s 22(1) [redacted]

Subject: Low risk products review - Homoeopathic products working group [SEC=UNCLASSIFIED]
Location: MR 8

Start: Wed 19/07/2017 11:30 AM
End: Wed 19/07/2017 12:30 PM
Show Time As: Tentative

Recurrence: (none)

Meeting Status: Not yet responded

Organizer: [redacted]
Required Attendees: [redacted]

Resources: MR 8

5/7/17 – next meeting (note room change)

Homoeopathic products workin...

Dear All

The Government accepted the three MMDR recommendations to further review 'low risk' products (recommendations 14, 23 & 48).

Homoeopathic products were considered in scope for this review and a number of options for the future regulation of homoeopathic products were included in the public consultation document 'Options for the future regulation of 'low risk' products. (public consultation closed 12 May)

We are now looking at the next steps and need your help and expertise to develop the specific policy proposals.

Attached is a conversation starter for looking at Homoeopathic products.

Homoeopathic products next st...

If you have any questions, please do not hesitate to contact me.

Regards

[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.

For those interested the entire consultation paper 'Options for the future regulation of 'low risk' products is available

Consultation
Options for the ...

Homoeopathic Products Working group meeting

Friday 9 June 2017

Attendees: s 22(1) [redacted]

Apologies:

Discussion: The paper "Homoeopathic products - next steps conversation starter" provided the background on the review of homoeopathic products and the public consultation submissions.

Main topics discussed during the meeting:

After an introduction and background on the review of homoeopathic products, discussion turned to the regulatory options proposed in the paper.

In setting the scene, a 2008 CMA homeopathic product market survey paper was discussed.

Based on the figures in the paper (approx. 60,000 exempt homeopathic products in 2008) and recent media reports on how much Australians spend on alternative therapies ($3.9 billion per year), we estimate that in 2017 there are in the order of 100,000 exempt homoeopathic products already on the Australian market (compared with 140 non-exempt homoeopathic products in the ARTG).

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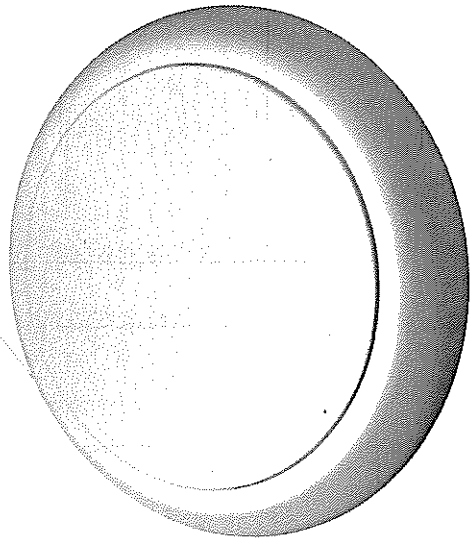
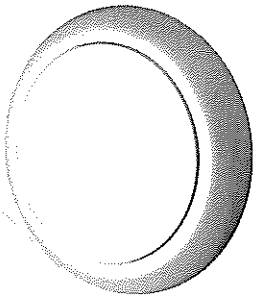
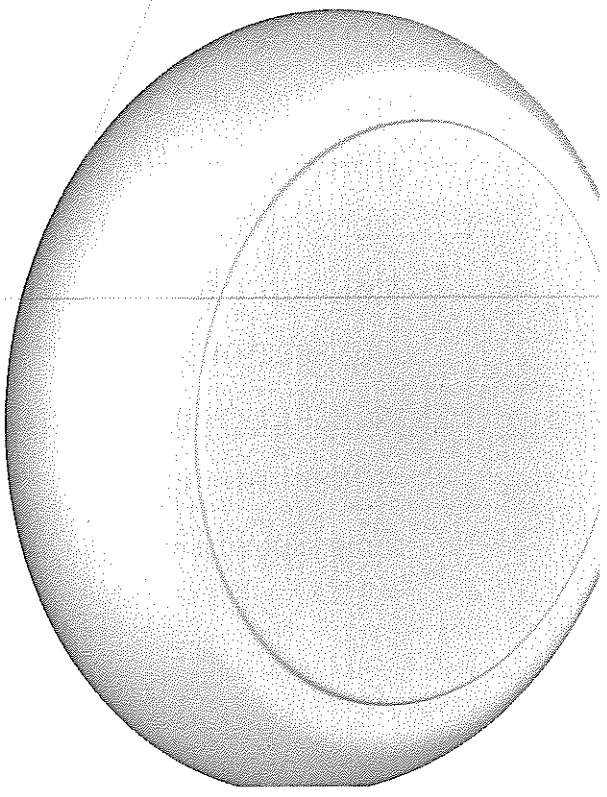
Date of next meeting: 19/07/2017





Homoeopathic products

Next steps conversation starter



Contents

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What we said – consultation paper

Homoeopathic products

Background: 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.

