Consultation: Options for the future regulation of "low risk" products – March 2017

This submission specifically relates to the section that covers - Review of certain complementary medicine products: Vitamins and minerals and Homoeopathic products.

HOMOEOPATHIC PRODUCTS-

In regards to Homoeopathic products I support options 1 and 3. Option1 will ensure public safety when using these products. A good example is that in Australia we have not had any serious, life threatening QA issues with homoeopathic products. In the USA, a Homoeopathic manufacturer Hylands has had 2 well documented cases of poor manufacturing leading to potential public harm. Having the government regulate homoeopathic products, ensuring safety and claims are reliable and consistent does not imply government endorsement of such products, it does help ensure safety of such products in the community. The current system in Australia, is not comparable to the UK example, where Homoeopathic medicine was covers by the NHS.

If option 1 is not accepted then option 3 would be preferred.

In regards to homoeopathic products I DO NOT support option 4,as it is likely to have negative effects on public safety and complementary medicine practitioners such as Naturopaths and Homeopaths.

- It would be inconsistent with the current regulatory framework particularly the definition of therapeutic goods.
 Homoeopathic products have traditionally been used and will continue to be used by the community as a therapeutic goods as per definition of therapeutic goods section 1, (a) (i) ie. For therapeutic goods- that is as a substance to be taken to assist or promote health. The perception by some members of the community will NOT change, even though the way in which the products are regulated would change under option 4. This would likely lead to people still using these as therapeutic products, yet without any of the protection the current system offers them.
- Access to homoeopathic goods by members of the public and complementary medicine practitioners is particularly important, especially in the context of safety. They are being used in the community to manage low risk illnesses. For example using Homoeopathically prepared Arnica 6X to alleviate minor arthritic type pains and general muscle soreness. This decreases the use of other higher risk products such as some pain relief mediations that may have side effects including GI bleeding, potential renal damage and hepatic toxicity.

- Homoeopathic products have been used as a therapeutic goods for over 100 years in Australia by people in the community. If Option 4 is taken, it would still be viewed as a therapeutic good by many Australians. Most commonly it is used as an oral ingestive medicine. The ACCC is not equipped to ensure quality manufacturing processes, and therefore it would possibly endanger the public using these products. For public safety it is essential that these homoeopathic products are manufactured correctly as seen with recent issues with the Hylands teething product and issues that arose from poor manufacturing – such events may arise if Option 4 is taken.
- Trained practitioners and Naturopaths also use Homoeopathic products to help many
 of their patients. It is especially of value in cases where a person may be on
 multiple prescribed medications that have potential interactions with nutrients and
 herbs. Option 4, removing homoeopathic products as a therapeutic good, would
 potentially stop complementary medicine practitioners from having access to quality
 medicines that can be used in cases such as those mentioned above. The impacts
 could be substantial both on the healthcare professionals that recommend these
 products and members of the public.

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Questions



Do you have a view on which (if any) of the above options **for vitamin and mineral 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.Any alternative recommendations would also be welcome.

In regards to proposed changes to Vitamin and mineral products I support option 1. Despite being low risk products vitamins and mineral supplements in Australia are very safe due to this level of regulatory requirement. It enables the public to have faith in these products as being of exceptionally high standard. The current system does offer the public protection from inferior quality and possibly harmful products as the manufacturing standards are very high.

Exempting vitamin and mineral products from Part 3-3 of the Act could potentially result in lower quality products being supplied if manufacturing standards are not appropriate. This would lead to an increase in consumer dissatisfaction and require post market regulatory action to correct. Low quality products may be contaminated and post market regulatory action will not prevent possible harm to the public.

A decrease in regulatory burden for the industry may not necessarily result in lower cost to consumer, but would result in possible increased risk to public safety.