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26 May 2017

Regulatory Reforms Team
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Submitted online and also by email (tgaregreforms@health.gov.au)

Dear Sir/Madam,

Submission to the Consultation on Options for the future regulation of 'low risk' products

We refer to your call for submissions re the above.

ASMI appreciates this opportunity to provide comment on the proposed reforms.

Contents

About ASMI

ASMI (Australian Self Medication Industry) is the peak body representing companies involved in the manufacture and distribution of consumer health care therapeutic goods (non-prescription over-the-counter and complementary medicines including vitamins, minerals and supplements) in Australia. ASMI also represents related businesses providing support services to manufacturers, including advertising, public relations, legal, statistical and regulatory consultants. More information about ASMI and our membership is available on our website.

Context of this consultation within the full suite of reforms

ASMI welcomes the opportunity to provide input into this consultation along with the numerous other consultations arising from the Review of Medicines and Medical Devices Regulation (the MMDR).

ASMI is supportive of the majority of the proposed MMDR recommendations.

It should be noted that all of the comments in this consultation response are provided without visibility of the overarching plans for the entire regulatory framework. The complete MMDR reforms project has many intersections within the medicines framework, and the full outcome of this current consultation can only be understood in the context of the whole. Changes to advertising, scheduling, complaints handling, sanctions, penalties, complementary medicines pathways, post-market monitoring, disclaimers, claimers, permitted indications, minor variations etc. are all being considered separately and will all have an impact on the suitability of the proposals within this consultation.

While ASMI will respond to each consultation separately, we reserve our final position and support until a review of the intersection of the completed consultations is made available for stakeholder consideration and input prior to any legislative changes being put forward.

ASMI therefore requests that the TGA provide a clear overview of how they intend to address each of the Government responses to the Expert Review recommendations. The current approach is segmented and stakeholders do not have transparency of the projected final product. ASMI also notes that these changes, along with associated reforms that are not specifically within the “low risk” products space, are likely to have a marked impact on the entire regulatory framework and this will come with business impacts and costs. ASMI therefore requests that a comprehensive Regulation Impact Statement (RIS) is provided to address these concerns, particularly where any TGA proposal does not align precisely with the Expert Review recommendations and Government response.

ASMI also emphasises the importance of maintaining consistency of the therapeutic goods framework across the various risk classes. Low risk (listed and registered) medicines are regulated by the TGA as part of the overall medicines and medical devices framework, and as such, it is essential that all reforms maintain consistency with the overall framework, do not create consumer confusion in relation to other product types, do not introduce unnecessary complexity, and do not introduce excessive regulatory burden.

Previous submissions

In our previous submissions to the Review of Medicines and Medical Devices Regulation (January 2015 and April 2015), we outlined the following relevant principles:

- There are benefits to all stakeholders when therapeutic goods are appropriately regulated.
- There should be a national system of controls, overseen by the TGA.
- Regulation should be risk-based.
- Regulation should reflect developments in comparable markets.
- "Risk" needs to incorporate more than just the toxicity of the ingredients.
- Low risk products should remain with the TGA, but the regulatory burden should be tempered to reflect the risks posed.
- There are numerous means by which the regulatory burden can be reduced.

ASMI continues to support these principles.

Regulation Impact Statement (RIS)

ASMI notes that the consultation paper makes no reference to the preparation of a Regulation Impact Statement (RIS).

ASMI also notes that the MMDR recommendations that formed the basis for this consultation (i.e. Recommendations 14, 23 and 48) were non-specific and simply recommended that the Australian Government "undertake a review" of certain aspects of the Australian regulations.

Given that the recommendations are of a high-level, general, nature that require further consultation with stakeholders and that are contingent on reforms to other aspects of the regulatory framework, it would be impossible to quantify the impact of the recommendations at this stage.

At a minimum ASMI would expect that refining of outcomes and recommendations from this consultation with stakeholders would be necessary to confirm practicality prior to making recommendations to Government. This would be consistent with the approach taken for other major proposals after the MMDR Review Report was released. ASMI would be concerned by any rush to change the legislation based on the outcomes of this initial consultation and without a proper consideration of the full impact of the reforms.

Consistent with the Government's best practice regulation requirements, we look forward to seeing a detailed RIS accompanying each of the finalised TGA reform proposals so as to demonstrate that the reforms have been fully costed.

Public Register of Therapeutic Goods

In our view, all stakeholders benefit from a publicly accessible register, which is essential for visibility of what products and ingredients are on the market.

A publicly accessible register is especially useful for pharmacovigilance activities and recalls.

Our responses to the various options put forward in the consultation paper are based on the premise that there must be a public register of all therapeutic goods.

In support of this position, we note that in the US (where there is no such mandatory register), a self-regulatory public register (called the Supplement OWL) has now been developed so as to overcome this regulatory shortcoming in relation to dietary supplements.

More information about the US register is available on the Council for Responsible Nutrition's website[1], where the Council for Responsible Nutrition makes the following statements, which serve to illustrate our position:

> *"[The Supplement Owl is] designed to provide a more complete picture of the dietary supplement marketplace for government and private stakeholders: legislators, regulators, retailers, industry and consumers."*
>
> *"Why is this label registry important? This initiative starts with a simple premise: regulators should know what ingredients and products are in the dietary supplement marketplace and who sells them".*

[1] https://www.crnusa.org/resources/supplement-owl-dietary-supplement-product-registry

GMP Standards for low risk medicines and actives

ASMI suggests that the TGA take this opportunity to re-examine the GMP requirements for low risk medicines and active ingredients. Reforms in this area have the potential to streamline processes and reduce regulatory costs whilst still ensuring appropriate consumer protection.

GMP standards are critical to the reputation and credibility of Australian therapeutic goods, however there is scope to amend GMP processes to increase the competitiveness of the Australian industry while still ensuring confidence of the Australian public. For medicinal products, ASMI supports maintenance of PIC/S combined with risk-appropriate interpretive guidance and expansion of some exemptions, along with revision of GMP processes to improve efficiency, clarity and international alignment. For example, aligning GMP clearance intervals for low risk medicines with overseas inspection frequencies would significantly reduce the regulatory burden.

