TGA Consultation - Options for the future regulation of "low risk" products

MTAA Submission - May 2017

MTAA Medical Technology ASSOCIATION OF AUSTRALIA

Medical Technology
ASSOCIATION OF AUSTRALIA

Level 12, 54 Miller St,
North Sydney
NSW 2060 Australia
P (+612) 9900 0600
F (+612) 9900 0655

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1 Executive Summary

On 31 March 2017 the TGA opened the consultation *Options for the future regulation of "low risk" products* which contains a range of options for the future regulations of 'low risk' therapeutic goods (including maintenance of the status quo) and potentially affecting certain categories of Class I medical devices.

The MTAA appreciates the opportunity to comment on this consultation. The MTAA supports the overarching intentions to simplify and streamline regulatory frameworks for 'low risk' therapeutic goods while maintaining safety standards and ensuring consumer protection.

In our 2015 Submission to the Medicines and Medical Devices Review (MMDR) Taskforce we expressed reservations is relation to the Expert Panel recommendation 23 which stated that "the Australian Government undertake a review of the range of products currently classified as Class I medical devices, with a view to reclassifying products as consumer goods in circumstances where the product poses little or no risk to consumers should it not perform as specified or malfunctions". In our submission we stated the following:

> *MTAA has reservations regarding Panel's Recommendation Twenty Three to reclassify Class I medical devices as consumer goods in circumstances where the product poses little or no risk to consumers should it not perform as specified or malfunction. This recommendation appears to be in contradiction with the way the determination is made whether a product is a medical device or not. By law, products are considered to be a medical device if its intended purpose is to:*
>
> - *diagnose, prevent, monitor, treat or alleviate a disease;*
> - *diagnose, monitor, treat, alleviate or compensate a handicap or injury;*
> - *investigate, replace or modify the anatomy or a physiological process;*
> - *control conception;*
>
> *or, if it is an accessory to such a product. That is, the decision of whether a product is a medical device is not made based on the product's level of risk, but rather on its intended purpose as declared by the manufacturer or sponsor. This approach for defining what is a medical device is aligned with the international guidelines of the Global Harmonization Task Force (GHTF) and with the medical device regulations in Europe, the USA, Canada and Japan. Hence, Class I medical devices are still medical devices even if they are low risk and cannot and should not be reclassified as consumer goods, because consumer goods have different intended purposes.*
>
> *The inclusion of Class I medical devices in the ARTG enables the TGA to have a record of sponsors legally responsible for placing the devices on the market, which allows recalls to be managed quickly and effectively.*
>
> *This recommendation should probably read: "[…] the Australian Government should undertake a review of the range of products currently classified as Class I medical devices, with a view to removing them from the ARTG and reclassifying them as consumer goods in circumstances where the intended use of the product is determined to be a consumer good and not a medical device."*

We agree with point 1 in Recommendation Fifteen to continue to include Class I, nonsterile and non-measuring devices, in the ARTG on the basis of a self-assessment by the manufacturer. However, allowing sponsors to include such devices in the ARTG by themselves without any filter, has resulted in some companies claiming "TGA approval" (for marketing reasons) supported by ARTG inclusion for products which should not be in the ARTG in the first place. We recommend that a requirement be introduced to include a prominent statement saying that the Sponsor/ Manufacturer of the Class I medical device is self-declaring compliance with regulations and that the device has not been reviewed by the TGA, both in the ARTG entry and on the Declaration of Conformity.

We believe that the TGA Consultation: *Options for the future regulation of "low risk" products* addresses the concerns expressed previously. In the next sections we provide detailed feedback to the proposed options for reform and the questions asked in the TGA consultation paper.

2 Low risk products currently regulated as medicines and other therapeutic goods (other than herbal complementary medicines)

2.1 Ear candles

Ear candles are currently included in the ARTG as Class I medical devices. In a recent BBC program, ENT surgeon Dr Gabriel Weston stated: "Research has shown that not only is ear candling ineffective at removing earwax, but it can be dangerous. It can burn the face and ear, it can leave wax in the canal, and it can also puncture the ear drum." (Dr Gabriel Weston, 2017)

The MTAA does not support the inclusion in the ARTG of substandard products that could be supplied to consumers with inappropriate therapeutic representations. Therefore we recommend **Option 3 – Exclude ear candles from the regulatory framework** (this approach is aligned with US and Canada; both countries have banned the importation of ear candles). This will result in ear candles no longer being considered therapeutic goods and removing the perceived 'approved by the TGA' legitimising of ear candles. Ear candles would hence be regulated as consumer goods under the jurisdiction of ACCC.

2.2 Nappy rash cream

Nappy rash creams are currently included in the ARTG as either listed medicines, registered medicines or Class I medical devices.

Nappy rash creams with claims such as 'treating severe cases of skin irritations caused by fungal infections' go beyond those of a cosmetic nature and therefore should continue to be regulated as therapeutic goods. The MTAA recommends **Option 4 – Review of registered nappy rash active ingredients**. These registered product types should be considered under the proposal for 'other low risk registered non-prescription medicines'.

Nappy rash creams that only make claims of cosmetic nature such as 'skin moisturising/ soothing effect' should be regulated as cosmetic/ consumer products regulated by the ACCC. For these products the MTAA recommends **Option 5 – Exclude nappy rash products from the regulatory framework**.

2.3 Antiperspirants

Topical antiperspirants that derive their antiperspirant properties from inorganic salts of aluminium, zinc or zirconium only and that are sold as roll-ons, lotions, creams, pump sprays or aerosols are currently classified as therapeutic goods exempt from GMP requirements and from inclusion in the ARTG.

