Advocate for the Consumer, Cosmetic, Hygiene and Specialty Products Industry

The Secretary
Senate Community Affairs Legislation Committee
Parliament House
Canberra ACT 2600

Inquiry into the Therapeutic Goods Amendment (2009 Measures No. 2) Bill 2009

1. About ACCORD and the Australian formulated products industry

ACCORD Australasia is the national industry association for the manufacturers and suppliers of formulated consumer, cosmetic, hygiene and specialty products - a key segment of Australia's chemical products industry. Representing approximately ten percent of nationwide manufacturing activity, Australia's chemical and plastics industries are a vital part of a healthy Australian economy. Industry products are important for Australian manufacturing and business.

ACCORD member companies *(see Attachment 1 - Membership list)* manufacture and/or supply formulated products for use in both households and industry. These are essential for:

- Keeping households, workplaces, schools and institutions clean, hygienic and well maintained
- Personal hygiene, grooming and beauty treatments
- Specialised uses that assist other industries and manufacturing
- Maintaining the sanitary conditions essential for infection control in the nation's hospitals and food/hospitality industries

This includes the following: *adhesives, aftershave, air-care products, antiperspirants, automatic dishwasher detergents, baby-care products, bar soaps, bath additives, body treatments, car-care products, carpet cleaners, cleaning solvents, cosmetics, dairy & poultry sanitisers, dishwashing detergents, deodorants, depilatories, fabric care products, fabric softeners, floor cleaners, furniture care products, gel cleaners, hard-surface cleaners, hair conditioner, hair colour treatments, hospital disinfectants, household insect sprays, hygiene products, industrial cleaners, industrial specialities, liquid bleach, liquid soaps, make-up, moisturisers, mouthwash, mould remover, nail-care products, oven cleaners, personal insect repellents, sanitising scrubs, sealants, shampoo, shoe care products, shower & bath cleaners, skin-care products, sunscreens, toilet cleaners, toothpaste, water treatment agents, window cleaners.*

Based on a survey conducted in mid-2008, the national employment footprint of ACCORD's members is more than 12,500 full-time equivalent positions. Additionally, our members operate 56 manufacturing sites across the nation and 36 member companies support local manufacturing by using third-party formulators.

Through ACCORD, the Australian cosmetic products industry also supports more than 8,000 Australian cancer patients annually via the *Look Good...Feel Better* program. This unique and practical support service has now been in operation for 19 years and has helped more than 70,000 Australians, mainly women, deal with the appearance-related side effects of chemotherapy and radiotherapy. The program offers free two-hour workshops in more than 150 community locations nationwide.

On behalf of our members we welcome this opportunity to document our industry's concerns and recommendations related to this Bill.

2. Summary of our industry's position on the Bill

2.1 Why the arrangements enacted by the Bill fail to meet industry and community needs for a more efficient, nationally integrated system of chemicals regulation...

a) ***Chemicals scheduling*** (or poisons scheduling as it is currently known) is a vital, but often unrecognised and underappreciated, risk management and control system within the existing system of Australian chemicals regulation. For our sector, in particular, given the predominance of industry products used in households, *chemicals scheduling* ensures products containing more hazardous ingredients that may require consumers to exercise some degree of caution are properly labelled with safe use directions and storage warnings.

b) Our industry supports an efficient, expert, risk-based *chemicals scheduling* system that is more effectively integrated with other key chemicals-related regulatory processes, such as the chemical ingredient assessment system controlled by the **National Industrial Chemical Notification and Assessment Scheme (NICNAS)**.

c) While the Bill does achieve the much-needed change of splitting *chemicals scheduling* from medicines scheduling, it achieves this by **inappropriately housing chemicals scheduling within the aegis of a regulatory agency unrelated to chemicals regulation**, viz. Australia's medicines regulator, the Therapeutic Goods Administration.

d) Our industry considers this a **retrograde step in terms of the important and overarching policy goal of improving Australia's overly complex and fragmented system of chemicals regulation** for the benefit of both improved industry productivity and community protection.

e) This goal of reforming the existing system to create a simpler, more efficient, nationally integrated chemicals regulation system was the subject of last year's **Productivity Commission**[1] report on chemicals regulation which produced a governance framework for a better system. Our industry supports the Commission's recommendations in this regard.

f) This overarching reform goal for chemicals regulation is now also embedded in work being undertaken by the **COAG Business Regulation and Competition Working Group** as part of COAG's 'seamless national economy' activity.

g) A key concern that ACCORD has with the Bill, as presented, is that it has not been accompanied by any policy statements of substance in relation to chemical regulation reform goals. As such, **it remains entirely unclear how the arrangements the Bill seeks to put in place will assist in creating a more efficient, nationally integrated system of chemicals regulation**.

h) At a more fundamental level, ACCORD believes **the legal validity of housing *chemicals scheduling* in the unrelated Therapeutic Goods Administration is also unclear**. This especially relates to future plans by this agency to implement industry cost-recovery arrangements. **For this reason, ACCORD has commissioned independent legal advice** which we will submit to the Committee once received. Put simply, we do not wish to see legislation passed for an arrangement which could be, at a later date, successfully challenged in the Courts, thereby raising uncertainty for business and governments.

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[1] *The Commission concluded that: "Current regimes are broadly effective in managing risks to health and safety, but are less effective at managing risks to the environment and national security. Efficiency can be improved through national uniformity in most areas."*

i) At a process level**, ACCORD is perturbed that the Senate is now in a position of having to review and consider technical policy matters that should ideally have been instead subject to more effective stakeholder consultation by the Therapeutic Goods Administration**. This is especially the case considering the number of detailed submissions our organisation has made previously to the TGA on this matter. Details documenting our concerns on these consultation processes are included further into this submission (see sub-section 4.).

2.2 ACCORD's position on the Bill and our recommendations for Committee consideration...

a) Our submission raises a number of important questions for which we believe **answers are required before we would be in a position to unequivocally endorse the passage of the Bill as written**.

b) Notwithstanding these questions, as well as the other concerns raised above, **our organisation takes a practical and realistic approach to policy development** and recognises that, unfortunately for the nation, there are often inherent problems progressing reforms within the framework of Australia's federal system of government.

c) In meeting recently with the Government to discuss our concerns with the Bill, we were **advised the legislative approach being adopted through this Bill is preferred because it avoids the need for new state and territory legislation**.

d) Our understanding of this position is that creation, at this point in time, of a **separate legislative approach to underpin *chemicals scheduling* would entail significant delays** in achieving a separation of *chemicals scheduling* from medicines scheduling.

e) **This is conditionally accepted, but still leaves our industry with a dilemma**.

f) As stated above**, the housing of *chemicals scheduling* within a non-chemical regulator, the TGA, is an entirely inappropriate administrative arrangement** for the goal of establishing a more efficient, nationally integrated system of chemicals regulation.

g) Additionally, **the Bill is short on key details** that would provide our industry with a better understanding of how the housing of *chemicals scheduling* in the TGA would actually work.

h) **These details are important.** Without them, industry and other chemicals-related agencies such as NICNAS and the Australian Pesticides & Veterinary Medicines Authority (APVMA), cannot adequately determine if the arrangements to be put in place by the Bill will actually be workable.

i) And further, **based on past experience with consultation at agency level on this policy matter**, statements promising further consultation with TGA on the subsequent regulations and Cost Recovery Impact Statement do not inspire any confidence that industry will experience meaningful consultation on these all-important implementation details.

j) Against all this, **our industry does not wish to stall progress with the ongoing reform of chemicals regulation** to create a more efficient, nationally integrated system.

k) **Were this Bill to be seen by both the parliament and the Government as simply an interim step** to a new *chemicals scheduling* system then this would help abate some of our industry's concerns. It must be noted, however, our position here is solely based on the reality

that the regrettable (but acknowledged) difficulties posed by existing federal-state legislative arrangements to underpin separate *chemicals scheduling*, mean that this Bill would appear the easiest option for immediate implementation.

l) Ideally, ACCORD **would like to see the Committee recommend an approach that obtains commitments that the arrangements put in place by this Bill in relation to *chemicals scheduling* are no more than interim arrangements**, either through:
   - amendments to the Bill itself, or;
   - via a firm commitment from the Government, in the broader context of the COAG agenda for chemicals regulation reform.

m) In this regard, **we note Recommendation 5.1 of the Productivity Commission**, which stated that (*our bolding and underlining)*:

"*The Australian Health Ministers' Conference should:*
- *proceed as soon as feasible with implementing its proposed reforms to separate poisons and medicines scheduling processes, including that poisons scheduling decisions be made by the Secretary of the Department of Health and Ageing, upon advice from a Chemicals Scheduling Committee*
- *undertake a review of the Australian Health Minister's Advisory Council model for poisons two years after commencement, **including**:*
   - *an analysis of the consistency between the recommendations of the Chemicals Scheduling Committee and the decisions of the Secretary of the Department of Health and Ageing*
   - *an analysis of the impact of the model on national uniformity of poisons regulations."*

n) On this basis, ACCORD recommends that a **review be undertaken two years after passing of the Bill to assess the effectiveness (or otherwise) of the interim *chemicals scheduling* arrangements**.

o) **Arising from this review, proposals should be tabled for new arrangements that a create clearer legislative split of *chemicals scheduling* from medicines scheduling**, in a manner which meets the overarching policy goal of a more efficient and streamlined national system of chemicals regulation.

p) The recommendations in *points n)* and *o)* above are, of course, **subject to ACCORD's independent legal advice confirming that the Bill's housing of *chemicals scheduling* in a non-chemical regulatory agency is legally valid**.

q) **Should this advice raise serious concerns about the legal validity of the Bill's arrangements, then ACCORD would instead recommend the urgent pursuit of separate legislative arrangements for *chemicals scheduling***.

