THE AUSTRALASIAN COLLEGE OF DERMATOLOGISTS

PO Box 3785 Rhodes NSW 2138 Australia
Suite 2A Level 2 9 Blaxland Road Rhodes NSW 2138 Australia
Telephone +61 2 8765 0242 | Australia Only 1300 361 821
Facsimile +61 2 9736 2194 | Email admin@dermcoll.edu.au
Website www.dermcoll.edu.au

17 May 2017

Health Products Regulation Group
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Dear Sir/Madam,

On behalf of The Australasian College of Dermatologists, thank you for the opportunity to comment on the Therapeutic Goods Administration's *Options for the future regulation of "low risk" products* consultation paper.

The Australasian College of Dermatologists is the leading authority in Australia for dermatology, providing information, advocacy and advice to individuals, communities, government and other health stakeholders concerning dermatological practice in Australia. Our focus is to train and maintain highly qualified dermatologist specialists who work to improve outcomes in skin health of individuals and communities.

The College has considered the issues raised in the consultation paper with respect to their impact on the practice of College Fellows and on the speciality of dermatology more broadly. Responses to consultation questions relevant to the College and its members are provided in the attached document.

Thank you for your consideration in this matter.

Please contact [redacted] should you have any further questions relating to this submission.

Kind regards,

[redacted]

[redacted]
The Australasian College of Dermatologists

The Australasian College of Dermatologists Response to Consultation

Therapeutic Goods Administration: Options for the future regulation of low risk products

Background

The Therapeutic Goods Administration (TGA) is seeking comments on proposed options for future regulation of 'low risk products', the outcome of which may potentially streamline the regulatory framework for certain products and increase consumer access.

In accordance with recommendations put forward by the Expert Panel Review of Medicines and Medical Devices Regulation (2015), the TGA have reviewed products currently listed in the Australian Register of Therapeutic Goods (ARTG) to identify those which may be best regulated through an alternative regulatory framework, or those that remain on the ARTG are regulated in a manner which is commensurate with risk. Under the current framework, therapeutic goods are either listed or registered on the ARTG, depending on the level of risk they pose to consumer health and safety. Listed medicines (lower risk) do not undergo individual evaluation by the TGA, whereas registered (higher risk) are fully evaluated prior to release to market.

This current consultation attempts to address the issue that, due to the broad definition of 'medicine' in the Therapeutic Goods Act, products can be captured within the medicine regulatory framework that are not considered to be medicines by consumers and the public. This leads to a regulatory process for these products (i.e. manufacturing, labelling etc.) that may be disproportionate with the level of risk, potentially delaying or preventing market access, impacting the range of products, driving costs of production or reducing affordability to the consumer.

This review has identified a range of products whereby regulatory reform may be appropriate to better reflect the low level of risk posed to the consumer. There are several products identified for which application to the skin or mucosal surfaces are the primary route of administration, or which involve direct skin contact. As the leading authority in Australia on dermatological diseases and conditions, the Australasian College of Dermatologists (ACD) has considered the options for regulatory reform of dermatological products and welcomes the opportunity to provide comment.

Nappy rash cream

Products in the ARTG indicated for alleviation or treatment of 'nappy rash' span three levels of regulation: listed products (body washes, soaps, creams and powders which make a range of cosmetic and/or therapeutic claims); registered products (predominantly anti-fungal preparations); and Class I medical devices (barrier creams).

Of the five options for regulatory reform presented, ACD is supportive of Option 3: *Exemption from listing in the ARTG.* Within this option, these products will continue to be considered therapeutic goods and meet manufacturing and advertising requirements. This is preferred over Option 5: *Exclude nappy rash products from the regulatory framework.* While consumer law may well be theoretically adequate, the ACCC may not be best placed to provide oversight of this range of products which will continue to have a therapeutic use within a sensitive and potentially vulnerable population.

In clinical practice, it is rare to see complications with these nappy rash products. The advent of disposable nappies has greatly reduced the occurrence of nappy rashes in the community, thus these products are used less frequently. It is noted that while Option 3 could potentially create greater market diversity as a result of ARTG exemption, there is no real clinical need for a wider range of products for consumers. The College has no major concerns about a potential lowering of manufacturing standards – to date, there is no evidence whereby poor manufacturing practice has occurred and has impacted on efficacy of products such as those containing a fungicidal component. While it is acknowledged that deregistering of these products may impact manufacturing standards, this is considered a small risk. Finally, the College is supportive of the removal of barrier creams from regulation as medical devices.

Antiperspirants

Antiperspirants meet the definition of "therapeutic good" as these products elicit effects of "…influencing, inhibiting or modifying a physiological process in persons …" This review is concerned with those products that derive their

antiperspirant properties from inorganic salts of aluminium, zinc or zirconium only and are exempt from ARTG listing, rather than those that are registered medicines (i.e. botox injections).

