Australian Skeptics (Victorian Branch) Inc
12th May 2017

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

The Australian Skeptics Victorian Branch are pleased to be offered an opportunity to contribute our views on the future regulation of low risk products.

Ear candles

Option 3 - Exclude ear candles from the regulatory framework

The claim is frequently made that ear candles can remove toxins or earwax by lowering the pressure in the aural cavity. However, there is nothing to suggest that detritus found in the remains of a burnt ear candle is extracted from the subject of the procedure.

As ear candles offer no therapeutic benefit, they are better regarded as a fraudulent parlour trick than a therapeutic good. By excluding them from the regulatory framework the TGA is giving a clear signal to alternative practitioners that there is no tacit endorsement or recognition of this crypto-medical performance.

The ACCC is an ideal body to deal with dishonest advertising of them or to consider product recalls or category wide ban on these goods owing to the dangers that they pose.

Nappy rash cream

Option 1 – Maintain the status quo regulation of nappy rash and skin care products

Antiperspirants

Option 1 – Maintain the status quo regulation of antiperspirant preparations.

Other low risk registered non-prescription (OTC) medicines

Option 1 – Maintain the status quo regulation of low risk OTC medicines

Hard surface disinfectants

Option 3 – Develop a series of monographs

Sunscreens

Option 2 – Streamline the regulatory pathways for sunscreen regulation

Tampons and menstrual cups

Option 1 – Maintain the status quo regulation of tampons and menstrual cups

Given the danger of Toxic Shock Syndrome it is necessary that tampons and menstrual cups remain under the regulatory oversite of the TGA, to maintain the highest manufacturing standards and product safety.

Essential oils

Option 3 – Declare essential oils not to be therapeutic goods

This option is acceptable If the sponsors of these products are no longer allowed to make therapeutic representations of them. Guidelines are required for general product safety and there needs to still be a regulatory framework controlling their sale and promotion.

Vitamins and minerals

Option 1 – Maintain the status quo regulation of vitamins and minerals

If anything, the sale and promotion of vitamins and minerals is under-regulated at present. We would like to see the TGA maintain its role, but more interest should be paid to the long term health effects of supplements and we question the assumption that they should be considered low risk when relatively little is known about the long term impact.

Homoeopathic products

Option 4 – Declare homeopathic products not to be therapeutic goods

The 2015 NHMRC Information Paper, “Evidence on the effectiveness of homeopathy for treating health conditions”, made a strong case that there was no evidence supporting any of its therapeutic claims. Instead we see frequent tragic cases of neglect where patients have been diverted from effective care by following the ineffective regime of a homeopath.

We hope that by not listing homeopathic preparations the TGA will send a clear signal to pharmacies that they are straying away from their mission by stocking these fraudulent products.

It should be noted that just because homoeopathy is ineffective, we should not presume it to be safe. The tragic situation in the USA where an FDA investigation has linked Hyland's teething products with at least ten infant deaths is a timely reminder of this.

Any removal of the homoeopathy from the TGA's remit must not lead to a situation where dangerous products are able to proliferate. As many of the homoeopathic products on the market contain non-negligible amounts of pharmacologically active substances, some products should still be within the TGA's jurisdiction. Given the lax quality assurance that is associated with many alternative medicine products it cannot be a priori determined that a homeopathic product is low risk based on the ingredient claims of the manufacturer.

If homoeopathic products are no longer classed as Therapeutic Goods it would be contradictory to be label them "as directed by your healthcare practitioner". Any labelling of homoeopathic products needs to unambiguously say that they have no therapeutic benefit. One clear suggestion from Dr Ken Harvey and Dr Prasad Ranaweera is to label them as follows:

Warning: This product's traditional claims are based only on theories of homeopathy from the 1700s that are not accepted by most modern medical experts. There is no scientific evidence that this product works.

We do not want to see a situation where the TGA relinquishes regulatory control of a broad sector of low risk products, when any subsequent regulatory body (such as the ACCC) is pharmacologically active inadequately resourced to handle these responsibilities.