A mother tincture in homoeopathy is the first extract of herb or plant upon which further dilutions are made.

As of October 2014, there were 220 products listed on the ARTG as 'homoeopathic' or 'homoeopathic/other products'. Of these 220 products:

- 91 met the criteria for exemption (Item 8 of Schedule 5 to the Regulations) and even though they are listed, they are not required to be included on the ARTG. It is assumed that the sponsors either listed these products because they were unaware of the regulatory requirements or believe that by doing so there was a marketing advantage in representing the product as a TGA-listed medicine.
- 29 were required to be listed on the ARTG as they contained ingredients at 1:1000 or lesser dilutions (1X, 2X or 3X).
- 16 were required to be listed on the ARTG because they had indications for the treatment of a disease, condition, ailment or defect.
- 84 were required to be listed on the ARTG as their formulations included non-homoeopathic ingredients in combination with homoeopathic ingredients.

As at February 2017, there were 142 homoeopathic preparations entered in the ARTG. The number of exempt homeopathic preparations on the market in Australia is unknown.

Current regulatory oversight: Homoeopathic preparations are exempt from being entered in the ARTG if it is more dilute than a one thousand fold dilution of a mother tincture[1] (4X and above), is not required to be sterile, does not include ingredients of human or animal origin and does not make reference to serious diseases or conditions. Preparations that meet these conditions are also exempt from requiring the manufacturer to hold a GMP licence.

Preparations less dilute than 4X, which only contain permitted ingredients, are not sterile and/or make reference to serious diseases or conditions, are required to be listed in the ARTG. Products that are required to be supplied sterile would require registration in the ARTG, as they can only be supplied as registered medicines.

An overview of the international approach to the regulation of homoeopathic products can be found in Appendix 2.

Options for reform

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[1] The first dilution of a Mother tincture is considered 2X so a one thousand fold dilution of a mother tincture is 4X

Option 1 - Maintain the status quo regulation of homoeopathic products

Under this option TGA continues to regulate homoeopathic products as listed complementary medicines or exempt goods depending on their composition and dilution and would continue to be required to meet the regulatory requirements detailed above.

> **Please note:** The Government has agreed to further MMDR recommendations to reform the regulation of complementary medicines. Recommendations 38 and 39 cover the establishment of three pathways for entry of complementary medicines in the ARTG based on a hierarchy of evidence and permitted indications for listed medicines.
>
> Those proposals are further detailed in a separate complementary medicines consultation paper which is currently open for consultation[2].

- An issue of maintaining the current regulation of homoeopathic products under the same framework as evidence based medicines is that it may imply government endorsement of these products. This is particularly relevant given the Australian National Health and Medical Research Council (NHMRC) recently concluded that there is no reliable scientific evidence that homeopathy is effective[3].

This issue is also being considered by other regulators. A 2009 U.K. government review[4] concluded that:

> 'By providing homeopathy on the NHS and allowing MHRA licensing of products which subsequently appear on pharmacy shelves, the Government runs the risk of endorsing homeopathy as an efficacious system of medicine. To maintain patient trust, choice and safety, the Government should not endorse the use of placebo treatments, including homeopathy.'

In November 2016, the US Federal Trade Commission in the USA concluded similar findings.[5]

An advantage with this option is that sponsors and manufacturers who are already familiar with the regulatory framework would not need to understand or implement any regulatory changes.

Option 2 – Serious therapeutic claims must be supported by scientific evidence.

Currently, Item 5 of Part 1 to Schedule 4 of the Regulations states that homoeopathic preparations that refer to the treatment of a disease, condition, ailment or defect specified in Part 1 or 2 of Appendix 6 to the Advertising Code are eligible for listing. This is inconsistent with the regulation of other listed medicines.

