Julie Abramson
Commissioner
Productivity Commission

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Dear Commissioner

Accord is pleased to provide the following comments to the Productivity Commission's Issues Paper: *Consumer Law Enforcement and Administration* (July 2016).

Accord Australasia is the peak national industry association representing the manufacturers and marketers of formulated hygiene, cosmetic and specialty products, their raw material suppliers, and service providers. Accord Members market fast-moving consumer and commercial goods primarily in Australia and New Zealand. Accord has just over 100 member companies which range from smaller Australian-owned family businesses to the local operations of large consumer brand multinationals (a full membership list is provided at Attachment 1).

Headline features and statistics[1] for our industry's economic footprint include:

- Estimated annual retail-level sales of industry products nudging the $10 billion mark.
- Accord member companies directly contribute more than 15,000 full-time equivalent jobs.
- Nationally more than 180 offices and more than 60 manufacturing sites are operated by Accord member companies.

Single law, single regulator

As a general position, Accord holds the view that all regulation related to business activities should be regulated at the national level. This includes both from a policy perspective as well as for post market monitoring, enforcement and compliance. For example, Accord supports the approach adopted in 2007 by COAG for a national system of trade measurement. The National Measurement Institute was given responsibility for managing the transition of trade measurement responsibilities from the states and territories to the Commonwealth. The new national system commenced on 1 July 2010 and industry regards this model as highly successful.

Interface of ACL with specialist safety regimes

Accord's main area of concern lies with the interface of the ACL and specialist safety regulators and the ACCC's administration of product safety interface issues. By way of example is the ACCC's position with the regulatory standards for teeth whitening products containing hydrogen peroxide and/or carbamide peroxide. In 2013, these ingredients were scheduled in the *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP). The entry was as follows:

> Schedule 10
> CARBAMIDE PEROXIDE (excluding its salts and derivatives) in teeth whitening preparations containing more than 18 per cent of carbamide peroxide except in preparations manufactured for, and supplied solely by, registered dental practitioners as part of their dental practice.
>
> HYDROGEN PEROXIDE (excluding its salts and derivatives) in teeth whitening preparations containing more than 6 per cent (20 volume) of hydrogen peroxide except in preparations manufactured for, and supplied solely by, registered dental practitioners as part of their dental practice.

[1] Results from Accord Industry Size and Scale Survey 2016

Teeth-whitening products are controlled through an Appendix C entry, where teeth-whitening products containing more than 6 per cent hydrogen peroxide are only allowed to be supplied by a registered dental practitioner as a part of their dental practice.

The control through Appendix C was considered necessary when teeth-whitening was starting to be offered by non-dental professionals in “pop-up” stores. These places were using high concentrations of hydrogen peroxide and posed a potential risk to consumers. The control through Appendix C recognises that teeth-whitening preparations are not therapeutic goods as they do not meet the definition of therapeutic goods. However, the risks arising from these products are still appropriately controlled through a non-medicinal schedule entry.

Scheduling is a classification system that controls how medicines and chemicals are made accessible to consumers. Medicines and chemicals are grouped into Schedules according to the appropriate level of regulatory control over their availability (e.g. Schedules 5, 6 and 7 include non-medicinal chemicals in increasing order of toxicity, and thus in increasing order of restricted availability).

Under revised scheduling arrangements which took effect on 1 July 2010, the Secretary to the Department of Health (Health) (or the Secretary's delegates) superseded the National Drugs and Poisons Schedule Committee (NDPSC) as the decision maker for the scheduling of medicines and chemicals. The revised arrangements also established two expert advisory committees, the Advisory Committee on Medicines Scheduling (ACMS) and the Advisory Committee on Chemicals Scheduling (ACCS), as statutory committees under the Therapeutic Goods Act 1989 (the Act) to advise and make recommendations to the Secretary of the Department of Health (or delegates) on the level of access required for medicines and chemicals. Under subsection 52E (2)(b) of the Act, the Secretary must comply with any guidelines of the Australian Health Ministers Advisory Council (AHMAC) and must have regard to any recommendations or advice of the ACMS or the ACCS.