The MTAA supports **Option 2 – Exclude antiperspirants from the regulatory framework**, because such products are overwhelmingly viewed by consumer as toiletries. As consumer goods they would be regulated under the jurisdiction of ACCC.

2.4 Other low risk registered non-prescription (OTC) medicines

OTC products such as registered desensitising toothpastes, first-aid antiseptics, antiseptic mouth washes etc., with an established history of safe use at particular ingredient levels and dosage forms, are low risk. The MTAA supports **Option 2 – Review of eligibility of active ingredients to become Listable**, which will reduce the regulatory burden for these types of products.

2.5 Hard surface disinfectants

Regulation of hard surface disinfectants (other than sterilants and instrument grade disinfectants intended for medical devices, which are Class IIb medical devices, or cleaners intended for medical devices, which are regulated as Class I) should be streamlined, considering that the current TGA safety evaluation is expensive and can take anywhere between 6 to 24 months.

The MTAA supports the following options:

- **Option 2 – Streamline the regulatory framework for hard surface disinfectants** – move currently 'Registered' disinfectants to 'Listable' status; exempt products that are currently 'Listable' from Part 3-2 of the Act and not require entry in the ARTG prior to supply.
- **Option 4 – Approval Process for New Ingredients** - accept overseas approvals for new ingredients by comparable regulatory agencies or Australian chemical substance regulators such as NICNAS. This could provide a fair balance between market access and safety, by removing the TGA pre-market assessment of testing data, but keeping the products on the ARTG to allow post-market actions.

The MTAA believes that the wording "hospital grade" on over-the-counter hard surface disinfectants is potentially misleading and should not be allowed unless the manufacturer/

sponsor clarifies what they mean by “hospital grade” and any specific claims are supported by evidence.

The MTAA does not object to any of the proposed options for managing products requiring safety evaluations and assessments in accordance with TGO 54:

- Develop a disinfectant monograph system for common formulations, ingredients and claims (Canadian model); this option could work if combined with an approval process for new ingredients. Access to innovative products is critical to the global challenge of infection prevention and antimicrobial resistance.
- Declare all OTG hard surface disinfectants as ‘not therapeutic goods’ and regulate them as consumer goods under the jurisdiction of ACCC, and maintain ingredients compliance with NICNAS requirements (US, Europe and New Zealand models); this would also be in line with other environmental control products such as air disinfection and UV surface disinfection.

2.6 Suncreens

The MTAA supports **Option 2 – Streamline the regulatory pathways for sunscreen regulations**, as well as these proposed pathways for the approval process:

- Create a modified GMP standard for primary sunscreens (i.e., sunscreens carrying an SPF claim greater than 4 but not greater than SPF 50+, and that are proposed to be regulated as Listable medicines) and allow manufacturers to choose between:
  - Continue to manufacture to the current PIC/S GMP standard, or
  - Manufacture to the new modified GMP standard which will combine elements of the current PIC/S GMP standard, the Australian Code of GMP for Sunscreen Products 1994 and elements of the ISO 22716 standard;
- Accept overseas approvals for new ingredients by comparable regulatory agencies or Australian substance regulators such as NICNAS;
- Apply alternative grades (e.g. food grade) to non-critical ingredients, for which pharmacopeia standards are considered excessive;

2.7 Tampons and menstrual cups

The MTAA supports the reform options that would result in streamlining the regulatory oversight of tampons and menstrual cups. These are:

- **Option 2 – Exemption from listing in the ARTG** and compliance with TGO 82 in conjunction with development of a monograph system with permitted materials of construction and claims for menstrual cups, as well as provision of guidance for compliance with such requirements (US model for menstrual cups);
- **Option 3 – Exclude tampons and menstrual cups from regulatory framework** and compliance with AS 2869: 2008 (UK model for tampons).

3 Low risk products that are currently considered medical devices

3.1 Product types for consideration by MMDR recommendation 23

The MTAA supports maintaining the current Australian classification system for medical devices which is aligned to that of the EU and the GHTF/IMDRF.

We believe that the actions proposed by the TGA which are aimed at "cleaning up" the Class I entries in the ARTG are appropriate and measured:

1. Systematically review the ARTG for potential non therapeutic goods
2. Engage with States and Territories
3. Update the Excluded Goods Order
4. Review Class I medical device ARTG entry process

However, in line with our previously stated position that all products need to be included on the ARTG where they meet the medical device definition, we suggest exploring the possibility of replacing the Excluded Goods Order with an appropriate screening process for Class I devices (non-sterile, non-measuring) to prevent inclusion in the ARTG of products that do not meet the definition of medical devices or of Class I devices with therapeutic claims that are not supported by evidence.

4 Review of certain complementary medicine products

4.1 Aromatherapy products

The MTAA supports streamlining the regulatory framework for aromatherapy products. In our opinion this could be achieved by implementing either **Option 2 – Exemption from listing in the ARTG and/or GMP** or **Option 3 – Declare essential oils not to be therapeutic goods**.

4.2 Rehydration or formulated sports products

The MTAA supports the proposed TGA course of action to have a clear demarcation between sports drinks (which are beverages designed specifically for the rapid replacement of fluid, carbohydrates and electrolytes), more appropriately regulated as foods, and oral rehydration products for therapeutic purpose, which are regulated as either listed or registered medicines, depending on the claims and composition of products.

4.3 Vitamins and minerals

Complementary medicines are outside the range of products manufactured and/or distributed by MTAA members therefore the MTAA abstains from commenting on this issue.

4.4 Homoeopathic products

Homoeopathic products are outside the range of products manufactured and/or distributed by MTAA members therefore the MTAA abstains from commenting on this issue.