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[2] https://www.tga.gov.au/consultation/consultation-reforms-regulatory-framework-complementary-medicines-assessment-pathways (consultation closes on 28 march 2017)

[3] https://www.nhmrc.gov.au/guidelines-publications/cam02

[4] https://www.publications.parliament.uk/pa/cm200910/cmselect/cmsctech/45/4507.htm

[5] https://www.ftc.gov/system/files/documents/reports/federal-trade-commission-staff-report-homeopathic-medicine-advertising-workshop/p114505_otc_homeopathic_medicine_and_advertising_workshop_report.pdf

Under this option it is recommended that the Regulations be amended to require homoeopathic products that make high level claims to be registered in the ARTG and require supporting scientific evidence, as per non homoeopathic medicines that make high level claims.

Homoeopathic products relying on traditional evidence would only be able to make therapeutic claims acceptable for minor claims in relation to self-limiting conditions that do not require healthcare practitioner supervision.

This option allows for greater consistency with international regulatory frameworks (see Appendix 2) by ensuring that those goods which refer to the treatment of a serious condition are not listable but rather must be registered and evaluated for their quality, safety and efficacy.

Premarket assessment of evidence could potentially cause delays to market for registrable homoeopathic medicines.

Option 3 – Exemption from listing in the ARTG and/or GMP

Under this option, it is proposed that all homoeopathic products would be exempted from Parts 3-2 and 3-3 of the Act.

Exempt products remain therapeutic goods under the auspices of the Act and therefore still subject to the regulatory requirements detailed above.

This option represents a lower barrier to market for those homeopathic products that were not previously exempt and could result in a greater range of products for consumers.

A potential risk under this proposal is that products are supplied into the market that contain therapeutically significant quantities of restricted ingredients. However, any product containing levels of substances captured in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) that breach the scheduled limits would be subject to appropriate regulatory action, as is currently the case.

Any homoeopathic product containing ingredients of human or animal origin as currently specified in Schedule 5 would be required to comply with the TGA policy on TSE and would not be subject to any further regulatory requirements.[6]

Option 4 – Declare homeopathic products not to be therapeutic goods

This option is to exclude all homoeopathic products from the regulatory framework, using an instrument under s7AA of the Act.

This would remove the regulatory burden under the Act for the sponsors of the existing 142 homoeopathic preparations listed in the ARTG, however homoeopathic preparations would continue to be consumer goods and be subject to the Australian Consumer Law enforced by the ACCC.

Under this option, it is proposed to also prevent homoeopathic products making therapeutic claims and requiring them to be clearly labelled as homoeopathic products with a direction for use statement such as "as directed by your healthcare practitioner".

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[6] https://www.tga.gov.au/transmissible-spongiform-encephalopathies-tse-tga-approach-minimising-risk-exposure

As per the previous option, if certain products supplied into the market contained therapeutically significant quantities of restricted ingredients, these products would still be subject to appropriate regulatory action, as is currently the case.

This option would allow the TGA to focus more resources on the regulation of higher risk therapeutic goods.

In the event that Option 4 (or a version thereof) is the supported way forward and the TGA were to no longer regulate homoeopathic products, then a new definition for what a 'homoeopathic' product represents must be developed. Further consideration should be given to defining the term with reference to concentrations, so that concentrated preparations remain within the purview of the therapeutic goods regime.

Questions

Do you have a view on which (if any) of the above options for homoeopathic products would be the most appropriate way forward? If so, please provide details on potential impacts to public health, access in the marketplace, business operations etc.