This approach ensures that the regulation of all medicines (including low risk products) in Australia refers to a single, international GMP standard that can be interpreted according to the risks posed by different product categories, which is already in place in Australia and is kept up to date by a global body. As a member of that global body, the TGA is in a position to influence the content of the principles whereas the TGA has no such influence over the content of other international standards.

Interpretive guidance documents for low risk medicines, such as those established for complementary medicines, are an effective mechanism for tempering requirements so that the application of PIC/S is commensurate with the risk of the goods. This approach should be further expanded and applied to other low risk medicines, such as sunscreens.

Clarity regarding GMP requirements for low risk *ingredients* is also needed, however these requirements must be suitable for the types of ingredients, considering the typical usage, the risk, and the ability for manufacturers to verify the quality. It is important to acknowledge that some of the active ingredients used in lower risk medicines can be difficult to source from a manufacturer regulated under pharmaceutical GMP. This is because the primary use of the substance globally may not be as a 'medicinal active ingredient'. For example vitamins are typically manufactured for inclusion in food/dietary supplements and sunscreen actives are typically manufactured to meet cosmetic standards.

For clarity of requirement for sponsors (& their finished product manufacturers) in meeting their responsibility to ensure that the active substance is manufactured to a standard consistent with the principles of the Code of Good Manufacturing Practice (GMP) (or in the case of overseas manufacturers, with an appropriate standard of GMP comparable to that required for Australian manufacturers) we suggest introducing into the Australian regulations the concept of 'atypical active ingredients'. This would facilitate an exemption from Part 3-3 of the Act for 'atypical active ingredients' from equivalence with PIC/S GMP where an appropriate food standard (e.g. HACCP) for oral use or cosmetic standard (e.g. ISO 9000) for topical use existed. This would be accompanied by routine batch QC testing to an appropriate pharmacopoeial monograph or specification prior to release for use in the finished product. This would also remove the PIC/S GMP impediment and provide parity for Australian businesses to manufacture these low risk ingredients and supply them as medicinal actives.

We note that Health Canada is considering an approach for GMP of 'atypical active pharmaceutical ingredients'.

ASMI also suggests considering a similar exemption from Part 3-3 of the Act for low risk active ingredients that undergo what is currently considered a 'first step of manufacture', but is an initial or simple processing as part of the manufacture of the active in the same plant. When considered a 'first step of manufacture', this manufacturer requires a TGA GMP clearance, however as the manufacturer is not regulated in other countries as a pharmaceutical manufacturer the sponsor cannot rely on equivalent overseas pharmaceutical agency inspections to confirm their suitability.

This exemption would recognise that active premixes are often manufactured and regulated for inclusion in food/dietary supplements or for inclusion in cosmetic products. This exemption would be provisional on QC acceptance testing by a licensed/certified manufacturer to confirm the content and quality of the active(s)/excipient(s), and appropriate supplier agreements and vendor qualification have been established to ensure quality of the finished goods. Where acceptance testing of a premixed active is not feasible e.g. active ingredients containing mixtures of herbal extracts or multiple probiotics, this would be considered to be an intermediate step in manufacture and would require evidence of pharmaceutical GMP.

Risk Classification System

ASMI agrees with the six broad criteria for risk assessment of medicines as identified in the consultation paper, as follows:

- The safety of the ingredients
- The route of administration
- The risk associated with the claims including labelled use
- The nature of the condition being treated or prevented
- The nature and number of the population using the product
- The impact of poor quality in manufacture

ASMI generally agrees with the resulting classification of product types, with the following two exceptions:

- We question the inclusion of oral homeopathic products in the "very low" category given the nature of some of the starting materials and the risks associated with poor quality in manufacture. On this point we note the recent TGA alert regarding variable levels of belladonna alkaloids in a homeopathic teething product[2]. We suggest that all oral products should be excluded from the "extremely low" and "very low" categories accordingly.

- We also question the inclusion of ear candles in the "very low" category. We suggest that any product that involves a naked flame in close proximity to the head of a prone patient should at least be considered to be a "low" risk. We also suggest that consideration needs to be given to how these products are marketed (e.g. for chronic ear infections, glue ear, etc.) which are conditions that may require different forms of treatment.

[2] https://www.tga.gov.au/alert/hylands-baby-homeopathic-teething-tablets

Executive Summary

This submission presents a range of views between, and within, each of the low risk product categories. While each of the categories is presented separately on the following pages, the following principles and assumptions underpin our response:

- If a product meets the definition of a therapeutic good[3] under the Therapeutic Goods Act, then it should be regulated as a therapeutic good by a national regulator.

- The TGA is already in place as that national regulator, and should continue to be the single regulator of all therapeutic goods:
    - Section 4 of the Therapeutic Goods Act[4] indicates that "The objects of this Act … are the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods…"
    - The TGA has the necessary expertise and focus to ensure that the regulation of therapeutic goods is not lost among a broader portfolio as would happen with a generalist agency.
    - Even if the TGA were to step back from regulating a particular group of products, those products will still need to be regulated in terms of quality, safety and efficacy by some agency.
    - There is nothing to be gained by the TGA surrendering oversight of a group of therapeutic goods to any other agency.

- The TGA's stated aims of adopting risk-based regulation[5] are supported.
    - If the regulatory requirements are too high, then products will be unnecessarily expensive and consumer choice will be limited.
    - If the regulatory requirements are too low, then consumers are put at risk and the reputation of the industry is damaged.
    - ASMI notes the following statement by the TGA on their website:

> *Our risk-based approach to regulating therapeutic goods is designed to ensure that regulation is only used where absolutely needed and, then, only to the extent needed to protect and advance public health. In practice, this means the level of regulation-and our regulation and compliance efforts-is commensurate with the risks posed by particular therapeutic goods.*

- There are benefits to all stakeholders from a comprehensive risk-based regulatory system:
    - Sponsors are able to make therapeutic claims. Care therefore needs to be taken that these reforms (and others such as the addition listing pathway and the "claimer") do not end up diluting the indications that can be applied and the claims that can be made. Sponsors need to be confident that the supported options for reducing the regulatory burden do not end up (inadvertently) restricting the claims that can be made.
    - There are published processes for having new ingredients and new products approved, which provide predictability and certainty and encourages innovation
    - Consumers are assured of appropriate controls over quality, safety, efficacy and timely availability of products

[3] http://www.austlii.edu.au/au/legis/cth/consol_act/tga1989191/s3.html
[4] http://www.austlii.edu.au/au/legis/cth/consol_act/tga1989191/s4.html
[5] https://www.tga.gov.au/product-regulation-according-risk

    - All stakeholders benefit from a publicly accessible register, which is essential for visibility of what products and ingredients are on the market (as discussed on page 5 under "Public Register of Therapeutic Goods").
    - Stakeholders can rely on the credibility of the TGA's public statements
    - Exporters benefit from the enhanced reputation of their goods

- Rather than develop uniquely Australian requirements, the TGA should seek to align regulatory requirements and standards with those of comparable markets (also taking into consideration where those comparable markets are heading). For example, the TGA should consider adopting a monograph system drawing from the systems already in place in other markets such as the US, Canada and Japan.