3. Key questions related to the Bill and the new arrangements it puts in place

A lack of detail or clear explanation of the broader policy intent underlying this Bill, as it relates to *chemicals scheduling*, leaves a number of key questions unanswered. This makes it somewhat difficult for ACCORD to respond with clarity and leaves us struggling with a large number of unknowns. These are summed up in the following questions:

a) Is the proposal to house *chemicals scheduling* within a non-chemical regulator, the Therapeutic Goods Administration (TGA) under the *Therapeutic Goods Act* legally valid?

b) What are the broader consequences of the new power for the Department Secretary's decisions on scheduling to automatically become a legislative instrument?

c) Is it appropriate that such decisions not be subject to merits review?

d) Is it appropriate for the Department Secretary to be granted the power to circumvent the new Scheduling Committees to seek advice from "any person"?

e) Can a legally legitimate industry cost-recovery process be established for *chemicals scheduling* from these arrangements? For example, while TGA regulates medicines and can readily apply service charges to those therapeutic product categories under its regulatory oversight, can the agency legitimately levy fees or service charges against chemical introducers for non-therapeutic chemical substances?

f) What is the justification for transferring the funding of these previously Budget-funded functions to cost recovery from industry, considering the net public benefit produced by the system?

g) What is the intended fee structure for the proposed cost-recovery arrangements?

h) Why does the Bill specify one aspect of the membership of the proposed Advisory Committee on Chemicals Scheduling - namely, that each state and territory can nominate a representative (see 52C(3)) - but remain silent on other key member bodies with both a role and expertise in chemicals regulation for public health - NICNAS, APVMA and the federal Department of Health & Ageing's Office of Chemical Safety and Environmental Health? What mechanisms will be in place to ensure that the states and territories nominate members with appropriate expertise to ensure the scientific integrity of the Advisory Committee's decisions?

i) How will the new arrangements, under Australia's medicines regulator, the TGA, deal with emerging local and international policy issues specifically related to chemicals? This includes, nanotechnology, the Globally Harmonised Scheme for Classification & Labelling of Chemicals, the recent proposal of the Environment Protection & Heritage Council for a national Environmental Chemicals Bureau and the soon-to-be-established COAG Standing Committee on Chemicals.

j) Is it appropriate that the National Coordinating Committee on Therapeutic Goods has oversight of *chemicals scheduling* when the membership of this group does not reflect either input or expertise from chemical regulators or the chemicals industry?

k) Have administrative arrangements that could more appropriately separate *chemicals scheduling* from medicines scheduling been adequately investigated (or indeed investigated at all) with the states and territories?

4. Development of scheduling reform policy since the 2001 Galbally Report and ACCORD submissions to the current and previous TGA consultation processes

Policy proposals to formally separate *chemicals scheduling* from medicines scheduling have been under consideration for many years, commencing in more recent times with the recommendations of the Galbally Report in 2001.

Recommendation 7 of this report called for the separation of poisons scheduling from medicines scheduling, through the establishment of two separate committees.

Since then, consultation on this important policy matter has proceeded as follows:

- July 2005 - A proposed new model for the scheduling of medicines and poisons within the Joint Agency[2],
- 13 June 2007 - Draft Standard for the Uniform Scheduling of Medicines and Poisons and Draft Scheduling Policy Framework[3]
- 17 April 2009 - Proposed new arrangements for the scheduling of medicines and poisons

The documentation publicly released by the Department and/or TGA for the above consultation processes is attached (see Attachment 2).

Our industry's detailed submissions to these processes are also attached for Committee reference:

- ACCORD submission to the TGA, 2 September 2005 (see Attachment 3)
- ACCORD submission to the TGA, 21 August 2007 (see Attachment 4)
- ACCORD submission to the TGA, 29 May 2009 (see Attachment 5)

A key matter highlighted in the TGA's public consultation documents (see Attachment 2) is the predominant focus on issues related to medicines scheduling as opposed to *chemicals scheduling*.

For example, the 2005 consultation documents list the objectives of the then proposed scheduling model, which relate primarily to arrangements required to support the proposed trans-Tasman joint medicines agancy:

"The proposed scheduling model has four key objectives:

1. *support for harmonised trans-Tasman scheduling arrangements for medicines;*
2. *to provide maintenance of the scheduling standard within the Joint Agency;*
3. *implementation of the Galbally Review recommendations relevant to scheduling;*
4. *to address other key weaknesses of the current model identified by stakeholders during the Galbally Review consultation process, in so far as possible."*

This predominant focus on medicines policy needs has continued to pervade the consultation process as evidenced by an August 2007 extract from the Department of Health and Ageing's *Annual Regulatory Plan 2007-08.*

The relevant extract (pg 16) is attached as Attachment 6. This mentions medicines only as follows: *"The proposed medicine scheduling model has been developed in close consultation with the National Coordinating Committee on Therapeutic Goods. Widespread consultation on the proposed scheduling model for medicines has occurred with face-to-face stakeholder meetings in August 2005 and more recently in November 2006 following release of the relevant draft Australia New Zealand Therapeutic Products Regulatory Scheme legislation."*

A major problem with the consultation processes has been the lack of formal feedback to, or engagement with, chemical industry stakeholder groups.

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[2] *This proposal was in the context of the then proposed joint Australia/New Zealand Medicines Agency which was abandoned in 2007. On the basis that this proposal would integrate the medicines systems of Australia and New Zealand, but keep the nations' chemicals regulation systems separate, ACCORD was also of the view that this would mean a clearer legislative separation of medicines scheduling from chemicals scheduling as an Australian-only chemicals scheduling system could not foreseeably be legally housed in a joint Australian-NZ Medicines Agency.*

[3] *This consultation was also in the context of the development of the joint Australia/New Zealand Medicines Agency, which was postponed in July 2007 and later abondoned.*

ACCORD has never received any official feedback from the TGA in relation to either our 2005 or 2007 submissions.

And, additionally, our most recent May 2009 submission to the TGA's April 2009 consultation **cannot** possibly be considered to have been afforded the opportunity of informing the development of this current Bill.

Put bluntly, ACCORD and the broader chemicals industry have been 'left in the dark' for several years now on the details of the likely policy arrangements for *chemicals scheduling*.

This especially so as our industry has never been provided with the details of the AHMAC agreed model on scheduling, which apparently, underlines the approach being adopted within this Bill.

For this reason, industry has at various times in this long-running process, had to resort to writing to the Prime Minister and/or other senior Government ministers seeking their intervention to improve the process of agency-level engagement with chemical stakeholders. A key example being the 19 August 2005 letter to then Prime Minister Howard signed by ACCORD, the Australian Paint Manufacturers' Federation, Avcare (now CropLife) and PACIA (see Attachment 7).

All of the above supports the concerns raised earlier in this submission regarding the apparent next phases of consultation on regulations and cost-recovery arrangements, should the Bill proceed as written.

Based on this history of highly unsatisfactory consultation, our industry remains deeply concerned that legitimate policy issues which we raise relating to creation of a workable *chemicals scheduling* system will continue to be ignored.

We are also left questioning how well a busy regulator like the TGA will go about servicing issues relating to products which are not part of its primary mandate - chemicals - as it administers the *chemicals scheduling* system.

This is where the Committee may be able to assist by compelling the TGA to reveal more details about the proposals that would be put in place subsequently, should this Bill be passed as written.

In terms of ACCORD's most recent submission (29 May 2009) to the TGA we recommended the following changes to align the current proposal more closely to the broader chemicals reform proposals recommended by the Productivity Commission:

> *"ACCORD believes that the Policy Framework can be improved upon to deliver a structure which is more in line with the PC's proposal and hence deliver significantly more benefits. Such a Framework would include the following elements:*
>
> - *The Secretariat would remain in OCSEH – there is no policy nor cost benefit analysis to demonstrate why change is required*
> - *The decision maker would be the Secretary of the Department or delegated decisionmaker The Medicines Scheduling Expert Advisory Committee would be managed by the TGA*
> - *The Chemicals Expert Advisory Committee would be managed by OCSEH and would be an independent expert body providing risk management advice to the Secretary or delegated decision maker regarding chemical scheduling decisions*
> - *The OCSEH would provide services to the TGA under a service level agreement*

- *All costing would be activity based, transparent and where the public is the identified beneficiary, governments would contribute to the costs*
- *The TGA and OCSEH would independently manage decisions of its experts committees*
- *The Poisons Schedule would be separated into a Medicines Schedule and a Chemicals Schedule, and*
- *Schedule 7 products would be automatically referred to Safe Work Australia and treated as a workplace safety matter and not be subject to any control of use through state and territory health officials in line with the PC Recommendation 5.3.*

As an absolute minimum the proposed arrangements in the NCCTG Policy Framework should deliver the following:

1. *the Schedule should be renamed to the Standard for the Uniform Scheduling of Medicines and Chemicals and that the terms* substances and/or chemicals replaces poisons*;*
2. *the policy oversight for chemical products be undertaken by the OCSEH in consultation with relevant Commonwealth, state and territory bodies responsible for the risk management of chemicals;*
3. *the Policy Framework should adopt enhanced accountability measures which includes public reporting on variations to scheduling decisions, annual reporting to health ministers (AHMC) and a reporting line be established between AHMC and the Standing Committee on Chemicals for scheduling matters."*

5. Some final comments on the vital importance of *chemicals scheduling* in the overall regulatory scheme for protecting public health and the need for a more efficient, nationally integrated chemicals regulation system

Australia's system of chemicals regulation is complex, fragmented and inefficient but is, as stated by the Productivity Commission, "*broadly effective in managing risks to health and safety*".

The existing system can be difficult to describe in its entirety with any ease or clarity.

ACCORD's submissions to last year's Productivity Commission study of chemicals regulation included the sobering statistics that there are currently:

- more than 140 separate pieces of legislation nationwide covering some aspect of chemicals or chemical industry regulation; and,
- almost 70 departments, agencies and ministerial councils with some role in chemicals regulation, each setting either regulatory rules or regulatory policy.

On this basis, it is imperative that the efforts being progressed under the COAG 'seamless national economy' agenda to reform chemicals regulation gain momentum as well as a coherent direction and not be taken down 'blind policy alleys' by piecemeal reform measures, such as the one enacted by this Bill.

A more efficient, nationally integrated chemicals regulation system will not only assist business but will also benefit the community.

Our industry strongly supports essential regulatory protections for public health, worker safety and the environment.

We simply believe that having one national set of integrated rules, based on good science and reliable risk assessment, free of unnecessary red-tape, is better than having nine sets of rules.

An improved, national integrated chemicals regulation system can be achieved by building on those core elements of the existing system that are working well, and this includes the important role of *chemicals scheduling* decisions as well the NICNAS system of ingredient safety assessment.

A recent article in the July edition of CHOICE magazine includes a fairly informative and balanced review of cosmetic product and cosmetic ingredient safety.

