product types.

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[1] This large number of submissions from individuals is due to a grass roots campaign that was run against any proposed changes to the regulation of homoeopathic products. This campaign focused on Option 4 (Declare homeopathic products not to be therapeutic goods) and claimed that this option was designed to ban homeopathic products in Australia. This is clearly not the case.

Homoeopathic products

The key stakeholders were divided, with those who subscribe to homoeopathy (primarily the homeopathy and complementary industry and practitioner associations, as well as manufacturers of these products) supporting Option 1 (maintain the status quo) in conjunction with Option 2 (serious claims must be supported by scientific evidence), and those who don't (such as the RACGP, the PSA, and Australian Skeptics) supporting Option 4 (declare homoeopathic products not to be therapeutic goods).

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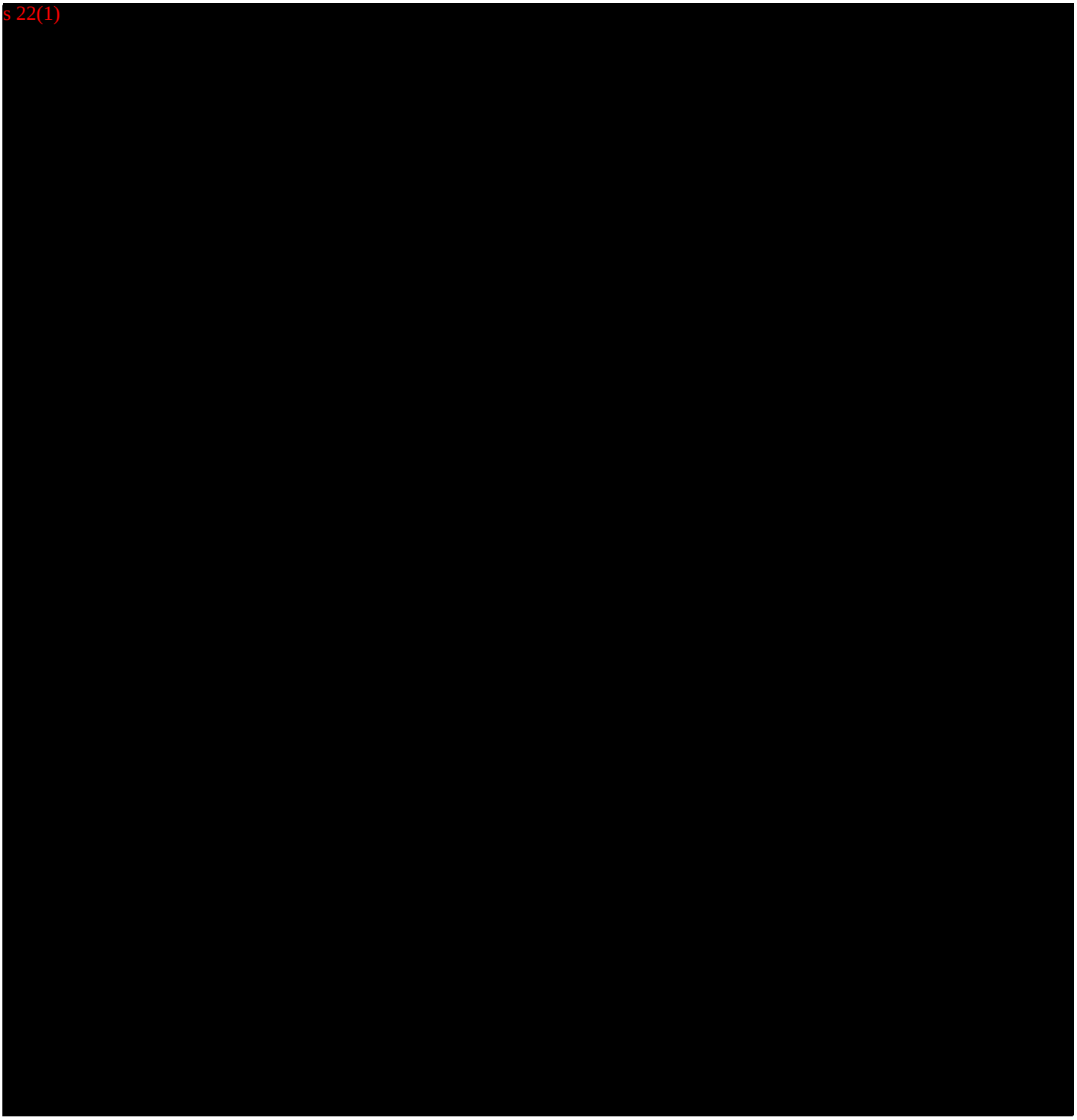