- While "maintaining the status quo" is supported for a number of the product categories, this does not mean that status quo is the preferred outcome. In all cases, where we have supported maintaining the status quo, we would also suggest that the TGA continue to explore a range of measures for reducing the regulatory burden on the product category.

- Where a number of options are supported for a particular product category, ASMI's expectation is that (unless these options are incompatible with each other) then they will be combined into a package of reforms for that product category.

- The consultation paper raises the possibility that the TGA's continued regulation of some product categories could be viewed as "legitimising" them. ASMI does not support this proposition. If the products are not legitimate then the TGA should take action against the sponsors and advertisers.

- ASMI looks forward to further stakeholder consultation to develop, refine and finalise the reforms. On this point we note that:
    - The (independently run) stakeholder workshops which were conducted for other MMDR reforms (e.g. scheduling and complementary medicines) were aimed at informing the TGA's advice to Government and provided a valuable opportunity for all stakeholders to comment on the details in an effective and transparent fashion. ASMI would expect that similar refining of outcomes and recommendations from this consultation would be necessary to confirm practicality prior to making recommendation to Government.
    - A large part of the success of the OTC BPR project was due to the establishment of an Industry/TGA Working Group set up to develop, test and refine proposals for reform. A similar working group should be established to have carriage of the reforms coming out of this consultation.

- There needs to be a measured and pragmatic approach to transition and ASMI looks forward to working with the TGA and other stakeholders to ensure a smooth transition over a reasonable time period.

- There needs to be a proper consideration of costs and benefits through the Regulation Impact Statement (RIS) process.

Alternatives to regulatory re-classification

While "maintaining the status quo" (i.e. maintaining the current regulatory classification) is supported for a number of the product categories, this does not mean that status quo is the preferred outcome. In all cases, where we have supported maintaining the status quo, we have also suggested that the TGA continue to explore a range of measures for reducing the regulatory burden on the product category. Where a number of options are supported for a particular product category, ASMI's expectation is that (unless these options are incompatible with each other) then they will be combined into a package of reforms for that product category.

Where ASMI supports maintaining the current regulatory classification, this support is conditional upon the TGA considering a range of measures to reduce the regulatory burden on these products.

ASMI suggests that the TGA consider the following measures as a starting point:

- Reducing the level of detail required in the ARTG entry:
    - This reduced level of detail would still allow stakeholders to uniquely identify a product, but would allow sponsors to make a range of product changes without triggering a regulatory impact.
    - A reduced level of detail reduces the regulatory burden associated with the initial listing and with product maintenance.

- Permitting variations to be made by way of notification.

- Minimising the impact of variations on the AUST L number and the cost of label changes to reflect any new AUST L due to a minor change.

- Streamlining the approval of new ingredients.

- Permitting appropriate non-pharmacopoeial (e.g. food or cosmetic) raw material standards and analytical methods.
    - This would reduce costs, permit greater flexibility for sponsors, present no appreciable increase in consumer risk and would allow greater parity of cost of goods in export markets.

- Maintaining PIC/S manufacturing standard but with category specific guidance materials.
    - This would allow sponsors to retain the principles and credibility associated with PIC/S standard.
    - This would permit some flexibility for appropriate and consistent interpretation of the PIC/S Guide (both by manufacturers and inspectors) for lowest risk products.
    - Consumers would still retain the protection of application of the PIC/S standard.

- Alignment of GMP clearance intervals with overseas inspection frequencies for the lowest risk medicines.

- Timely recognition of the regulatory requirements and standards of comparable markets.

- Expansion of the exemptions in Part 3-3 of the Act for low risk active ingredients and premixes would remove the requirement for pharmaceutical GMP for ingredients regulated as foods/dietary supplements or cosmetics in other markets.

- Revising TGO 54 (Standard for Disinfectants and Sterilants) with a focus on appropriately differentiating between the microbial efficacy test criteria for household grade disinfectants and hospital grade disinfectants.

- Revising TGO 77 (Microbiological Standards for Medicines) with a focus on allowing alternative Preservative Efficacy Testing specifically in relation to sunscreens where application is to healthy skin, and similar to that allowance already provided for antacids.

- Revising TGO 78 (Standard for Tablets and Capsules) with a focus on the impact of default standards on complementary medicines, the disproportionate impacts on registered complementary medicines, the list of ingredients in schedule 1 and the limits imposed by schedule 1

- Revising TGO 82 (Standard for Tampons – Menstrual) with a focus on removing the uniquely Australian requirements.

- Adopting a system of efficacy monographs drawing on the best elements from systems already in place in other markets such as the US, Canada and Japan. While these efficacy monographs are discussed in more detail under “Vitamins and Minerals” on page 33, they could also be applied to the other “low risk” product categories. Efficacy monographs would provide sponsors with an easier regulatory pathway for routine products, reduced regulatory costs and reduced timelines. Consumers would also be protected through the use of standardised claims.

Maintaining Access to Current Indications and Claims

It is unclear how these options for reform (and the various other reforms currently being consulted on, for example the additional listing pathway for listed medicines and the TGA "claimer") will affect the sponsors' ability to make therapeutic claims about the products. Care therefore needs to be taken that any reforms arising from these consultations do not end up diluting the indications that can be applied and the claims that can be made about these products.

In such an uncertain setting, sponsors need to be confident that the supported options for reducing the regulatory burden do not end up either:

- Inadvertently restricting the claims that can be made, or
- Diminishing consumer confidence in the listed medicine when it is compared to another listed product which carries the proposed TGA efficacy "claimer".