Part of this article explains the regulatory system governing cosmetic ingredients, with specific emphasis on NICNAS ingredient assessment and ACCC rules for ingredient disclosure (see Attachment 8). This provides a good introduction to these key elements of the system.

However, the article makes no mention of *poisons* or *chemicals scheduling* and the role this plays in the system.

While this may be due to the subject matter and the fact that the vast majority of cosmetics contain mild, low hazard ingredients[4] and are therefore not subject to *chemicals scheduling* intervention, ACCORD's experience when dealing with NGOs and also other areas of government, such as dangerous goods authorities, is that they are often ignorant of the *chemicals scheduling* system.

Burying *chemicals scheduling* deeper within the health department bureaucracy, and in particular embedding it within the aegis of the Australian medicines regulator, the Therapeutic Goods Administration, will do nothing to help promote wider awareness of its role in ensuring safety for consumer use of chemicals and products containing chemicals.

This is, in essence, a retrograde step that diverts us from the path towards a more efficient, nationally integrated chemicals regulation system and, as such, must only be viewed solely as interim step, necessitated by current time constraints related to establishing a legislatively separate model for *chemicals scheduling*.

6 July 2009

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[4] *A notable exception would be some semi-permanent hair dyes, which require caution in use and are therefore subject to chemical scheduling so that they are labelled with appropriate warnings for the public.*

Attachment 1

ACCORD List of Member Companies

ACCORD
Advocate for the Consumer, Cosmetic, Hygiene and Specialty Products Industry

Members

Consumer, Cosmetic and Personal Care:

Advanced Skin Technology Pty Ltd
Alberto Culver Australia
Amway of Australia Pty Ltd
Apisant Pty Ltd
AVON Products Pty Limited
Beiersdorf Australia Ltd
Chanel Australia
Clorox Australia Pty Ltd
Colgate-Palmolive Pty Ltd
Combe Asia-Pacific Pty Ltd
Cosmax Prestige Brands Australia Pty Ltd
Coty Australia Pty Limited
Creative Brands Pty Ltd
De Lorenzo Hair & Cosmetic Research Pty Ltd
Elizabeth Arden Australia
Emeis Cosmetics Pty Ltd
Estée Lauder Australia
Frostbland Pty Ltd
GlaxoSmithKline Consumer Healthcare
Helios Health & Beauty Pty Ltd
Johnson & Johnson Pacific
Kao (Australia) Marketing Pty Ltd
Keune Australia
Kevin Murphy Business Services P/L
Kimberly Clark Australia
KPSS Australia Pty Ltd
La Biosthetique Australia
La Prairie Group
L'Oreal Australia Pty Ltd
LVMH Perfumes and Cosmetics
Mary Kay Australia Pty Ltd
Nak & NIOXIN Pty Ltd
Nutrimetics Australia
NYX Pty Ltd
Procter & Gamble Australia Pty Ltd
Pure Products Pty Ltd
PZ Cussons Australia Pty Ltd
Quantum Pacific Ltd
Reckitt Benckiser
Revlon Australia
Sabre Corporation Pty Ltd
Scental Pacific Pty Ltd
Shiseido (Australia) Pty Ltd
The Heat Group Pty Ltd
The Purist Company Pty Ltd
Three Six Five Pty Ltd
Trimex Pty Ltd
Ultraceuticals
Unilever Australasia

Hygiene and Specialty Products

Albright & Wilson (Aust) Ltd
Applied Australia Pty Ltd
BP Castrol Australia Pty Ltd
Callington Haven Pty Ltd
Campbell Brothers Limited
Castle Chemicals Pty Ltd
Chemetall (Australasia) Pty Ltd
Clariant (Australia) Pty Ltd
Cleveland Chemical Co Pty Ltd
Deb Australia Pty Ltd
Dominant (Australia) Pty Ltd
Ecolab Pty Limited
Huntsman Corporation Australia Pty Ltd
Jalco Group Pty Limited
Lab 6 Pty Ltd
Novozymes Australia Pty Ltd
Nowra Chemical Manufacturers Pty Ltd
Peerless JAL Pty Ltd
Recochem Inc
Rohm and Haas Australia Pty Ltd
Solvay Interox Pty Ltd
Sonitron Australasia Pty Ltd
Sopura Australia Pty Ltd
Tasman Chemicals Pty Ltd
Thor Specialties Pty Limited
True Blue Chemicals Pty Ltd
Whiteley Corporation Pty Ltd

Associate Members

Equipment and Packaging Suppliers

HydroNova Australia NZ Pty Ltd

SCHÜTZ DSL (Australia) Pty Ltd

Graphic Design and Creative

Ident Pty Ltd

Legal and Business Management

FCB Lawyers

Middletons Lawyers

TressCox Lawyers

Logistics

Star Track Express Pty Ltd

Recruitment

Chemskill

Regulatory and Technical Consultants

Archer Emery & Associates

Competitive Advantage

Engel Hellyer & Partners Pty Ltd

Robert Forbes & Associates

Sue Akeroyd & Associates

Toxikos Pty Ltd

Specialist Laboratories and Testing

ams Laboratories

Dermatest Pty Ltd

June 2009

Attachment 2

Scheduling consultation documentation

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

A proposed new model for the scheduling of medicines and poisons within the Joint Agency

Consultation document
July 2005

This document was released in July 2005 for comment. It remains on this website as a historical reference.

Related information

- Consultation outcome: Stakeholder consultation on the proposed medicines and poisons scheduling model and draft scheduling policy framework (15 December 2005) <http://www.tga.gov.au/consult/2005/scheduling-update.htm>

The information on this page relates to the following consultation papers:

- A proposed model for the scheduling of medicines (pdf,92kb)
- A proposed model for the scheduling of poisons in Australia (pdf,81kb)
- Draft scheduling policy framework for medicines and poisons (pdf,133kb)

Current scheme in Australia

Presently, scheduling decisions on medicines and poisons are made by the National Drugs and Poisons Schedule Committee (NDPSC), which is a statutory committee under the therapeutic goods legislation. These decisions are included in the *Standard for the Uniform Scheduling of Drugs and Poisons* (SUSDP) and implemented in State/ Territory legislation by reference or other means.

Considerations for the development of a new model

The Galbally Review

In Australia, the *COAG[1] Review of Drugs, Poisons and Controlled Substances Legislation (the Galbally Review)* <http://www.tga.gov.au/docs/html/rdpdfr.htm> was undertaken in 1999-2000 to examine State and Territory drugs, poisons and controlled substances legislation in relation to obligations under National Competition Policy and the Competition Principles Agreement.

One of the terms of reference of the Galbally Review was to consider the processes and arrangements for decisions on scheduling. The Review process included extensive consultation with stakeholders, including submissions and face-to-face meetings. In reviewing the submissions to the Galbally Review which are relevant to scheduling there were a number of common calls for changes to certain aspects of the current scheduling arrangements, including the need for:

- national uniformity in implementing scheduling decisions and dates of effect;
- the timely finalising of NDPSC decisions;
- better coordination of decisions on registration of medicines and scheduling;
- separate committees to be established to consider scheduling of poisons and the scheduling of

medicines;

- equal voting rights for all members of these committees; and
- support for the scheduling standard to be more readily accessible to users.

In considering these stakeholder comments, the report of the Galbally Review recommended that:

- all States and Territories adopt all scheduling decisions by reference (Recommendation 4);
- the National Drugs and Poisons Scheduling Committee (NDPSC) be disbanded and replaced with two separate committees, one responsible for medicines and the other responsible for poisons (ie agricultural, veterinary and domestic chemicals), (Recommendation 7);
- relevant registration authorities to make scheduling recommendations to these Committees; and
- cost recovery of activities associated with scheduling be introduced.

1. COAG is the Council of Australian Governments

The Treaty

At the time of the release of the Galbally Review, the various options for addressing the exemption for therapeutic goods under the Trans Tasman Mutual Recognition Act were still being discussed. Hence, the Review did not consider these recommendations in the context of the Treaty which has been since been signed between the Australian and New Zealand Governments to establish a single regulatory agency for therapeutic products (the Agency). The AHMAC Working Party response to the recommendations of the Galbally Review <http://www.tga.gov.au/docs/html/rdpdfr.htm> therefore propose that these recommendations be progressed in a trans-Tasman environment.

The Treaty provides for the Agency to develop and maintain a scheduling framework for medicines which will apply in Australia and New Zealand. It is therefore necessary for Australia and New Zealand to agree on a scheduling model for medicines which is suitable for both countries.

The need for a consistent approach to the scheduling of medicines and poisons

The National Co-ordinating Committee on Therapeutic Goods (NCCTG) is the inter-jurisdictional sub-committee of the Australian Health Ministers' Advisory Council which currently has responsibility for overarching policy guidance and protocols for scheduling in Australia. In considering a new model for scheduling, the Australian States and Territories (as represented on the NCCTG) have agreed that the scheduling model for medicines and the scheduling model for poisons should be as closely aligned as possible in the interests of consistency and supporting a national outcome.

Objectives of the new scheduling model

The proposed new scheduling model is not part of a national reform agenda for the scheduling of medicines and poisons but rather is intended to be a model which builds upon the current arrangements in implementing the recommendations of the Galbally Review in a trans-Tasman context.

The present scheduling model in Australia is based on the fundamental principle that Commonwealth legislation provides for a scheduling standard to be developed to facilitate national uniformity and relevant Australian State/Territory legislation implements the scheduling decisions as reflected in the scheduling standard. There is no mandate to change this arrangement under the new therapeutic products legislation, other than to provide for New Zealand legislation to also adopt the scheduling standard for medicines, in as much as possible.

Against this background, the Australian Health Ministers' Conference (including New Zealand)

has agreed to implement a model for the scheduling of medicines and poisons in Australia which is consistent with the recommendations of the Galbally Review and the trans-Tasman medicines scheduling scheme. This model has been developed by the NCCTG in consultation with the Australian Department of Agriculture, Fisheries and Forestry and the Director of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS).

The proposed scheduling model has **four** key objectives:

1. support for harmonised trans-Tasman scheduling arrangements for medicines;
2. to provide for the maintenance of the scheduling standard within the Joint Agency;
3. implementation of the Galbally Review recommendations relevant to scheduling;
4. to address the other key weaknesses of the current model identified by stakeholders during the Galbally Review consultation process, in so far as possible.

