Australian Government
Department of Health
Therapeutic Goods Administration

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

Version 1.0, March 2017

TGA Health Safety Regulation

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Contents

Scope and purpose

The Therapeutic Goods Administration (TGA) is seeking comments on proposed options for future regulation of 'low risk products', noting that decisions on significant changes to the regulatory framework would be made by government.

We are specifically looking for feedback on the potential regulatory options for low risk products that are discussed in this document, including which (if any) might be most appropriate and why. The options presented in this paper represent a range of possible regulatory directions for the identified 'low risk' products.

Executive summary

The Expert Panel Review of Medicines and Medical Devices Regulation (MMDR) made three recommendations in relation to performing further reviews of the regulation of 'low risk' products (MMDR recommendations 14, 23 and 48).

These recommendations were accepted by Government in its response released on 15 September 2016. In conducting these further reviews, the TGA has met with other product regulators, industry associations and some individual companies, to understand the product types that are considered 'low risk' in the context of these recommendations. Having developed candidate product types, the purpose of this paper is to enable broader public consultation on possible regulatory options for different product types.

In order to more objectively assess whether or not these products types could be considered low risk, the review team worked with experts (van Gelder Monk, University of Melbourne) to develop and implement a product assessment tool. Using the 'wisdom of crowds' and a simple linear model, this tool confirmed the opinions that had presented by the experts around particular product types.

In consolidating the expert opinions and tool outcomes, options for reform to the regulation of a range of products and options has been identified. It is believed that many of these options could be implemented without a detrimental impact on public health and safety. Indeed, by reforming the regulatory approach around certain products, it would allow sponsors and TGA to better focus on the areas of risk with these products as well as on other, higher-risk products.

The guiding principles of this review are:

- It was **not our intention to fundamentally change the definition of a medicine or medical device** under the *Therapeutic Goods Act 1989* (the Act), although it would be possible to change the regulatory approach taken for particular groups of products regulated under the Act.
- We considered what **the purpose of our regulation** of therapeutic goods is and considered how the tenets of safety, quality and efficacy are applied for each product type.
- In developing some options we **considered the concept of 'regulatory familiarity' of particular products**, from the perspective of both regulators and consumers. This concept recognises that risk of products may reduce when the handling and use of the product becomes commonplace.
- We recognise that the option of moving some product types to regulation by Food Standards Australian New Zealand (FSANZ) or under the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) are not necessarily options that provide for decreasing

regulation. It should be noted, however that Australian Consumer Law provides for default Australian Competition and Consumer Commission (ACCC) oversight of all consumer goods in Australia under Australian Consumer Law, including therapeutic goods used by consumers.

Introduction

In October 2014 the Expert Panel Review of Medicines and Medical Devices Regulation (MMDR) was announced by Government. The Panel delivered two reports[1] that assessed the regulatory framework for medicines and medical devices in Australia, and made 58 recommendations for reform.

The Panel commented on the benefits of aligning international regulatory frameworks where possible. The Government accepted the recommendations that further reviews be undertaken to potentially streamline the regulatory framework for certain low-risk products and to potentially increase consumer access to these products.

Three recommendations will be addressed in this paper:

- **Recommendation Fourteen**: The Panel recommends that the Australian Government undertake a review of the range of products currently listed in the Australian Register of Therapeutic Goods (ARTG) (not including complementary medicines) and subject to regulation under the medicines framework, with a view to ensuring that:

    1. Products that might best be regulated under other regulatory frameworks, without undermining public health and safety, are removed from the auspices of the Act; and

    2. Goods remaining under the auspices of the Act are subject to regulatory requirements that are commensurate with the risk posed by the regulated products.

- **Recommendation Twenty-Three:** The Panel recommends 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.

- **Recommendation Forty-Eight:** The Panel recommends that the Australian Government undertakes a review of the range of complementary medicinal products, currently listed in the ARTG and subject to regulation under the medicines framework, with a view to ensuring that products that might best be regulated under other regulatory frameworks, without undermining public health and safety, are removed from the auspices of the Act.

In making these recommendations, the expert panel expressed the concern that *"there are a range of products listed in the ARTG that are subject to a level of regulation which is not commensurate with the risk posed by these products to Australian consumers".*

Some potential options raised by the Panel to remedy this include: excluding such goods from the auspices of the Act[2] and regulating them under other regulatory frameworks, such as those

[1] Expert Panel, Review of Medicines and Medical Devices Regulation: Report to the Minister for Health on the Regulatory Framework for Medicines and Medical Devices (31 March 2015) and Report to the Minister for Health on the Regulatory Frameworks for Complementary Medicines and the Advertising of Therapeutic Goods (31 July 2015) available at www.health.gov.au/internet/main/publishing.nsf/Content/Expert-Review-of-Medicines-and-Medical-Devices-Regulation

[2] https://www.legislation.gov.au/Series/C2004A03952

administered by NICNAS or ACCC; or retaining them under the Act but with the application of different regulatory requirements (particularly Good Manufacturing Practice (GMP) standards) to those that apply to higher risk products.

It should be noted that some product type 'status quo' options expressed in this paper may be superseded by the implementation of other MMDR recommendations.

Background information on the current therapeutic goods regulatory framework has been included as Appendix 1 and an overview of the international approach to the regulation of the product types discussed in this paper can be found in Appendix 2.

Australian Consumer Law and relationship with the therapeutic goods legislation

In Australia, consumer rights in respect to consumer goods are covered by the Australian Consumer Law (ACL).[3] Schedule 2 of the Competition and Consumer Act 2010 specifies certain quality, safety and advertising requirements. From the ACL:

> Section 29 and 33 requires that a person must not mislead consumers through the representation that goods are of a particular value, quality and efficacy. Section 54 sets grounds that guarantee acceptable quality and that the goods are fit for purpose, free of defects and safe. Under section 104, the Commonwealth Minister may make a safety standard for consumer goods of a particular kind, which may consist of performance, composition, content, manufacture methods, packaging, testing, warnings, instructions and or markings that accompany consumer goods.

All therapeutic goods in Australia are consumer goods and are thus (also) covered by the ACL; however, the TGA is the specialist regulator of therapeutic goods and administers the provisions of the Act to protect public health and safety.

This however, does not prevent the ACCC from taking action on matters related to therapeutic goods in collaboration with the TGA.

The Productivity Commission recently reviewed Consumer Law Enforcement and Administration and released its draft report in December 2016. [4]

A particular focus was an examination of the interface between the Australian Consumer Law (ACL) regulators and the specialist consumer safety regimes (including the therapeutic goods regulatory framework). The report noted that "The ACL regulators and specialist safety regulators generally understand the delineation of their remits and interact effectively", and did not make specific recommendations that would change the interface between TGA and ACCC other than recommending more frequent dialogue between the two.

What is low risk?

The Government agreed that this review focus on the range of products that poses little or no risk to the health of consumers. This raised the question of how to define 'low risk' for the purposes of these recommendations.

The Act establishes a risk-based framework for the regulation of therapeutic goods in Australia. The level of regulatory "touch" for therapeutic goods is intended to be commensurate with the

[3] http://www.comlaw.gov.au/Details/C2015C00019/Html/Volume_3#_Toc409081831
[4] http://www.pc.gov.au/inquiries/current/consumer-law/draft

risk that the product poses to the health and safety of the Australian public. Reviewing this level of regulatory intervention was a key theme of the Government's response to the MMDR.

The current hierarchy of low risk products (organised into classes of products) is illustrated by Figure 1 on the next page.

The MMDR report suggested that products such as "some secondary sunscreens, medicated soaps, desensitising toothpastes and gels, lozenges for soothing dry throats, and personal care products such as anti-nappy rash treatments" may fall into this 'low risk' category.

To determine whether or not these classes of products are 'low risk' for the purposes of this review, the criteria or characteristics of the goods needs to be clearly defined. These can then be used to produce a transparent and consistent mechanism for determining if new or existing products are similarly low risk

Six broad criteria for risk assessment for both medicines and medical devices have been identified by this review.

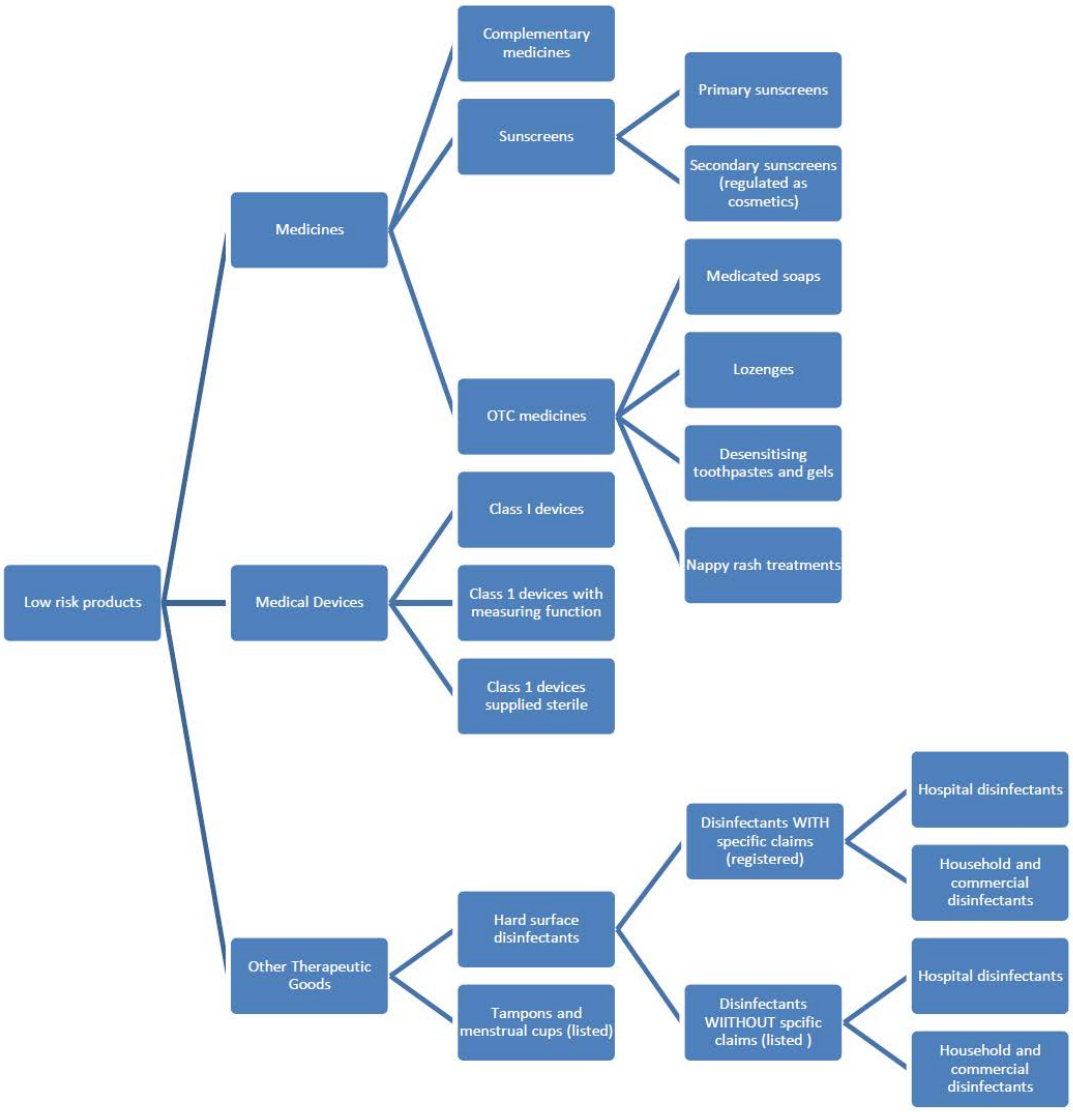
Medicines

- 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.

Medical devices

- The safety of the materials and construction
- The method of use
- The risks associated with the intended purpose
- The nature of the conditions being diagnosed, treated and/or prevented
- The nature and size of the population using the product
- The impact of poor quality manufacturing and performance.

Figure 1 Current hierarchy of low risk products organised into classes of products.



The Australian Pesticide and Veterinary Medicines Authority (APVMA) have recently considered this concept of low risk in relation to their application process.[5]

They found that in addition to the 'physical and use' criteria, a criterion that takes into account the 'degree of regulatory familiarity' also needs to be considered when identifying product types for consideration. That is, product types that pose well known risks.

Examples of this concept applied to therapeutic goods are tampons and hard surface disinfectants, which could both be considered moderate to high risk product types, however the 'everyday' use of both of these products by consumers and well known regulatory risks, lowers their risk when used correctly.

[5] http://apvma.gov.au/node/20291

Overview of the low risk classification system

The concept of 'low risk' is a simple one, however what is actually meant by this term varies with opinion. To allow this review to objectively define what is meant by 'low risk' it became apparent that a mechanism was needed, to assist in scoping and identifying products that could be considered low risk for the purposes of the review of these recommendations.

The Low Risk Classification System (LRCS) was developed to provide that mechanism. In using the LRCS, the user selects a product type, and selects a qualitative risk level against each of the following criteria:

Criteria for Medicines	Criteria for Devices
Ingredients	Materials and Construction
Route of administration	Method of Use
Claims including labelled use	Intended purpose
Nature of condition(s) being treated and/or prevented	Nature of the condition(s) being diagnosed, treated and/or prevented
Nature and size of the population using the product	Nature and size of the population using the product
Impact of poor quality manufacturing	Impact of poor quality manufacturing or performance

The qualitative risk levels are:

- High
- Moderate
- Low
- Very Low
- Extremely Low
- Negligible.

Associated with these options are descriptive labels to help guide the user in selecting an appropriate level of risk. These labels differ depending on the criterion.

An example of the descriptive labels used as guidance for users of the LRCS is as follows:

Manufacturing /Performance	High	6	manufacturing quality, poor product quality or non-performance likely to cause serious injury
	Moderate	5	manufacturing quality, poor product quality or non-performance likely to cause minor injury

Manufacturing /Performance	High	6	manufacturing quality, poor product quality or non-performance likely to cause serious injury
	Low	4	manufacturing quality, poor product quality or non-performance unlikely to cause any injury
	Very Low	3	manufacturing quality, poor product quality or non-performance likely to be noticed before use
	Extremely low	2	manufacturing quality, poor product quality or non-performance likely to cause inconvenience
	Negligible	1	manufacturing quality, poor product quality or non-performance unlikely due to simple nature of product

In this example, when considering the impact of poor quality manufacturing or performance it is assumed that all applicable standards and requirements have been applied in the manufacture or performance and is a judgement on the impact if something goes wrong or does not perform as required.

Once ratings on all the criteria have been entered, the LRCS:

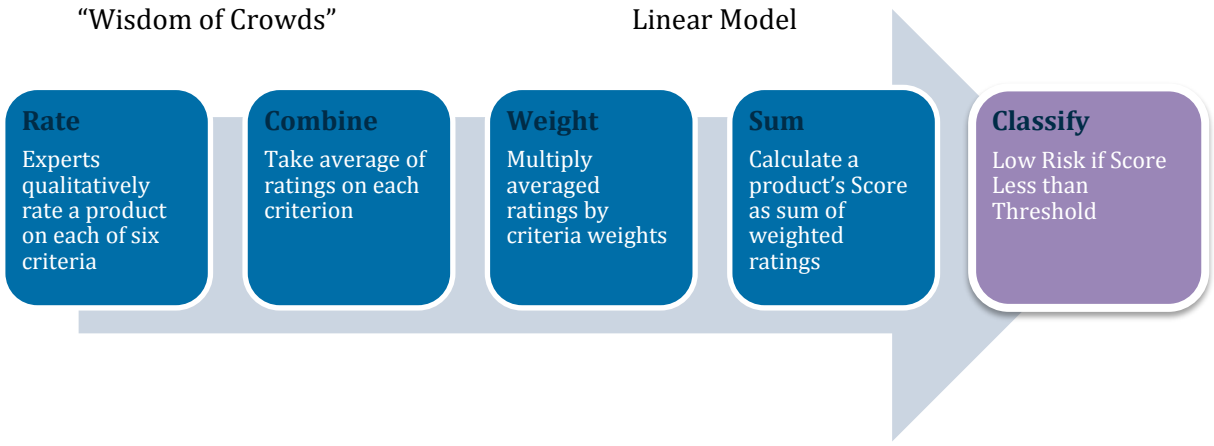
1. calculates an overall risk score for product type; and
2. classifies the product type as Low Risk if the overall risk score is lower than a threshold.

