

To Whom it May Concern  
The Therapeutics Goods Administration  
P O Box 100  
Wooden ACT 2606



Submitted online

Thursday, 11<sup>th</sup> May 2017.

SUBMISSION:

***RE: Call for Submissions on the classification and regulation of Low Risk Products***

We only came to know about this review in the last few days, so our comments are restricted by severe lack of time to fully research your document/s. We use a great many of the products and services being considered. Due to special medical needs and allergies as well as preference we use a great many 'natural remedies' at considerable expense as they are not covered by Medicare or the PBS. We find them integral to the health and wellbeing of our entire family. We stress the point that we do NOT wish to see these services and products to become more difficult to access or inaccessible nor do we wish to see greater regulation/s that makes them more expensive. It is very disturbing to us that our health and welfare could be so easily affected negatively by ego and bias. Below we outline briefly some of our uses for complimentary medicines and low risk products.

For the benefit of the readers' understanding of this submission – we have a counter opinion on the 'low risk' nature of some of the items discussed in your document explaining this review. This is due to a significant medical condition which deems us severely affected by some of the products. Depending on your source of data, approximately 6% to 50% of the population falls into this category – allergies and chemical sensitivities and neurological issues associated with certain product usage. This is a significant percentage of the population [epidemic even]. Why does this happen? This is still not fully understood but there are a number of issues that seem to interplay including genetic factors that have been triggered and have not been able to be turned off. So, some of the items in the assessment are high risk for us. Not just to use internally or externally but if other people around us use them – the main example from your listed products are sunscreens, hard surface disinfectants, antiperspirants, aromatherapy products, nappy rash cream, some OTC items, and some class 1 medical devices. It is for these items we would like to see more examination.

Electric mobility scooters are included in your low risk items it seems. We are actually very disturbed by this. We live in an area where there has been a massive increase in the use of these. We also have significant areas of strip shops here. So, there are many people now speeding around on their mobility scooters/devices. We urgently would like to see something about this done. We certainly have empathy for people wishing to remain mobile and to run errands for themselves but this is a big issue and it will only get worse with the aging population.

We make extensive use of Ear Candles due to allergies and problematic medical conditions that make alternative products to them not possible for us. They are a great product when used properly and we go through quite a few annually depending on our winter time health. We, on average, use 5-10 pairs of ear candles per annum in a family of four.

Nappy rash cream is not currently something used by our family as our children are well past that stage. We would hope that natural products in this sector would remain easily accessible so as to maintain affordability. There are other legal regulations that would potentially oversee them too. See also our second paragraph.

Antiperspirants may be contributing factors to a decline in lymphatic health in the armpit area. As such, we do not see them as low risk. [Deodorants are a different item and we see them as low risk generally.] We do not use antiperspirants for medical reasons and we have not done so for close to 25 years.

Over the counter products. We generally do not use any of the OTC products discussed in your document. Most of them fall into a category of troublesome products for us as briefly discussed above.

Hard Surface Disinfectants *are* chemicals and contain dangerous ingredients. They should be treated that way *in most instances*, especially where it is not a 'natural product' [these too can have dangerous impacts].

Sunscreens are another that can have concerning ingredients in a base of moisturiser. Some are synthetic and not environmentally friendly while others use natural ingredients in a natural moisturiser base. We use the latter for medical necessity. At the very least the active ingredients should be regulated. There can also be need for careful monitoring of non-active ingredients too – as with all personal care products.

Feminine hygiene products should not be expensive or have their costs added to in any way but those used internally are very concerning to us. This is more so if they are made from synthetic fibre or contain plastics or rubbers or latex or

silicon. They are being used in a most sensitive part of the body and we believe attitudes are generally too lax.

With respect to Class I medical devices we do not have time to investigate these items and the options.

Essential oils are somewhat misunderstood [as are fragrances]. They are a dangerous product for several reasons. Not all are natural and where they are, they can contain non-natural ingredients that may be a safety issue. Just because they may be natural does not make them low risk. They are extremely strong concentrations of oil. It has taken massive amounts of raw ingredients from massive amounts of plants to produce small amounts of highly concentrated supposedly therapeutic oils. Sniffing the natural perfume emanating out of the plants in one's garden or a neighbour's garden is vastly different to essential oils. Your document mentions lavender as a headache relief. It does the opposite to many people. This author gets migraines from it.

We believe aromatherapy – massage or otherwise is not as much of an issue as someone who is sensitive [and knows they are] is unlikely to enter a premises or make appointments for such services.

So, the products themselves should be stringently monitored. The bottles they come in should not be easily openable – they should be child proof. Many of them are toxic if ingested or otherwise used incorrectly.

Rehydration products are a marketing cash cow and possibly should be investigated. Some members of our family have used, others won't touch them. Adding certain compounds to water does make it tastier and can enable the body to rehydrate better but how much of what is claimed is appropriate is uncertain.

### **Vitamins, Minerals & Homeopathics**

We have used the services of qualified natural therapists [AKA Complimentary Medicine practitioners], including Nutrition, Naturopathy and Homeopathy and Homeopathic goods for over 30 years. They are an integral part of our medical care protocols for ourselves and our children. With respect to Homeopathy, if that becomes a non-viable career for trained Homeopaths, how will they be able to earn a living and re-pay their debts? Some have been able to study utilising VET-Fee Help. While the government is not subject to ACCC, it seems harshly cruel and unethical to stop people being able to work in a field that is well accepted elsewhere in the world.

Allowing some supplements of vitamins and minerals to be manufactured under a different regulatory regime appears problematic to us and confounds our sense of logic. This is especially so if it will fall to States to oversea various products – some items will be available in some States but not others or a manufacturer will create their product to comply with the requirements of the most stringent state which means it will be overpriced for some consumers. There have in the past been a few products that have fallen into this area and producers/manufacturers have existed in one state to service another. While Australia is a federation of states, it seems like a poor decision to go down that path by replacing a higher standard level with a more complexity [in dealing with different States and Territories].

We strongly object to any plan to make Homeopathy and or Homeopathic goods more regulated. The current regulatory environment is more than sufficient to cover ALL health care practitioners in Australia. Australia is close to being the most regulated country in the world. We do not need more in this area. This would be a massive detriment to Australia and Australians.

We have a large set of allergy issues in our family and sometimes homeopathics are the only treatment options available to us. It is our legal right to access this methodology for ourselves and our children.

Where an item is potentially being over regulated by the status quo but would become unavailable or available at increased regulatory and hence financial burden then perhaps some sort of exemption, as discussed in your document, is the better option.

We thank you for the opportunity to make our submission and hope we have been helpful in some way to the pool of feedback.