We have assumed that any option for exclusion from the Act would mean the loss of current indications. Where the option is for a registered product to become a listed product, it is important for sponsors to continue to have access to the current indications and claims for these low risk products and for consumer confidence to be maintained.

ASMI support for any option is therefore conditional on maintaining access to the current indications and claims for these "low risk" products.

Ear candles

Option 1 – Maintain the status quo regulation of ear candles.

Supported. Where a product is represented in any way to be for therapeutic use (or is likely to be taken to be for therapeutic use) then the product should be on the public register (the ARTG) and should be regulated by the TGA.

The consultation paper raises the possibility that the TGA's continued regulation of these products could be viewed as "legitimising" them. ASMI does not support this proposition. If the products are not legitimate then the TGA should take action against the sponsors and advertisers. The legitimacy or otherwise of a group of products should have no bearing on whether the TGA (or some other agency) regulates them. If they are therapeutic goods, they are the TGA's responsibility. If they are not legitimate goods, then the TGA has an obligation to take action. Handing responsibility on to another agency is not an appropriate solution.

As mentioned above on page 8 under "Risk Classification System", the advertising & claims made for these products can be problematic and if there is a lack of enforcement then these problems can be made worse.

Option 2 – Exemption from listing in the ARTG

Not supported. All stakeholders benefit from a publicly accessible register.

See the discussion on page 5 under "Public Register of Therapeutic Goods".

Option 3 – Exclude ear candles from the regulatory framework

Not supported. All stakeholders benefit from a publicly accessible register.

See the discussion on page 5 under "Public Register of Therapeutic Goods".

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

No further comments.

Nappy rash cream

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

Supported. Where a product is represented in any way to be for therapeutic use (or is likely to be taken to be for therapeutic use) then the product should be on the public register (the ARTG) and should be regulated by the TGA.

These products are applied to very young children and possibly to broken skin. Consumers are therefore entitled to assume an appropriate level of regulatory oversight.

While ASMI supports maintaining the current regulatory classification, this support is conditional upon the TGA considering a range of measures to reduce the regulatory burden on these products. See the discussion on page 11 under "Alternatives to regulatory re-classification".

Option 2 – Review of medical device nappy rash products

Only supported for barrier creams, where there is a pharmacological action this is not appropriate.

Option 3 – Exemption from listing in the ARTG

Not supported. All stakeholders benefit from a publicly accessible register. See the discussion on page 5 under "Public Register of Therapeutic Goods".

Option 4 – Review of registered nappy rash active ingredients

Supported. See above comments under option 1 and see the discussion on page 11 under "Alternatives to regulatory re-classification".

Option 5 – Exclude nappy rash products from the regulatory framework

Not supported. All stakeholders benefit from a publicly accessible register. See the discussion on page 5 under "Public Register of Therapeutic Goods".

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.

ASMI suggests that the current regulation of nappy rash products is too complex. In the current system it is possible that a nappy rash cream could be a cosmetic product, a device, a listed medicine or a registered medicine. The TGA should consider options for reducing the regulatory burden in relation to both listed and registered products.

Antiperspirants

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

Supported by some ASMI members on the basis that the current regulatory approach provides consumers with an appropriate level of protection.

Option 2 – Exclude antiperspirants from the regulatory framework

Supported by some ASMI members on the basis that regulation as a cosmetic products would align the Australian requirements with the requirements in comparable overseas markets such as New Zealand and Europe.

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.

There are mixed views within the ASMI membership as to whether or not reform to antiperspirant regulation is warranted.

In any event, ASMI is concerned that the TGA (despite comments otherwise in the consultation paper regarding risk and risk classification – see for example the criteria specified on page 10 of the consultation paper) believe that other criteria such as "community expectations" and "public perceptions" could reasonably be used to determine the risk of a product category.

Other Low risk registered OTC Medicines

Registered desensitising toothpastes

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

Supported by some ASMI members on the basis of the product indications.

Support for maintaining the current regulatory classification is conditional upon the TGA considering a range of measures to reduce the regulatory burden on these products. See the discussion on page 11 under "Alternatives to regulatory re-classification".

Option 2 – Review of eligibility of active ingredients to become Listable

Supported by most ASMI members on the basis that the risks are low and that regulation as a listed product would reduce the regulatory complexity (and costs) associated with the products and yet still retain an appropriate level of TGA oversight.

Support for option 2 is conditional on maintaining access to the current indications and claims.

In either case, members were in agreement that the current regulation of desensitising toothpastes was too complex. In the current system it is possible that a toothpaste could be a cosmetic product, a device, a listed medicine or a registered medicine. The TGA should consider options for reducing the regulatory burden in relation to *both* listed and registered desensitising toothpastes.

Antiseptics for first aid treatment of minor cuts and abrasions

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

Supported by some ASMI members on the basis of the indications (i.e. application to broken skin) and on the basis of the claims that the current level of regulatory oversight permits advertisers to make. Because of the range of concurrent consultations ongoing, there are concerns that the proposed changes to the listing system, and the introduction of an additional pathway for listed medicines may reduce the claims that are permitted.

Support for maintaining the current regulatory classification is conditional upon the TGA considering a range of measures to reduce the regulatory burden on these products. See the discussion on page 11 under "Alternatives to regulatory re-classification".

Option 2 – Review of eligibility of active ingredients to become Listable

Supported by some ASMI members on the basis that the risks are low and that regulation as a listed product would reduce the regulatory complexity (and costs) associated with the products and yet still retain an appropriate level of TGA oversight.

Support for option 2 is conditional on maintaining access to the current indications and claims.

Lozenges for relief of sore throats (these contain anti-microbial active ingredients)

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

Supported by some ASMI members on the basis of the claims that the current level of regulatory oversight permits advertisers to make. Because of the range of concurrent consultations ongoing, there are concerns that the proposed changes to the listing system, and the introduction of an additional pathway for listed medicines may reduce the claims that are permitted.

Support for maintaining the current regulatory classification is conditional upon the TGA considering a range of measures to reduce the regulatory burden on these products. See the discussion on page 11 under "Alternatives to regulatory re-classification".

Option 2 – Review of eligibility of active ingredients to become Listable

Supported by some ASMI members on the basis that the risks are low and that regulation as a listed product would reduce the regulatory complexity (and costs) associated with the products and yet still retain an appropriate level of TGA oversight.