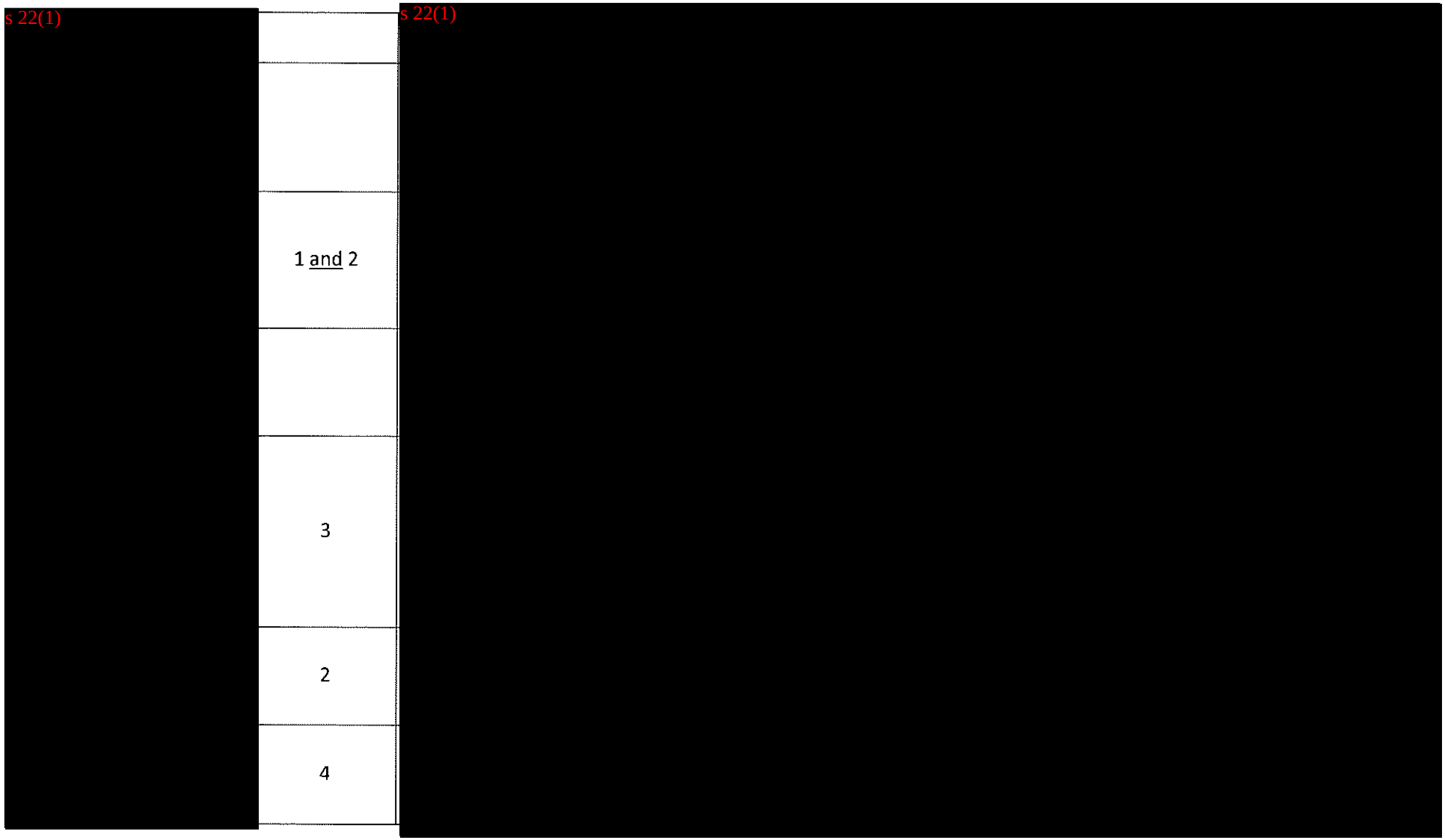
Comments on the potential development of a new definition for what a 'homoeopathic' product represents are also sought.

Any alternative recommendations would also be welcome

What stakeholders said - Summary of responses from organisations

Organisation	Option supported	Notes and comments
s 22(1) [redacted]	1	s 22(1) [redacted]
	2	
	3 and 4	
	Acknowledge option 2	
	Modified version of option 4	
	1	

s 22(1)	2	s 22(1)
	1 and 2	
	4	
	4	
	1 and 2	
	1 and 2	
	1 and 2	
	1 and 2	


s 22(1)
s 22(1)
1 and 2
3
2
4

Homoeopathic products*	**Option 1 - Maintain the status quo regulation of homoeopathic products**	756	2	106
	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	

* A negative 'grass roots' campaign was run against the homoeopathic products consultation resulting in a large number of individual responses that basically all "supported options 1 & 2 and strongly opposed options 3 & 4" which has skewed the response numbers as seen in this table.

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Pages 16-26 inclusive exempt in full under section 22(1) of the FOI Act