Call for comment

Comments from stakeholders were invited on the proposed new scheduling model and the scheduling policy framework.

Comments received will be considered by the National Co-ordinating Committee on Therapeutic Goods, which will then finalise the scheduling policy framework and agree on any recommendations which should be made to Health Ministers to change the proposed scheduling model.

The final scheduling model will need to be given legal underpinning in the draft Rules and Australian-only Regulations for the new legislation, specifically in regard to the role and powers of the Agency, the role and membership of the scheduling committees, scheduling processes, public consultation arrangements and rights to review. The scheduling of poisons relates only to Australia and would therefore be dealt with in Australian-only Regulations.

These draft Rules and Regulations to implement the approved scheduling model will be released for public comment, together with the other Rules and Regulations which will give legal effect to the broader joint scheme, later in 2005.

Draft scheduling standard

Please note that a new draft scheduling standard is also being developed by NCCTG and stakeholders in Australia will be invited to submit comments as soon as the draft for consultation is finalised. This document will mirror the current SUSDP in that it will include Chapters on interpretation, labelling and containers and miscellaneous regulations plus a number of appendices and will be drafted so as to implement a number of the Galbally Review recommendations. It is expected that the Australian States and Territories will adopt these Chapters and appendices by reference into their drugs and poisons legislation, in as much as possible.

In response to calls from stakeholders, the scheduling standard is also to be redeveloped into an electronic format which will be included on the Agency website. Users will be able to readily search and print the scheduling entries.

In moving from the hard-copy SUSDP to a new web-based scheduling standard, it is intended that the previous scheduling decisions of the NDPSC will be retained. However, where a current single entry in the SUSDP is qualified dependent on the use of the substance, the single entry will be split into two or more entries which will be specific to the purpose of use (ie as a medicine, ag/vet chemical, industrial/domestic chemical).

Fees and charges

Consultation on the fees and charges associated with scheduling activities is a separate process which will be conducted as part of the broader consultation arrangements for fees and charges for the Agency.

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URL: http://www.tga.gov.au/consult/2005/scheduling.htm
PDF: http://www.tga.gov.au/consult/2005/schmedicines.pdf
PDF: http://www.tga.gov.au/consult/2005/schpoisons.pdf
PDF: http://www.tga.gov.au/consult/2005/schpolicy.pdf

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH

Draft Standard for the Uniform Scheduling of Medicines and Poisons and Draft Scheduling Policy Framework

13 June 2007

Please note: This consultation closed on 25 July 2007.

Written submissions are invited on the following consultation documents:

Draft Standard for the Uniform Scheduling of Medicines and Poisons (pdf,581kb)

Draft Scheduling Policy Framework (pdf,450kb)

In addition the following accompanying resource document is also available:

Table of changes from SUSDP to SUSMP (pdf,82kb)

Background

The draft Standard for the Uniform Scheduling of Medicines and Poisons (Scheduling Standard) has been developed by the National Co-ordinating Committee on Therapeutic Goods (NCCTG) (as the Committee which provides recommendations on the administrative and regulatory controls for therapeutic goods) comprising representatives from Australia, New Zealand, and Australian State and Territory governments. The Scheduling Standard is substantially based on the current Australian Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) which contains a significant number of medicines, the scheduling of which has been harmonised with New Zealand.

The scheduling harmonisation process being undertaken by Australia and New Zealand will continue up to the commencement of the joint regulatory scheme and the Scheduling Standard, when released, will include all of the new and previously harmonised schedule entries.

While the Scheduling Standard is in hard copy for the purposes of consultation, it has been established in the draft Australia New Zealand Therapeutic Products Regulatory Scheme (Administration and Interpretation) Rule 2006 as an electronic register that will be made available for inspection on the Australia New Zealand Therapeutic Products Authority (ANZTPA) website. The Scheduling Standard will come into effect at the commencement of the joint regulatory scheme.

The Scheduling Standard will include a record of ANZTPA's decisions relating to the scheduling of medicines which will apply in Australia and New Zealand. New Zealand has proposed only to recognise recommendations for scheduling of substances for human therapeutic use included in Schedules 2, 3 and 4 of the Scheduling Standard (the remaining schedules and appendices of the Scheduling Standard will not be adopted in New Zealand). Decisions relating to the scheduling of poisons will apply in Australia only. New poisons scheduling legislation is under development which implements the poisons scheduling model agreed by the Australian Health Ministers' Conference in November 2006 (out of session). The model included the Department of Health and Ageing as the decision-maker for matters relating to the scheduling of poisons in Australia.

Scheduling decisions for medicines and poisons will take the form of entries in the Scheduling Standard. These entries will be a scheduling recommendation to New Zealand and to the Australian States and Territories and will be given effect by Australian State and Territory and New Zealand legislation.

A table comparing the SUSDP provisions with their comparable entries in the new draft Scheduling Standard has been prepared to assist stakeholders in cross referencing the scheduling requirements and to understand the reasons for amendments.

At the commencement of the joint regulatory scheme the draft Scheduling Policy Framework is intended to replace the Australian National Drugs and Poisons Schedule Committee (NDPSC) Guidelines and the requirements and criteria used by New Zealand's Medicines Classification Committee. The Scheduling Policy Framework will be maintained by the Medicines and Chemicals Scheduling Committees and overseen by the NCCTG.

An earlier draft of the Scheduling Policy Framework was released for stakeholder consultation, along with the scheduling model for medicines and poisons in July 2005. Stakeholder comments on the earlier draft have been taken into account in the development of the latest draft.

URL: http://www.anztpa.org/consult/dr-scheduling.htm

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Consultation on regulatory reforms for therapeutic goods

Overview

The TGA has recently completed stakeholder consultations on a number of regulatory reforms proposed for each therapeutic product sector. The consultations were not intended to re-open discussion on issues already considered and agreed as part of the reforms to be adopted when establishing the joint Australia New Zealand therapeutic products regulatory scheme but to provide an opportunity for discussion of how these reforms are to be implemented in the Australian context.

Four consultation sessions were held at Parliament House, Canberra on the dates below:

Sector	Date	Time
Prescription medicines	Thursday 24 July 2008	9am - 1pm
Complementary medicines	Wednesday 30 July 2008	1pm - 5pm
Over-the-counter medicines	Monday 4 August 2008	1pm - 5pm
Medical devices	Wednesday 6 August 2008	9am - 1pm

All sessions were very well attended. The active involvement of participants contributed to the success of each session.

Introduction by the Parliamentary Secretary to the Minister for Health and Ageing

Each session was opened by Senator the Hon Jan McLucas, Parliamentary Secretary to the Minister for Health and Ageing, who outlined the Government's plans for reform in therapeutic goods regulation.

The Parliamentary Secretary emphasised the importance the Government places on reducing the burden of inappropriate, ineffective or unnecessary regulation while still achieving the objectives set out in the Therapeutic Goods Act (1989) (TG Act) of ensuring the:

- safety
- quality
- efficacy and
- timely availability

of medicines and medical devices to the people of Australia.

She then outlined the Government's broad areas of reform for therapeutic goods which includes:

- Legislative amendments deferred in anticipation of the joint regulatory scheme with New Zealand
- Opportunities for reducing regulatory burden

- Increasing the transparency and availability of consumer information
- Enhancements to post-market monitoring, and
- Future directions for reform.

The consultations did not cover reforms to regulation of the advertising of therapeutic goods or the scheduling of medicines and poisons.

Discussion of key reform areas

Following a presentation by a senior TGA executive, participants were able to ask questions and seek clarification on the issues raised.

Discussion was facilitated by Dr Rohan Hammett, TGA's National Manager, on the key areas of reform for each of the product sectors. He outlined for participants the way ahead to progress these reforms. Legislative changes in general have to pass a clearance process and be included in the Government's drafting priorities, to be assured of consideration at a particular sitting of Parliament. Practically this means that while some changes to the TG Act have already been tentatively scheduled for consideration in the spring 2008 sittings, others may be delayed depending on Government priorities. The TGA is working to have the remaining legislative changes ready for introduction into the Parliament by mid to late 2009.

The reforms common across all product sectors include:

- Low Volume/Low Value Exemptions (LVLV)
- Default standards
- Export scheme (medicines)
- Product licences
- Infringement notices
- GMP fees and charges
- Improved access to information
- Improved arrangements for statutory committees
- Pharmacovigilance framework and establishment of the "Medicines Safety Committee"
- "Fit and proper person"
- Suspension from Register
- GMP sampling provisions
- Good distribution practice
- Clinical trials

Further information on the discussion of these and the sector specific reforms can be found at:

- Reforms common to all product sectors
  <http://www.tga.gov.au/regreform/common.htm>
- Prescription medicines (discussion summary & presentation)
  <http://www.tga.gov.au/regreform/pm.htm>
- Complementary medicines (discussion summary & presentation)
  <http://www.tga.gov.au/regreform/cm.htm>
- Over-the-counter medicines (discussion summary & presentation)
  <http://www.tga.gov.au/regreform/otc.htm>

- Medical devices (discussion summary & presentation)
  <http://www.tga.gov.au/regreform/md.htm>

The discussion summaries should be read in conjunction with the corresponding presentation.

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URL: http://www.tga.gov.au/regreform/cons0807.htm

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Proposed new arrangements for the scheduling of medicines and poisons

Scheduling Policy Framework and Standard for the Uniform Scheduling of Medicines and Poisons

17 April 2009

This consultation closed on 29 May 2009.

Documents

Written submissions are invited on the following documents:

- Proposed Scheduling Policy Framework (pdf,237kb)
- Proposed Standard for the Uniform Scheduling of Medicines and Poisons (pdf,168kb)

In addition, the following accompanying resource documents are also available:

- Flowchart (pdf,71kb) depicting new arrangements for the scheduling of medicines and poisons
- Table highlighting changes (pdf,35kb) made to the Standard for the Uniform Scheduling of Drugs and Poisons to bring about the new Standard for the Uniform Scheduling of Medicines and Poisons

Background

The proposed Scheduling Policy Framework and proposed Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) have been developed by the National Co-ordinating Committee on Therapeutic Goods (NCCTG) (as the committee which oversees scheduling policy) comprising representatives from the Australian, state and territory governments and the New Zealand government. The Scheduling Policy Framework is intended to replace the current *National Drugs and Poisons Schedule Committee (NDPSC) Interim Guidelines* and the SUSMP is intended to replace the current *Standard for the Uniform Scheduling of Drugs and Poisons* (SUSDP).