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Development of specific policy proposals

Due to the large number of product types and options presented in the consultation paper, products are being considered in categories in the next steps.

Internal working groups have been established to facilitate the development of consolidated TGA positions for the specific policy proposals. Once developed, these proposals will be brought to ERIC for endorsement prior to seeking policy approval from the Minister.

The categories and upcoming discussions with the working groups are as follows:

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- **Homoeopathic products**
  - Discussions likely to focus on how to implement Option 4 (exclude homeopathic products from the regulatory framework). Although opposed by those responding to the (misinformed) campaign, this is supported by professional healthcare provider associations. There are also broad views that such products should not be regulated under the therapeutic goods framework since the evidence base is questionable. You may need to say that products that are not actually homeopathic (i.e. contain concentrations of actives at levels greater than the 4x "homeopathic dilution" or contain animal origin substances) would remain within the TG complementary medicines framework (if they contained permitted ingredients and were manufactured under GMP) or would be policed as unapproved medicines if they did not.

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It should be noted that the above are indicative only and subject to further internal discussion with the relevant business areas.

Next steps:

1. Notifying the Minister of the consultation outcomes in late **July 2017.**
2. Subject to clearance, publication of consultation submissions and a brief response on the TGA website in late **July 2017.**
3. Further internal consultation to develop specific policy proposals for ERIC for endorsement in late **July/August**, prior to seeking Ministerial approval in **August/September.** It is possible that some of the more straightforward and/or less contentious policy proposals will be ready for consideration prior to this, subject to further internal discussions.

Contact Officer:	[redacted]	Approved by:	[redacted]
Position:	Assistant Director,	Position:	Senior Advisor, Regulatory Reforms
Phone No:	[redacted]	Phone No:	
		Mobile:	[redacted]
		Date Cleared:	

Attachments:

A. A list of all organisation stakeholders that provided a submission (key stakeholders highlighted).

	Submissions received from named organisations
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Pages 11-13 inclusive exempt in full under section 22(1) of the FOI Act

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Recommendation Forty-eight Review of certain complementary medicine products	Options	Supported	Opposed

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[redacted]

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Homoeopathic products	**Option 1 - Maintain the status quo regulation of homoeopathic products**	756	2
	Option 2 – Serious therapeutic claims must be supported by scientific evidence.	328	22
	Option 3 – Exemption from listing in the ARTG and/or GMP	83	279
	Option 4 – Declare homeopathic products not to be therapeutic goods	24	492

Pages 16-17 inclusive exempt in full under section 22(1) of the FOI Act

Homoeopathic products

Options presented for consultation	
Homoeopathic products	Option 1 - Maintain the status quo regulation of homoeopathic products
	Option 2 – Serious therapeutic claims must be supported by scientific evidence.
	Option 3 – Exemption from listing in the ARTG and/or GMP
	Option 4 – Declare homeopathic products not to be therapeutic goods

Summary of key organisation responses for Homoeopathic products

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[redacted]

Summary of key organisation responses for Homoeopathic products

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[redacted]

Summary of key organisation responses for Homoeopathic products

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[redacted]

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Pages 21-31inclusive exempt in full under section 22(1) of the FOI Act