[redacted]

From: [redacted]
Sent: Monday, 22 May 2017 4:09 PM
To: HPRG Parliamentary
Cc: [redacted]
Subject: RE: URGENT Information request - MB17- 002105 homeopathic medicines due TGA parliamentary COB today 22 May [SEC=UNCLASSIFIED]
Attachments: MB17-002105 : MIR for adviser - please email to DLOs - Due COB Tuesday 23 May: Homeopathic Medicine - TGA [SEC=UNCLASSIFIED]; [D17-401349]
MB17-002105-Information Request-Homeopathic Medicine (draft....tr5

Hi [redacted]

Please see our draft input

Cheers

[redacted]

Regulatory Reforms | Health Products Regulation Group
Australian Government Department of Health
[redacted]
Location: Symonston GE 05

PO Box 100, WODEN Canberra ACT 2606, Australia

The Department of Health acknowledges 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 elders both past and present.

From: [redacted] **On Behalf Of** HPRG Parliamentary
Sent: Monday, 22 May 2017 10:52 AM
To: [redacted]
Cc: [redacted]
Subject: URGENT Information request - MB17- 002105 homeopathic medicines due TGA parliamentary COB today 22 May [SEC=UNCLASSIFIED]
Importance: High

Hello [redacted]

We have received an information request on proposed changes to homeopathic medicines regulation as described in the Consultation paper on Options for the future regulation of 'low risk' products (attached). I have attempted a first draft (also attached) for further information/ edits.

To allow time for [redacted] to clear and have it to MPEG by 3pm tomorrow, I would ask for your cleared final by **COB today Monday 22 May.**

Apologies for the short turnaround , but this is due to the MO COB tomorrow.

Many thanks
[redacted]

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

MINISTERIAL INFORMATION REQUEST

MB17-002105

Date Sent to MO:<dd/mm/yy>

MPEG to Complete

MINISTER: Greg Hunt

Issue: MINISTERIAL INFORMATION REQUEST: Homeopathic Medicine

Response:

In September 2016 the Government agreed to recommendations made by the Expert Review of Medicines and Medical Devices Regulation (MMDR) 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. The paper was released on the TGA website on 31 May 2017 and closed on 12 May 2017.

As discussed in the paper, the four potential options for regulatory reform of homeopathic products are:

- Maintain the status quo regulation of homoeopathic products
- Serious therapeutic claims must be supported by scientific evidence
- Exemption from listing in the ARTG and/or GMP
- Declare homeopathic products not to be therapeutic goods

A negative grass roots campaign has been run by an organisation known as "Homeopathy Plus", calling for strong opposition to any changes to the regulation of homoeopathic products, in particular option 4 (Declare homeopathic products not to be therapeutic goods).[1] This campaign is based on the misconception that option 4 is designed to prevent consumer access to homeopathic products in the future. We estimate that in excess of 90% of the responses to the consultation (to date are in excess of 1000) are likely as a direct result of this campaign.

[1] http://homeopathyplus.com/tga-consultation-urgent-help-needed/

Option 4 is to exclude all homoeopathic products from the therapeutic goods regulatory framework. It is important to note, however, that any such move 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 these products, which would continue to be subject to any other relevant regulatory frameworks (such as the Australian Consumer Law).

Under option 4 there would need to be clearly defined conditions under which homeopathic products would be excluded from the regulatory framework. For example, the paper proposes to prevent homoeopathic products being labelled with therapeutic claims and instead requiring them to be clearly labelled as homoeopathic products with a direction for use statement such as "as directed by your healthcare practitioner". In addition, a new definition for what constitutes a 'homoeopathic' product would need to be developed to be consistent with the changed regulatory paradigm.

Any decision on which options will be further developed in relation to homoeopathic medicines will be made by Government and require careful consideration and further public consultation. All concerned stakeholders will be given further opportunity to comment.

We are currently in the process of analysing the large number of submissions received in response to the low risk consultation paper. We will be providing you with a comprehensive analysis of the results, together with some recommendations for next steps, in the coming weeks.

Background

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 (ARTG), 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.

A 'homoeopathic product/preparation/medicine' is based upon the principles of homoeopathic pharmacy 'potentisation,' which is the serial dilution and succussion of a stock. Homoeopathic products are derived from a wide variety of natural source materials, mostly plants and minerals. Some of these source materials are poisonous, for example: Atropa belladonna. The highly diluted nature of homoeopathic products is considered to render the starting materials non-toxic and therefore safe for therapeutic use.

Minister	**Greg Hunt**
PDR Number	**MB17-002105**
Issue	**MINISTERIAL INFORMATION REQUEST: Homeopathic Medicine**
Contact Officer	[redacted]
Clearance Officer	[redacted]
Division/Branch	**Medicines Regulation**

Adviser/DLO Comments:

Return for Redraft ☐