Support for option 2 is conditional on maintaining access to the current indications and claims.

Antacids – containing carbonates, hydroxides, silicates, and/or alginates

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

Supported by some ASMI members, on the basis of the indications.

Support for maintaining the current regulatory classification is conditional upon the TGA considering a range of measures to reduce the regulatory burden on these products. See the discussion on page 11 under "Alternatives to regulatory re-classification".

Option 2 – Review of eligibility of active ingredients to become Listable

Supported by some ASMI members on the basis of the safety of the ingredients and on the potential for reduced regulatory complexity.

Support for option 2 is conditional on maintaining access to the current indications and claims.

Salicylic acid plasters for removal of corns and warts

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

Supported by some ASMI members on the basis of the indications and the safety of the ingredients.

Support for maintaining the current regulatory classification is conditional upon the TGA considering a range of measures to reduce the regulatory burden on these products. See the discussion on page 11 under "Alternatives to regulatory re-classification".

Option 2 – Review of eligibility of active ingredients to become Listable

Supported by some ASMI members on the basis of the route of administration and on the potential for reduced regulatory complexity.

Support for option 2 is conditional on maintaining access to the current indications and claims.

Menthol-based inhalers and chest rubs

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

Supported by some ASMI members on the basis of the indications.

Support for maintaining the current regulatory classification is conditional upon the TGA considering a range of measures to reduce the regulatory burden on these products. See the discussion on page 11 under "Alternatives to regulatory re-classification".

Option 2 – Review of eligibility of active ingredients to become Listable

Supported by some ASMI members on the basis of the safety of the ingredients, the route of administration and the potential for reduced regulatory complexity.

Support for option 2 is conditional on maintaining access to the current indications and claims.

Antiseptic mouth washes

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

Not supported.

Option 2 – Review of eligibility of active ingredients to become Listable

Supported by ASMI members on the basis of the indications, the route of administration and the potential for reduced regulatory complexity. Because of the range of concurrent consultations ongoing, there are however concerns that the proposed changes to the listing system, and the introduction of an additional pathway for listed medicines may reduce the claims that advertisers are permitted to make.

Support for option 2 is conditional on maintaining access to the current indications and claims.

Acne treatments containing benzoyl peroxide

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

Supported by some ASMI members on the basis of the indications and the safety of the ingredient.

Support for maintaining the current regulatory classification is conditional upon the TGA considering a range of measures to reduce the regulatory burden on these products. See the discussion on page 11 under "Alternatives to regulatory re-classification".

Option 2 – Review of eligibility of active ingredients to become Listable

Supported by some ASMI members on the basis of the route of administration and the potential for reduced regulatory complexity.

Support for option 2 is conditional on maintaining access to the current indications and claims.

Rubefacient preparations for minor aches and pains of muscles

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

Supported by some ASMI members on the basis of the indications and the safety of the ingredients.

Support for maintaining the current regulatory classification is conditional upon the TGA considering a range of measures to reduce the regulatory burden on these products. See the discussion on page 11 under "Alternatives to regulatory re-classification".

Option 2 – Review of eligibility of active ingredients to become Listable

Supported by some ASMI members on the basis of the route of administration and the potential for reduced regulatory complexity.

Support for option 2 is conditional on maintaining access to the current indications and claims.

Certain laxatives

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

Supported by some ASMI members on the basis of the indications, the route of administration and the inclusion of children in the population using the product.

Support for maintaining the current regulatory classification is conditional upon the TGA considering a range of measures to reduce the regulatory burden on these products. See the discussion on page 11 under "Alternatives to regulatory re-classification".

Option 2 – Review of eligibility of active ingredients to become Listable

Supported by some ASMI members on the basis of the potential for reduced regulatory complexity.

Support for option 2 is conditional on maintaining access to the current indications and claims.

Antidandruff and antifungal shampoos

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

Supported by some ASMI members on the basis of the indications.

Support for maintaining the current regulatory classification is conditional upon the TGA considering a range of measures to reduce the regulatory burden on these products. See the discussion on page 11 under "Alternatives to regulatory re-classification".

Option 2 – Review of eligibility of active ingredients to become Listable

Supported by some ASMI members on the basis of the topical application and on the potential for reduced regulatory complexity. Support for option 2 is conditional on maintaining access to the current indications and claims.

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.

There are mixed views within the ASMI membership as to which options are preferred for which category of products.

Support for option 1 is conditional upon the TGA considering a range of measures to reduce the regulatory burden on these products. See the discussion on page 11 under "Alternatives to regulatory re-classification".

Support for option 2 is conditional on maintaining access to the current indications and claims.

It is unclear how these options for reform (and the various other reforms currently being consulted on, for example the additional listing pathway for listed medicines and the TGA "claimer") will affect the sponsors' ability to make therapeutic claims about the products. Care therefore needs to be taken that these reforms do not end up diluting the indications that can be applied and the claims that can be made about these products. In such a setting, sponsors need to be confident that the supported options for reducing the regulatory burden do not end up (inadvertently) restricting the claims that can be made.

ASMI suggests that the TGA's lists of ingredients identified in the above categories should be reviewed for completeness and expanded in consultation with all stakeholders (for example the ingredient Simethicone has been omitted from the antacids category – Simethicone is commonly used in antacid products, is not systemically absorbed and should have been included here).

See also the discussion on page 5 under "Public Register of Therapeutic Goods".

Hard surface disinfectants

Option 1 - Maintain the status quo regulation of hard surface disinfectants.

Supported. Where a product is represented in any way to be for therapeutic use (or is likely to be taken to be for therapeutic use) then the product should be on the public register (the ARTG) and should be regulated by the TGA.

Support for maintaining the current regulatory classification is conditional upon the TGA considering a range of measures to reduce the regulatory burden on these products. See the discussion on page 11 under "Alternatives to regulatory re-classification".

Option 2 – Streamline the regulatory framework for hard surface disinfectants

Supported. See above comments in relation to Option 1.

Support for option 2 is conditional on maintaining access to the current indications and claims.

In addition the TGA should review the pre-market requirements in relation to microbial efficacy. The TGA should revise TGO54 so there is a different microbial efficacy test criteria for household grade disinfectants vs hospital grade disinfectants. The TGA should also consider using alternative terms to "hospital grade" and "household grade" so as to avoid misunderstandings as to the appropriate application environments for the products.