The LRCS implements a "simple linear model." This just means that the product type receives an overall risk score which is a linear combination of its risk scores on the various criteria or dimensions.

The numerical risk scores are obtained from the qualitative risk ratings entered by users using a simple conversion: 1 point for Negligible, 2 points for Extremely Low, and so on.

The LRCS also implements a modest form of the "**wisdom of crowds**." The wisdom of crowds is the situation where, under suitable conditions, the aggregated opinion of a group is superior to most or even all members of the group. This approach is increasing used to publicly rate hotels and restaurants (e.g. on "Trip Advisor"), car smash repairers or even health care providers. The LRCS takes advantage of the wisdom of crowds by allowing for multiple experts to independently rate a product type on each criterion, and aggregating those ratings by taking the average.[6]

[6] Other forms of aggregation might also be explored, e.g. taking the mode.



Rationale for the Low Risk Classification System

The LRCS satisfies four relevant criteria for a risk classification system. It is:

- Scientifically well-founded[7],[8]
- Performs well in practice
- Easy to use
- Transparent.

The results from LRCS largely supported the original assumptions on 'low risk' product types and the following are the product by risk ratings outcomes from the LRCS:

Extremely Low	**Product type**
	Examination gowns

Very Low	**Product type**	
	Oral homoeopathic products	Mattresses
	Hard surface disinfectants (Hospital grade without claims)	Light sources (examination, surgical, head mounted)

[7] e.g. Meehl, P. E. (1986) Causes and effects of my disturbing little book. Journal of Personality Assessment, 50, 370-375, p.373-4; Chapter 1 of Burgman, M. A. (2016). Trusting Judgements: How to Get the Best out of Experts. Cambridge UK, Cambridge University Press.
[8] Surowiecki, J. (2005). The wisdom of crowds : why the many are smarter than the few. London, Abacus; Tetlock, P. and D. Gardner (2015). Superforecasting: The Art and Science of Prediction. London, Random House.

Very	Product type	
	Hard surface disinfectants (Household grade)	Antiperspirants
	Examination tables	Chairs and stools
	Exercise equipment (treadmills, weights, etc)	Pillows and cushions
	Aromatherapy products	Ear Candles
	Magnetic items (static, apparel and bedding)	Enzymatic detergents
	Breast pumps	Spectacle frames
	Marker pens	

Low	Product type	
	Registered desensitising toothpastes	Rubefacient preparations for minor aches and pains of muscles (e.g. methyl salicylate, menthol, capsicum, etc.)
	Antacids – containing carbonates, hydroxides, silicates, and/or alginates	Personal lubricants
	Acne treatments containing benzoyl peroxide	Menstrual cups
	Oral Water soluble vitamin products	Rehydration or formulated sports products
	Antidandruff antifungal shampoos	Nappy rash cream
	Hard surface disinfectants (Hospital grade with claims)	Examination gloves
	Menthol-based inhalers & chest rubs	Magnetic items (static, apparel and bedding)
	Lozenges – for relief of sore throats, contain anti-microbial active ingredients	Primary sunscreens
	Antiseptic mouth washes	Moisturisers with sunscreen SPF
	First aid antiseptics for minor cuts & abrasions	Personal aids (specialty toilet seats,)
	Massagers	Biofeedback systems
	Tampons	Safety rails
	Mobility scooters/walkers	

Medium	Product type	
	Oral vitamin and mineral products	Salicylic acid plasters for corns & warts
	Laxatives	

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

The following product types were identified as candidates and objectively confirmed as low or very low risk by the tool for the purposes of recommendation 14:

- Ear candles
- Nappy rash cream
- Antiperspirants
- Low risk OTC products
- Hard surface disinfectants
- Sunscreens
- Tampons and menstrual cups

An overview of the international approach to the regulation of these product types can be found in Appendix 2.

Ear candles

Background: Ear candling is an alternative medical practice that involves inserting and lighting a hollow candle (ear candle) in the ear canal.[9]

Current regulatory oversight: Ear candles are regulated by the TGA as listed other therapeutic goods and are required to be entered in the ARTG as Listed Other Therapeutic Goods (OTG) before being supplied.

The listing application process for ear candles includes providing the presentation, claims and labelling for the products to demonstrate product safety and that the products are appropriate.

Listed other therapeutic goods are exempt from the requirements of GMP however they must comply with Therapeutic Goods Order (TGO) 37 and are subject to post market compliance reviews, recall procedures and therapeutic goods advertising compliance.

There are currently 15 ear candles in the ARTG with therapeutic claims to the effect of "*for relaxation*", "*general wellbeing*" and "*ear wax cleaning*".

There are currently seven Class I medical device entries in the ARTG that also appear to be ear candles; however these entries do not use the term 'ear candle'. These seven ARTG entries would be further considered under the section on Class I medical devices discussed later in this paper.

[9] https://en.wikipedia.org/wiki/Ear_candling

Options for reform

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

Under this option the TGA would continue to regulate ear candles as listed "other therapeutic goods" in the current manner, as described above.

- The disadvantage of this option is that in maintaining the ARTG entries for these products, it could be viewed as legitimising ear candles and creating a consumer perception of efficacy as if they are 'approved' and fit for purpose by the TGA.
- An advantage with this option, as with all status quo options discussed herein, is that sponsors and manufacturers who are already familiar with the regulatory framework would not need to understand or implement any regulatory changes.

Option 2 – Exemption from listing in the ARTG

Under this option ear candles would be exempted from Part 3-2 of the Act, which would not require them to be listed in the ARTG. They would still be considered therapeutic goods under the therapeutic goods regulatory framework and would remain subject to post market compliance reviews, recall procedures and therapeutic goods advertising compliance.

- A potential risk of this option is that with no regulatory barrier before products enter the market, substandard products could be supplied to consumers that could make inappropriate therapeutic representations. Such products would only be identified by consumer complaints, adverse event reports or through targeted compliance reviews.

Option 3 – Exclude ear candles from the regulatory framework

Under this option, ear candles would be taken out of the regulatory framework using an instrument under s7AA of the Act, which allows the Minister to make a determination that specified goods are excluded goods for the purposes of the Act.

Ear candles would no longer be considered therapeutic goods and would be regulated as consumer goods which would prevent them from making therapeutic claims.

This approach would align closely with the approach taken in the US and Canada (see Appendix 2).

- A potential benefit of this proposal is the removal of the perceived 'approved by TGA' legitimising of ear candles.
- A potential risk of this proposal is that with no regulatory barrier before products enter the market, substandard products could be supplied to consumers and inappropriate representations made.
- An outcome of this option is, with such products being regulated solely as consumer goods, they would fall under the auspices of ACCC and not a specialist regulator.

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.

Nappy rash cream

Background: Nappy rash treatments in Australia are topical products that range from listed medicines that are indicated to provide a "soothing effect" to the rash area through to registered products, mostly anti-fungal preparations that are aimed at treating severe cases of skin irritations caused by fungal infection. There are also topical cream products included in the ARTG as medical devices indicated as 'skin moisturising/barrier dressings, lubricant or liquid barrier dressing'.

As at December 2016, there were 127 products in the ARTG for supply in Australia that are indicated for alleviation or treatment of 'nappy rash'.

The 127 ARTG entries span three different levels of regulatory requirements:

- 65 listed medicines
- 50 registered medicines
- 12 Class I medical devices

The listed medicine 'nappy rash' products range from body washes and soaps to creams and powders which make a range of soothing and moisturising cosmetic claims as well as therapeutic claims for relieving the symptoms of nappy rash, eczema and dermatitis.

Current regulatory oversight: Listed medicines must be entered in the ARTG before supply and are not evaluated by the TGA prior to marketing. Sponsors are not required to submit evidence to support the therapeutic claims before the medicines can be supplied, but are required to hold the appropriate evidence. This may include non-scientific evidence such as traditional evidence.[10]

Listed medicines are only permitted to contain unscheduled substances and are available for general sale in supermarkets and pharmacies. The claims for listed medicines are restricted to claims of assisting with relief of the symptoms of skin conditions which makes the presentation and claims similar to 'moisturising and replenishing' cosmetic skin care products such as hand creams and body lotions.

Registered medicines must submit evidence to support their therapeutic claims during the premarket application process.

Both listed and registered medicines must be manufactured under medicine GMP requirements.

The manufacturers of Class I medical devices are required to issue a Declaration of Conformity to state that they have applied the appropriate standards for safety and performance. Class I

[10] https://www.tga.gov.au/publication/evidence-guidelines

medical devices are automatically included in the ARTG subject to certain attestations from the applicant. There is no application fee or premarket assessment.

All products are subject to post market compliance reviews, recall procedures and therapeutic goods advertising compliance.

Options for reform

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

This option maintains the status as therapeutic goods and would continue to be required to meet their respective requirements (described above) to be entered in the ARTG prior to supply in the market as well as continuing to be subject to post market compliance reviews, recall procedures and therapeutic goods advertising compliance.

- The benefit of continuing the current regulatory oversight of nappy rash products is that it supports the availability of high quality products for consumers which will help maintain a high level of consumer confidence in this range of products.
- A disadvantage of maintaining the current regulatory oversight of these products is that they are potentially being over regulated, which in turn imposes additional costs and delays to market.

Option 2 – Review of medical device nappy rash products

Under this option, it is proposed that the regulatory avenue of including these dermal products as Class I medical devices be reviewed as the formulations and indications of Class I medical devices are not assessed under the current Class I auto inclusion process.

This potentially leads to misclassification of these products or inappropriate claims being made.

This option would be carried out in conjunction to the further actions recommended for Class I medical devices mentioned later in this review.

Option 3 – Exemption from listing in the ARTG

Under this option, the currently listed nappy rash products would be exempt from entry in the ARTG but still be considered therapeutic goods and would continue to be required to meet requirements such as GMP and advertising.

- The benefit of this option would be the lower barrier to market for sponsors of products which could result in a wider range of product for consumers.
- Potential disadvantages of this option could include:
    - A consumer perception of a lowering of quality of the products
    - Potentially result in lower quality products being supplied if manufacturing standards are not appropriate. This would lead to an increase in consumer dissatisfaction and require post market regulatory action to correct.

Option 4 – Review of registered nappy rash active ingredients

Registered products are mostly anti-fungal preparations that are aimed at treating severe cases of skin irritation due to fungal infection. These registered product types could be further

considered under the proposal for "Other 'low risk' registered non-prescription medicines' which are mentioned later in this review.

Option 5 – Exclude nappy rash products from the regulatory framework

This option proposes the regulation of nappy rash products solely under the consumer law framework and would require an instrument under s7AA of the Act, to declare all nappy rash products not to be therapeutic goods.

An outcome of this option is, with such products being regulated solely as consumer goods, they would fall under the auspices of ACCC and not a specialist regulator.

As such, the advertising and labelling of nappy rash products would be captured by the Consumer law 'false or misleading statements[11]' provisions, which still require suppliers of nappy rash products to hold evidence for their claims.

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.

Antiperspirants

Current regulatory oversight: In Australia, the term "Antiperspirants" meets the definition of "therapeutic good" within the Act, because the definition of therapeutic use under the Act includes: "…influencing, inhibiting or modifying a physiological process in persons …".

Whilst considered therapeutic goods under the Act, antiperspirants that derive their antiperspirant properties from inorganic salts of aluminium, zinc or zirconium only, are exempt from the requirements to be listed in the ARTG and GMP.

It is important to differentiate antiperspirants (which limit sweating) from deodorants (which target bacteria that metabolise components in sweat). Deodorants which may contain alcohol- or chelate-based ingredients along with antibacterial chemicals are generally seen as cosmetics and are declared not to be therapeutic goods in the Excluded Goods Order [12] and therefore are not regulated by TGA.

Antiperspirants that derive their antiperspirant properties from other substances are regulated as medicines. An example of these types of products is botox (*Botulinum* toxin) injections for "*treatment of severe primary hyperhidrosis of the axillae*" (severe underarm sweating). These products are regulated as medicines with the requirements dependant on the substance, mode of action and route of administration and must meet the GMP requirements and be entered in

[11] http://www.accc.gov.au/business/advertising-promoting-your-business/false-or-misleading-statements
[12] https://www.tga.gov.au/therapeutic-goods-excluded-goods-order-no-1-2011

the ARTG before they can be supplied. These types of antiperspirants are not considered in the scope of this review.

The "Review of the regulation of products at the interface between cosmetics and therapeutic goods" in 2005 by Newgreen[13] considered the marketing, positioning and representation of antiperspirants in the market and concluded that antiperspirants behave in the market as toiletries and are viewed by consumers as toiletries.

In making this conclusion, Newgreen noted that "*Topical antiperspirants typically contain inorganic salts of aluminium, zinc or zirconium that are sold as roll-ons, lotions, creams, pump sprays and aerosols in supermarkets.*"

Options for reform

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

Under this option, the TGA would continue to regulate antiperspirant preparations that derive their antiperspirant properties from inorganic salts of aluminium, zinc or zirconium only as exempt goods and require other antiperspirants that derive their antiperspirant properties from other substances such as quaternary ammonium anticholinergics to be regulated as described above.

- The benefit of this option is that exempted antiperspirants continue to have a very low barrier to market; however they are still subject to therapeutic goods level recall and advertising compliance.
- An issue with the current regulatory framework is that all antiperspirants are technically therapeutic goods and this is considered out of step with community expectations for this type of product.

Option 2 – Exclude antiperspirants from the regulatory framework

Under this option, antiperspirant preparations that derive their antiperspirant properties from inorganic salts of aluminium, zinc or zirconium only would be declared not to be therapeutic goods and be excluded from the regulatory framework.

The benefit of this option is that they would be regulated as consumer goods which would align the regulatory framework with the public perception of these products as noted by Newgreen.

A potential disadvantage of this proposal could be the supply of substandard antiperspirants to the market; this however is seen as a very low risk due to consumer and manufacturer familiarity with this product type and market.

This option would align the Australian regulation of antiperspirants with New Zealand and Europe and during the Newgreen review was supported by respondents to the consultation[14] as the preferred option.

[13] "Review of the regulation of products at the interface between cosmetics and therapeutic goods" March 2005 by David B Newgreen, Pages 47 - 51 https://www.tga.gov.au/sites/default/files/consult-cosmetics-regulation-050303.pdf

[14] https://www.tga.gov.au/sites/default/files/consult-cosmetics-regulation-050303-summary.pdf

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.

Other low risk registered non-prescription (OTC) medicines

Current regulatory oversight: OTC medicines are medium risk medicines that are available to consumers without prescription generally at pharmacies and supermarkets. They can contain substances that are either scheduled in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) which places controls over the access of these substances to the public, or are just not permitted for use in Listed medicines.[15]

Other OTC medicines are required to be registered in the ARTG prior to supply in the market.

The current regulatory process for a new registered OTC medicine requires the pre-market evaluation of evidence of efficacy and safety as well as the manufacturer requiring GMP.

These products are also subject to post market regulatory oversight such as post market compliance reviews, recall procedures and therapeutic goods advertising compliance.

A number of well-known OTC products that have a long history of use at particular ingredient levels and dosage forms have been identified as 'lower risk'. These product types contain unscheduled substances and are currently available for general sale.

