From: [redacted]
To: [redacted] Medicines Scheduling
Cc: [redacted]
Subject: Re: Cosmetics chemicals scheduing review [SEC=UNCLASSIFIED]
Date: Friday, 8 June 2018 11:31:17 AM
Attachments: image001.png

Hi [redacted]

I am very supportive of this project and look forward to collaborating with the consultant as much as possible. Happy to meet at the appointed time with the consultant on 26th June after ACMS.

Best regards,

[redacted]

On Friday, 8 June 2018, 11:23:37 am AEST, Medicines Scheduling wrote:

Dear [redacted]

As an extension of the Scheduling Policy Framework Review, the Department of Health is conducting a review of the scheduling of cosmetic chemicals (including fragrances, colourants, surfactants etc) to identify how closely Australia's decisions align with other regulators (E.g. the EU, UK and USA). 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 (see attached) 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). Accord also proposes to mandate compliance with the International Fragrance Association (IFRA) Standards for fragrance materials.

We would like to discuss this review with the both of you and give you the opportunity to ask questions and/or provide advice to the consultant who will be conducting the review, [redacted]. We propose this briefing to occur at the Chairs meeting for the Joint ACMS-ACCS at 5:00pm on Tuesday 26 June 2018 following the ACMS meeting. You will receive an invitation shortly. Should you wish to contact [redacted] before this meeting to discuss the project, feel free. His details are [redacted] and [redacted].

Further background information regarding the review is as follows:

Issues

Issues to be considered and addressed include:

- 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.

- 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 .

• 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.

• 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.

• Address the following issues specifically raised by Accord:

• How to provide certainty for industry in a changing regulatory environment for industrial chemicals resulting from the NICNAS reforms;

• 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'.

• Consideration of an exemption for trace amounts of prohibited (Schedule 7 or 10) substances in cosmetics [along the lines of Part 1(2)(j) of the SUSMP].

Phase 1

Phase 1 of the project will focus on the following:

• Project plan development based on Accord proposal.

• Comparison of NICNAS assessed substances against the EU cosmetics list.

• For substances assessed by both the EU and NICNAS identify those where the EU assessment report is available.

• For a representative number of assessments, conduct a technical comparison to identify any discordance and the source of that discordance.

• Provide a report discussing the findings and making recommendations regarding further work (Phase 2).

Phase 2

Phase 2 is expected to a deliver a comparative analysis of regulatory frameworks for cosmetic and fragrance ingredients in Australia and its major trading partners (to be determined based on Phase 1), detailing the extent and impact of regulatory differences, including a review of each regulatory environment:

(i) Compare and contrast systems

(ii) Consider use of IFRA assessments by other agencies including JECFA, identifying 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, and

(iii) Identify any policy or process changes required to achieve alignment.

(iv) 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

[redacted] of the Scheduling Secretariat, who has been coordinating the project on the

Department's behalf, is away for the next two weeks, however [redacted] has availability most days should you have any questions. Her number is [redacted]

Kind regards

[redacted]

[redacted]

[redacted] | Scheduling & Committee Support

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Regulatory Engagement & Planning Branch | Regulatory Practice and Support Division

Health Products Regulation Group
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The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.
