PHAA submission on TGA review of chemical scheduling in relation to cosmetic and fragrance ingredients

1 April 2019

Dr Nena Waight-Sharma
Director
Regulatory Engagement and Planning Branch
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Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606 Australia

Dear Dr Waight-Sharma,

TGA consultation paper ‘Review of chemical scheduling in relation to cosmetic and fragrance ingredients’

The Public Health Association of Australia (PHAA) is recognised as the principal non-government organisation for public health in Australia working to promote the health and well-being of all Australians. It is the pre-eminent voice for the public’s health in Australia, and seeks to drive better health outcomes through increased knowledge, better access and equity, evidence informed policy and effective population-based practice in public health.

PHAA welcomes the opportunity to provide input to the TGA review of chemical scheduling in relation to cosmetic and fragrance ingredients.

PHAA has a strong interest in the regulation of chemicals for the protection of people and the environment, including for the chemicals in cosmetics and fragrances. The regulation of these chemical ingredients is complicated because of the different State and Federal authorities with responsibilities for the testing, regulation, labelling, advertising and post-market monitoring of the products.

It is appropriate for the TGA to follow-up on the recommendations from the Medicines and Medical Devices Review to examine the scheduling process for such chemicals for any improvements from harmonisation with the requirements of comparable overseas regulators. The Australian Government is also undertaking a number of regulatory reviews with the aim of reducing the reporting burden on industries through a risk-based focus rather than hazard-based processes. The PHAA and other community organisations remain concerned that this does not lead to lowering of the risk management standards that protect people and the environment.

Industry stakeholders should not be burdened with excessive reporting requirements, but this needs to be balanced by the ongoing concerns of the public about the safety of chemicals, including those in cosmetics and fragrances. The community is also concerned about injuries from chemicals in personal-care products arising from failures by regulators to properly identify risks and their reliance on post-market compliance.

Our major concerns are as set out below.
1. Policy improvements

The PHAA understands the benefits from adopting international standards from comparable overseas regulators to reduce the administrative burden on industry and improve productivity. However, this needs to follow a rigorous evaluation of the overseas regulatory authority and its mechanisms.

The TGA paper recommends adopting by reference, or incorporating in the Poisons Standard, the EU Cosmetics Regulation. The EU is a comparable regulator, but in this instance the EU Regulation incorporates the IFRA standards, where IRFA is not a comparable regulator.

IFRA is an industry association and its reports reflect the interests of its member companies, and it does not provide the type of comprehensive reports appropriate for an Australian regulator.

In addition, IFRA standards do not form part of the EU Cosmetics Regulation, but are separate industry standards. The TGA paper proposes adopting both, but does not clarify how differences between these standards should be reconciled.

IFRA standards are prepared using a model that has not been validated by any Government regulator (in fact, the EU expert committee (SCCS) has explicitly stated that the IFRA methodology has not been scientifically validated.

This Consultation Paper on possible changes to Australian regulatory procedures would have been more meaningful if it had included the views of the other Australian regulators with related interests, including NICNAS, APVMA and the ACCC, to provide all stakeholders with a more critical overview of the issues.

Taking these matters into account, PHAA is oppose to this proposal.

2. Improved processes

The PHAA supports these proposed improvements for guidance for applicants on scheduling applications, and improved engagement between relevant TGA advisory committees where a substance under consideration crosses regulatory boundaries.

3. Derivatives

The PHAA supports the need for more accurate descriptions of derivatives, including the use of CAS numbers, to ensure appropriate categorisation for different toxicological or other end points driving a scheduling decision. For example, amyl and hexyl cinnamaldehyde are not derivatives of cinnamaldehyde, but are listed as derivatives in Example 4 on page 28.

4. Managing the “low level presence” of impurities

The significance of impurities present in “low levels” in cosmetics and fragrances needs to be regularly reviewed as their biological activities are better understood and techniques improve for the detection of low concentrations.
5. Improved mechanisms for scheduling cosmetic and fragrance substances

PHAA recognises this as a complex but important area for improvements since it can benefit both industry applicants, regulators and the broader community.

PHAA supports the general need as stated in the review for better interaction between regulators when decisions will impact ingredients of cosmetic, consumer and household goods in Australia, such as APVMA, FSANZ, ACCC, and NICNAS, ahead of consideration of particular substances by the scheduling committee.

However, PHAA does not support, for reasons outlined above:

- Adoption by reference, or incorporation in the Poisons Standard, the EU Cosmetics Regulation; or
- Establishment of an Australian standard that references the IFRA and EU standards and requirements.

6. Skin sensitisation

The TGA paper implies that skin sensitisation is a relatively minor matter that can be adequately managed through warning statements on product labels. PHAA suggests this matter requires further consideration.

People who become sensitised to a chemical acquire a life-long condition. Skin sensitisation has two stages: induction and elicitation. From the perspective of overall health, regulations should aim to stop people becoming sensitised to the chemical in the first place, that is, to prevent induction. For chemicals that are already in widespread use (and many people are already sensitised), concentration limits should be determined so as to prevent people who are sensitised from reacting.

This is particularly important for chemicals in fragrances, cosmetics and domestic cleaning products that have widespread and repeated exposure, including in workplaces (e.g., hairdressing and beauty salons). SCC discussions on reactions to fragrances are pertinent in this context.

In conclusion, PHAA is pleased to provide these comments in relation to this review of chemical scheduling in relation to cosmetic and fragrance ingredients because of the importance of ensuring the safety of the whole community, including workers, exposed to these chemicals.

Please contact us should you require additional information or have any queries in relation to this submission.

Yours Sincerely,

Terry Slevin
Chief Executive Officer
Public Health Association of Australia