These product types include:

- Registered desensitising toothpastes
- Antiseptics for first aid treatment of minor cuts and abrasions
- Lozenges for relief of sore throats (these contain anti-microbial active ingredients)
- Antacids – containing carbonates, hydroxides, silicates, and/or alginates (but not medicines containing a proton pump inhibitor or H2 antagonist)
- Salicylic acid plasters for removal of corns and warts
- Menthol-based inhalers and chest rubs
- Antiseptic mouth washes
- Acne treatments containing benzoyl peroxide
- Rubefacient preparations for minor aches and pains of muscles (e.g. methyl salicylate, menthol, capsicum) but not creams or ointments containing a non-steroidal anti-inflammatory medicine
- Certain laxatives

[15] Permitted ingredients for Listed medicines are those described under 26BB of the Act

- Antidandruff and antifungal shampoos

An overview of the international approach to the regulation of the OTC product types can be found in Appendix 2.

Options for reform

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

Under this option, the categories of products identified above continue to be regulated under the regulatory framework for registered non-prescription (OTC) medicines, which includes premarket assessment and evaluation of evidence to support therapeutic claims.

- The robust regulatory oversight of this option will help maintain a high level of consumer confidence in this range of products.
- A disadvantage of maintaining the current regulatory oversight of these products is that they are potentially being over regulated, which in turn imposes additional costs and delays to market.

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

This option would look at the potential for some or all of these 'low risk' OTC products to become eligible for the 'Listed' part of the therapeutic goods regulatory framework, based on specific feedback from this consultation.

It would also require a risk review of the active ingredients used in these OTC product types to determine if some or all well-known ingredients in these products could be permitted for listed medicines.

- This proposal would reduce the regulatory burden and therefore potentially reduce the costs of bringing these types of product to market which would in turn potentially reduce the cost of these products to consumers.

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.

Hard surface disinfectants

Current regulatory oversight: Hard surface disinfectants are regulated by the TGA and form part of the "other therapeutic goods" group. Hard surface disinfectants include hospital, household and commercial grade disinfectants. [16]

[16] https://www.tga.gov.au/regulation-disinfectants-and-sterilants

Below is a summary of how disinfectants are currently regulated in Australia[17]:

Type of disinfectant	How is it regulated?
Sterilants and instrument grade disinfectants - intended to be used on medical devices	Class IIb Medical Device Applications for these types of devices must be reviewed by TGA (i.e. selected to undergo an application audit) prior to inclusion in the ARTG.
Cleaners intended to be used on medical devices	Class I Medical Device – included by the Sponsor without review by TGA
Hospital grade and commercial/household grade disinfectants with specific claims	'Other Therapeutic Goods' – registered Must comply with TGO 54 (performance and packaging and labelling requirements). A pre-market review of these goods is conducted. Information to be submitted for review includes; instructions for use, promotional material, labels, product specifications, and microbial efficacy, stability and quality control data
Hospital grade disinfectants without specific claims	'Other Therapeutic Goods' – listed Must comply with TGO 54. Information to be submitted for review includes; instructions for use, promotional material, and labels. However microbial efficacy, stability and quality control data is not required to be submitted for review.
Household or commercial grade disinfectant without specific claims	'Other Therapeutic Goods' - must comply with TGO 54 but exempt from listing or registration so no regulatory interaction with TGA.
Antibacterial cleaning wipes Sanitisers, Sanitary fluids/powders (that do not make disinfectant claims)	Antibacterial cleaning wipes, sanitisers, sanitary fluids/powders are exempt from listing or registration. Disinfectant and sterilant gases, products for water treatment only or products regulated under the *Agricultural and Veterinary Chemicals Code 1994* are excluded

- **Hospital grade disinfectants** are defined as those suitable for general purpose disinfection of building and fitting surfaces, and purposes not involving surgical instruments or surfaces likely to come into contact with broken skin. Hospital grade disinfectants are currently either listed or registered on the ARTG. Those with specific biocidal claims (virucidal, sporicidal, tuberculocidal, fungicidal or other) must be registered, whereas those without specific biocidal claims are listed.

[17] https://www.tga.gov.au/summary-disinfectant-regulation

- **Household and commercial grade disinfectants** are disinfectants that are suitable for general purpose disinfection of building or fitting surfaces, and for other purposes, in premises or involving procedures other than those specified for a hospital grade disinfectant. Unless a household or commercial disinfectant has specific biocidal claims (that is, claims to kill some or all types of micro-organisms), these disinfectants are exempt from being entered on the ARTG. However, these disinfectants are required to comply with TGO 54[18].

- TGO 54 details the minimum performance requirements for each grade of disinfectant or sterilant as well as the requirements for packaging and labelling of these products.

- All hard surface disinfectant manufacturers are exempt from requirements of GMP unless the product is supplied for the Pharmaceutical Benefits Scheme (PBS) (Schedule 7 of the Therapeutic Goods Regulation 1990 refers). As at December 2016, no hard surface disinfectants were found on the PBS[19] so all currently supplied hard surface disinfectants would be exempt from the requirements of GMP.

- The safety of the ingredients of the hard surface disinfectants are regulated by NICNAS under the AICS.

Anecdotally, some companies benefit in the supermarket and cleaning product marketplace from being able to claim that their products are "hospital grade" even though they are only marketed for consumer household use. Thus the product description and class is perhaps more of a marketing tool rather than representing a separate and higher grade of hard surface disinfectant.

The current regulatory framework for hard surface disinfectants requires that products making hospital grade and specific claims comply with the requirements of TGO 54. This provides some assurance that quality products are being supplied to the Australian public.

This review is only looking at hard surface disinfectants, not those used on critical instruments and surfaces which are higher risk (Class IIb medical devices) or cleaners regulated as Class I medical devices.

As at February 2017, there are 95 listed disinfectants and 12 registered disinfectants in the ARTG.

Options for reform

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

Under this option, TGA would continue to regulate hard surface disinfectants as registered, listed or exempt depending on the claims or purpose (as described above).

Issues identified by stakeholders with the current framework include:

- Regulatory requirements are confusing

- Timeframes for application processing are very long

- Safety evaluations for different formulations are expensive

[18] https://www.legislation.gov.au/Details/F2009C00327
[19] https://www.pbs.gov.au/browse/medicine-listing

The regulation of hard surface disinfectants is confusing, being based both upon the intended use assigned by the manufacturer as well as the specific claims being made regarding its efficacy.

New ingredients and formulations for hard surface disinfectants are required to be evaluated to ensure that they are safe for the Australian public and meet the requirements of TGO 54. It is unlikely that an applicant will know whether their application will require a safety evaluation prior to submitting their application to the TGA. Safety evaluations are expensive (currently $17,600) and can take 6 – 12 months depending on the quality of the safety data package provided by the applicant.

These timeframes and costs create significant delays to market for applicants.

- Keeping the status quo has the benefit of maintaining familiar regulatory requirements, and not requiring industry to invest resources into understanding the change or communicating these to consumers. In addition, no changes to operations would be required to enable compliance.
- A perceived benefit of continuing the current regulatory oversight of hard surface disinfectants is that it supports the availability of high quality products for consumers.
- Disadvantages are that the current system is confusing, costly and has long timeframes as described above.

Option 2 – Streamline the regulatory framework for hard surface disinfectants

Under this option, the TGA would retain responsibility for all hard surface disinfectant regulation but the regulatory framework would be streamlined and simplified.

Under this option, regulations would be amended to move currently 'Registered' disinfectants to 'Listable' status.

However, applications for listing of disinfectants making specific biocidal claims, or hard surface disinfectants containing a new chemical entity as the active ingredient, would be required to undergo a pre-market assessment for compliance with relevant parts of an amended TGO 54, as is currently the case.

Products that are currently listable would be exempted from Part 3-2 of the Act and not require entry in the ARTG prior to supply.

Products which are currently exempt from listing on the ARTG will remain exempt.

This new streamlined regulatory framework would look something like the table below:

Type of disinfectant	How would it be regulated under this option?
Sterilants and instrument grade disinfectants - intended to be used on medical devices	Class IIb Medical Device Applications for these types of devices must be selected to undergo an audit prior to inclusion in the ARTG.
Cleaners intended to be used on medical devices	Class I Medical Device

Type of disinfectant	How would it be regulated under this option?
Hospital grade and commercial/household grade disinfectants with specific claims*	'Other Therapeutic Goods' – listed Must comply with Therapeutic Goods Order 54. A pre-market review of these goods is conducted. Information to be submitted for review includes; instructions for use, promotional material, labels, product specifications, and microbial efficacy, stability and quality control data
Hospital grade disinfectants without specific claims* Household or commercial grade disinfectant without specific claims* Antibacterial cleaning wipes Sanitisers, Sanitary fluids/powders (that do not make disinfectant claims)	'Other Therapeutic Goods' - exempt from listing or registration but must still comply with TGO 54. (Antibacterial cleaning wipes Sanitisers, Sanitary fluids/powders some would remain excluded depending on their claims)

- This option would result in a simplified regulatory framework for hard surface disinfectants which in turn should result in greater access to market for more products. The result would be greater product choice for consumers and higher competition in the market place.
- Stakeholder advice is required on whether these products should still be able to be called “hospital grade”, or whether this term is potentially misleading.

To help improve the application processing timeframe and reduce the number of applications that need safety evaluations and assessments against TGO 54, a disinfectant monograph system could be introduced for common formulations, ingredients and claims. This has the potential to allow rapid entry to market if the proposed product complies with the monograph criteria as the product would not have to undergo a safety evaluation which has the additional benefit of reducing the expense associated with safety evaluations.

Products that do not comply with the monograph would require a full application including a safety evaluation.

- The benefit of this option would be a simplified way for sponsors to demonstrate compliance with the regulatory framework for hard surface disinfectants which in turn should result in greater access to market for more products. If combined with Option 2 for example, no pre-market assessment of quality, safety and efficacy for products in the new ‘listed’ paradigm would be required.
- The result could also be greater product choice for consumers and higher competition in the market place.
- Disadvantages of this option are that the production of monographs is resource intensive, there are no relevant international standards that could be used and there is a perceived lack

of 'marketing edge' for products that conform to a monograph which could limit the use of monographs by industry.

This option to develop and use monographs aligns significantly with the Canadian regulatory approach (see Appendix 2).

The approval process for new ingredients could take advantage of overseas ingredient approvals by comparable regulators or Australian chemical substance regulators such as NICNAS who maintains the Australian Inventory of Chemical Substances (AICS), [20] which is a database of chemicals legally available for industrial use in Australia. Under this option, TGA would not reassess specific ingredients.

TGO 54 would need to be reviewed to ensure that it remains consistent with any changes to the regulatory framework, and to better reflect modern quality standards for these types of products.

- This option would allow for a faster application process for innovative products containing new ingredients which in turn should result in greater access to market for more products.
- Again, the result could be greater product choice for consumers and higher competition in the market place.

Under this option all OTG hard surface disinfectants would be declared to not be therapeutic goods using an instrument under s7AA of the Act.

By declaring hard surface disinfectants not to be therapeutic goods, they would no longer be covered by the Act; however the ingredients would continue to be assessed and regulated under the AICS which is the responsibility of NICNAS.

- This option provides very low regulatory hurdle for suppliers of hard surface disinfectants.
- An outcome of this option is, with such products being regulated solely as consumer goods, they would fall under the auspices of ACCC and not a specialist regulator.
- A potential disadvantage of this option is that substandard products could be supplied to the market without the regulatory overview of a specialist regulator.

This option aligns with the regulatory approaches of US, Europe and New Zealand where hard surface disinfectants are regulated as chemicals rather than therapeutic goods (see Appendix 2).

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

[20] https://www.nicnas.gov.au/chemicals-on-AICS

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.

Sunscreens

Background: In Australia 'primary' sunscreens are regulated via the medicines regulatory framework. The rationale for this level of regulation is the high prevalence of skin cancer in Australia and the critical role that sunscreens play in reducing exposure to UV radiation which is linked to preventing skin cancer.

Current regulatory oversight: The regulation of sunscreens in Australia is currently shared between TGA (therapeutic claims), NICNAS (chemicals) and ACCC (consumer law). The four current sunscreen regulatory pathways are summarised in this following table[21]:

Product category	Sub-category	Currently regulated by:
Listable sunscreens	• Primary sunscreens carrying SPF claims of at least SPF 4 and not greater than SPF 50+ • Secondary sunscreening products that meet the definition of a therapeutic sunscreen	Listing in the ARTG under s.26A of the Act
Registrable sunscreens	Sunscreens that make therapeutic claims other than sunscreening and/or reduction of risk of skin cancer, solar keratosis, sunspots or premature ageing.	Registration in the ARTG under s.25 of the Act
Exempt sunscreens	Primary sunscreens with an SPF less than 4 and not containing ingredients of human or animal origin.	Exempt from the requirement of listing or registration in the ARTG

[21] Page 9 Australian regulatory guidelines for sunscreens https://www.tga.gov.au/sites/default/files/sunscreens-args.pdf

Product category	Sub-category	Currently regulated by:
Cosmetic sunscreens (Excluded sunscreens)	Some secondary sunscreens that are excluded from regulation by the TGA but meet the definition of a cosmetic.	Regulated by NICNAS and the ACCC as cosmetics and not regulated under the Act.

This regulatory framework with a number of categories, along with the use of some products primarily as cosmetics rather than therapeutic goods often creates confusion for many, including importers, manufacturers, consumers and regulators.

Sunscreens classified as therapeutic goods (unless exempt) are required to be included in the ARTG before they can legally be marketed in Australia.

Sunscreens are required to be manufactured in accordance with the principles of GMP and must comply with the Australian and New Zealand Sunscreen Standard *AS/NZS 2604 Sunscreen products - Evaluation and classification* in force at the time of listing on the ARTG.

Products required to be entered in the ARTG require a premarket application to be made which includes details such as formulation, indications and warning, as well as licenced manufacturer details.

Primary sunscreens (products used primarily for protection from UV radiation, SPF 4 or more) and moisturisers containing sunscreen with SPF greater than 15 are regulated as therapeutic goods by the TGA.

The TGA also regulates all sunscreens (SPF 4 or more) that contain an insect repellent and sunscreens with ingredients derived from humans or particular organs of some animals.

Most **secondary sunscreens** (those with a primary purpose other than sunscreening but also contain sunscreening agents) are regulated as cosmetics. These cosmetics must comply with the Industrial Chemicals (Notification and Assessment) Act 1989 (ICNA) and Cosmetics Standard 2007[22] which are administered by NICNAS and claims and labelling are regulated by the ACCC.

The NICNAS is currently undergoing regulatory reforms and is no longer going to be a cosmetic product regulator; however their regulation will still extend to the industrial chemicals used in cosmetics.

These cosmetic products include:

- moisturisers with sunscreen with SPF up to and including 15
- sunbathing products (e.g. oils, creams or gels, including products for tanning without sun and after sun care products) with SPF between 4 and 15
- make-up products with any SPF
- lip-sticks and lip balms with sunscreen with any SPF.

As at December 2016, there were 932 listed sunscreen entries (173 are secondary sunscreens that meet the definition of a therapeutic good) and 2 registered sunscreen entries on the ARTG.

[22] Cosmetics Standard and sunscreens https://www.nicnas.gov.au/cosmetics-and-soaps/cosmetics-standard-and-sunscreens

The number of secondary sunscreens regulated as cosmetics is unknown.

An overview of the international approach to the regulation of sunscreens can be found in Appendix 2.

Options for reform

Option 1 - Maintain the status quo regulation of sunscreens.

This option would maintain the four levels of sunscreen regulation and require a premarket application to supply products in Australia and maintains the current medicine grade GMP standard (as described above).

