SUBMISSION FROM THE AUSTRALIAN TRADITIONAL MEDICINE SOCIETY (ATMS)

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

1. Ear Candles

Questions
Do you have a view on which (if any) of the above options for ear candles 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.

Response
Option 1 – Maintain the status quo regulation of ear candles.
Comment - Ear candles are therapeutic devices and should be regulated as such. No other option allows for this.

2. Nappy Rash Creams

Questions
Do you have a view on which (if any) of the above options for nappy rash 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. A combination of the above options would also be feasible in certain cases. Any alternative recommendations would also be welcome.

Response
Option 1 – Maintain the status quo regulation of nappy rash and skin care products.
Comment - As per the above but with the requirement that sponsors submit evidence for claims before listing is granted.

3. Antiperspirants

Questions
Do you have a view on which (if any) of the above options for antiperspirants 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.

Response
Option 2 – Exclude antiperspirants from the regulatory framework.

4. Other low risk registered non-prescription (OTC) medicines

Questions
Do you have a view on which (if any) of the above options for these OTC products would be the most appropriate way forward? Are there particular products, which in your opinion definitely should (or shouldn't) be reviewed? 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.

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

5. Hard surface disinfectants

Questions
Do you have a view on which (if any) of the above options or combination of options for hard surface disinfectants 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. Note that the options proposed are NOT mutually exclusive and that it would be possible to implement certain combinations of options. Stakeholder advice is required on whether these products should still be able to be called "hospital grade", or whether this term is potentially misleading. Comments on the potential development of a monograph system are also sought, including whether or not this might simplify and streamline regulatory requirements. Any alternative recommendations would also be welcome.

Response
Option 5 – Declare hard surface disinfectants not to be therapeutic goods.
Comment - Some form of properly regulated oversight and confirmation of antimicrobial activity is still required for these products.

6. Sunscreens

Questions
Do you have a view on which (if any) of the above options or combination of options for sunscreens 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.

Response
Option 2 – Streamline the regulatory pathways for sunscreen regulation.
Comment - Independent confirmation of each product's SPF should be provided by the sponsor prior to release for sale.

7. Tampons and menstrual cups

Questions
Do you have a view on which (if any) of the above options for tampons and menstrual cups 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 monograph system are also sought, including whether or not this might

simplify and streamline regulatory requirements. Any alternative recommendations would also be welcome.

Response
Option 1 – Maintain the status quo regulation of tampons and menstrual cups.
Comment - in the absence of the above, an independently regulated monograph or MSDS system would be acceptable, although the TGA still needs to be mindful of the historical risks (toxic shock syndrome etc.) posed by these products.

8. Low risk products that are currently considered medical devices

Questions
Do you have a view on any (or all) of the above actions for Class I medical devices? If so, please provide details on potential impacts to public health, access in the marketplace, business operations etc. Do you have a view on any specific product types currently included in the ARTG that should specifically be considered during the review Class I medical devices in the ARTG? If yes, please provide reasoning. Any alternative recommendations would also be welcome.

Response
Action 1 – Systematically review the ARTG for potential non-therapeutic goods.
Comment - Any device making diagnostic or therapeutic claims should have the evidence for those claims assessed prior to release for sale.

9. Aromatherapy products

Questions
Do you have a view on which (if any) of the above options for aromatherapy 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.

Response
Option 1 – Maintain the status quo regulation of aromatherapy products.

10. Rehydration or formulated sports products

Questions
Do you have a view on the above further action for rehydration products? 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.

Response
Further Action – Review of rehydration products on the ARTG to remove food claims.
Comment - Regulation by FSANZ may be more appropriate than regulation by the TGA.

11. 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.

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

12. Homoeopathic products

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

Response
Option 1 - Maintain the status quo regulation of homoeopathic products.
Option 2 – Serious therapeutic claims must be supported by scientific evidence.
Comment - The current definition of a homeopathic product should be modified to properly reflect the homeopathic paradigm of a single ingredient. The current definition allows for multi-ingredient products to be defined as homeopathic - this is inconsistent with the traditional homeopathic paradigm. The current ELF system should be modified to require sponsors to have traditional or scientific evidence for claims assessed prior to listing being granted.

Ends

Approved and authorised by ATMS
Thursday, 11 May 2016