Statement of Requirements

Introduction

The TGA is seeking to engage a contractor from the TGA Product Evaluation Panel to provide external evaluation services for the Scheduling Secretariat as outlined in the Background and Specifications below.

Background

In 2016-2017, the Department of Health reviewed the Scheduling Policy Framework (SPF) and scheduling process for medicines and chemicals. It was identified that improvements were required to streamline the process by which chemicals are scheduled.

As part of a project seeking to consider opportunities to further amend and implement these changes, we require an Expert Review to be conducted of current process and scheduling decisions in relation to cosmetic and fragrance ingredients to identify how closely Australia's decisions align with other regulators (in particular the EU, UK and US). In particular, we wish to explore whether there are opportunities to harmonise chemical scheduling with comparable overseas regulators (CORs).

The Review will include consideration of a proposal from Accord Australasia Pty Ltd[1] to create a new Appendix entry in the Poisons Standard for substances used in cosmetic products (including incorporating Annexes II-VI of the European Union (EU) Cosmetics Regulation, which details prohibited and restricted ingredients). Further, Accord proposes to mandate compliance with the International Fragrance Association (IFRA) Standards for fragrance materials.

Specifications

A. Services to be provided

Preparation of a report for consideration by the TGA Executive, Chemicals Scheduling Delegate and/or expert committees, and suitable for public consultation, addressing the following:

(1) Comparative analysis of regulatory frameworks for cosmetic and fragrance ingredients in Australia, the EU, UK and the USA, detailing the extent and impact of regulatory differences.

(2) Accord refers to an 'unprecedented number of referrals of chemicals used in cosmetic products for scheduling consideration from the NICNAS IMAP programme that were already subject to risk management controls in other jurisdictions'; the report should include an analysis of the magnitude of this problem, identifying which cosmetic ingredients continue to be restricted (or are unavailable for use) in cosmetics in Australia compared with the EU .

(3) Identify opportunities for harmonising the scheduling of cosmetic and fragrance ingredients to align with the regulatory frameworks of our major trading partners, whilst maintaining appropriate access restrictions to protect public health.

[1] Accord Australasia Pty is the national industry association representing manufacturers and suppliers of hygiene, cosmetic and speciality products, their raw materials and service providers

(4) *Develop options for harmonising cosmetic and fragrance chemical scheduling with regulatory measures of CORs, in order to address the issues raised by Accord in their submission.*

(5) *Address the following issues specifically raised by Accord:*

a. *How to provide certainty for industry in a changing regulatory environment for industrial chemicals resulting from the NICNAS reforms;*
b. *Difficulties identifying regulated substances and understanding impacts on all possible substances that may be captured as derivatives, which Accord contends is particularly problematic given the current broad definition of 'derivative'.*
c. *Consideration of an exemption for trace elements of prohibited (Schedule 7 or 10) substances in cosmetics [along the lines of Part 1(2)(j) of the SUSMP].*

B. Timeframes

End of week 1: face-to-face progress meeting.

End of weeks 2 and 3: progress reports by teleconference.

End of Week 4: Face to face meeting: deliver draft report and present on its contents.

TGA reviews draft report (2 weeks).

End of week 6: Teleconference to discuss requirements for report finalisation.

End of week 8: Deliver final report.

C. Progress confirmation

The Contractor should confirm successful receipt of materials and maintain regular communication with the TGA Project Officer on the progress of the work and any issues possibly impacting on timeframes.

D. Documents to be provided

- D18-10099047 – Internal Meeting information brief - Progressing chemicals scheduling reforms (8 pages).
- D18-10437084 - Accord (draft) Proposal to incorporate EU Cosmetic Annexes and IFRA standards into Poisons Standard _ 23 May 2016 (19 pages).
- D17-700612 - Accord Submission - TGA Review of SPF and Advertising of S3 Medicines submission (Attachment 3: 16 pages).

E. Contact Details

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