Issues that stakeholders have raised with the current model included:

- Medicine level GMP being required for a topical product such as sunscreens is considered to be an excessive barrier to market, and very expensive in cases where TGA inspections are required overseas (as data from comparable regulators is often not available that would have obviated the need for a TGA inspection for the purposes of an Australian GMP clearance).
- The process for review of New Ingredients by TGA is slow and expensive, and constrains the introduction of new sunscreens to the Australian market (or may not make such an introduction cost-effective).
- Application of pharmacopeial standards for all ingredients (both active and excipients), including the water that is used in sunscreens, can be expensive and is considered excessive for this particular type of topical product.
- Many different levels of regulation and different regulators are a source of confusion for importers, manufacturers, consumers and government regulators.

It has been argued that a greater focus on critical parameters such as stability, active ingredient content and efficacy and sunscreening ability (SPF) could be achieved if regulatory requirements that did not directly contribute the performance of the product were modified.

- The benefit of continuing the current regulatory oversight of sunscreens is that it supports the availability of high quality products for consumers and will help maintain a high level of consumer confidence in this range of products.
- Disadvantages of maintaining the current regulatory framework include:
    - potential over regulation of products, which in turn imposes additional costs and delays to market.
    - the current regulatory framework contains a number of categories which can cause confusion for sponsors, manufacturers, consumers and regulators.

This option most aligns with the regulatory approach taken in US and Canada. It could also be argued that this option is also similar to Europe where sunscreens are regulated as cosmetics, but under a framework with requirements similar to the Australian listed medicines system (see Appendix 2).

Option 2 – Streamline the regulatory pathways for sunscreen regulation

This option would be to streamline the pathways of sunscreen regulation into two categories: Listable Sunscreens (Primary sunscreens), and Excluded sunscreens (Secondary sunscreens).

The regulation of sunscreens under this option would be simplified to the following:

Product category	
Listable sunscreen	Primary sunscreen carrying an SPF claim greater that 4 but not greater than SPF 50+
Excluded sunscreen	All secondary sunscreens as well as Primary sunscreens with SPF claims 4 or less

This proposal would require the removal of the category of registered and exempt sunscreens and only retain listable and excluded sunscreens.

There are only two registered sunscreens on the ARTG. One of these appears to be exclusively marketed in Europe and the second product appears to be a secondary sunscreen product which has been 'grandfathered' at the higher registered classification.

Under this option, primary sunscreens are still regulated as therapeutic goods and must comply with the Sunscreen standard as well as being subject to post market compliance reviews, recall procedures and therapeutic goods advertising compliance.

Under this option it is proposed that all secondary sunscreens be declared not to be therapeutic goods using an instrument under s7AA of the Act. Removal of secondary sunscreens from the regulatory framework will allow TGA to focus resources on compliance activities of primary sunscreens to ensure the Australian public continue to have access to high quality sun protection.

Most secondary sunscreens are already regulated as cosmetics by NICNAS and the ACCC, however the current NICNAS reforms[23] which removes NICNAS from this cosmetic regulator role, will influence this option. The NICNAS reforms package has implications for the Cosmetic Standard 2007 which was implemented under the ICNA. In the event that NICNAS no longer regulates cosmetics, these products could be regulated solely as consumer goods by the ACCC, although the therapeutic claims that these products are permitted to make would need to be addressed to avoid unintentional contravention of the Therapeutic Goods Act.

The advantage of this option is a simplified regulatory framework that should reduce confusion for sponsor, manufacturers, consumers and regulators.

Option 3 – Prevent all secondary sunscreens from making SPF claims

Secondary sunscreens are marketed as cosmetics but also claim a sun screening function. These types of products are often expensive, sold in small containers and applied sparingly to a specific area of the body (for example, facial moisturiser with an SPF rating).

[23] NICNAS reforms https://www.nicnas.gov.au/have-your-say/nicnas-reforms/About-the-Reforms

Products claiming an SPF rating must comply with the Sunscreen Standard, however due to their presentation and cost, consumers do not apply them with the same quantity and frequency to achieve a true therapeutic level of sun protection. [24]

To reduce consumer confusion and make the demarcation between primary and secondary sunscreens clear, under this option it would be proposed to prevent secondary sunscreens from making SPF claims and limit the allowed claims to cosmetic claims such as "anti-aging" and "protect from the harmful effects of the sun".

Most secondary sunscreens are already regulated as cosmetics by NICNAS and the ACCC, however the current NICNAS reforms[25] which removes NICNAS from this cosmetic regulator role, will impact this option. The NICNAS reforms package has implications for the Cosmetic Standard 2007 which was implemented under the ICNA. In the event that NICNAS no longer regulates cosmetics, these products could be regulated solely as consumer goods by the ACCC.

Option 4 – Creation of a GMP standard for primary sunscreens

It is proposed to create a modified GMP standard for primary sunscreens.

Sunscreen manufacturers would have the option of either:

- continuing to manufacture to the current PIC/S GMP standard, or
- manufacturing to a new standard which could be developed based on a combination of elements of the current PIC/S GMP standard, the Australian Code of GMP for Sunscreen Products 1994 and elements of the ISO 22 716 standard (used for sunscreen manufacture in Europe).

The approach taken would be about providing industry with a range of options to meet the GMP standard that is appropriate for sunscreens to be supplied in Australia.

Such an approach would create a new standard that maintains a high standard for the critical elements of GMP (such as material and process controls) and allow for elements that are less critical for topical sunscreen, for example facility air sterile filtration systems, may be more appropriate at a food/cosmetic level rather than the same as that applied to the manufacture of prescription medicines.

Option 4 – New ingredient approval process

The approval process for new ingredients could take advantage of overseas ingredient approvals by comparable regulators (such as the US Cosmetic Ingredient Review (CIR) and the European Union (EU) Scientific Committee on Consumer Safety (SCCS)) or Australian substance regulators such as NICNAS who maintain the AICS. Whilst there are a number of exemptions for chemicals that need to be included in the AICS, many new industrial chemicals are assessed by NICNAS for risks to the environment and human health before it can be imported and/or manufactured.

The cream bases used for sunscreens are also similar in nature to those used in cosmetic products. Cosmetic ingredients fall within the scope of the industrial chemicals regulatory framework. TGA could rely on the NICNAS substance assessments for these excipient ingredients which would allow TGA to concentrate resources on finished product regulation.

[24]British Association of Dermatologists http://www.bad.org.uk/for-the-public/skin-cancer/sunscreen-fact-sheet

[25] NICNAS reforms https://www.nicnas.gov.au/have-your-say/nicnas-reforms/About-the-Reforms

This has the potential to reduce double regulation of excipient ingredients which could reduce costs and delays for products to come to market, and encourage more innovative products into the Australian market while maintaining assurance of manufacturing quality.

Option 5 – Alternative ingredient standards for excipients

Another area of concern from industry is the requirement for application of pharmacopeial standards for all sunscreen ingredients. Due to the nature and usage of sunscreens it might be appropriate for alternative grades of non-critical ingredients, for example using a food standard of excipients such as dl-alpha-tocopheryl acetate which is also a common ingredient in cosmetic products.

Acceptance of recognised international standards for these excipients could also improve harmonisation with comparable overseas regulatory systems.

Using alternative grades of ingredients may impact the quality of products and this would need to be controlled though GMP.

Option 6 – Exclude all sunscreens from the regulatory framework

This option proposes that all sunscreens be declared not to be therapeutic goods using an instrument under s7AA of the Act.

- Sunscreens would solely be consumer goods however the sunscreen standard would remain an applicable standard for quality, safety and efficacy enabling the ACCC's enforcement powers. This option would entail a very low regulatory burden for suppliers of sunscreens which would allow products to be brought to market very quickly.
- The risk of this option is that a reduction in oversight of sunscreens could result in sub quality products being supplied into the market, and corresponding impacts on the prevalence of melanomas in Australia.

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.

Tampons and menstrual cups

Background: The regulation of tampons as healthcare products was in response to a spike in incidences in Toxic Shock Syndrome (TSS) in the 1980s. In response to this the TGA (then known as the National Biological Standards Laboratory) conducted a significant testing survey of tampons which led to the development of Therapeutic Goods Order (TGO) 64 Standard for Tampons – Menstrual.[26] TGO 64 has been superseded by TGO 82 which is aligned to the current Australian Standard (AS 2869:2008).

[26]A History of Therapeutic Goods Regulation in Australia
https://www.tga.gov.au/sites/default/files/history-tg-regulation.pdf

The incidence of TSS associated with using tampons is now considered very rare (1 -2 in 100,000)[27] which could be attributed to improved standards, improved manufacturing practices and user education.

The incidence of TSS associated with the use of a menstrual cup is exceptionally rare, with the first confirmed case documented in 2015.[28]

As at December 2016, there were 114 entries for tampons and 4 menstrual cups in the ARTG.

Current regulatory oversight: Tampons and menstrual cups are regulated by the TGA and form part of the "other therapeutic goods" group (OTG) which are currently required to be listed on the ARTG before they can be supplied in Australia.

Applications are subject to an assessment process which is carried out once the TGA receives the application and prior to listing on the ARTG. Information to be submitted for review includes product information, instructions for use and promotional material, labels (draft or sample) supply and primary pack. All tampons must comply with TGO 82 and a test certificate demonstrating compliance with this order (also Australian Standard /NZS 2869:2008 Tampons - Menstrual) for the first batch that is imported is also required to be submitted.

Menstrual cups are assessed for material safety prior to listing in the ARTG and must meet the labelling requirements of TGO 37 General Requirements for Labels for Therapeutic Devices.

Both tampons and menstrual cups are exempt from the requirements of GMP.

Products are subject to post market compliance reviews, recall procedures and therapeutic goods advertising compliance.

An overview of the international approach to the regulation of tampons and menstrual cups can be found in Appendix 2.

Options for reform

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

Under this option the TGA would continue to regulate tampons and menstrual cups as listed “other therapeutic goods” in the current manner, as described above.

Issues with the current scheme, as identified by stakeholders include:

- Timeframes for application processing are long. Clear guidance on how to demonstrate compliance with the standards and presentation of information would assist the industry and potentially improve timeframes; and
- Applications to list menstrual cups of new composition require a safety evaluation, which is expensive (currently $17,600) and lengthy (assessment timeframes of 6–12 months).
- The benefit of continuing the current regulatory oversight of tampons and menstrual cups is that it supports the availability of high quality products for consumers will help maintain a high level of consumer confidence in this range of products.

This option most aligns with the US regulation of tampons and Canadian approaches for both tampons and menstrual cups (see Appendix 2).

[27] Statistic reported from USA based surveillance study in 1987 http://wwwnc.cdc.gov/eid/article/5/6/99-0611_article

[28] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4556184/

Option 2 – Exemption from listing in the ARTG

Tampons and menstrual cups would be exempted from Parts 3-2 and 3-3 of the Act, which would not require them to be listed in the ARTG and they would remain exempt from GMP requirements. They would still be considered therapeutic goods under the therapeutic goods regulatory framework, which means for example subject to post market compliance reviews, recall procedures and therapeutic goods advertising compliance, and tampons would still be required to meet the requirements of TGO 82.

- The benefit of this option would be the lower regulatory hurdle for entry into the market which in turn should result in greater access to market for more products. The result would be greater product choice for consumers and higher competition in the market place.
- A potential negative of this option would be the lack of premarket assessment of tampons and menstrual cups prior to entering the market which could enhance the likelihood of substandard products being supplied. The risk of this is seen as low because these products would still be subject to TGO 82 and therapeutic goods regulatory compliance activities.

This option is most aligned with the US approach for menstrual cups (see Appendix 2).

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

Tampons and menstrual cups would be taken out of the regulatory framework using an instrument under s7AA of the Act, which allows the Minister to make a determination that specified goods are excluded goods for the purposes of the Act.

Tampons and menstrual cups would no longer be considered therapeutic goods and would be regulated as consumer goods, as is the case for menstrual pads. Tampons would still be required to meet the Australian Standard (AS 2869:2008).

This option would align with the UK model where tampons are regulated under the General Product Safety Directive (see Appendix 2).

- The benefit of this option would be more rapid access to market for products, potentially greater product choice for consumers and higher competition in the market place.
- An outcome of this option is, with such products being regulated solely as consumer goods, they would fall under the auspices of ACCC and not a specialist regulator.
- Potential disadvantages of this option could include:
    - A consumer perception of a lowering of quality of the products
    - Potentially result in lower quality products being supplied if manufacturing standards are not appropriate. This would lead to an increase in consumer dissatisfaction and require post market regulatory action to correct.

In the event that Options 1 or 2 (or a version thereof) is agreed by government, consideration should be given to development of a monograph system to cover permitted materials of construction and claims for menstrual cups, for example what constitutes a “new material”, as well as providing clear guidance on how to demonstrate compliance with such requirements.

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.

Low risk products that are currently considered medical devices

Current regulatory oversight: In Australia**,** medical devices are regulated by the TGA and must be included in the ARTG prior to supply (unless exempted e.g. custom made medical devices).

The medical devices regulatory framework has a risk based classification system for devices that is based on:

- manufacturer's intended use of the device
- level of risk to patients, users and other persons
- degree of invasiveness in the human body
- duration of use

The classification levels for medical devices are:

Classification	Level of risk
Class I	low
Class I—supplied sterile Class I—incorporating a measuring function Class IIa	low–medium
Class IIb	medium–high
Class III	high risk
Active implantable medical devices (AIMD)	high risk

The broad groups of Class I medical devices are shown on the next page in Figure 2.

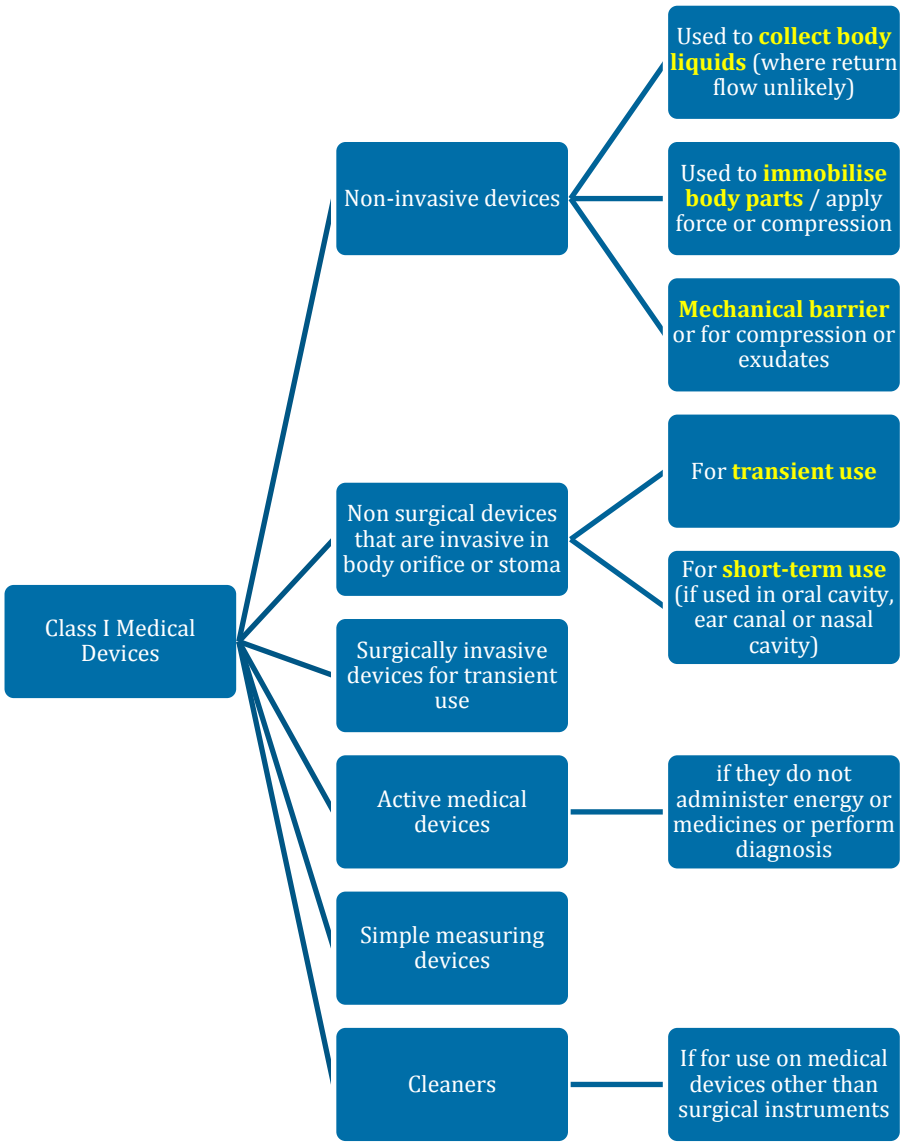
This review is focused on Class I medical device that are similar to consumer goods.