The proposed SUSMP is substantially based on the current SUSDP, updated to reflect contemporary practise and to implement recommendations of the National Competition Policy Review of Drugs, Poisons and Controlled Substances Legislation (the 'Galbally Review'). A table highlighting changes made to the SUSDP to bring about the new SUSMP has been prepared to assist interested parties in cross referencing the scheduling requirements and to understand the reasons for amendments.

The Scheduling Policy Framework and SUSMP are key components of the new arrangements for the scheduling of medicines and poisons, endorsed by the Australian Health Ministers' Conference. An overview of the proposed scheduling and rescheduling processes is depicted in the flowchart above.

At this stage the Government intends to introduce amendments to the *Therapeutic Goods Act 1989* during the winter 2009 sitting of the Australian Parliament that will underpin the new scheduling

arrangements, which are expected to commence in July 2010.

Enquiries

Enquiries should be directed via email to the above email address, or to 02 6232 8186.

Notes on submissions

A list of names of parties making submissions will be published on the TGA website.

All submissions will be placed on the TGA's website unless marked confidential. For submissions made by individuals, all personal details other than your name will be removed from your submission before it is published on the TGA's website. Confidential material should be provided under a separate cover and clearly marked 'IN CONFIDENCE'. Reasons for a claim to confidentiality must be included in the submission coversheet.

Please note that we will be unable to accept late submissions due to the timing of the winter Parliamentary sitting.

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URL: http://www.tga.gov.au/regreform/drscheduling.htm

Attachment 3

ACCORD submission on
A new scheduling model for chemicals and medicines
2 September 2005

ACCORD

Advocate for the Consumer, Cosmetic, Hygiene and Specialty Products Industry

Dr David Graham
National Manager
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Dear Dr Graham

A new scheduling model for chemicals and medicines

ACCORD Australasia (formerly the Australian Consumer & Specialty Products Association) is the peak national industry association that represents the manufacturers and marketers of formulated consumer, cosmetic, hygiene and specialty products, their raw material suppliers, and service providers.

ACCORD, welcomes the opportunity to provide the attached submission to the draft Consultation Documents for the:

- Proposed Model for the Scheduling of Poisons in Australia;
- Proposed Model for the Scheduling of Medicines in Australia; and
- Scheduling Policy Framework for Medicines and Poisons.

ACCORD, on behalf of its member companies, has a specific and direct interest in the proposed scheduling arrangements and in particular the proposed model for chemicals' scheduling under the joint trans-Tasman therapeutic products agency. ACCORD will continue to work collaboratively with the TGA's Joint Agency Establishment Group (JAEG) and the National Co-ordinating Committee on Therapeutic Products (NCCTG) in the further development of the proposed scheduling models in line with our recommendations.

Yours sincerely

Bronwyn Capanna
Executive Director

2 September 2005

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ACCORD

Advocate for the Consumer, Cosmetic, Hygiene and Specialty Products Industry

A new scheduling model for chemicals and medicines

2 September 2005

Contents

Foreword

ACCORD Australasia (formerly ACSPA) is the peak national industry association that represents the manufacturers and marketers of formulated consumer, cosmetic, hygiene and specialty products, their raw material suppliers, and service providers.
Our industry's products play a vital role in:

- keeping our households, workplaces, schools and institutions clean, hygienic and comfortable;
- personal hygiene, grooming and beauty treatments to help us look and feel our best;
- specialised uses that assist production and manufacturing to keep the wheels of commerce and industry turning; and
- maintaining the hygienic and sanitary conditions essential for our food and hospitality industries and our hospitals, medical institutions and public places.

With an estimated $3 billion plus in annual product sales (ex-factory), the formulated consumer, cosmetic, hygiene and specialty products industry is a significant part of a prosperous Australian economy. We are a dynamic and growing industry, employing Australians and - through our industrial and institutional sector - supplying products essential for Australian businesses, manufacturing firms, government enterprises, public institutions, farmers and consumers.

Our industry has more than 50 manufacturing operations throughout Australia and member companies include large global consumer product manufacturers to small dynamic Australian-owned businesses.

A list of ACCORD member companies is provided at *Attachment 1.*

ACCORD, on behalf of its member companies, has a specific and direct interest in chemicals and medicines scheduling. Industry's competitiveness and capacity to maintain local production into the future is heavily dependent on reducing the regulatory burden Australian businesses face.

Industry believes that implementation of the Galbally Review's Recommendation 7 provides an opportunity for the Department of Health and Ageing to not only deliver a streamlined approach for the assessment and scheduling of chemicals in Australia but could also provide for an improved approach to a national, integrated control framework for the management of chemicals.

We believe that this approach will deliver at a national and strategic level, enhanced policy development, and more efficient, effective and streamlined regulatory controls.

ACCORD welcomes the opportunity to provide this submission and recommendations for consideration, and as a basis for further consultation and dialogue.

Bronwyn Capanna
Executive Director

2 September 2005

Executive Summary

ACCORD is very disappointed in the Therapeutic Goods Administration's (TGA's) Consultations Documents for the proposed models for the scheduling of chemicals and medicines. Industry has been waiting five years for the Government response to the recommendations of the *National Competition Review of Drugs, Poisons and Controlled Substances Legislation* (Galbally Review), in particular, the response to Recommendation 7 regarding the scheduling of chemicals and medicines in Australia.

ACCORD does not support a joint therapeutic products agency having responsibility for the Australia only function of chemicals' scheduling. In considering its response to the TGA's proposed scheduling model for chemicals, ACCORD along with the industry sector, undertook an impact assessment (*Attachment 2*) to determine the best model for Australia. Option 2 of *Attachment 2* is the preferred model, and is the agreed position of industry.

Option 2 places the chemicals' scheduling arrangements with the chemicals' regulator, NICNAS. We believe that this meets all the criteria set out in Recommendation 7 yet maintains control over the Australia only function of chemicals' scheduling. It also meets the criteria set by the TGA and the NCCTG in developing its scheduling model as it enables the:

- States and Territories to retain their right to make different scheduling decisions;
- the scheduling standard to be maintained within the Health portfolio;
- scheduling secretariat to provide services for both chemicals and medicines committees; and
- implementation of an agreed scheduling policy framework.

In developing the new arrangements, consideration should be given to changing the names of the scheduling committees to better reflect current practices. This has already been done for the Medicines Committee with the change of name from 'drug' to 'medicine'. Similarly, we suggest that a name change be undertaken to replace 'poison' with 'chemical', whereby 'chemical' refers to domestic, industrial and agricultural and veterinary chemicals. For the purposes of this submission, ACCORD is using the term 'domestic' chemical to represent the full range of ingredients/products covered by our members including cosmetic, personal care, household disinfectants and cleaning products etc.

The implementation of the Galbally Recommendation 7 regarding the separation of scheduling of medicines and chemicals provides an excellent opportunity to reform the current system. From an industry perspective, a more integrated chemical control framework within the Department of Health and Ageing (DOHA) but separate from the joint therapeutic products agency, will deliver a streamlined approach for the assessment and scheduling of chemicals in Australia reducing the cost to industry but maintaining the current high standard of public health and safety.

ACCORD has identified a range of concerns with the Consultation Documents, and has provided 11 priority recommendations which we believe will greatly improve the proposed arrangements and are consistent with regulatory best practice to ensure transparency, accountability, efficiency and effectiveness.

ACCORD will continue to work with the TGA and NCCTG in further developing the scheduling models.

ACCORD Recommendations

Recommendation 1

That the DoHA uses the opportunity provided by the reforms to establish the joint therapeutic products agency to also undertake reforms to deliver a more integrated approach to a national set of controls for chemicals management in Australia.

Recommendation 2

That the TGA in partnership with its stakeholders, develop a transparent stakeholder engagement strategy which includes clearly identified processes for nominating and selecting committee and/or working party members.

Recommendation 3

That the chemicals industry as represented by ACCORD, Avcare, the APMF and PACIA nominate two members to the Chemicals' Scheduling Committee, one to represent the agvet industry and the other to represent domestic and industrial chemicals.

Recommendation 4

That the TGA develops a flow chart for all scheduling and rescheduling decisions for medicines and chemicals separately which includes time frames for all decision points for consideration by industry.

Recommendation 5

That the appeal processes for chemical scheduling decisions be strengthened to enable the appellant to appeal against the decision of the Chemicals' Scheduling Committee to the Administrative Appeals Tribunal (AAT).

Recommendation 6

That the TGA and the NCCTG adopt Option 2 as the model for the Australia only function of chemicals' scheduling.

Recommendation 7

That the TGA and the NCCTG revise its model for chemicals' scheduling classification decisions where a chemical is first assessed as unscheduled in line with the COAG Principles for minimum effective regulation.

Recommendation 8

That the TGA and the NCCTG define what is meant by the term 'public interest' and develop criteria and guidelines to determine public interest.

Recommendation 9

That the NCCTG revises its model for medicines' scheduling classification decisions whereby a chemical is first assessed as unscheduled in line with the COAG Principles for minimum effective regulation.

Recommendation 10

That the role and membership of the NCCTG be revised to reflect appropriate reporting structures regarding the provision of policy advice on chemical scheduling.

Recommendation 11

That the NCCTG in consultation with industry, develop clear and concise legislative criteria and guidelines for the separate classification of chemicals and medicines.

1. Introduction

ACCORD is very disappointed in the Therapeutic Goods Administration's (TGA's) Consultations Documents for the proposed models for the scheduling of chemicals and medicines. Industry has been waiting five years for the Government response to the recommendations of the *National Competition Review of Drugs, Poisons and Controlled Substances Legislation* (Galbally Review).

Due to our concern about the apparent lack of progress, the chemical industry wrote to the Council of Australian Governments (COAG) on 31 May 2005 urging its earliest 'sign-off' regarding the recommendations contained in the Galbally Review, specifically in regard to Recommendation 7.

Industry also sought COAG's support to ensure that Health Ministers consulted and engaged with the relevant sectors of the chemicals industry in the development of a revised scheduling system for domestic chemicals and agricultural and veterinary (agvet) chemicals.