Option 3 – Develop a series of monographs

Supported. See above comments in relation to Option 1.

Support for option 3 is conditional on maintaining access to the current indications and claims.

Option 4 – Approval process for new ingredients

Supported. See above comments in relation to Option 1.

Option 5 – Declare hard surface disinfectants not to be therapeutic goods

Not supported. All stakeholders benefit from a publicly accessible register.

See the discussion on page 5 under "Public Register of Therapeutic Goods".

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.

No further comments.

Sunscreens

Option 1 - Maintain the status quo regulation of sunscreens.

Supported by most ASMI members. Where a product is represented in any way to be for therapeutic use (or is likely to be taken to be for therapeutic use) then the product should be on the public register (the ARTG) and should be regulated by the TGA.

However, ASMI suggests that the TGA consider a range of measures for reducing the regulatory burden on sunscreens (as outlined below and as discussed on page 6 under "GMP Standards for low risk medicines and actives" and page 11 under "Alternatives to regulatory re-classification").

Option 2 – Streamline the regulatory pathways for sunscreen regulation

Supported by some ASMI members.

Option 3 – Prevent all secondary sunscreens from making SPF claims

Supported by some ASMI members on the basis of simplifying both the regulatory system and the claims that can be made about the different types of products. This option would also help reduce consumer confusion.

Option 4 – Creation of a GMP standard for primary sunscreens

Supported by some ASMI members.

While all ASMI members agree that an appropriate GMP standard needs to be applied to sunscreen manufacture, there are differing views as to which standard should apply. The majority of ASMI members support application of the principles based approach described in the *PIC/S Guide for GMP for medicinal products* (accompanied by risk-appropriate interpretive guidance).

Option 5– New ingredient approval process

Supported. See above comments under Option 1.

Option 6 – Alternative ingredient standards for excipients

Supported. See above comments under Option 1.

Option 7 – Exclude all sunscreens from the regulatory framework

Not supported. All stakeholders benefit from a publicly accessible register.

See the discussion on page 5 under "Public Register of Therapeutic Goods".

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.

There are a range of views within the ASMI membership.

In addition to the views described above, most members support a combination of options.

Concerns were also expressed that, with the incidence of skin cancer in Australia, any deregulation of sunscreens places consumers at greater risk of exposure to products that are not tested and/or manufactured according to best practices. Noting that even now as listed medicines, there is already regular media coverage that leads to potentially low trust in sunscreen technology. Also noting that, lowering testing and manufacturing standards would likely amplify such lack of trust.

The ASMI position can be summarised as follows:

1. Primary sunscreens should be regulated as therapeutic goods by the TGA by virtue of the fact that they make therapeutic claims, i.e. the prevention of sunburn and skin cancer. The TGA should continue to regulate sunscreens as medicines rather than devices.
2. Apart from the risks associated with the product ingredients the main risk to be managed is potential product failure in relation to efficacy, i.e. preventing sunburn and skin cancer. This is particularly important as product failure will only become evident after harm has occurred. ASMI therefore continues to support the adoption of the current AS/NZS 2604 in the Therapeutic Goods Regulations 1990 as the Standard for SPF and Broad Spectrum performance.
3. Consequently, it is vital to ensure that primary sunscreens perform as described from batch to batch over the designated shelf life of the products. ASMI members unanimously agree that this consistency will be ensured by application of appropriate GMP standards to the product's manufacture.
4. For the majority of ASMI members the preferred starting point to achieve appropriate quality, safety and efficacy of sunscreens, is through application of the principles based approach described in the *PIC/S Guide for GMP for medicinal products* (accompanied by risk-appropriate interpretive guidance). This then ensures that the regulation of all medicines (including sunscreens) in Australia refers to a single, international GMP standard, which can be interpreted according to the risks posed by different product categories, which is already in place in Australia and which is kept up to date by a global body. As a member of that global body, the TGA is in a position to influence the content of the principles whereas the TGA has no such influence over the content of other international standards.
5. To ensure the appropriate regulatory touch for lower risk listable therapeutic goods, the majority of ASMI members support initiatives to develop risk-appropriate interpretative guidance for the application of PIC/S principles to sunscreens. This would significantly reduce the regulatory burden.

6. The ISO Cosmetic Standard of GMP has been proposed as an alternative to the PIC/S principles, ASMI members unanimously agree that the ISO standard alone falls short in the following key areas:
    - No system of control for starting materials,
    - No standards for control of finished product including assay of active ingredients,
    - No Authorised Person review for batch release in compliance with conditions of TGA Listing,
    - No system to confirm the product continues to be stable over the shelf-life,
    - No detailed system for Change Control,
    - No requirement for analytical validation,
    - No requirement manufacturing process validation,
    - No system for Corrective and Preventive Action.
7. The majority of ASMI members believe the current system for distinguishing between sunscreens regulated as therapeutic goods and cosmetics containing sunscreens (based on the Newgreen Review[6]) provides an appropriate level of protection for Australian consumers and therefore remains appropriate. All ASMI members agree that the classification of 300mL plus packs sizes of cosmetics as therapeutic goods, could be removed in the interests of simplification (so that classification is not dependent on pack size).
8. ASMI does not believe that the regulation of sunscreens in Australia is "out of step" with other comparable markets where regulatory differentiation exists between sunscreens and cosmetics (for example, the US, Canada, the EU).
9. ASMI supports measures that would reduce the regulatory burden and streamline business processes applicable to primary sunscreens. See the discussion on page 11 under "Alternatives to regulatory re-classification".

[6] Review of the regulation of products at the interface between cosmetics and therapeutic goods March 2005
Prepared for the TGA by David B Newgreen.

Tampons and menstrual cups

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

Supported in relation to tampons (ASMI makes no submission in relation to menstrual cups).

Support for maintaining the current regulatory classification is conditional upon the TGA considering a range of measures to reduce the regulatory burden on these products. See the discussion on page 11 under "Alternatives to regulatory re-classification".

In particular, ASMI suggests that the TGA consider the following actions:

- TGO 82 (Standard for Tampons – Menstrual) should be updated:
  - To remove the unique Australian requirements.
  - To recognise other international standards (for example the EDANA standard in the EU and the US FDA requirements).
  - To remove the need for further testing of imported products.
- The current Tampon standard, Australian/New Zealand Standard AS/NZS 2869:2008 should be reviewed (the standard has not been reviewed in 10 years).