Medical devices for export only, all classified as Class I, and Class 1 In Vitro Diagnostic devices, have not been considered for the current analysis. Also out of scope are higher risk medical devices under medical devices regulatory framework.

Examples of Class I medical devices assessed as follows:

- A **non-invasive device** is Class I, unless the device is classified at a higher level under another rule. The general rule for "non-invasive" devices is that they either do not touch the patient or contact only intact skin. Some examples of non-invasive devices include:

Figure 2 Broad groups of Class I medical devices.



- Those **used to collect body liquid where a return flow is unlikely**. Class I Examples include urine collection bottles, ostomy pouches, wound drainage collection bottles and incontinence pads.
    - However a non-invasive device used to channel or store blood or body liquids that are (later) to be infused, administered or introduced into a patient is classified as Class IIa.

- Devices **used to immobilise body parts and/or to apply force or compression**. Class I examples include non-sterile dressings, plaster bandages, cervical collars and gravity traction devices or compression hosiery.
- A non-invasive device to be used as a **mechanical barrier or for compression or for absorption of exudates.** Class I examples include absorbent pads, island dressings, cotton wool, wound strips and gauze dressings to act as a barrier or absorb exudates from the wound. Note that if the device is sterile conformity evidence is required.
    - A non-invasive device to be used in contact with injured skin (including a device the principal intention of which is to manage the microenvironment of a wound) is Class IIa. Examples of Class IIa devices include adhesives for topical use, polymer film dressings, hydrogel dressings and non-medicated impregnated gauze dressings.
- **Non-surgical devices that are invasive in a body orifice or stoma (not surgical) and for t**ransient use or short-term use (if only in oral cavity, ear canal or nasal cavity) are usually classified as Class I devices. Examples include: handheld dental mirrors, dental impression materials, examination gloves, prostatic balloon dilation catheters, dressing for nose bleeds or dentures removable by the patient.
- **Surgically invasive devices intended for transient use** (i.e. used continuously for less than 60 minutes) and that are reusable surgical instruments are also classified as Class I. Examples include scissors, artery forceps, tissue forceps, tissue clamps, excavators, osteotomes, chisels.

An overview of the international approach to the regulation of medical devices can be found in Appendix 2.

As at March 2017, there were approximately 23,600 Class I medical devices included in the ARTG.

Product types for consideration by MMDR recommendation 23

This review does not recommend changing the current Australian classification system for medical devices as that would put Australia out of step with international regulators and could create Australian specific regulatory conditions, potentially impacting the range of medical devices available to the Australian market.

No specific products have been singled out under this review; rather the following are proposed further actions:

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

There are a significant number of Class I medical devices that could be more appropriately considered consumer goods but, having been assigned a therapeutic intent by the sponsor, are arguably captured under the definition of a medical device.

Compounding the issue of consumer good-like products on the ARTG are factors outside the direct control of the TGA. An identified example of this is an Australian state hospital tender process for the procurement of equipment. These tender processes sometimes contain requirements that create an incentive for sponsors of products to include the products in question in the ARTG as a Class I medical device, which has resulted in a large number of products in the ARTG that should not have been included in the first place.

It is proposed that an in-depth review of the Class I medical devices in the ARTG be conducted to identify those products that are consumer goods and not medical devices and if necessary, remove them from the ARTG. Once identified, and if required these product types could be declared not to be therapeutic goods using a legislative instrument under s7AA of the Act.

Action 2 – Engage with States and Territories

In addition to the ARTG "clean-up" activity, it is proposed that the TGA engages in dialogue with procurement branches of State and Territory health departments to prevent external tendering processes providing an incentive for including products that are not therapeutic goods in the ARTG.

Action 3 – Update the Excluded Goods Order

Prior to the current medical devices regulatory framework, a range of products of dubious evidence or non-therapeutic purpose were declared not to be therapeutic goods. The wording of these exclusions from the 1998 Excluded Goods Order is as follows:

- Non-implantable devices, equipment or apparel intended for use in; improving comfort, enhancing relaxation, exercising or improving physiological fitness, modifying anatomical physique, improving appearance, muscle or skin tone, easing minor aches and pains, fatigue or tiredness (due to normal ageing or day to day activities), or stimulating circulation (via exercise or the application of heat or massage)
- Devices that emit, measure or absorb, or claim to emit, measure or absorb, vibrations, waves, particles, or energy for which health benefit claims are made, the principles of which have not been scientifically validated.

These exclusions were subsequently removed with the intention that these types of products would be assessed during the application process to include them in the ARTG, which would then be an effective barrier to market for these types of products. This intention has not been realised as the subsequent automatic inclusion process developed for most Class I medical devices does not include the level of review intended and has instead resulted in such products being included in the ARTG.

It is proposed that the Excluded Goods Order be updated to reintroduce these exclusions as per the 1998 version as well as any other updates required following the review of Class I medical devices in the ARTG.

Action 4 – Review Class I medical device ARTG entry process

It is proposed that the TGA review the current Class I inclusion process with intent to implement additional verification processes to prevent non-therapeutic goods or misclassified products being included in the ARTG.

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.

Review of certain complementary medicine products

Recommendation 48 of the expert panel, which was accepted by the Government, was that there be a further **review of the range of complementary medicinal products**, **with a view to ensuring that products that might best be regulated under other regulatory frameworks**, without undermining public health and safety.

The following product types were identified as candidates and objectively confirmed as low or very low risk by the LRCS for the purposes of recommendation 48:

- Aromatherapy products
- Rehydration formulas
- Certain Vitamins and minerals (particularly water soluble ones at low-doses)
- Homoeopathic products

An overview of the international approach to the regulation of these product types can be found in Appendix 2.

Aromatherapy products

Background: Aromatherapy uses plant materials and aromatic plant oils, including essential oils, and other aromatic compounds for the purpose of altering one's mood, cognitive, psychological or physical wellbeing.[29]

Practitioners of aromatherapy apply essential oils using several different methods, including:

- indirect inhalation via a room diffuser or drops of oil placed near the patient (e.g., on a tissue)
- direct inhalation used in an individual inhaler (e.g., a few drops of essential oil floated on top of hot water to aid a sinus headache)
- aromatherapy massage, which is the application to the body of essential oils diluted in a carrier oil.

[29] https://www.ncbi.nlm.nih.gov/pubmedhealth/PMHT0024879/

In Australia, the purpose of a product containing an essential oil determines which part of government regulates it. That is, if the product makes only cosmetic claims the chemicals within the oil are regulated by NICNAS, but if the product makes a therapeutic claim it would be considered a therapeutic good and regulated by the TGA. Like all products, general safeguards under consumer law also apply.

Many of these products would likely have a safety profile that is comparable to other cosmetic or consumer products. For example, non-orally ingested aromatherapy products such as lavender oils with indications for 'aiding relaxation' or 'stress relief' may have the same safety profile as other oils or bath salts.

As at December 2016, there were 81 essential oil aromatherapy products in the ARTG.

Current regulatory oversight: Sponsors of products containing essential oil(s), which are considered to be therapeutic goods, must list their product in the ARTG prior to supply and must comply with all statutory requirements, including:

- Mandatory quality standards (such as the British Pharmacopoeia),
- the Poisons Standard,
- Therapeutic goods labelling Order as current and in force and
- TGO No. 80—Child Resistant Packaging Requirements for Medicines.

Essential oils that are supplied solely as starting materials to practitioners are generally exempt from the requirement to be included on the ARTG and the requirements of GMP unless they pre-packaged for therapeutic purpose or formulated as a dosage form.

Options for reform

Option 1 – Maintain the status quo regulation of aromatherapy products

Under this option, essential oils that make therapeutic claims continue to be regulated as described above.

- Keeping the status quo has the benefit of not introducing any change to the regulatory landscape. By maintaining the familiar regulatory requirements it will help maintain a high level of confidence in essential oils supplied to the Australian public.
- Disadvantages of the current regulatory framework are that the different types of regulation of the essential oils and different regulators depending on whether therapeutic claims are made is a significant source of confusion for importers, manufacturers, consumers and government regulators. It is also a questionable use of TGA's resources.

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

Under this option, essential oils would be exempt from Part 3-2 and/or Part 3-3 of the Act, which exempts them from the requirements of listing on the ARTG and from medicine level GMP, respectively.

- The potential benefits of this proposal include:
- Exempt products remain therapeutic goods under the auspices of the Act and therefore must still meet the statutory requirements mentioned above which continues to support public health and safety.

- Would allow rapid entry to market for essential oil suppliers.
- Potentially encourage a greater range of essential oil products in the market.

Potential disadvantages of this proposal include:

- Exempting aromatherapy products from Part 3-3 of the Act could potentially result in lower quality products being supplied if manufacturing standards are not appropriate. This would lead to an increase in consumer dissatisfaction and require post market regulatory action to correct.

Option 3 – Declare essential oils not to be therapeutic goods

This option proposes to declare all essential oils to not be therapeutic goods using an instrument under s7AA of the Act.

Regulatory oversight of individual essential oils in Australia would occur via the Australian Inventory of Chemical Substances (AICS). Following this assessment, NICNAS may impose a condition of use on the chemical to limit how it can be used which would maintain public health and safety.

Essential oils would be prevented from making therapeutic claims but rather be labelled with general use statements and relaxation claims as with other massage oils or bath salts.

- This option provides very low regulatory hurdle for suppliers of essential oils which would allow rapid access to the market.
- An outcome of this option is, with such products being regulated solely as consumer goods, they would fall under the auspices of ACCC and not a specialist regulator.

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.

Rehydration or formulated sports products

Background: There are currently 91 products on the ARTG for supply in Australia, making claims associated with rehydration (14 registered, 77 listed).

The dosage forms for these products range from sachets of oral powders and effervescent tablets to ice blocks and ready to drink solutions.

Rehydration products are similar in composition and presentation to electrolyte drinks, also known as sports drinks, which are beverages designed specifically for the rapid replacement of fluid, carbohydrates, and electrolytes.

To further complicate regulation, rehydration products in the ARTG are represented for a range of indications that are not solely therapeutic but are represented more in the range of sports supplement.

Electrolyte drinks are regulated under Standard 2.6.2 (non-alcoholic beverages and brewed soft drinks) of the Australia New Zealand Food Standards Code. Beverages which are marketed as electrolyte drinks in Australia must meet the compositional standards set out in the Code such as maximum and minimum levels of carbohydrates and must comply with the labelling requirements.

With these similarities in composition and intended purpose, this category of product is a source of confusion for both regulators and suppliers.

Current regulatory oversight: Rehydration products for therapeutic purpose are considered medicines and are regulated as either listed or registered products depending on the claims and composition of the products. They must be entered in the ARTG prior to supply in Australia and manufacturers must have medicine level GMP.

Options for reform

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

Rehydration products are a complicated product type due to their similarity with sports drinks. This causes considerable confusion with regulators and suppliers of these products.

It is recommended that the TGA reviews the rehydration products that are entered in the ARTG with the aim to ensure that there is clear demarcation between sports drinks, more appropriately regulated as foods, and other oral rehydration products with a specific therapeutic purpose.

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.

Vitamins and minerals

Background: When considering the risk of vitamin and minerals, not all of these supplements represent equal risk.

Water soluble vitamins (for example vitamin C) have a lower risk profile than fat soluble vitamins (for example vitamin A) as they are readily excreted from the body, whereas fat soluble vitamins have been associated with toxicity.

Similarly minerals such as calcium have a lower risk profile, compared to higher risk minerals which are included in a schedule of the Poisons Standard, such as some iron preparations.

Claims of vitamin and mineral supplementation must also be accompanied by a statement that "Vitamins can only be of assistance if the dietary vitamin intake is inadequate" OR "Vitamin supplements should not replace a balanced diet."

In recent years, a significant change to the food/medicine interface has been the introduction of *Standard 1.2.7 – Nutrition, Health and Related Claims* in 2013 by Food Standards Australia New Zealand (FSANZ). This Standard allows for both general health claims for foods and high level

claims that refer to osteoporosis and neural tube defects. However it should be emphasised that this standard relates to foods rather than products traditionally presented as medicines.

Current regulatory oversight: In Australia, vitamins and minerals supplements are regarded as complementary medicines and are regulated as either listed or registered medicines under the Act.

The listing process for complementary medicines is a risk based regulatory process with sponsors submitting applications via the TGA online portal. Manufacturers of listed medicines must meet medicine level GMP.

Listed medicines must only include permitted ingredients, meet standards for labelling and quality and are only allowed to make low level health maintenance and/or health enhancement and supplementation claims.

The listing application process is counterbalanced by post market regulatory oversight such as post market compliance reviews, recall procedures and therapeutic good advertising compliance.

Options for reform

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

Under this option, all vitamin and mineral products continue to be regulated as therapeutic goods and are required to meet the regulatory requirements described above.

The benefits of maintaining the current regulatory process for vitamin and mineral products include:

- the Australian public continue to have confidence in high quality vitamin and mineral products
- industry is familiar with the regulatory requirements and do not need to invest in changing their processes
- previous consultation with industry realised a preference that these products continue to be regulated as therapeutic goods as it gives the products “a higher standing” with consumers and in international markets.

The disadvantage of this option is that all vitamin and mineral products in Australia – including some products with very little safety risk - will continue to be regulated as medicines rather than as food or dietary supplements, which imposes higher standards on quality and manufacturing than food regulation.

This option most aligns with the New Zealand approach that is currently being developed (see Appendix 2).

Note that the Government has agreed to a further MMDR recommendation that certain listed medicines such as listed vitamin and mineral products should be the subject of TGA monographs, which will list the permitted indications considered to be supported by evidence.

This monograph system would make it easier for sponsors of vitamin and mineral products that meet the monograph requirements to demonstrate compliance with claims and labelling, although it will be important to assess the level of interest from sponsors in using such monographs.

This monograph system is detailed further in a separate consultation paper to be released later in 2017.

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

Under this option, certain vitamin and mineral products would be exempt from Part 3-2 and/or Part 3-3 of the Act, which exempts them from the requirements of listing on the ARTG and/or from medicine level GMP. A list of suitable vitamin and mineral products and maximum levels of vitamin and mineral active substances would need to be established, focussing for example on lower risk water soluble substances rather than higher- risk fat soluble substances.

Under this option, all vitamins and mineral products remain as therapeutic goods and therefore still subject to the regulatory requirements detailed above.

- Disadvantages of this option would include:
    - It may also create a consumer perception of a lowering of quality of the products.
    - This option could potential impact the highly regarded international reputation of Australian goods and impact on the export marketability of these products.
    - Exempting vitamin and mineral products from Part 3-3 of the Act could potentially result in lower quality products being supplied if manufacturing standards are not appropriate. This would lead to an increase in consumer dissatisfaction and require post market regulatory action to correct.
- Advantages of this option are that it lowers the regulatory burden for industry (costs, regulatory fees, manufacturer requirements) which would allow quicker access to market and potentially lower costs to consumers.

This option would mostly align with the new proposed Canadian 'Self-Care Products' scheme (see Appendix 2).

