HEALTH CONSUMERS' COUNCIL
YOUR VOICE ON HEALTH

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Unit 6 Wellington Fair
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Submission to the Therapeutic Goods Administration- *Consultation: Options for The Future Regulation of 'Low Risk' Products.*

This submission is made by [redacted]
on behalf of [redacted]

May 2017

The product [redacted] wishes to raise is Homoeopathy and she requests that Option 1 be adopted and for Option 4 to be removed from the agenda.

[redacted] argues that the exclusion of Homoeopathy from the TGA's regulatory framework would be a violation of her rights as a health consumer and would seek to restrict her access to what she believes to be a safe, low-risk medicine. [redacted] believes her view is mirrored by many drug regulating authorities around the globe who also consider Homoeopathy to be 'low-risk'. Furthermore, Homeopathy is recognised by the World Health Organization (WHO) as the most popular and widely used complementary medicine worldwide which [redacted] believes further supports her argument. [redacted] is adamant that there is not sufficient justification for the TGA to abruptly change their position with only two weeks' notice for opposition.

The Homeopathy Research Institute (HRI) in their 'Complaint to the Commonwealth Ombudsman regarding the National Health and Medical Research Council's (NHMRC) assessment of Homeopathy (submitted August 2016),' state that NHMRC have, *'misled the public by giving the impression that 'no stone has been left unturned' in the Homeopathy Review process- the most rigorous, open and transparent methods were used to evaluate all available evidence concerning the effectiveness of Homeopathy for any health condition- and they failed to find a single piece of valid scientific evidence that Homeopathy works.'*

The HRI suggest that the investigation carried out by NHMRC, *'revealed that multiple customary safeguards against bias were removed, facilitating a flawed process that appeared to be engineered to reach predetermined conclusions, sympathetic to the views of anti-Homeopathy vested interests.'*

[redacted] raises that Professor Peter Brooks, Chair of the NHMRC committee that conducted the 2015 review, initially failed to declare that he was a member of the anti-homeopathy lobby group 'Friends of Science in Medicine'. [redacted] argues that in violation of NHMRC's own guidelines there was not one homeopathy expert on the committee. Furthermore, she considers that NHMRC did the review twice, they rejected the first report, despite it being undertaken by a reputable scientist who is an author of NHMRC's own guidelines on how to conduct reviews.

[redacted]

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[redacted] also raises that the existence of the first report has never been disclosed to the public – it was only discovered by Australian Homoeopathic Association (AHA) through Freedom of Information (FOI) requests. She goes on to argue that NHMRC said the results of their 2015 report were based on a "rigorous assessment of over 1800 studies"; [redacted] recalls results were based on only 176 studies.

[redacted] believes that NHMRC used a method that has never been used in any other review, before or since; NHMRC decided that for trials to be 'reliable' they had to have at least 150 participants and reach an unusually high threshold for quality. She argues that this is despite the fact that NHMRC itself routinely conducts studies with less than 150 participants.

[redacted] argues that these unprecedented and arbitrary rules meant the results of 171 of the trials were completely disregarded as being 'unreliable' leaving only 5 trials NHMRC considered to be 'reliable' as they assessed all 5 of these trials as negative, this explains how NHMRC could conclude that there was no 'reliable' evidence.

The complaint submitted to the Ombudsman was presented by the HRI in August 2016 and the outcome is still unresolved. Therefore, [redacted] believes It improper that the TGA should now push ahead with the submission process given that the credibility of the NHMRC report is in dispute.

[redacted] intention here is to validate her right to have access to safe medicines, something she believes the TGA are entrusted to ensure, however she believes the TGA wish to stand itself apart from other governments worldwide by seeking to remove consumer access to "low-risk" medicines. The TGA's role is to ensure that the products and treatments available to Australians are safe for use; [redacted] believes that when the safety of a product is not in question, in this instance Homoeopathy, then the TGA should allow the consumer freedom of choice on whether to use the product or not.

[redacted] requests:

- To continue to have free and unwavering access to self-help information about homeopathy and the symptoms and ailments it treats.
- Unrestricted access for information and remedies from homoeopathic prescribers – government agencies should not regulate or restrict my ability to gain access to information.
- That high-risk medicines be dealt with in the appropriate manner and that Homoeopathy remain under a 'low-risk' status.
- To have unlimited access to the safest medicines she chooses, so the importation, exportation, or manufacturing of homoeopathic remedies – whether in pilliule, liquid or cream form, should not be restricted.

[redacted]

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[redacted] is concerned that changes to the status, coupled with what she views as ambiguous claims made by the NHMRC, could lead to further vexation from those who are unknowledgeable about the benefits of Homoeopathy. She is highly concerned that she should be vilified and ostracised for her healthcare choices by the very group that should be protecting them.

[redacted] respectfully asks the TGA to desist from restricting her health consumer rights and continue with the status quo and adopt Option 1.

Sincerely,

[redacted]

Advocate

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