

Consultation: Options for the future regulation of “low risk” products – May 2017

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

DATE: 5/11/2017

HOMOEOPATHIC PRODUCTS

Regarding 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 covered by the NHS.

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

Regarding 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 Homoeopaths.

- 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 good, as per definition of therapeutic goods section 1, (a)(i) i.e. *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 medications

that may have side effects including GI bleeding, potential renal damage and hepatic toxicity.

- Trained practitioners also use homoeopathic medicine 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.
- 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 qualified 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 remedies are manufactured correctly as seen with recent issues with the Hylands teething product and issues that arose from poor manufacturing.

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VITAMINS AND MINERALS

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.

Regarding 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.

TGA primary responsibility is public safety and homeopathy does not breach the Hippocratic principle of *'primum non nocere'* – *first do no harm*. The current legislative framework is fulfilling its role regarding public safety. The public has a democratic right to make informed choices and access to 'safe' medicines.

What do patients really think of homeopathy?

Have you ever thought you were incurable? Has your doctor said there are no options left for your particular health problem? If so, it may not yet be time to give up completely.

Many who took part in the following studies had been told they could not be helped but to their delight, homeopathy brought relief.

The following article looks at results from clinical outcome and observational studies in which patients were asked how much they had improved with homeopathy.

Introduction

People regularly receive homeopathic treatment at hospitals and medical clinics throughout England, Europe, South America, Cuba, and India.

Data collected from these clinics reveal the type of complaints treated, the speed and longevity for any improvements, and the degree of satisfaction patients had with their treatment.

Results showed that some of the happiest patients following homeopathic treatment were those whom mainstream medicine had already given up on. Let's call them the 'untreatables'. Some of the improvements they reported following homeopathy are truly remarkable.

1. England: Chronic disease improved in 70% of patients

In a 6-year outpatient study at Bristol Homeopathic Hospital, over 70% of patients with chronic diseases, often of many years duration, said they had improved with the homeopathic treatment. 6544 patients were involved in the

study and 70.7% reported positive health changes with 50.7% recording their improvement as better or much better. ⁱ

The conditions treated were:

- Eczema
- Asthma
- Migraine
- Irritable bowel syndrome (IBS)
- Menopausal problems
- Inflammatory bowel disease (ulcerative colitis and Crohn's disease)
- Myalgic encephalomyelitis / chronic fatigue syndrome (ME/CFS)
- Cancer
- Depression
- Arthritis.

2. Northern Ireland: “I now have hope”.

A Northern Ireland Government study of 713 patients discovered that alternative and complementary therapies offer significant health benefits for patients, plus savings in government healthcare costs – and that homeopathy did the best of all.

Therapies involved in the study included acupuncture, chiropractic, osteopathy, homeopathy, reflexology, aromatherapy and massage but patients who received homeopathic treatment had the greatest improvement (79%), followed closely by acupuncture (77%). Chiropractic or osteopathic patients experienced 56% improvement.

Patients were referred by local doctors, often when conventional treatment had failed, for problems such as:

- Arthritis
- Joint, back and neck pain
- Fibromyalgia
- Myalgic encephalitis (ME) or chronic fatigue syndrome (CFS)
- Stress related problems
- Anxiety
- Panic attacks
- Depression
- Insomnia
- Anger and aggressiveness
- Headaches and migraines
- Shaking and trembling
- Chest infections
- High blood pressure
- Obesity
- Psoriasis

Patient reports within the study contained heart-warming statements such as, ‘I feel alive again, instead of being dead’; ‘I now have hope’. ⁱⁱ

3. Dorset, England: “It was the homeopathy”.

A study at the Dorset NHS Community Homeopathy Clinic led to 84% of patients experiencing an improvement in their health with 81% saying it was due to the homeopathy. A wide variety of conditions were seen, the greatest in incidence being depression, anxiety and grief. ⁱⁱⁱ

4. UK NHS Facility: “Positive outcome”

Almost 80% of 958 patients having two or more appointments in this study experienced a “positive outcome” .^{lv} The greatest improvements occurred in:

- Anxiety
- Catarrh
- Colic
- Cystitis
- Depression
- Eczema
- Irritable bowel syndrome (IBS)
- Pre-menstrual syndrome (PMS)

5. Germany and Switzerland: “Disease severity and quality of life demonstrated marked and sustained improvements ...”

In a multi-centre study, information was collected from 3,079 first-time patients from 103 different centres across Germany and Switzerland. ^vThe patients were observed over an 8 year period. Interesting findings to emerge from the study were:

- On average, disease severity decreased dramatically and improvements were sustained
- Those who were sickest at the beginning of the study often noticed the greatest improvement
- Three in ten patients stopped treatment because of major improvement
- Mental and physical quality of life scores increased substantially
- Children improved more rapidly than adults

The authors of the study concluded by saying, “Disease severity and quality of life demonstrated marked and sustained improvements following homeopathic treatment period. Our findings indicate that homeopathic medical therapy may play a beneficial role in the long-term care of patients with chronic diseases.”

6. Germany: Homeopathy Used for Childhood Cancer – “I would recommend it to others”.

Homeopathy is more frequently used in the treatment of childhood cancer in Germany than any other complementary therapy. Most parents who chose to use homeopathy in this study had experienced it previously and said they would recommend it to others in a similar situation. Compared to other complementary therapies, satisfaction with homeopathy was rated as very high. The majority of prescriptions were made in by non-medical homeopaths. ^{vi}

7. Switzerland: “Completely Satisfied”

Overall satisfaction was significantly higher for the homeopathic patients in this large survey (3,126 patients) conducted by the Swiss government in which homeopathic care was compared to conventional care. The homeopathic treatments were considered to be low-risk with two to three times fewer side effects than the conventional treatment. Researchers found that 53% of the homeopathic patients were “completely satisfied,” and reports of “positive effects” were significantly higher in the homeopathic group in spite of the greater incidence of chronic conditions (40% vs. 17%). ^{vii}

Homeopathy – Worth the Investment?

Clinical outcome and observational studies like those above are preferred for examining the real-world effect of an approach or a treatment. These studies, combined, cover a large range of conditions, many of them severe or chronic, in which significant health improvements were achieved and in which patients expressed a high degree of satisfaction. Several studies also reported savings in healthcare costs. When “health is gold” and positive real-world benefits are desperately needed for all manner of health problems, homeopathy is one form of medicine that is certainly worth investigating further.

Sources

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