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

Under this option certain low risk vitamins and mineral products would be declared not to be therapeutic goods using a legislative instrument under s7AA of the Act.

It is proposed under this option that vitamin and mineral products would be limited to health and nutritional claims similar to the European and proposed Canadian models.

If regulated as a food supplement, vitamins and minerals would need to conform to an appropriate standard as specified by FSANZ; however the regulatory oversight of these food supplements would by the individual States and Territories.

- A benefit of this option is the removal of the need to list the products in the ARTG prior to supply in the market as well as the removal of the requirement for the manufacturers of vitamin and mineral products to meet GMP.
- Disadvantages of this option would include:
    - It may create a consumer perception of a lowering of quality of the products.
    - This option could potentially result in lower quality products being supplied if manufacturing standards are not appropriate. This could lead to an increase in consumer dissatisfaction.

This option most aligns with the approach taken in the US (see Appendix 2).

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.

Homoeopathic products

Background: A 'homoeopathic product/preparation/medicine' is based upon the principles of homoeopathic pharmacy 'potentisation,' which is the serial dilution and succussion of a stock. Homoeopathic products are derived from a wide variety of natural source materials, mostly plants and minerals. Some of these source materials are poisonous, for example: *Atropa belladonna*. The highly diluted nature of homoeopathic products is considered to render the starting materials non-toxic and therefore safe for therapeutic use.

A mother tincture in homoeopathy is the first extract of herb or plant upon which further dilutions are made.

As of October 2014, there were 220 products listed on the ARTG as 'homoeopathic' or 'homoeopathic/other products'. Of these 220 products:

- 91 met the criteria for exemption (Item 8 of Schedule 5 to the Regulations) and even though they are listed, they are not required to be included on the ARTG. It is assumed that the sponsors either listed these products because they were unaware of the regulatory requirements or believe that by doing so there was a marketing advantage in representing the product as a TGA-listed medicine.
- 29 were required to be listed on the ARTG as they contained ingredients at 1:1000 or lesser dilutions (1X, 2X or 3X).
- 16 were required to be listed on the ARTG because they had indications for the treatment of a disease, condition, ailment or defect.
- 84 were required to be listed on the ARTG as their formulations included non-homoeopathic ingredients in combination with homoeopathic ingredients.

As at February 2017, there were 142 homoeopathic preparations entered in the ARTG. The number of exempt homeopathic preparations on the market in Australia is unknown.

Current regulatory oversight: Homoeopathic preparations are exempt from being entered in the ARTG if it is more dilute than a one thousand fold dilution of a mother tincture[30] (4X and above), is not required to be sterile, does not include ingredients of human or animal origin and does not make reference to serious diseases or conditions. Preparations that meet these conditions are also exempt from requiring the manufacturer to hold a GMP licence.

Preparations less dilute than 4X, which only contain permitted ingredients, are not sterile and/or make reference to serious diseases or conditions, are required to be listed in the ARTG.

[30] The first dilution of a Mother tincture is considered 2X so a one thousand fold dilution of a mother tincture is 4X

Products that are required to be supplied sterile would require registration in the ARTG, as they can only be supplied as registered medicines.

An overview of the international approach to the regulation of homoeopathic products can be found in Appendix 2.

Options for reform

Option 1 - Maintain the status quo regulation of homoeopathic products

Under this option TGA continues to regulate homoeopathic products as listed complementary medicines or exempt goods depending on their composition and dilution and would continue to be required to meet the regulatory requirements detailed above.

> **Please note:** The Government has agreed to further MMDR recommendations to reform the regulation of complementary medicines. Recommendations 38 and 39 cover the establishment of three pathways for entry of complementary medicines in the ARTG based on a hierarchy of evidence and permitted indications for listed medicines.
>
> Those proposals are further detailed in a separate complementary medicines consultation paper which is currently open for consultation[31].

- An issue of maintaining the current regulation of homoeopathic products under the same framework as evidence based medicines is that it may imply government endorsement of these products. This is particularly relevant given the Australian National Health and Medical Research Council (NHMRC) recently concluded that there is no reliable scientific evidence that homeopathy is effective[32].

This issue is also being considered by other regulators. A 2009 U.K. government review[33] concluded that:

> 'By providing homeopathy on the NHS and allowing MHRA licensing of products which subsequently appear on pharmacy shelves, the Government runs the risk of endorsing homeopathy as an efficacious system of medicine. To maintain patient trust, choice and safety, the Government should not endorse the use of placebo treatments, including homeopathy.'

In November 2016, the US Federal Trade Commission in the USA concluded similar findings.[34]

An advantage with this option is that sponsors and manufacturers who are already familiar with the regulatory framework would not need to understand or implement any regulatory changes.

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

Currently, Item 5 of Part 1 to Schedule 4 of the Regulations states that homoeopathic preparations that refer to the treatment of a disease, condition, ailment or defect specified in Part 1 or 2 of Appendix 6 to the Advertising Code are eligible for listing. This is inconsistent with the regulation of other listed medicines.

[31] https://www.tga.gov.au/consultation/consultation-reforms-regulatory-framework-complementary-medicines-assessment-pathways (consultation closes on 28 march 2017)
[32] https://www.nhmrc.gov.au/guidelines-publications/cam02
[33] https://www.publications.parliament.uk/pa/cm200910/cmselect/cmsctech/45/4507.htm
[34] https://www.ftc.gov/system/files/documents/reports/federal-trade-commission-staff-report-homeopathic-medicine-advertising-workshop/p114505_otc_homeopathic_medicine_and_advertising_workshop_report.pdf

Under this option it is recommended that the Regulations be amended to require homoeopathic products that make high level claims to be registered in the ARTG and require supporting scientific evidence, as per non homoeopathic medicines that make high level claims.

Homoeopathic products relying on traditional evidence would only be able to make therapeutic claims acceptable for minor claims in relation to self-limiting conditions that do not require healthcare practitioner supervision.

This option allows for greater consistency with international regulatory frameworks (see Appendix 2) by ensuring that those goods which refer to the treatment of a serious condition are not listable but rather must be registered and evaluated for their quality, safety and efficacy.

Premarket assessment of evidence could potentially cause delays to market for registrable homoeopathic medicines.

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

Under this option, it is proposed that all homoeopathic products would be exempted from Parts 3-2 and 3-3 of the Act.

Exempt products remain therapeutic goods under the auspices of the Act and therefore still subject to the regulatory requirements detailed above.

This option represents a lower barrier to market for those homeopathic products that were not previously exempt and could result in a greater range of products for consumers.

A potential risk under this proposal is that products are supplied into the market that contain therapeutically significant quantities of restricted ingredients. However, any product containing levels of substances captured in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) that breach the scheduled limits would be subject to appropriate regulatory action, as is currently the case.

Any homoeopathic product containing ingredients of human or animal origin as currently specified in Schedule 5 would be required to comply with the TGA policy on TSE and would not be subject to any further regulatory requirements.[35]

Option 4 – Declare homeopathic products not to be therapeutic goods

This option is to exclude all homoeopathic products from the regulatory framework, using an instrument under s7AA of the Act.

This would remove the regulatory burden under the Act for the sponsors of the existing 142 homoeopathic preparations listed in the ARTG, however homoeopathic preparations would continue to be consumer goods and be subject to the Australian Consumer Law enforced by the ACCC.

Under this option, it is proposed to also prevent homoeopathic products making therapeutic claims and requiring them to be clearly labelled as homoeopathic products with a direction for use statement such as “as directed by your healthcare practitioner”.

[35] https://www.tga.gov.au/transmissible-spongiform-encephalopathies-tse-tga-approach-minimising-risk-exposure

As per the previous option, if certain products supplied into the market contained therapeutically significant quantities of restricted ingredients, these products would still be subject to appropriate regulatory action, as is currently the case.

This option would allow the TGA to focus more resources on the regulation of higher risk therapeutic goods.

In the event that Option 4 (or a version thereof) is the supported way forward and the TGA were to no longer regulate homoeopathic products, then a new definition for what a 'homoeopathic' product represents must be developed. Further consideration should be given to defining the term with reference to concentrations, so that concentrated preparations remain within the purview of the therapeutic goods regime.

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

Appendix 1: Current regulatory framework

The *Therapeutic Goods Act 1989* provides a uniform national framework for import, export, manufacture and supply of therapeutic goods. The overall objective of the Act is to provide a framework and systems of controls relating to the safety, quality, efficacy and timely availability of therapeutic goods, including medicines, medical devices and biologicals that are supplied in or exported from Australia. The Act is supported by the Therapeutic Goods Regulations 1990 (the Regulations) and various Therapeutic Goods Orders (TGOs) and determinations.

Unless exempt or otherwise approved, any 'therapeutic goods' must be entered on the Australian Register of Therapeutic Goods (ARTG) to be legally imported, exported, manufactured or supplied for use in Australia.

Australia has a risk-based approach with a two-tiered system for the regulation of all medicines. Lower risk medicines are listed on the ARTG while higher risk medicines are registered on the ARTG. Listed medicines are not individually evaluated by the TGA before they are available for supply. In contrast, registered medicines, including prescription medicines, are fully evaluated for quality, safety and efficacy before they can be supplied in Australia.

The regulation of medical devices in Australia differs from that of medicines in that certain cases make considerable use of overseas conformity assessments in assessing devices for inclusion in the ARTG).

There are a number of definitions in the regulatory framework that are important to the discussion.

Definition of therapeutic goods

Current legislation under the Act defines the following:

1. therapeutic goods means goods:

    a. that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be:

        i. for therapeutic use; or

        ii. for use as an ingredient or component in the manufacture of therapeutic goods; or

        iii. for use as a container or part of a container for goods of the kind referred to in subparagraph (i) or (ii); or

    b. included in a class of goods the sole or principal use of which is, or ordinarily is, a therapeutic use or a use of a kind referred to in subparagraph (a)(ii) or (iii);

    and includes biologicals, medical devices and goods declared to be therapeutic goods under an order in force under section 7, but does not include:

    c. goods declared not to be therapeutic goods under an order in force under section 7; or

    d. goods in respect of which such an order is in force, being an order that declares the goods not to be therapeutic goods when used, advertised, or presented for supply in the way specified in the order where the goods are used, advertised, or presented for supply in that way; or

e. goods (other than goods declared to be therapeutic goods under an order in force under section 7) for which there is a standard (within the meaning of subsection 4(1) of the Food Standards Australia New Zealand Act 1991); or

f. goods (other than goods declared to be therapeutic goods under an order in force under section 7) which, in Australia or New Zealand, have a tradition of use as foods for humans in the form in which they are presented; or

g. goods covered by a determination under subsection 7AA(1) (excluded goods); or

h. goods covered by a determination under subsection 7AA(2) (excluded goods), if the goods are used, advertised, or presented for supply in the way specified in the determination.

2. **therapeutic use** means use in or in connection with:

a. preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons; or

b. influencing, inhibiting or modifying a physiological process in persons; or

c. testing the susceptibility of persons to a disease or ailment; or

d. influencing, controlling or preventing conception in persons; or

e. testing for pregnancy in persons; or

f. the replacement or modification of parts of the anatomy in persons.

3. The Act defines a **medicine** as:

a. therapeutic goods (other than biologicals) that are represented to achieve, or are likely to achieve, their principal intended action by pharmacological, chemical, immunological or metabolic means in or on the body of a human; and

b. any other therapeutic goods declared by the Secretary, for the purpose of the definition of therapeutic device, not to be therapeutic devices.

This definition is broad and has resulted in a range of products being captured within the regulatory framework for medicines that most consumers would not traditionally consider as 'medicines'.

Types of products in this category include some secondary sunscreens, medicated soaps, desensitising toothpastes and gels, lozenges for soothing dry throats, and personal care products such as anti-nappy rash treatments.

4. The Act defines a **device** as

a. any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following:

i. diagnosis, prevention, monitoring, treatment or alleviation of disease;

ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;

iii. investigation, replacement or modification of the anatomy or of a physiological process;

iv. control of conception;

and that **does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means**; or

b. an accessory to such an instrument, apparatus, appliance, material or other article.

5. Thirdly, there is a class of **"Other therapeutic goods"** that are not regulated specifically as medicines, biologicals or medical devices. They include sterilants and disinfectants, tampons and menstrual cups.

6. Finally, a number of products that could be considered low risk because of low-level therapeutic claims are **"Excluded Goods"** which were excluded from the regulatory regime by the Therapeutic Goods (Excluded Goods) Order No. 1 of 2011. [36]

   The Excluded Goods Order breaks these products into three subclasses with varying levels of conditions for their exclusion and includes a list of products.

   - Goods that are not therapeutic goods
   - Goods that are not therapeutic goods when used, advertised, or presented for supply in a particular way
   - Goods that are not therapeutic goods, with allowable limited therapeutic use when advertised, represented or presented for supply in a particular way

Regulatory framework for medicines

Australia's regulatory framework for medicines is risk-based. That is, differing regulatory standards are adopted in the assessment and management of medicines according to the perceived risk to the public of their use. Products carrying a higher risk, including all prescription medicines, receive a significantly higher degree of pre-market assessment compared to lower risk medicines with well known, ingredients. Higher risk medicines must be registered in the ARTG and this is indicated by the inclusion of an AUST R number on the product label. Risk assessment of products through medicines scheduling is also utilised to determine how consumers can gain access to a medicine. For example, some very low-risk medicines may be sold in a supermarket, whereas a higher risk medicine may only be supplied after consultation with a health professional. Whether a medicine is classified as prescription, OTC, or is available on general sale is determined by the scheduling of substances on the *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP), known as the *Poisons Standard.*

Lower risk medicines are listed, rather than registered, in the ARTG before being supplied in Australia and are required to display an AUST L number on the product label. Most listed medicines are complementary medicines, but there are a small number of other OTC products, for example menthol throat lozenges and some cough and cold preparations, that are listed in the ARTG. Most sunscreens are also included in the ARTG as listed medicines.

A listed medicine can only be marketed in Australia if:

1. It contains only pre-approved low-risk ingredients. These ingredients have been evaluated by the NRA for quality and safety but not for efficacy.

[36] Therapeutic Goods (Excluded Goods) Order No. 1 of 2011 https://www.tga.gov.au/therapeutic-goods-excluded-goods-order-no-1-2011

2. The manufacturing site (if in Australia) is inspected and licensed by TGA or, if manufactured in a facility overseas, the site has been assessed by TGA and determined as meeting appropriate standards.

3. In general, it does not make claims or imply that it will be useful in the treatment or prevention of serious illnesses that would require the involvement of a health professional.

TGA does not individually evaluate listed medicines before they are entered in the ARTG. Rather, when listing a medicine in the ARTG, the sponsor must make certifications about quality; compliance with labelling, packaging and Good Manufacturing Practice (GMP) standards; and use of approved ingredients. The sponsor must also certify that they hold evidence to support any therapeutic claims. This allows for early market access, with sponsors of listed medicines generally able to supply their product in Australia within 48 hours of submitting an electronic application.

Regulatory framework for medical devices

The Australian medical devices regulatory framework is based on the principles of conformity assessment developed by the GHTF. As a result, the Australian and European systems of device regulation are closely aligned.

Assessments may be conducted before a device is able to be supplied to the market in Australia, and while a medical device is available on the market.

The TGA's regulatory requirements vary, depending on what the device is and how it is to be used.

The Regulations outline the basic characteristics, such as safety, quality and efficacy that medical devices must demonstrate before they can be lawfully imported, manufactured, supplied or exported. Efficacy in the context of medical devices refers to *'the performance of the device as the manufacturer intended.'*

These medical device classification rules are based on the:

- manufacturer's intended use of the device
- level of risk to patients, users and other persons
- degree of invasiveness in the human body
- duration of use.