As a consequence of COAG's positive intervention, the chemicals industry has now been engaged in consultations with the National Co-ordinating Committee on Therapeutic Products (NCCTG) and the Joint Agency Establishment Group (JAEG) within the TGA.

Recommendation 7 is of particular importance to the chemicals industry and during the five year intervening period, industry has not been consulted on the development of the proposed models for the separation of chemicals and medicines scheduling.

We believe that had we been consulted, that a more robust model for chemicals' scheduling could have been developed and would have had the support of the entire chemicals sector going into the consultation period.

The TGA has presented only one option for consideration. ACCORD believes that this singular model for the scheduling of chemicals has little to offer industry in its current state.

ACCORD believes that in the interests of regulatory best practice, and consistent with the COAG regulatory requirements, that a range of options should have been considered and assessed, and their various costs and benefits weighed up to see which is the optimal model for the Australian regulatory system, not only now, but for the future competitiveness of the chemicals industry.

In our consideration of the Consultation Documents, ACCORD, along with the other sectors of the chemicals industry, has undertaken a regulation impact assessment in the development of alternative and preferred models for chemicals' scheduling.

The impact assessment for a National Model for the Scheduling of Chemicals (National Model) is at Attachment 2 of this submission. The National Model for domestic and industrial, agricultural and veterinary (agvet) chemicals, is industry's contribution to the implementation of Recommendation 7 of the Galbally Review into the control, access and supply of drugs, poisons and controlled substances and should be taken as an integral part of this submission.

ACCORD supports Recommendation 7 of the Galbally Review and notes that in reaching this recommendation, extensive work was undertaken during the Review process including an impact assessment of the various options in reaching each of the final recommendations. For this reason it was not necessary for ACCORD to re-visit the Galbally decision and undertake an assessment of the basis of this recommendation. The issue for ACCORD is how best to give effect to Recommendation 7. This is where ACCORD is disappointed that the TGA did not consult with industry prior to releasing its model, nor consider a range of options prior to settling on their preferred model.

2. *Summary and General Overview*

Summary

ACCORD in considering the Consultation Documents has general comments regarding the contents of all three documents and then specific comments related to each of the documents.

With regard to ACCORD's general observations on the Consultation Documents, ACCORD is concerned with the:

- Australia only functions being managed by the joint therapeutic products agency;
- appointment process for expert members;
- lack of time frames for decision making processes; and
- lack of adequate appeal process.

In relation to the scheduling of chemicals, ACCORD has concerns about:

- the location of chemicals scheduling within a medicines agency;
- the decision making powers of the Managing Director;
- use of terminology for chemicals' scheduling;
- cost recovery; and
- the automatic default to Schedule 7 for all substances under consideration.

In relation to the scheduling of medicines, ACCORD has concerns about the:

- lack of definition of 'public interest';
- automatic default to Schedule 4 for all substances under consideration; and
- role of the NCCTG regarding provision of policy advice.

In relation to the scheduling policy framework for medicines and chemicals ACCORD has concerns about the:

- proposed joint decision making processes; and
- classification of chemicals and poisons.

General Overview

Australia only functions managed by the joint therapeutic products agency - why?

Industry is not convinced that the administration of this Australian-only function of chemicals' scheduling will be best served through the joint agency.

For the chemicals industry, we would like to see the development of the best model which will serve Australia's needs now and into the future. We do not see how the

Australian chemical industry or the regulation thereof will benefit from decisions regarding the scheduling of chemicals being made by a bi-national medicines and medical devices agency.

The implementation of the Galbally Recommendation 7 regarding the separation of scheduling of medicines and chemicals provides an excellent opportunity to look at how best to develop an improved integrated chemical management framework for Australia. This cannot be achieved by placing Australia's premier chemicals regulator, the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and the Office of Chemical Safety (OCS) within the auspices of the joint therapeutic products agency.

From an industry perspective, a more integrated chemical control framework within the Department of Health and Ageing (DOHA) but separate from the joint agency, will not only deliver a streamlined approach for the assessment and scheduling of chemicals in Australia but could also provide for an improved approach to the national management of chemicals including chemicals of interest from a security or illicit drug manufacture perspective.

We believe that this approach would deliver at a national and strategic level, enhanced policy development, and more efficient, effective and streamlined regulatory controls.

The Government is currently considering its response to the Final Report by the Chemicals and Plastics Leadership Group (CPLG) on progress against the Chemicals and Plastics Industry Action Agenda. We understand there is in-principle support for the Final Report's recommendation for a review of the current system of regulation of chemicals and plastics in Australia.

We consider that the findings of the proposed review regarding the regulatory controls and recommendations for reform will provide further opportunity to enhance the efficient and effective regulation of the chemicals industry.

The proposed review provides an opportunity to consider the management of these issues, something that we would not wish to see impeded by the implementation of the proposed model and legislation for chemicals currently being recommended.

Recommendation 1

That the DoHA uses the opportunity provided by the reforms to establish the joint therapeutic products agency to also undertake reforms to deliver a more integrated approach to a national set of controls for chemicals management in Australia.

Improvements to appointment process for expert members

ACCORD has reservations about the appointment process of experts to the proposed Medicines' and Chemicals' Scheduling Committees. Apart from the appointment of jurisdictional representatives, the process lacks transparency. The proposed appointment process for the two Expert Committees is unacceptable. Industry requires assurances that it will be represented by appropriately qualified people recognised by industry as being able to reflect and articulate their interests. Terms of appointment also need to be assigned for all members.

For the Chemicals' Committee, ACCORD would expect two industry members to be appointed, one to represent the chemicals sector and the other to represent the agvet sector.

In identifying suitable 'experts' it would be considered appropriate to have clearly defined criteria to be eligible for consideration. These criteria would apply equally to the selection of jurisdictional representatives as well as 'other experts'. ACCORD believes that a joint therapeutic products agency should not determine if there is a lack of coverage of the required areas of professional expertise for the Chemicals' Scheduling Committee, or the chemical sector as a whole, and would object to the Managing Director of the joint therapeutic products agency having a role in nominating relevant experts for the chemicals industry. Additionally, the reference to 'any expert advisory committee' as a source of expert advice on scheduling decisions is unclear. Will additional 'expert' bodies' be referenced in legislation or will they only be consulted at the discretion of the Managing Director?

It is unclear why the Chair of the Chemicals' Scheduling Committee needs to be represented by the joint therapeutic products agency, and would not continue to be a Ministerial appointment of a Commonwealth officer as is the current arrangement.

Need for a transparent stakeholder engagement strategy

ACCORD has on various occasions raised with the TGA the need for it to develop principles for effective consultation consistent with Government policy. The Government is committed to community consultation and recognises that effective industry and community engagement enables it to tap into diverse perspectives and develop solutions in partnership with its stakeholders which improves decision making. This process will result in improved decision making and consensus building amongst all parties.

ACCORD supports the development of an official Stakeholder Engagement Strategy by individual regulatory agencies as a means of improving processes for meaningful and timely dialogue with their respective stakeholders. A Stakeholder Strategy also introduces transparency into the process as key stakeholder groups are identified and processes for nominating participants onto committees are clearly outlined. Engagement covers a wide variety of Government-industry connections, ranging from information sharing to consultation and, in some instances, active participation in Government policy development and decision-making processes.

The COAG Principles and Guidelines for National Standard Setting and Regulatory Action (COAG Principles) also recognise that for regulatory agencies public consultation is an important part of any regulatory development process. In addition, the Uhrig Review of the *Corporate Governance of Statutory Authorities and Office Holders* also noted that effective consultation is a key to success for regulatory bodies.

ACCORD believes that there is a critical need to consider mechanisms for stakeholder engagement across the TGA and its successor to ensure a fully integrated and transparent approach when undertaking consultation.

From a first-principles basis we believe there is need to:

- identify stakeholder engagement objectives;
- identify the right target audiences; and
- develop the right strategies for stakeholder engagement.

Commonwealth, State and Territory Small Business Ministers have endorsed, *Giving small business a voice – Achieving best practice consultation with small business (2000)*. This publication identifies 10 key principles of consultation that are useful when considering the development of an engagement model, as follows:

- flexibility;
- appropriate targeting;
- timeliness;
- accessibility;
- appropriate medium;
- transparency;
- responsiveness;
- appropriate resources;
- evaluation; and
- continuity.

The principles are closely linked and need to be considered in their entirety for designing stakeholder engagement strategies. We believe that these could be adopted by the TGA or its successor as the basis for the development of its strategy in full consultation with its stakeholders.

Need for clear selection criteria

As part of this process, each committee and/or working party whether formal or informal, should have, as a matter of course, clear selection criteria to assist the nominating body in identifying the best person to be put forward for consideration. Simply requiring 'requisite expertise' in one of the nominated areas is not sufficient criteria and requires further elaboration. In considering appointments to Government bodies, the following criteria might be considered a good starting point:

- an understanding of the processes of government;
- an ability to contribute effectively to the decision making processes of a committee; and
- an understanding of the policy framework within which the committee is operating.

In addition, the TGA should clearly identify which of its many stakeholder groups are to be recognised as national nominating bodies and the criteria for determining this.

Our consistent view has been that for the TGA to ensure its decision making is informed, it must necessarily involve consultation with a broad cross section of the community. Engagement acknowledges the right of industry and the community to have a say and to get involved in the business of Government.

ACCORD urges the development of a consultation model which recognises industry as an equal partner in the development of a range of issues and policies affecting industry. Through equal partnership, the TGA will achieve better outcomes, improved compliance and a better informed industry able to understand its obligations.

Recommendation 2

That the TGA in partnership with its stakeholders, develop a transparent stakeholder engagement strategy which includes clearly identified processes for nominating and selecting committee and/or working party members.

Recommendation 3

That the chemicals industry as represented by ACCORD, Avcare, the APMF and PACIA nominate two members to the Chemicals' Scheduling Committee, one to represent the agvet industry and the other to represent the domestic and industrial chemicals.

Clarification of time frames for decision making processes

The Consultation Documents do not have any time frames for decision making processes. It is unclear how the Committees will operate, when they will meet and what are the statutory time frames around the meetings to get decisions. More detail needs to be provided to enable an understanding of how the system will operate. There does not seem to be any improvement to the current decision making arrangements. While the Consultation Document states that the Joint Agency Gazette will be updated monthly as decisions become known, for chemicals scheduling there will be little change as the States and Territories are expected to give effect to scheduling decisions only three times a year.