The ACD is supportive of Option 2: E*xclude antiperspirants from the regulatory framework.* This will result in the reclassification of antiperspirants as consumer goods and thus be regulated within the consumer law framework under the auspices of the ACCC. This will align with consumer expectation and international regulation and the risk of poor manufacture is considered very low. There is no evidence to suggest that increased sensitivities at a population-wide level will occur as a result of such reclassification.

Other 'lower risk' over the counter (OTC) medicines

OTC medicines are 'medium risk', in that they can contain substances that are either scheduled in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) or are not permitted for use in Listed medicines. However a number of well-known OTC products have been identified as 'lower risk' as they have a history of use at particular ingredient levels and dosage forms and/or contain unscheduled substances.

Lower risk product types of interest to the College include: antiseptics for first aid treatment of minor cuts and abrasions; salicylic acid plasters for removal of corns and warts; menthol-based chest rubs; antiseptic mouth washes; acne treatments containing benzoyl peroxide; rubefacient preparations; and antidandruff and antifungal shampoos.

The ACD is supportive of Option 2: *Review of eligibility of active ingredients to become Listable.* In this option, risk review of active ingredients to determine whether they could be permitted for listed medicines may reduce regulatory burden and subsequent costs of bringing products to market, as well as the cost to the consumer. There is no clinical evidence to suggest that regulation of certain products as Listable, assuming a systematic and appropriate risk analysis is performed, will negatively impact the Australian public and indeed a refreshed and updated assessment of such products is warranted.

Sunscreens

Currently there are four pathways for sunscreen regulation which are shared between TGA (therapeutic claims), NICNAS (chemicals) and ACCC (consumer law). The regulatory pathway utilised is dependent on the product category (listable, registrable, exempt or cosmetic).

Primary sunscreens (primary function is UV protection; ≥SPF4) and moisturisers containing sunscreen (>SPF15) are regulated as therapeutic goods by the TGA. There are over 900 listed and only 2 registered sunscreens on the ARTG. Most secondary sunscreens (those with a different primary purpose but contain sunscreen agents) are regulated as cosmetics by NICNAS and the ACCC; the number of these products is unknown.

It is noted that the current regulatory model may be considered confusing by importers, manufacturers, consumers and regulators. The consultation paper lists a range of other confounding issues. It is clear that an alternative model for regulation of sunscreen is required. However in the interest of maintaining consumer safety, the continued rigorous assessment which occurs under the current model (Option 1: *maintain the status quo*) may be the best option given the potential public health impact of poor manufacturing standards.

The College is however tentatively supportive of a combination of Option 2: *Streamline the regulatory pathways for sunscreen regulation* and Option 3: *Prevent all secondary sunscreens from making SPF claims*. The simplification from four to two pathways (1. Listable sunscreen [primary sunscreen with SPF claim >4 but not >50+] and 2. Excluded sunscreen [all secondary sunscreens as well as primary sunscreens with SPF claims ≤4]) may help to clarify much of the regulatory and public confusion around the types of sunscreen products and their efficacy.

SPF is the measurement of protection against UVB only, the main cause of sunburn, and using a broad-spectrum sunscreen – one that protects against both UVA and UVB – is recommended. Many primary sunscreens contain both physical and chemical sunscreen ingredients which protect against UVA and UVB. In contrast, most secondary sunscreens such as cosmetics block UVB only, and as outlined in the consultation paper, are often applied

inadequately such that the reliability of the SPF claim may be questionable. By combining Option 2 and 3, preventing cosmetic products from claiming SPF values may limit consumers from using an underperforming product. Rather, they will seek products with clearly specified SPF values which are listed and regulated by the TGA, helping to secure public confidence as well as maintain reliable sun protection.

The College disagrees with Option 7: *Exclude all sunscreens from the regulatory framework.* Given the high incidence of melanoma and non-melanoma skin cancers in Australia, it is inappropriate to consider sunscreens as consumer goods, rather than therapeutic. It is imperative that oversight by the TGA remains in place even with the continued implementation of the sunscreen manufacturing standard due to the high risk consequence at the population level.

Aromatherapy products

The College is supportive of Option 3: *Declare essential oils not to be therapeutic goods*. Cases of allergic contact dermatitis from people inappropriately applying neat (undiluted) essential oils to their skin have been observed by dermatologists working in this field. It is strongly suggested that product warning labels should be utilised, advising consumers that these products should not be applied in this way. It is noted that should Option 3 be implemented, regulatory oversight would occur via the Australian Inventory of Chemical substances, and that NICNAS may impose such a condition of use on these chemicals to maintain public health and safety.