The classification levels for medical devices are:

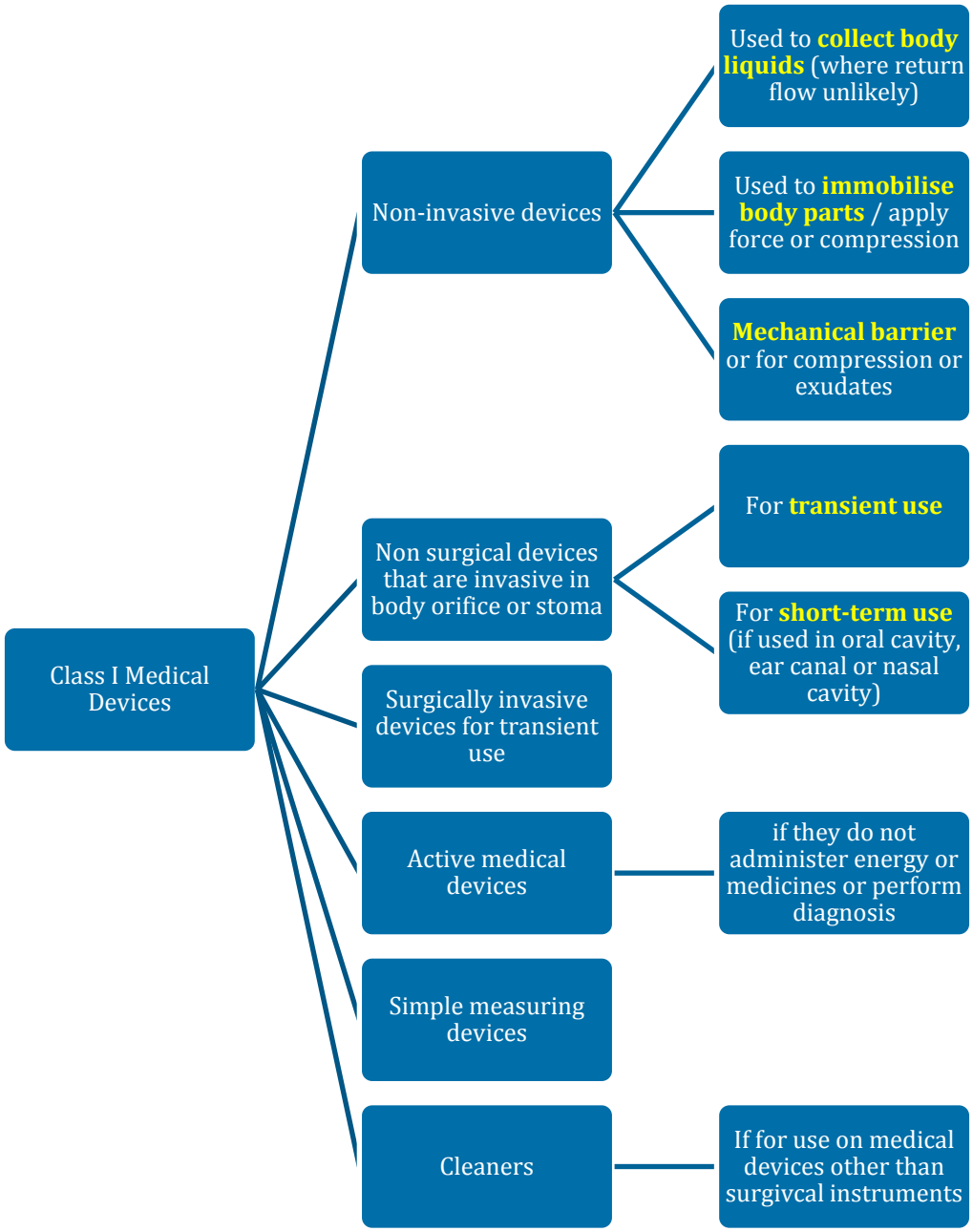
Classification	Level of risk
Class I	low
Class I—supplied sterile Class I—incorporating a measuring function Class IIa	low–medium
Class IIb	medium–high

Classification	Level of risk
Class III	high risk
Active implantable medical devices (AIMD)	high risk

The classification rules are explained in more detail in the Australian Regulatory Guidelines for Medical Devices (ARGMD).

This review focuses on medical devices classified as Class 1. The diagram below shows the broad groups of class I medical devices.

Figure 3 – Class I medical devices



Manufacturer compliance

Good Manufacturing Practice (GMP) describes a set of principles and procedures that when followed helps ensure that therapeutic goods are high quality.

Basic tenets of GMP are that:

- Quality cannot be tested into a batch of product
- Quality must be built into each batch of product during all stages of the manufacturing process.

There are different codes of GMP, depending on the type of therapeutic good. Section 36 of the Act allows the Minister of Health to determine manufacturing principles that are to be applied in manufacture of therapeutic goods.

The *Therapeutic Goods (Manufacturing Principles) Determination No 1 (2013)* specifies that medicinal products supplied in Australia have to meet the PIC/S Guide to GMP – 15 January 2009, PE 009-8, except for its Annexes 4, 5 and 14 which are not adopted by Australia. Through the operation of section 36 and other provisions within the Act, the PIC/S Guide to GMP has legal fore in Australia.

Australian manufacturers of all types of therapeutic medicines must be licensed under Part 3.3 of the Act and must comply with the principles of GMP, unless specifically exempted. Overseas manufacturers of medicines imported into Australia must comply with an equivalent standard of GMP.

A different system, conformity assessment, is used to ensure that medical devices are of high quality. Manufacturers take full responsibility for the design and production of a medical device whether they make the device themselves or subcontract some of these activities.

Australian manufacturers of medical devices, and other specified manufacturers of devices incorporating a medicine or biological material, must be issued with a Conformity Assessment Certificate under Part 4 of the Act. Their quality management systems must comply with a recognised QMS standard.

All other overseas manufacturers must have evidence of the application of the conformity assessment procedures. This evidence is usually in the form of an equivalent assessment undertaken by recognised conformity assessment bodies. Manufacturers are required to implement a comprehensive post market vigilance and adverse incident reporting program.

Advertising of therapeutic goods

The advertising of therapeutic goods to consumers and health practitioners is controlled by a combination of statutory measures administered by the TGA and the Australian Competition and Consumer Commission (ACCC) and self-regulation through Codes of Practice administered by the relevant therapeutic goods industry associations.

Advertisements for therapeutic goods in Australia are subject to the requirements of the Act, the Regulations and the *Competition and Consumer Act 2010*. Advertisements for therapeutic goods must also comply with the Therapeutic Goods Advertising Code (the Code).

The fundamental principle for the advertising of medicines is set out in the Act which specifies that advertising of a therapeutic good can only refer to the indications or purposes which are included in the ARTG for that specific good.

Post market data

Once a medicine has been registered or listed in the ARTG, it is subject to monitoring by the TGA. The extent of this monitoring depends on the risk classification of the medicine. Post-market monitoring by the TGA is focused on the safety of the medicine rather than on its efficacy and, as such, generally includes the collection and analysis of adverse event reports from consumers, health professionals and industry. Reports from overseas NRAs or from the medical and scientific literature are also assessed.

The regulatory process for listed complementary medicines allows for early market access for low-risk complementary medicines. In facilitating early market access, there is reliance on a comprehensive risk-based system of post market monitoring.

The TGA undertake a laboratory testing program which complements the desk-based compliance reviews of listed complementary medicines and medical devices, as well as other post market regulatory activities.

Recall

A product recall is the removal of therapeutic goods from supply on the Australian market for reasons relating to their quality, efficacy or safety. Recall of any distributed goods is required whenever public safety is at risk as a result of product noncompliance. A recall can occur because of problems such as:

- labelling or packaging errors;
- contamination issues; or
- an increase in unexpected side effects.

Appendix 2: An overview of International regulation of the product types discussed in this paper

Ear candles

In Europe, some ear candles are classified as Class I medical devices and bear the CE mark (93/42/EEC)[37], however these CE markings for Class I medical devices are mostly self-issued by the manufacturer following a self-certified Declaration of Conformity. This mark indicates that the device is designed and manufactured so as not to compromise the safety of patients, but no supporting independent testing is required.

While ear candles are widely available in the US, selling or importing them with medical claims is illegal. This means that one cannot market ear candles as products that "Diagnose, cure, treat, or prevent any disease".

Health Canada has **not** issued any licences for ear candles. Selling ear candles for medical reasons in Canada is illegal[38].

Both Canada and the United States have banned the importing of ear candles.[39]

Some promoters try to circumvent Health Canada's *Medical Devices Regulations* by advertising that ear candles are "for entertainment purposes only". But Health Canada maintains that these people are selling the product illegally (for medical purposes), as there is no other reasonable use for ear candles.

Nappy rash creams

In Canada and the US Diaper Rash products are listed in monographs. In the UK/EU, products containing zinc oxide are available as creams for local administration. Some zinc oxide containing products, depending on their claims and intended use, might be covered by Directive 76/768/EEC on cosmetic products.

Antiperspirants

In Australia, Canada and the USA, antiperspirants are treated as falling within the definition of "therapeutic goods" or "drugs". In New Zealand and the EU, they are cosmetics. The FDA regulates antiperspirants as both drugs and cosmetics requiring them to conform to both sets of provisions.

[37] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:01993L0042-20071011
[38] http://healthycanadians.gc.ca/drugs-products-medicaments-produits/buying-using-achat-utilisation/medical-procedures-medicales/ear-oreille-eng.php
[39] http://www.accessdata.fda.gov/cms_ia/importalert_225.html

OTC products

In the US, the FDA regulates over the counter products using a drug monograph system. Products that conform to the monographs do not require additional review by the FDA.

Health Canada are currently reviewing and consulting on proposed changes to their regulatory framework on 'Self –Care Products' which includes non-prescription medicines, which under the proposed new scheme, would be considered 'moderate risk'. Health Canada would continue to perform some review and licence these products based a monograph system, with therapeutic claims requiring Health Canada approval.[40]

Hard surface disinfectants

US Environmental Protection Agency (EPA) regulates chemical germicides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) of 1947. (The FDA does regulate disinfectants that are for use on medical devices, which are outside the scope of this review).

All pesticides sold or distributed in the United States (including imported pesticides) to be registered by EPA. Manufacturers of pesticides require a 'company number' as well as a 'pesticide-producing establishment number'[41]

European Chemical Agency regulates disinfectants in Europe under the Biocidal Products Regulation (Regulation (EU) No 528/2012 of the European Parliament (MHRA regulates disinfectants that are considered medical devices which are outside the scope of this review).

All active biocidal ingredients must be approved prior to use in a product as well as a separate approval process for the biocidal product before they can be supplied to the market.

Health Canada regulates hard surface disinfectants as drugs under the *Food and Drug Act* using a Hard Surface Disinfectant monograph[42] which describes the permitted active ingredients, minimum in-use concentrations, target microorganism classes, contact times, and associated use areas for these products for market authorisation. (This does not include disinfectants for use on critical and semi-critical medical devices which have a different approval process).

In New Zealand, hazardous substances, including disinfectants, sanitisers and cleaners are regulated by the Environmental Risk Management Authority New Zealand (ERMA NZ).

Sunscreens

The US FDA regulates sunscreens as non-prescription drugs and they must meet standards for safety, effectiveness and Current Good Manufacturing Practices (GMP). The majority of sunscreens are marketed via the OTC drug monograph process does not require premarketing review or approval by the FDA if the product conforms to an applicable monograph and general OTC requirements. However new sunscreen ingredients, for which a monograph does not yet exist either require special review by the FDA or require FDA to develop a new monograph. This has resulted in delays to market for new sunscreens in the US.

[40] https://www.canada.ca/en/health-canada/programs/consultation-regulation-self-care-products/consulting-canadians-regulation-self-care-products-canada.html
[41] https://www.epa.gov/compliance/pesticide-establishment-registration-and-reporting
[42] Hard Surface Disinfectant Monograph http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/disinfect-desinfect/hsd-rev-dsd-eng.php

The FDA applies the same requirements to cosmetics and moisturizers labeled with SPF values[43].

Sunscreens are regulated in Europe as cosmetics[44] and must comply with requirements for efficacy and advertising of sunscreen claims. These requirements are similar to those for listed medicines in Australia and include:

- Requires nomination of a responsible person who is legally accountable for the product

    1. Cosmetics must be listed in the central database Cosmetic Products Notification Portal (CPNP)

    2. Cosmetics may only use permitted ingredients (see REGULATION (EC) No 1223/2009[45]):

        - Must not include an ingredient in the list of substances prohibited in cosmetic products (annex II)

        - list of substances which cosmetic products must not contain except subject to the restrictions laid down (Annex iii)

        - List of colorants allowed in cosmetic products (Annex iv)

        - List of preservatives allowed in cosmetic products *(Annex v)*

        - List of UV filters allowed in cosmetic products *(Annex vi)*

    3. Manufacturers must have GMP that complies with the Cosmetics — Good Manufacturing Practices (GMP) — Guidelines on Good Manufacturing Practices (ISO 22716:2007)

    4. The Regulation also includes requirements for a cosmetic product safety assessment prior to supply in the market

In Canada sunscreens are regulated as either natural health products (NHPs) or as drugs both of which require a premarket application for market authorisation. Products that comply with the health Canada Sunscreen Monograph[46] can be licenced without providing additional evidence.

Health Canada is currently updating their Sunscreen monograph and has aligned the requirements for sunscreens containing 'Drug medicinal ingredients' with the US FDA *Sunscreen Drug Products for Over-the-Counter Human Use: Final Rule 2011.*

The proposed updated monograph details requirements for labelling, claims, unacceptable indications as well as warnings and use statements.

The new proposed monograph also outlines a range of options for demonstrating that the product complies with an appropriate standard which is required for active ingredients (for NPH products) and all ingredients (active and excipient) as well as finished product specifications for drug product.

Under the Canadian framework sunscreens include moisturisers and other cosmetic products that claim an SPF.[47]

[43] http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/understandingover-the-countermedicines/ucm258468.htm#Q1_Why_is_FDA
[44] Sunscreen products https://ec.europa.eu/growth/sectors/cosmetics/products/sunscreen_en
[45] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02009R1223-20160812&from=EN
[46] Sunscreen Monograph http://webprod.hc-sc.gc.ca/nhpid-bdipsn/atReq.do?atid=sunscreen-ecransolaire&
[47] http://www.hc-sc.gc.ca/dhp-mps/consultation/natur/sunscreen-ecransolaire-eng.php

Manufacturers of sunscreens must meet the same requirements as all drugs under the *Food and Drug Regulations,* to ensure that their products are safe, effective, and of high quality.

In New Zealand, sunscreens are regulated as cosmetics that may contain hazardous ingredients by the New Zealand Environment Protection Authority (EPA). The EPA has developed the Cosmetic Products Group Standard (CPGS) 2006[48] which is very closely aligned to the European Cosmetics Directive.

The CPGS, like the European Directives, contains lists of permitted and prohibited requirements for ingredients as well as labelling requirements which include manufacturer details.

Tampons and menstrual cups

In Canada, menstrual tampons are regulated as medical devices. Health Canada checks that tampons are safe, effective, and of high quality based on requirements for licensing, quality manufacture, and post-market surveillance. Before a device licence is given to a manufacturer, tampon-package labeling must contain specific information about absorbency. Labels must also provide details about the risks and symptoms of Toxic Shock Syndrome, and instructions on what to do if you have these symptoms (*http://healthycanadians.gc.ca/drugs-products-medicaments-produits/buying-using-achat-utilisation/products-canada-produits/drugs-devices-medicaments-instruments/tampons-eng.php*).

In the UK, tampons are regulated by the General Product Safety Directive (EEC Directive 2001/95/EC) which holds manufacturers responsible for the safety of the products.

In the USA, tampons are regulated by the FDA as Class II medical devices, which require a 510(k) application and requires the manufacturer to declare conformity to the appropriate product standards.[49]

Internationally, menstrual cups are regulated by comparable regulators in a number of ways.