Recommendation 4

That the TGA develops a flow chart for all scheduling and rescheduling decisions for medicines and chemicals separately which includes time frames for all decision points for consideration by industry.

Lack of adequate appeal process

While the internal process to seek a review of a scheduling decision appears to be well explained, ACCORD is concerned that on the information provided, the final resolution of the internal review process could be a lengthy process given the lack of specified time frames.

For external appeals, the only appealable decision is that made by the joint therapeutic products agency delegate with regard to the entry in the scheduling standard. There is no appeal process for the actual scheduling decision itself. This appears to be contrary to Government policy for an independent review process for all administrative decisions made by the Australian Government.

Recommendation 5

That the appeal processes for chemical scheduling decisions be strengthened to enable the appellant to appeal against the decision of the Chemical Scheduling Committee to the Administrative Appeals Tribunal (AAT).

3. *Specific comments regarding the proposal for chemicals' scheduling*

Industry's preferred alternative model for chemicals' scheduling

ACCORD does not support a joint therapeutic products agency having responsibility for the Australia only function of chemicals' scheduling. In considering its response to the TGA's proposed scheduling model for chemicals, ACCORD along with the industry sector, undertook an impact assessment (*Attachment 2*) to determine the best model for Australia. Option 2 of *Attachment 2* is the preferred model, and is the agreed position of industry.

Option 2 places the chemicals' scheduling arrangements with the chemicals' regulator, NICNAS. We believe that this meets all the criteria set out in Recommendation 7 yet maintains control over the Australia only function of chemicals' scheduling. It also meets the criteria set by the TGA and the NCCTG in developing its scheduling model as it enables the:

- States and Territories to retain their right to make different scheduling decisions;
- the scheduling standard to be maintained within the Health portfolio;
- scheduling secretariat to provide services for both chemicals and medicines committees; and
- implementation of an agreed scheduling policy framework.

Option 2 provides for a recognised Australia-only decision maker, the Director, NICNAS, thus enabling a proper appeal process to be established. This will ensure transparency and integrity in the decision making process. The Consultation Documents only allow for an appeal against a decision to publish the decision of a scheduling committee in the Standard for the Uniform Scheduling of Medicines and Chemicals (SUSMC), not against the decision itself.

Option 2 also enables scheduling decisions for new substances to be made during the assessment and/or registration process for domestic, industrial and agvet chemicals, similar to the process proposed for medicines in the Consultation Documents. This streamlined process would have significant benefits for industry as it would reduce time and money in getting new products/ingredients onto the marketplace. Better integration of the registration processes with scheduling decisions is an important aspect of the Galbally Recommendation 7 which has been overlooked by the TGA's proposed model with regard to chemicals' scheduling.

Existing levels of public health and safety will not be undermined by the adoption of Option 2 and thus industry's preferred model will maintain community confidence in the integrity of the scheduling process.

Removing relevant sections of the Therapeutic Goods Act should be relatively simple and would be undertaken as part of the consequential amendments in the establishment of the joint therapeutic products agency. As NICNAS is part of the OCS and is already involved in chemicals' scheduling there will be no loss of efficiency in the transfer of administrative arrangements to NICNAS. The States and Territories will be required to make consequential minor amendments to their respective legislation once the joint agency legislation is given Royal Assent. The adoption of Option 2 will not require any additional legislative changes by the States and Territories than would have been required for the NCCTG model.

NICNAS is within the DoHA thereby ensuring consistency in decision making for Australian only public health matters. NICNAS maintains a Memorandum of Understanding (MOU) with the States and Territories in regard to information exchange about new and existing chemicals. The MOU Group has links with State and Territory health, environmental and occupational health and safety agencies thereby enabling use of the network to better communicate scheduling decisions.

NICNAS is part of the OCS which currently provides the secretariat to the NDPSC. The changed legislative arrangements would therefore not impinge upon the effectiveness of the current administrative arrangements. NICNAS is currently located within the OCS as a regulatory assessment scheme for chemical substances. As scheduling decisions are public health assessments made for chemical substances there is an alignment of scheduling-decisions with NICNAS's assessments regarding chemical substances.

Recommendation 6

That the TGA and the NCCTG adopt Option 2 as the model for the Australia only function of chemicals' scheduling.

Concerns over decision making powers of the Managing Director

The Managing Director of the joint therapeutic products agency is given extensive decision making powers regarding scheduling matters. For example, the Managing Director will have the decision making power to publish details for new applications and rescheduling decisions received. Currently the Chair of the National Drugs and Poisons Schedule Committee (NDPSC) has this power under the legislation. ACCORD is not sure why this decision making power needs to reside with the Managing Director and more explanation is required as to why the role of the Chair needs to be diminished, particularly in regard to this Australia only function of chemicals' scheduling.

In Option 2, the Secretary of the DoHA would retain the decision-making powers within the meaning of the Act, as is the current situation. The Secretary would delegate these powers to the Director, NICNAS. There would therefore be complete accountability for Australian only decisions as they would be made by the statutory appointee by the Minister. There would be no conflict of interest in the duel responsibilities by the decision maker and much better integration with the existing chemical control framework.

Preferred terminology for chemicals' scheduling
In developing new arrangements, consideration should be given to changing the names of the scheduling committees to better reflect current practices. This has already been done for the Medicines Committee with the change of name from 'drug' to 'medicine'. Similarly, we suggest that a name change be undertaken to replace 'poison' with 'chemical', whereby 'chemical' refers to domestic, industrial and agvet chemicals.

Cost recovery
The issue of cost recovery is an important one for industry. Part C of Recommendation 7 states that, '*The Therapeutic Goods Act 1989 be amended to enable the costs of operating the Medicines Scheduling Committee and the Poisons Scheduling Committee to be fully recovered by implementing a charge for re-scheduling applications by industry'.* ACCORD notes that cost recovery will be subject to a separate consultation regarding fees and charges for the joint therapeutic products agency.

The Commonwealth Government adopted a formal cost recovery policy in 2002 to improve consistency, transparency and accountability of the Commonwealth's cost recovery arrangements and to promote the efficient use of resources. Cost recovery encompasses fees and charges related to the provision of government goods and services (including regulation) to the private and other non-government sectors. Costs should reflect the fee for the service and should not include those services provided in the public interest.

ACCORD supports the Government's cost recovery policy and as an industry association, has acted responsibly in assisting the Government bed down its policy and gain general acceptance for it by our members. If Option 2 is adopted, fees and charges for scheduling of new substances would be included as part of the assessment registration process for domestic, industrial and agvet chemicals. If industry has put forward a submission for a rescheduling decision, then it would expect to pay, on a fee for service basis using activity based costing, for the cost of that decision. ACCORD believes that where a scheduling or rescheduling decision has been brought to the Chemicals' Scheduling Committee's attention by State, Territory and/or Federal Government agencies, that Government appropriation would be used to support this process as these would be done in the public interest.

No automatic default to Schedule 7 for chemicals' scheduling
ACCORD does not accept the NCCTG's proposal for automatic default to Schedule 7 for all chemicals in their first assessment. This principle of starting at the highest scheduling level is contrary to the COAG Principle to minimise the impact of regulation - ' '*Working from an initial presumption against new of increased regulation, the overall goal is the effective enforcement of stated objectives. Regulatory measures and instruments should be the minimum required to achieve the pre-determined and desirable outcomes.*'

On the basis of the COAG Principles, the starting point for consideration of a scheduling classification should be 'unscheduled' and if proven that scheduling is required, the first consideration should be classification against Schedule 5 criteria. Rather than the adoption of the proposed 'cascading principle', the 'escalating' principle should be put in place.

In considering harmonisation of scheduling decisions, the NCCTG has already adopted the following practice for trans-Tasman harmonisation of scheduling that '*where differences in scheduling exist between Australia and New Zealand that the underlying principle is to harmonise on the less restrictive schedule while giving due consideration to public health and safety issues and/or specific jurisdictional needs*'. Given the current practice by the NDPSC to harmonise on the less restrictive schedule, we do not understand why the Scheduling Committees would automatically default to the highest schedule.

Recommendation 7

That the TGA and the NCCTG revise its model for chemicals' scheduling classification decisions where a chemical is first assessed as unscheduled in line with the COAG Principles for minimum effective regulation.

4 *Specific comments regarding the proposal for medicines scheduling*

Need for definition of public interest test

The Consultation Documents make reference to the Managing Director making decisions in the 'public interest' yet there is no definition of what constitutes the 'public interest.' This needs to be amended in order to ensure transparency in decision making.

Recommendation 8

That the TGA and the NCCTG define what is meant by the term 'public interest' and develop criteria and guidelines to determine public interest.

No automatic default to Schedule 4 for medicines' scheduling

ACCORD's concerns regarding the automatic assumption for new scheduling classifications to commence at the highest classification rather than at the lowest, as explained for chemicals' scheduling, also applies to medicines' scheduling.

Recommendation 9

That the NCCTG revises its model for medicines' scheduling classification decisions whereby a chemical is first assessed as unscheduled in line with the COAG Principles for minimum effective regulation.

Clarification of role of the NCCTG regarding provision of policy advice
The role of the NCCTG in relation to the provision of policy advice and its relationship and reporting lines with the DoHA, the joint therapeutic products agency and the Australian Health Ministers' Advisory Council (AHMAC) needs to be elaborated. The role of the NCCTG is to take action necessary to bring about co-ordination of legislative and administrative controls on therapeutic goods and poisons and to make recommendations to AHMAC. Currently, New Zealand participates as an observer.

The Uhrig Report emphasised the need to ensure that portfolio secretaries remain the principal source of advice to Ministers in relation to all matters within the portfolio.

In the Consultation Documents, the role of the NCCTG as a policy advising body and its relationship with the joint therapeutic products agency needs clarification. The joint therapeutic products agency will be a regulatory body, not a policy body, as this is the preserve of the DoHA. The NCCTG should therefore have a relationship with the DoHA in relation to policy development. The proposals and reporting lines contained in the Consultation Documents need to be revisited to reflect this policy/regulatory split between the respective bodies. In terms of the operation of the individual committees, it is unclear, for example, why the Chemicals' Scheduling Committee would provide policy advice to the joint therapeutic products agency on chemicals scheduling matters.

