[redacted]

From: [redacted]
Sent: Monday, 29 May 2017 11:12 AM
To: [redacted]
Subject: RE: Ministerial - MC17-009445 - Brand - Due back to TGA PARL by Tuesday 6 June 2017 [DLM=For-Official-Use-Only]
Attachments: [D17-406411] MC17-009439 - Brand - Homeopathic Medicines - 23 May 2017.tr5; [D17-408141] MC17-009439 - Brand - Homoeopathic medicines - 23 May 2017 ....tr5

Follow Up Flag: Follow up
Flag Status: Flagged

I have included a paragraph that I lifted from the ministerial information brief last week (with a few minor tweaks) – see what you think

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From: [redacted]
Sent: Monday, 29 May 2017 11:00 AM
To: [redacted]
Subject: FW: Ministerial - MC17-009445 - Brand - Due back to TGA PARL by Tuesday 6 June 2017 [DLM=For-Official-Use-Only]

I think the response to our bit should be very similar to the previous one. [redacted] seems to have used the same text.

From: [redacted]
Sent: Monday, 29 May 2017 9:07 AM
To: HPRG Parliamentary
Cc: [redacted]
Subject: Ministerial - MC17-009445 - Brand - Due back to TGA PARL by Tuesday 6 June 2017 [DLM=For-Official-Use-Only]

Morning [redacted]

Because this one is about recommendation 49 [redacted] will be best placed to take carriage and sign. I can chat with [redacted] about this, thanks!

[redacted]

[redacted]
Assistant Director
Management and Operations
Complementary and OTC Medicines Branch

[redacted]

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606 Australia
www.tga.gov.au

From: [redacted] **On Behalf Of** HPRG Parliamentary
Sent: Tuesday, 23 May 2017 12:53 PM
To: [redacted]

Cc: HPRG Parliamentary; [redacted]
Subject: Ministerial - MC17-009445 - Brand - Due back to TGA PARL by Tuesday 6 June 2017 [SEC=UNCLASSIFIED]

Dear [redacted]

We have received a Ministerial in relation to Homoeopathic Medicines. Attached is the incoming correspondence and a draft response.

I have used previously cleared words from MC17-009084 – Kent.

Could you please review/edit the draft and let us know when you have cleared.

Please note, we will need your cleared response by Tuesday 6 June.

Many thanks

[redacted]

TGA Parliamentary
Ministerial Correspondence / Ministerial Submissions: [redacted]
Ministerial Briefs/QTBs: [redacted]

Reporting and Collaborative Services Section
Regulatory Engagement & Planning Branch
Health Products Regulation Group
Mobile: [redacted]
Email: [redacted]

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606 Australia
www.tga.gov.au

[redacted]

From: Health Referrals
Sent: Friday, 12 May 2017 3:14 PM
To: MPEG Benefits
Subject: FW: PARLEC D response - FW: URGENT: Safeguard access to Homeopathic Medicines for Australians [SEC=UNCLASSIFIED]
Attachments: image002.emz

Importance: High

Categories: [redacted] to Action

MC17-009439

D Response - 20 Days - [GH] - [MedReg]

From: Minister Hunt
Sent: Friday, 12 May 2017 3:02 PM
To: Health Referrals
Subject: D response - FW: URGENT: Safeguard access to Homeopathic Medicines for Australians [SEC=UNCLASSIFIED]
Importance: High

From: [redacted]
Sent: Friday, 12 May 2017 2:54 PM
To: Minister Hunt
Subject: URGENT: Safeguard access to Homeopathic Medicines for Australians [SEC=No Protective Marking]
Importance: High

Dear Minister Hunt,

The ANPA has been representing Naturopaths in Australia since 1975.

The scope of practice of our members includes Homeopathy as a modality together with the prescribing of homeopathic remedies.

Millions across the world use homeopathy with good effect. This includes the Australian public. Countries like Canada and USA include homoeopathy in the scope of practice of naturopathic physicians. India includes homoeopathy as a distinct profession within the Ministry of Health. Switzerland and the UK include the access to homeopathy in their public health systems.

Australia is a signatory to the World Health Organisation (WHO).
The WHO recognises homeopathy and the use homeopathic medicines as a traditional health practice.

Minister Hunt we are requesting that you safeguard and ensure the full, fair and free access for all Australians to Homeopathic medicines as a fundamental personal health choice.

The TGA is considering deregistering Homoeopathic Medicines in Australia.
(see Option 4 of their most recent consultation paper on Low Risk Products.)

These moves are based on discriminatory and biased evidence presently being investigated by the Ombudsman.