In the US, menstrual cups FDA[50] are 510(k) exempt and do not require a premarket notification application and FDA clearance; however the manufacturer is still required to register their establishment and list the generic category or classification name of the products.[51]

Canada regulates menstrual cups as Class 2 medical devices and requires that manufacturer must hold a medical device licence prior to supply as well as meet GMP requirements.[52]

Class I medical devices

The establishment of the Global Harmonisation Task Force (GHTF),[53] in 1992 set the international scene for the regulation of medical devices by encouraging convergence in

[48] http://www.epa.govt.nz/Publications/Cosmetic%20Products%20Group%20Standard.pdf

[49] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077274.htm

[50] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm?ID=3736

[51] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/315.cfm

[52] Standard of Canada CAN/CSA-ISO 13485:03, *Medical devices — Quality management systems — Requirements for regulatory purposes*

regulatory practices related to ensuring the safety, effectiveness/performance and quality of medical devices as well as, promoting technological innovation and facilitating international trade.

The GHTF model was fundamentally based on the European regulatory system. In late 2011, GHTF was replaced by the International Medical Devices Regulators Forum (the IMDRF).

This work has driven a convergent international landscape for the regulation of medical devices globally.

United Kingdom

In the UK, the Medicines and Healthcare Products Regulatory Agency and is responsible for regulating medical devices.

The relevant EU Directive for the discussion on low risk medical devices is the Medical Device Directive (93/42/EEC) (the MDD), which divides medical devices into four classes of risk:

Class	Risk Classification	Examples
I	Low-risk	Sticking plasters, corrective glasses
IIa	Medium to low-risk	Tracheal tubes, dental filling material
IIb	Medium to high-risk	X-ray machines, bone implants and screws, urethral stents
III	High-risk	Heart valves, total hip replacements, breast implants

In Europe, medical devices are not directly subject to any pre-market authorisation by a regulatory authority. Instead manufacturers must demonstrate that they have applied the conformity assessment procedures appropriate for the risk of the medical device.

Low-risk devices only require a supplier/manufacturer declaration of conformity, where the manufacture is responsible for ensuring that the device complies with the relevant requirements and then produces a self-declaration statement.

United States

The medical devices legislative framework is set out in the Federal Food Drug and Cosmetic Act.

[53] GHTF was conceived in 1992 in an effort to achieve greater uniformity between national medical device regulatory systems. This was done with two aims in mind: enhancing patient safety and increasing access to safe, effective and clinically beneficial medical technologies around the world. A partnership between regulatory authorities and regulated industry, the GHTF was comprised of five Founding Members: European Union, United States, Canada, Australia and Japan.

The US uses a risk based classification for medical devices which takes into account the intended use of the product - one of three regulatory classes based on the level of control necessary to assure the safety and effectiveness of the device:

- Class 1 general controls (with and without exemptions),
- Class II General Controls and Special controls (with and without exemptions)
- Class II General Controls and pre-market approvals.

There are two ways of obtaining pre-marketing clearance/approval:

- A pre-market Approval (PMA) which is the most stringent type of device marketing application required by the FDA
- A pre-market notification (known as 510(k)) which is a pre-market submission made to the FDA to demonstrate that the device to be marketed is safe and effective. The submission must demonstrate that the device is substantially equivalent to a legally marketed device in the United States.

FDA has exempted almost all class I devices (with the exception of Reserved Devices[54]) from the premarket notification requirement.[55]

Manufacturers of Class I devices are required to register their establishment and list the generic category or classification name as well as notify the FDA of any malfunction, serious injury or death associated with a medical device.

The FDA has also released guidance on General Wellness: Policy for Low Risk Devices. [56]

General wellness products may include exercise equipment, audio recordings, video games, software programs and other products that are commonly, though not exclusively, available from retail establishments (including online retailers and distributors that offer software to be directly downloaded).

General wellness products must meet the following two factors: (1) are intended for only general wellness use, as defined in the FDA guidance, and (2) present a low risk to the safety of users and other persons.

The guidance states that the FDA "does not intend to examine low risk general wellness products to determine whether they are devices within the meaning of the FD&C Act or, if they are devices, whether they comply with the premarket review and post-market regulatory requirements for devices under the FD&C Act and implementing regulations".

Canada

In Canada, Medical devices are regulated by Health Canada's Health Products and Food Branch and are subject to the Medical Devices Regulations under the Food and Drugs Act.

As one of the founding members of the GHTF it is natural that the Canadian classification system borrows significantly from those in the European Union's Council Directive 93/42/EEC.

[54] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/3151.cfm
[55] Medical Device Exemptions 510(k) and GMP Requirements
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/315.cfm
[56] General Wellness: Policy for Low Risk Devices; FDA
http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm429674.pdf

Medical devices are classified as Class I, II, III or IV based on the risks associated with their use, including the degree of invasiveness, duration of contact with the patient, energy transmission hazard, and consequences of device malfunction or failure.[57]

Class I medical devices represent the lowest potential risk and do not require a licence to be supplied.

Health Canada monitors Class I medical devices by monitoring the supplier using 'establishment licenses' which requires importers, distributors and manufacturers of Class 1 devices to identify themselves. The licenced establishments are also required to provide assurance to TPD that regulatory requirements related to post-production activities have been met.

Singapore

The Health Sciences Authority of Singapore administers the *Health Products Act 2007* and the Health Products (Medical Devices) Regulations.

The Singaporean definition of a medical device is similar to the definition provided in Australia under the Act and the classification rules are adopted from the guidance developed by the GHTF.

Table 1: Classification system for General Medical Devices[58]

Class	Risk Leve	Examples
A	Low Risk	Wheelchairs / tongue depressors
B	Low-moderate Risk	Hypodermic Needles / suction equipment
C	Moderate-high Risk	Ventilators / bone fixation plates
D	High Risk	Heart valves / implantable defibrillators

Before medical devices can be supplied in Singapore it must be registered on the Singapore Medical Devices Register (SMDR).

Non-sterile low risk medical devices (Class A)[59] are exempted from having to be registered on the SMDR however they must still comply with the Essential Principles for Safety and

[57] Schedule 1 to the Canadian Medical Devices Regulations provides the Rules based classification system.

[58] MEDICAL DEVICE GUIDANCE GN-15 Revision 6.1 Page 10 http://www.hsa.gov.sg/content/dam/HSA/HPRG/Medical_Devices/Overview_Framework_Policies/Guidances_for_Medical_Device_Registration/GN-15-R6.1%20Guidance%20on%20Medical%20Device%20Product%20Registration.pdf

[59] MEDICAL DEVICE GUIDANCE, GN-22: Guidance for Dealers on Class A Medical Devices Exempted from Product Registration (Revision 6.1) http://www.hsa.gov.sg/content/dam/HSA/HPRG/Medical_Devices/Overview_Framework_Policies/Guidances_for_Medical_Device_Registration/GN-22_R6_Guidance_for_Dealers_on_Class_A_Medical_Devices_Exempted_from_Product_Registration.pdf

Performance for Medical devices as well as the standard legal requirements for suppliers of medical devices which include advertising and appropriate presentation of the devices.

Aromatherapy products (essential oils)

- Health Canada regulates essential oils as natural health products and requires a product licence application and labelling for market authorisation.[60]
- In the USA, the FDA regulate essential oils depending on the claims being made, if it makes therapeutic claims then it is regulated as a drug.[61] While FDA regulates labeling for cosmetics and drugs, advertising claims are regulated by the Federal Trade Commission.
- In the EU, products making medicinal claims on labels, promotional material or websites, require either a Product Authorisation (e.g. under the UK Medicines Act) or a Traditional Herbal Registration under the Traditional Herbal Medicinal Products Directive.
- In New Zealand, herbal remedies that do not make any therapeutic claims do not require ministerial approval or manufacturer licencing before being supplied.

Rehydration or formulated sports products

In New Zealand, Medsafe regulates oral rehydration therapy products indicated for the treatment of dehydration due to a condition or illness, as medicines. Sports drinks for rehydration of athletes and dehydration caused by exercise are regulated as electrolyte drinks under FSANZ Standard 2.6.2 (non-alcoholic beverages and brewed soft drinks) (which has been adopted under the *Food Act 2014*).

MHRA regulate oral rehydration salts in the UK as medicines however the claims are for treatment of dehydration caused by diarrhoea[62], not for rehydration from sporting activities.

In the US, the FDA regulates oral rehydration salts as medical foods. Medical foods are not regulated as drugs; however do have labelling and food level GMP requirements[63].

Vitamins and minerals

New Zealand is currently in the process of establishing a new Natural Health and Supplementary Products regime[64] which aims to provide a framework for low-risk natural health products. The regime will allow claims to be made about the health benefits of products which are not permitted under the Dietary Supplements Regulations 1985.

The proposed regime introduces a regulatory environment similar to the Australian complementary medicines framework, with controls on therapeutic indications, manufacturing and permitted ingredients.

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[60] http://webprod.hc-sc.gc.ca/nhpid-bdipsn/atReq.do?atid=aromatherap&lang=eng
[61] http://www.fda.gov/cosmetics/productsingredients/products/ucm127054.htm
[62] Sample product patient information http://www.mhra.gov.uk/home/groups/spcpil/documents/spcpil/con1474608242049.pdf
[63] http://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM500094.pdf
[64] http://www.health.govt.nz/our-work/regulation-health-and-disability-system/natural-health-and-supplementary-products

The FDA regulates dietary supplements under Dietary Supplement Health and Education Act 1994 (DSHEA)[65]. Under the DSHEA, the term 'dietary supplement' refers to a product intended to 'supplement the diet and contains ingredients such as vitamins, minerals, herbs (or other botanicals) amino acids, enzymes, organ tissues and metabolites in various forms'.

Dietary supplements are regulated as a special category of food. Like Australia, they cannot make claims of curing or treating diseases but can make low level claims. Many substances used in dietary supplements have been "grandfathered" from 1994. While in the strict sense the pre-market notification system is based on ingredients, in reality it is based on products because FDA require unique notifications for a combination of the ingredient, the way it is formulated and the supplier. The notifications are made public and while FDA does not have a single register some trade associations are constructing lists.

New products / substances can be used in dietary supplements if there is a history of use or evidence of safety and the substances have not been chemically altered in nature. The company has to notify FDA 75 days prior to marketing; FDA can decline to permit the product to be sold. If insufficient evidence of product safety is provided, the product is considered "adulterated".

FDA do enforce post market actions if a supplement is adulterated (i.e. contains an unapproved ingredient), misrepresentations are made on product labelling or cannot be marketed as a dietary supplement (e.g. contains a prescription drug). FDA also conducts inspections to check that (food-product type) GMP is being followed.

The Natural and Non-prescription Health Products Directorate (NNHPD) of Health Canada regulate complementary medicines under the *Natural Health Products Regulations*, which came into force in 2004 and fall under the Canada's *Food and Drugs Act*.[66]

Natural Health Products (which includes vitamins and mineral products) must be licenced by Health Canada before they can be supplied.

Health Canada are currently reviewing and consulting on proposed changes to their regulatory framework on 'Self –Care Products' which includes Natural Health Products. Under the proposed new scheme vitamins and mineral products would be considered 'low risk' and would not require Health Canada review and licencing. These low risk products would not be allowed to make therapeutic claims.[67]

In the UK, dietary supplements are either regulated as foods or medicines depending upon whether the ingredients are generally regarded as medicinal and whether the product is indicated for a medicinal purpose.

Vitamins and minerals are defined as food supplements under Directive 2002/46/EC (Food Supplements Directive – FSD) which contains the list of permitted vitamins and minerals. Food supplements are only permitted to make health and nutritional claims, which are regulated under Regulation EC 1924/2006 by the European Food Safety Authority.

[65] http://www.fda.gov/newsevents/testimony/ucm115163.htm
[66] http://www.hc-sc.gc.ca/fn-an/legislation/acts-lois/act-loi_reg-eng.php
[67] https://www.canada.ca/en/health-canada/programs/consultation-regulation-self-care-products/consulting-canadians-regulation-self-care-products-canada.html

Homoeopathic products

In the US, homeopathic remedies are classified as Drugs under the Food, Drug and Cosmetic Act and regulated by the Food and Drug Administration (FDA) and must be labelled as homoeopathic, must meet the Homoeopathic Pharmacopeia. They are not reviewed for safety or effectiveness.

Since 1988, they have been able to be sold without a prescription, and manufactured and distributed without FDA approval. The product has to be labelled as homeopathic but no GMP is required. The products are not approved for efficacy or safety but FDA allows them to be marketed as long as they address self-limiting conditions that can be self-diagnosed and the intended use is labelled. They are also only allowed to contain certain ingredients. Essentially there have been no major new homeopathic products since 1988 in the USA as it would require an OTC medicines monograph to be developed for the product.

In Europe, the MHRA (Directive 92/73/EC implemented in 1992) has a 'simplified' regulatory procedure for homoeopathic products which requires sponsors to demonstrate safety (sufficiently dilute) and quality. While Australian homoeopathic products may make indications for the treatment of conditions, products registered through this scheme cannot make therapeutic claims regarding descriptions of diseases or conditions.[68]

In the UK, Homeopathic products with indications for the relief or treatment of minor symptoms and conditions must be registered under the 'National Rules Scheme'[69] and supported by a dossier of data on quality, safety and efficacy. The levels and kinds of data accepted are similar to the Australian listed medicines framework.

In Singapore, homoeopathic products[70] are exempted from the general medicine provisions such as premarket approval as well as manufacturing and wholesale provisions for medicinal products[71]. Whilst exempt from these premarket requirements, homoeopathic medicines are still subject to medical advertisement control which prohibits efficacy claims for serious medical diseases, disorders and conditions as well as no reference to a list of conditions prohibited by legislation. Any advertisement that contains a therapeutic claim requires preapproval.[72]

Health Canada regulates homoeopathic medicines as natural health products which must have a product licence, and the Canadian sites that manufacture, package, label and import these products must have site licenses prior to supply. Homoeopathic medicines are only permitted to make specific claims if the claim is appropriate for self-care and does not require healthcare practitioner supervision. These specific claims must also not describe a condition listed in the

[68] https://www.gov.uk/guidance/register-a-homeopathic-medicine-or-remedy

[69] http://www.legislation.gov.uk/uksi/2006/1952/contents/made

[70] http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Complementary_Health_Products/HM.html

[71] Provided for in the Singaporean Medicines (Traditional Medicines, Homoeopathic Medicines and other Substances) (Exemption) Order. http://www.hsa.gov.sg/content/dam/HSA/HPRG/Useful_Information_for_Applicants/Legislation/MEDICINES%20(TRADITIONAL%20MEDICINES,%20HOMOEOPATHIC%20MEDICINES%20AND%20OTHER%20SUBSTANCE.pdf

[72] http://www.hsa.gov.sg/content/dam/HSA/HPRG/Medical_Advertisements_Sales_Promotion/Guidelines%20on%20Medical%20Advertisements/GuideAdvertTradMedMaterialsMar2005.pdf

Food and Drugs Act (Schedule A)[73] and must not imply relief of cold and flu symptoms aimed at children 12 years and under.[74]

In New Zealand[75], a homeopathic product which is diluted to not more than 20 parts per million of the active ingredient and does not make therapeutic claims does not normally require Ministerial consent before distribution. A homeopathic product which is labelled or advertised with a therapeutic purpose, is sterile and intended for injection or is administered to the eyes are considered medicines and are subject to the full control of the Medicines legislation.

[73] http://laws-lois.justice.gc.ca/eng/acts/F-27/FullText.html#h-21
[74] http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/ehmg-nprh-eng.php#a5.2
[75] http://www.medsafe.govt.nz/regulatory/Guideline/Full%20-%20NZ%20Regulatory%20Guidelines%20for%20Medicines.pdf

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