Director-General

Cosmetics Europe
the personal care association

Regulatory Reforms Team
Therapeutic Goods Administration
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To Whom It May Concern:

Please accept the comments below from Cosmetics Europe - The Personal Care Association as their contribution to the public consultation of the Australian Government Department of Health Therapeutic Goods Administration on different options for future regulation of "low risk" products.

Cosmetics Europe is the trade association representing the interests of the European cosmetics and personal care industry. Cosmetics Europe membership consists of more than 4000 companies, ranging from major international cosmetics manufacturers to small, family-run businesses, operating in niche markets. The membership of Cosmetics Europe is committed to the continuing development of safe, innovative and effective products. Since many of our members are operating globally, international convergence of cosmetic regulation and minimising technical trade barriers are key priorities for our association.

The positions of Cosmetics Europe:

Cosmetics Europe would like to support, as **its preferred option, option 7, "Exclude all sunscreens from the regulatory framework".**

In the EU, as in other jurisdictions including ASEAN, New Zealand and South Africa, sunscreens are regulated as cosmetic products. Because of their very nature, the EU has different regulatory approaches for cosmetics and drugs. Cosmetics products are fast-moving consumer goods, with inherently low risk, whereas drugs are slow-moving goods, with high biological / systemic activity and, therefore, an inherently higher risk. Within EU Regulation 1223:2009, cosmetics do not require pre-market approval but are, rather, regulated via an in-market control system. This system, in place within the EU for the last 40 years, has provided a high level of consumer safety through continuous adaption to fast-moving consumer goods, contributing significantly to the development of EU industry and fostering greater innovation.

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To regulate sunscreens as cosmetics will, therefore, encourage innovation, facilitate the approval of new UV filters and improve technical sunscreen performance. Importantly, by reducing the cost of compliance, manufacturers will expand their range of product offerings, allowing consumers access to an even broader range of sunscreen innovation. Finally, by removing sunscreens from a pre-approval regulatory framework, TGA will be able to focus more resource on post-market surveillance, allowing greater in-market control and improved safety of products in the Australian market.

As a **second preferable option**, Cosmetics Europe would encourage TGA to consider the **option 2 "streamline the regulatory pathways for sunscreen regulations".**

Cosmetics Europe would support this option so long as there is a clear delineation between listable (primary) sunscreens and excluded (secondary) sunscreens. For clarity, sun protection can be the primary function of a product designed to protect consumers during deliberate and potentially-prolonged exposure to the sun (e.g., beach / recreational products). However, products not designed as such primary sunscreens can also provide UV protection benefits as a secondary function (e.g., daily products such as moisturisers, colour cosmetics, etc.). For such secondary products, usage patterns and expected UVR exposure are quite different from those of primary products. We believe strongly, therefore, that sun protection claims should be allowed for secondary sun protection products, but without positive or negative listing. Lastly, we would encourage TGA to ensure that companies would retain the prerogative to list / register their products should they wish to.

Cosmetics Europe would like **to support option 5 "new ingredient approval process" and option 6 "alternative ingredient standards for excipient".**

With regards to these 2 options, we believe that:

- Australian authorities should recognise International Nomenclature of Cosmetic Ingredients (INCI) and remove mandatory requirements for Australian Approved Names. Indeed, ingredient listing is, above all, a safety measure. This is, of course, why INCI names are not mere "descriptors" but, rather, technical "codes" incorporating scientific and Latin pharmacopeia names, understood by scientists and health professionals worldwide. Furthermore, use of an international nomenclature helps facilitate more agile updating, according to existing and emerging scientific knowledge.

- Australian authorities should accept any ingredient that has been reviewed and approved by a comparable market for the same use, or has been reviewed by NICNAS or another

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regulatory agency in Australia. More specifically, the Australian authorities should recognized UV filters approved under other regulations. Notably, in EU, the approval of a new UV filter follows a strict process of evaluation led by independent structure, the Scientific committee on Consumer Safety (SCCS). The Australian authorities have recognized that the EU regulatory approach is comparable in requirements to the Australian approach for sunscreen. Therefore, there is no safety justification to have ingredients revised and approved twice.

Cosmetics Europe would like to express **limited support to option 4 "Creation of a GMP standard for primary sunscreens".**

In EU Cosmetic Products Regulation, compliance with Good Manufacturing Practices (GMP) is mandatory. The same requirement is applied to all cosmetic products and needs to be declared by the responsible person, legally accountable for the product. One way to demonstrate such compliance is to implement the international standard ISO 22716:2007 (mandating a management systems approach to documenting and regulating the production, control, storage, and shipment of cosmetic products). Compliance to GMP can also be demonstrated in other ways, e.g., via industry-recognised standards and codes, etc. In the EU, external certification is not required. When controlling, authorities can ask for full GMP documentation and / or an on-site inspection may be performed.

We would like to encourage the Australian authorities to accept GMP documentation as proof of compliance, and to use random or scheduled on-site audits as necessary.

This system is especially appropriate for secondary sunscreen products under options 1 & 2.

Cosmetics Europe additionally recommends recognizing that GMP compliance audit be performed by external experts accredited by TGA to allow flexibility for non-Australian facilities.

Cosmetics Europe would like to **strongly oppose option 3 "prevent all secondary sunscreens from making SPF claims".**

Cosmetics Europe sincerely appreciates the considerable work and effort being undertaken by TGA in preparing this reform proposal. Our experts stand by ready to answer any and all questions you may have in relation to our comments.

Yours sincerely,

[redacted]

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