Homeopathic medicines are in the very low risk category on the TGA listings as they have been shown to cause minimal harm. Any move to de-legitimise or de-register these medicines will affect the public's choice. In addition, practitioners ability to prescribe these remedies will be threatened, and there are dire consequences for the manufacturers of these medicines as well.

Australia's Health Ministry reputation internationally is at risk if these measures are enacted. The reputation of the NHMRC is already in question in regards to the processes and subsequent findings of the second NHMRC Review on Homeopathy. *This second NHMRC Review is presently under investigation with a formal complaint before the Ombudsman*. The biased findings of this review have led to the unfair denigration and discrimination of an entire bone fide profession in Australia. *The results of the first NHMRC Review were never made public.* This is a serious matter. The Health Ministry is expected to maintain transparency when it comes to reviews, consultations and findings of these processes.

We request that the results of the first NHMRC review are made public.

Minister Hunt, we urgently request your response to these two highlighted matters.

If you need any further information, please make contact.

Kind regards,

[redacted]

Tel: [redacted]
Freecall: 1800 422 885
www.anpa.asn.au

A.N.P.A.
Australian Naturopathic Practitioners Association Inc.

ANPA Office Hours:
M/W/F 9.00am-4.30pm, T/9.30am-2.30pm
Public Holidays Closed

Excellence, Leadership and Integrity in Naturopathic Health Care

Australian Government

Department of Health

Ref No: MC17-009439

[redacted]
Australian Naturopathic Practitioners Association Inc
[redacted]

Dear [redacted]

Thank you for your correspondence of 12 May 2017 to the Minister for Health and Minister for Sport, the Hon Greg Hunt MP, regarding homoeopathic medicines. The Minister has asked me to reply on his behalf.

The role of the Therapeutic Goods Administration (TGA) is to ensure that therapeutic goods available for supply in Australia are safe and fit for their intended purpose to protect the public health of consumers.

In Australia herbal products, vitamins, minerals and nutritional supplements, some aromatherapy products and certain homoeopathic products are regulated as complementary medicines under the *Therapeutic Goods Act 1989* (the Act) by the TGA. Currently in Australia, most homoeopathic medicines are generally considered to be of very low risk and are not required to be on the Australian Register of Therapeutic Goods, providing they contain ingredients more dilute than a 1,000 fold dilution of a mother tincture, do not contain substances of human origin or certain animal parts, and do not make therapeutic claims that refer to serious conditions or diseases.

In September 2016 the Government agreed to recommendations made by the Expert Review of Medicines and Medical Devices Regulation to conduct further reviews of the regulation of "low risk" products in Australia, with a view to ensuring that the level of regulatory oversight for these products is commensurate with the level of risk posed to the Australian public.

As part of this program of work, the TGA conducted an initial public consultation on a range of high level options on the possible future regulation of a variety of low risk therapeutic goods, including homoeopathic products. The options explored for all identified product types ranged from maintaining the status quo to removal from the TGA's regulatory framework altogether.

Any decision on which options will be further developed in relation to homoeopathic medicines or any other of the identified products will be made by Government. It is important to note, however, that any decision to remove products from the TGA's regulatory framework would not in itself constitute a ban on such products from being supplied in Australia. It would mean only that the requirements of the Act would no longer apply to such products, which would continue to be subject to any other relevant regulatory frameworks (such as the Australian Consumer Law).

Any new regulatory arrangements that may be specifically proposed for homoeopathic products in the coming months will require careful consideration and further public consultation. All concerned stakeholders will be given further opportunity to comment.

The National Health and Medical Research Council (NHMRC) provides evidence-based advice so Australians can make informed choices about their health care options. All health treatments, whether conventional, traditional or complementary, should be subject to a rigorous evaluation of the evidence for their effectiveness.

NHMRC uses standardised, internationally-accepted methods and quality assurance processes to ensure that evidence has been identified, appraised and interpreted in an appropriate and transparent manner and that the health advice it develops is robust and evidence-based.

I can advise that NHMRC conducted one Homoeopathy Review. The approach to the review, the evidence base and the final report are all detailed on NHMRC's website at www.nhmrc.gov.au/health-topics/complementary-medicines/homeopathy-review.

I trust this information is of assistance to you.

Yours sincerely

[redacted]

Therapeutic Goods Administration
Health Products Regulation Group
June 2017

KEEP WITH FILE COPY
- DO NOT DISPATCH-

PDR Number	**MC17-009439**
Action Officer	[redacted]
Clearance Officer	[redacted]
Division/Branch	**Regulatory Reforms**

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