Option 2 – Exemption from listing in the ARTG

Limited support.

Option 3 – Exclude tampons and menstrual cups from the regulatory framework

Not supported. Removing these products from a specialist regulator such as the TGA to a generalist regulator (such as the ACCC) is very likely to expose consumers to unacceptable labelling and advertising claims.

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.

Concerns have been expressed in relation to the unique AUS/NZ standard for tampons with a suggestion being put forward that the EU standard would be preferred.

Low risk products that are currently considered medical devices

Product types for consideration by MMDR recommendation 23

Action 1 – Systematically review the ARTG for potential non therapeutic goods

Supported. Where a product is represented in any way to be for therapeutic use (or is likely to be taken to be for therapeutic use) then the product should be on the public register (the ARTG) and should be regulated by the TGA.

However, where non-therapeutic goods have been included on the register (either through sponsor error or through incentives in hospital tenders) then those goods should be reviewed with the aim of removing them. ASMI suggests that the review process should involve all stakeholders in the development of exclusion/inclusion criteria.

ASMI would not support changes to the overall registration process for devices.

Action 2 – Engage with States and Territories

Supported. However, ASMI would not support changes to the overall registration process for devices.

Action 3 – Update the Excluded Goods Order

Supported in relation to declaring products with non-therapeutic purposes to be excluded. ASMI suggests that the review process should involve all stakeholders in the development of exclusion/inclusion criteria.

Not supported in relation to declaring products of "dubious evidence" to be excluded (and hence the responsibility of some other agency apart from the TGA). If products are of dubious evidence then the TGA should take action against the sponsors and advertisers (rather than passing them on to some other agency). The legitimacy or otherwise of a group of products should have no bearing on whether the TGA (or some other agency) regulates them. If they are therapeutic goods, they are the TGA's responsibility. If they are not legitimate goods, then the TGA has an obligation to take action. Handing responsibility on to another agency is not an appropriate solution.

As indicated above under options 1 and 2, ASMI would not support changes to the overall registration process for devices.

Action 4 – Review Class I medical device ARTG entry process

Supported in principle. While ASMI does not support changes to the overall registration process for devices, we support refinements to the process provided that:

- The review process involves all stakeholders
- There is no resulting increase in regulatory burden.
- Legitimate medical devices are not excluded.

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.

While the proposed actions could be helpful, potentially they could remove products that do provide therapeutic effects. The current regulatory path for Class I medical devices provides access to products that have been developed and manufactured to therapeutic standards and provide treatment for a wide range of conditions with minimal concern for safety. By removing the current requirements, the risk for the introduction of products that do not provide equivalent therapeutic benefits would increase, ultimately lowering the confidence consumers have in the efficacy of therapeutic products.

The review of the Class I medical device entry process could better addressed with additional clear information on what products are class 1 medical devices and perhaps an online decision tree or similar. Sponsors could be assisted with examples of claims and with advice on aspects to consider prior to making the application. Flagging product type by GMDN term would seem a better option. Additionally, given the number of class 1 inclusions, how would this be resourced at the TGA and what consequences would this have to businesses in terms of registration fees and timeframes for approval.

The proposed general clean-up of class 1 devices is supported, provided there is no negative impact on legitimate medical devices. Goods that have no therapeutic use or therapeutic claims should be removed from the ARTG and reclassified as consumer goods.

While the classification of medical devices often results in the inclusion of products with low risk, the classification is based on current ISO international standards and definitions. Changes to this classification process locally may be in conflict with international classification and as a result negatively impact on the export of devices in this space. If products are not covered as medicines or devices then what controls will be applied to set a quality standard?

Aromatherapy products

Option 1 – Maintain the status quo regulation of aromatherapy products

Supported. Where a product is represented in any way to be for therapeutic use (or is likely to be taken to be for therapeutic use) then the product should be on the public register (the ARTG) and should be regulated by the TGA.

Because the essential oils are inhaled and/or applied to the skin, there are risks that need to be mitigated.

However, ASMI suggests that the TGA could consider a range of measures for reducing the regulatory burden on aromatherapy products (as described elsewhere in this submission).

Option 2 – Exemption from listing in the ARTG and/or GMP

Not supported. All stakeholders benefit from a publicly accessible register. See the discussion on page 5 under "Public Register of Therapeutic Goods".

Not supported. Like Option 3 this option would capture essential oils that are used for other therapeutic products apart from aromatherapy (such as products that are taken orally).

Option 3 – Declare essential oils not to be therapeutic goods

Not supported. Like Option 2 this option would capture essential oils that are used for other therapeutic products apart from aromatherapy (such as products that are taken orally).

This would impact the numerous essential oils that are currently used in therapeutic goods apart from aromatherapy, for example:

- Evening Primrose Oil
- Eucalyptus Oil
- Fennel Oil
- Lavender Oil
- Melaleuca Oil
- Peppermint Oil
- Thyme Oil
- Wintergreen Oil

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.

No further comments.

Rehydration or formulated sports products

Further Action – Review of rehydration products on the ARTG to remove food claims

Supported. The TGA should ensure there is a clear demarcation between sports drinks (i.e. foods) and oral rehydration products (i.e. therapeutic goods).

Rehydration products are to treat a potential life threatening condition and should not be confused with foods, there should be a clear separation between formulated sports drinks and rehydration products.

While members were supportive of a clearer demarcation between foods and therapeutic goods, concerns were expressed about the potential lack of enforcement to ensure that food products only made claims permitted for foods.

Oral rehydration products with a therapeutic purpose that comply with the OTC Monograph for ORS should also be allowed to make the claim "to prevent or treat mild dehydration that may occur as a result of sustained strenuous exercise."

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.

No further comments.

Vitamins and minerals

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

Supported. Where a vitamin or mineral product is represented in any way to be for therapeutic use (or is likely to be taken to be for therapeutic use) then the product should be on the public register (the ARTG) and should be regulated by the TGA.

While ASMI supports maintaining the current regulatory classification, this support is conditional upon the TGA considering a range of measures to reduce the regulatory burden on these products. See the discussions on page 6 under "GMP Standards for low risk medicines and actives" and on page 11 under "Alternatives to regulatory re-classification".