The secretariat and assessment resources for the ACCS are located within the Health Products Regulation Group within the Department of Health. The states and territories adopt the scheduling recommendations in the Poisons Standard and give effect to them through their relevant drugs and poisons legislation. States and Territories adopt the Poisons Standard in a variety of ways i.e. by reference or specifically stipulated in legislation. Each jurisdiction reserves the right to implement a different scheduling decision to that included in the Poisons Standard to accommodate local circumstances.

The Secretary, when making a decision to amend the Poisons Standard must take into account the matters stipulated under subsection 52E (1) of the Act. This includes the

a) the risks and benefits
b) the purpose for which the substance is to be used
c) the toxicity
d) the dosage, formulation, labelling, packaging and presentation
e) the potential for abuse
f) any other matters the Secretary considers necessary to protect public health.

The ACCS and its assessment resources have very high levels of skills and expertise in toxicology, pharmacology and chemical analysis. The ACCS comprises of nine nominated members and no more than six appointed members. Under the Act, the Commonwealth, each State, the Australian Capital Territory and the Northern Territory are entitled to nominate a member on each of these Committees. These Committee members are referred to as 'nominated' members. These Committee members are referred to as 'appointed' members. In accordance with the Regulations, all Committee members are required to have expertise in at least one of the following fields:

- the regulation of scheduled chemicals in Australia

- veterinary medicines or veterinary pathology
- toxicology
- industrial or domestic chemicals
- agricultural or veterinary chemicals
- clinical aspects of human poisoning
- occupational health issues, particularly as a medical practitioner
- consumer health issues relating to the regulation of chemicals; and
- industry issues relating to the regulation of chemicals

The Poisons Standard is a legislative instrument for the purposes of the Legislative Instruments Act 2003. In order to ensure certainty in the continuing application of state and territory laws, the Poisons Standard is not a disallowable instrument. Scheduling decisions are legislative, the lawfulness of the Secretary's decision is not reviewable under the Therapeutic Goods Act 1989, in the AAT or in Federal Court.

The Poisons Standard applies across all products that are available to the general public and manages the public health risks of these products e.g. through restrictions of concentration, presentation, packaging and labelling of their ingredients. These controls can apply in addition to any controls applied by other regulators such as the TGA, NICNAS or the APVMA, but they also apply to products that are not under the control of these three national regulators.

Inexplicably, the ACCC decided that the scheduling controls were not adequate and stated that all persons including dental practitioners, are NOT permitted to provide take-home teeth whitening kits to patients that contain >6% hydrogen peroxide or >18% carbamide peroxide. The ACCC advised concerned industry members from both the dental industry and Accord members that the scheduling decision did not have a bearing on the restrictions under the ACL. This meant that in the view of the ACCC, dental practitioners were not able to provide consumers with take-home teeth whitening kits at the levels as prescribed in the SUSMP.

This action on behalf of the ACCC to usurp the role of the public health risk manager has led to confusion and uncertainty in the market place. Regarding decisions by Commonwealth risk managers such as the Scheduling Delegate on public health matters, the TGA on therapeutic goods and the Australian Pesticides and Veterinary Medicines Authority (APVMA) for agvet products, the enforcement arm of the ACL should defer to their decisions and not take further unilateral action. Additionally, clearer guidance is required regarding the hierarchy of legislation and whether an Act of general application such as the ACL has precedence over specialist Acts such as the Therapeutic Goods Act and/or additional information on the inter relationship between the two.

A further area of confusion for industry is the tension and lack of clarity of the intersection between product safety and competition policy within the ACCC. For example, when the ACCC raised a product safety issue that they wished Accord to deal with through, for example, the application of an industry guideline, concerns were then raised with the implementation of a deadline for compliance with such a guideline, given that this could be misconstrued as industry collective action and therefore anti-competitive.

Should you have any questions in relation to the matters raised please do not hesitate to contact me

Yours sincerely
Authorized for electronic submission
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Director, Regulatory Reform

31 August 2016