Changes to TGO 78 (Standard for Tablets and Capsules) are needed to address the current issues concerning: the impact of default standards on complementary medicines, the disproportionate impacts on registered complementary medicines, the small number of active ingredients which are included in schedule 1 and the inappropriate limits which are imposed by schedule 1.

The TGA should apply a more pragmatic approach to how the risk-based regulatory framework applies to GMP requirements for active ingredients used in listed and registered complementary medicines. Vitamin and mineral active ingredients (including premixes) used in therapeutic goods manufacture will typically already be used in the manufacture of foods. ASMI suggests legislating exemptions from Part 3-3 of the Act and the pharmaceutical standard of GMP for ingredients that are routinely consumed as foods, and where the quality and content of active ingredients is assured through supplier agreements and vendor qualification, and able to be verified by licenced/certified manufacturers through QC testing.

As part of the overall regulatory framework, the TGA should also consider introducing a system of efficacy monographs whereby the TGA publishes sets of claims for well-established ingredients (or combinations of those ingredients) so that if sponsors market products with those ingredients and claims then they would not have to hold additional evidence to substantiate those claims. Such a system would align with regulatory controls in other markets (e.g. Canada) and would reduce the regulatory burden on sponsors who chose to supply such products. The most likely types of products would be:

- Vitamins and minerals for supplementing inadequate dietary intake.
- Herbal and other products for health maintenance purposes.
- Products making structure/function claims.

Efficacy monographs would provide sponsors with an easier regulatory pathway option for routine products, reduced regulatory costs and reduced timelines.

Efficacy monographs could be further simplified (and made easier to maintain) if they were to refer to recognised reference texts (as opposed to referring to the specific claims etc.).

Efficacy monographs could also be applied to the other "low risk" product categories.

Option 2 – Exemption from listing in the ARTG and/or GMP

Supported by some ASMI members on the basis that it offers a reduction in regulatory burden commensurate with the low risks posed.

There are concerns that these products would then no longer be on the public register. See the discussion on page 5 under "Public Register of Therapeutic Goods".

There are also concerns that a lowering of the standards could put consumers at risk and could damage the reputation of the industry and the reputation of the products.

Option 3 – Declare vitamins and mineral not to be therapeutic goods

Not supported.

This option provides very little protection to consumers and has the potential to damage the reputation of the industry and the reputation of the products.

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

There are other consultations currently underway which will have a direct bearing on these reforms, but of which we have no clear indication of outcomes. For example, the recently closed consultation on the regulatory framework for complementary medicines. The comments in this response have therefore been kept at a general level, given this uncertainty.

GMP requirements and TGO 78 are major pressure points for vitamins and minerals that are sourced from overseas. Changes to these specific requirements would therefore help align with other comparable markets.

The TGA should consider an alignment with the foreshadowed NZ natural health product regulations so that there is some consistency between countries. Alignment in terms of vitamins permitted, maximum levels permitted, GMP requirements, and labelling would be desirable.

The TGA could consider expanding the reforms beyond water soluble vitamins and specific minerals. The food standards code permits foods to include the addition of fat soluble vitamins and also minerals such as zinc, iron and selenium, for example:

- For BREAKFAST CEREALS (Pro vitamin A, Vitamin D, Vitamin E, folate, iron, zinc).
- For FORMULATED BEVERAGES (folate, Pro vitamin A, Iron, Vitamin D, Vitamin E, selenium).

If reforms for low risk vitamin products are going to be introduced it should allow a decent multivitamin/mineral product to be included that has at least 25% RDI of most vitamins and minerals per dose. Reforms should allow more than is currently permitted for foods under the food standards code.

In assessing the risks associated with these types of products, the TGA should also consider:

- The potential for long-term correct use
- The impact of substandard GMP
- The potential incorrect use
- The impact of unsubstantiated claims
- The different risks within the category as between a single active supplement (e.g. Vitamin C 500mg) and a multi active supplement with a specific higher risk therapeutic purpose (e.g. a pregnancy supplement).

Homoeopathic products

Option 1 - Maintain the status quo regulation of homoeopathic products

Supported. Where a product is represented in any way to be for therapeutic use (or is likely to be taken to be for therapeutic use) then the product should be on the public register (the ARTG) and should be regulated by the TGA.

The consultation paper raises the possibility that the TGA's continued regulation of these products may imply government endorsement or could be viewed as "legitimising" them. ASMI does not support this proposition. If the products are not legitimate then the TGA should take action against the sponsors and advertisers. The legitimacy or otherwise of a group of products should have no bearing on whether the TGA (or some other agency) regulates them. If they are therapeutic goods, they are the TGA's responsibility. If they are not legitimate goods, then the TGA has an obligation to take action. Handing responsibility on to another agency is not an appropriate solution.

Options 3 and 4 represent a real risk to consumers. Even though the final products should pose very little risk when manufactured properly, poor quality control could expose consumers to variable levels of toxic substances. See for example the recent TGA alert regarding variable levels of belladonna alkaloids in a homeopathic teething product[7].

Option 2 – Serious therapeutic claims must be supported by scientific evidence.

Not supported. All claims made in relation to therapeutic goods should be supported. There should be a level playing field across all therapeutic goods in terms of substantiation.

Option 3 – Exemption from listing in the ARTG and/or GMP

Not supported. All stakeholders benefit from a publicly accessible register.

See the discussion on page 5 under "Public Register of Therapeutic Goods".

Option 4 – Declare homeopathic products not to be therapeutic goods

Not supported. All stakeholders benefit from a publicly accessible register.

See the discussion on page 5 under "Public Register of Therapeutic Goods".

[7] https://www.tga.gov.au/alert/hylands-baby-homeopathic-teething-tablets

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

Homeopathic products need to be clearly labelled as such. ASMI members have raised concerns about the potential for homeopathic labelling to confuse consumers. Unless the label clearly identifies the product as being part of the homeopathic paradigm, then consumers are likely to be misled into thinking that the products have the same mechanism of action (and evidentiary support) as other listed and registered medicines. While we anticipate that the new Labelling Order will help address this issue, the new Order will only apply to products included on the ARTG and so care needs to be taken before any homeopathic products are removed from the register or removed from TGA oversight.

Please contact me should you require any further clarification relating to this submission.

Yours sincerely,

[redacted]