The role of New Zealand on the NCCTG needs to be clarified and the NCCTG membership will need to be revisited in relation to decisions on Australia only chemical scheduling functions. The policy reporting lines for the NCCTG should be between the DoHA and AHMAC, not the joint agency. The NCCTG membership should consist of Commonwealth appointees as represented by the DoHA once the joint agency is given legal effect.

Recommendation 10

That the role and membership of the NCCTG be reviewed to reflect appropriate reporting structures regarding the provision of policy advice on chemical scheduling.

5. Specific comments regarding the scheduling policy framework for medicines and poisons

ACCORD's additional key points on the scheduling policy framework are recorded below. Appropriate constructive comments and further development of relevant guidelines for application, information requirements and public consultation for chemicals' scheduling processes should be developed upon acceptance of industry's preferred Option 2 as the model for Australia only chemicals' scheduling.

Scheduling decisions on intended use
ACCORD does not understand the rationale behind the joint working parties as outlined in the Scheduling Policy Framework document. We do not understand why the joint therapeutic products agency would seek policy advice on scheduling issues for

medicines and chemicals. As indicated previously in our submission, policy matters need to be dealt with through the DoHA and AHMAC.

In addition, it is unclear as to why there would need to be joint meetings of the two committees. Scheduling decisions are made on the intended use of a product. If the same chemical has a number of different uses, then each Committee decision would be made on the scheduling criteria established for medicines and chemicals respectively.

Legislative underpinning for separate classification of chemicals and medicines

The Scheduling Policy Framework document is unclear as to the legislative underpinning of the classification criteria. Currently the criteria are in legislation within the Therapeutic Goods Act. ACCORD supports the principle for clear, objective criteria and guidelines rather than 'factors' which could lead to subjectivity and the exercise of 'bureaucratic discretion' contrary to COAG Principles.

Notwithstanding our earlier comments regarding the need for 'escalating up' approach in accordance with COAG Principles, ACCORD notes with concern that revisions of the proposed 'factors' when compared to the existing Schedule 5, 6 and 7 guidelines have been proposed without any justification or explanation. For example, the guidelines for Schedule 5 currently reference 'low to moderate hazard' whereas the new proposed 'factors' for Schedule 5 refer only to 'low hazard'. A comprehensive critique and comparison has not been provided herewith, as we recommend that the NCCTG in consultation with industry, must develop clear and concise legislative criteria for the scheduling of chemicals. Any such significant changes to the existing considerations of NDPSC would need to undergo a regulatory impact assessment to justify any additional requirements.

Recommendation 11

That the NCCTG in consultation with industry, develop clear and concise legislative criteria and guidelines for the separate classification of chemicals and medicines.

ATTACHMENT 1

ACCORD Australasia Membership

Advance Chemicals Pty Ltd
Albright & Wilson (Aust) Ltd
Amway of Australia Pty Ltd
Applied Australia Pty Ltd
Auto Klene Solutions Pty Ltd
Beiersdorf Australia Ltd
Callington Haven Pty Ltd
Campbell Brothers Limited
Canpoint International Pty Ltd
Castle Chemicals Pty Ltd
Castrol Australia Pty Ltd
Chemetall (Australasia) Pty Ltd
Ciba Specialty Chemicals
Clariant (Australia) Pty Ltd
Cleveland Chemical Co Pty Ltd
Clorox Australia Pty Ltd
Colgate Palmolive Pty Ltd
Creative Brands Pty Ltd
Deb Australia Pty Ltd
Dominant (Australia) Pty Ltd
DuPont Chemical Solutions Enterprise
Ecolab Pty Limited
GlaxoSmithKline Consumer Healthcare
G S B Chemical Co Pty Ltd
Healthcare Manufacturing Group
Henkel Australia Pty Limited
Huntsman Corporation Australia Pty Ltd
Jalco Group Pty Limited
Jasol Australia
Johnson & Johnson Pacific Pty Ltd
Kao (Australia) Marketing Pty Ltd
Lab 6 Pty Ltd
L'Oreal Australia Pty Ltd
Milestone Chemicals Pty Ltd
Northern Chemicals Pty Ltd
Novozymes Australia Pty Ltd
Nowra Chemical Manufacturers Pty Ltd
Peerless JAL
Procter & Gamble Australia Pty Ltd
PZ Cussons Pty Ltd
Reckitt Benckiser
Recochem Inc
Rohm and Haas Australia Pty Ltd
Scental Pacific Pty Ltd
Selkirk Laboratories Pty Ltd
Solvay Interox Pty Ltd
Sonitron Australasia Pty Ltd
Sopura Australia Pty Ltd
Tasman Chemicals Pty Ltd
Thor Specialties Pty Limited
True Blue Chemicals Pty Ltd
Unilever Australasia
Whiteley Industries Pty Ltd

Associate Members:

AMS Laboratories Pty Ltd
Cintox Pty Ltd
Competitive Advantage
Dermatest Pty Ltd
DSL Packaging
E-Three & Associates Pty Ltd
Hydro Nova Controls
Middletons Lawyers
Silliker Microtech Laboratories Pty Ltd
Sue Akeroyd & Associates
Tonic Creative
Visy Industrial Packaging

ATTACHMENT 2

A National Model for the Scheduling of Chemicals

Regulation Impact Statement

Introduction

The development of a preferred National model for the scheduling of chemicals, namely domestic, agricultural and veterinary (agvet) chemicals, is industry's contribution to the implementation of Recommendation 7 of the *National Competition Review of Drugs, Poisons and Controlled Substances Legislation* (Galbally Review) into the control, access and supply of drugs, poisons and controlled substances.

Background

In 1999, the state, territory and Australian governments commissioned a national competition review to examine the legislation and regulation imposing controls over access to, and supply of, drugs, poisons and controlled substances. An independent Chair, Ms Rhonda Galbally undertook the review with advice from a steering committee representing all jurisdictions.

Review progress

Submissions against the terms of reference were invited and these informed the development of the options paper, which was released for comment in February 2000. A draft report was released in September 2000 and provided a further opportunity for interested parties to comment.

The Galbally Review's final report was presented to the Australian Health Ministers' Conference (AHMC) in December 2000. The review's terms of reference required AHMC to forward the report to the Council of Australian Governments (COAG) with its comments. The final report was publicly released in January 2001. A working party of the Australian Health Ministers' Advisory Council (AHMAC) was established to assist in the preparation of comments on the report for COAG. The Primary Industries Ministerial Council (PIMC) was consulted as a number of the Galbally Review recommendations potentially effect the management of agvet chemicals.

Government response

The government response to the Galbally Review was released to the public on 1 July 2005 by the AHMAC Working Party.

Galbally Review recommends changed administrative arrangements for scheduling.

Recognising the problems within the existing Australian scheduling framework, Recommendation 7 calls for the establishment of two scheduling committees, one for medicines, and the other for domestic and agvet chemicals. **Attachment A** provides the details of how the two scheduling committees as proposed in the Galbally Review would operate.

Recommendation 7

a) The Therapeutic Goods Act 1989 and relevant sections of State and Territory Legislation be amended to:

- change the title of the Standard for the Uniform Scheduling of Drugs and Poisons to the Standard for the Uniform Scheduling of Medicines and Poisons; and
- disband the National Drugs and Poisons Schedule Committee and replace it with two separate committees – the Medicines Scheduling Committee, responsible for scheduling human medicines; and the Poisons Scheduling Committee, responsible for scheduling agricultural, veterinary and household chemicals – and that:
    - membership of the Committees include a mix of jurisdictional representatives, appropriate experts and representatives of relevant government and community sectors;
    - decisions of both the Medicines Scheduling Committee and the Poisons Scheduling Committee be decided by a majority vote of the members provided that majority also includes a majority of the jurisdictions; and
    - the decisions of both Committees be included in the Standard for the Uniform Scheduling of Medicines and Poisons.

b) The Therapeutic Goods Act 1989 and the Agricultural and Veterinary Chemicals Code Act 1994 and related subordinate legislation be amended, as necessary, to enable the Therapeutic Goods Administration, in the case of human medicines, and the National Registration Authority for Agricultural and Veterinary Products, in the case of agricultural and veterinary products, acting on the advice of the Commonwealth health portfolio in relation to public health matters to:

- make decisions about the labelling and packaging of medicines and agvet products during evaluation of those products;
- recommend the schedule in which a new substance should be included; and Executive summary
- recommend changes to the schedule of a substance where, in evaluating new formulations, new presentations and new uses of substances currently included in the Standard for the Uniform Scheduling of Medicines and Poisons, a significant change in the risk profile of the substance is identified.

c) The Therapeutic Goods Act 1989 be amended to enable the costs of operating the Medicines Scheduling Committee and the Poisons Scheduling Committee to be fully recovered by implementing a charge for re-scheduling applications by industry.

Proposal to establish a Joint Therapeutic Products Agency with administrative responsibility for Australia only functions

Since the release of the Galbally Review, the Australian and New Zealand Governments have agreed to establish a joint therapeutic products agency for the regulation of therapeutic products. The Therapeutic Goods Administration (TGA) and the New Zealand Medicines and Medical Devices Safety Authority (Medsafe) will be replaced by a single agency accountable to both the New Zealand and Australian Governments. The joint agency will also have responsibility for some Australia and New Zealand only functions as agreed by the respective Ministers.

A project team of Australian and New Zealand officials is continuing to develop the final details of the regulatory framework and the legislation to regulate therapeutic products in both countries. Rather than reviewing and reforming the therapeutic goods legislation which is likely to be repealed in 2006, the Government proposes that the

Galbally Review recommendations which require Commonwealth legislative changes be implemented as part of the joint therapeutic products agency legislation.

The TGA is continuing to work with relevant health officials in the Australian states and territories and New Zealand to coordinate those changes required to state/territory legislation to implement relevant Galbally recommendations and the development of the joint agency legislation. The National Co-ordinating Committee on Therapeutic Goods (NCCTG) has also been working towards implementation of the recommendations in anticipation of COAG endorsement.

Industry concerns with lack of consultation

Industry was first advised in December 2004 through the release of the Description of the Joint Regulatory Scheme by the TGA, that in line with Recommendation 7 of the Galbally Review, two scheduling committees will be established. In addition to medicines scheduling, it is proposed that the joint therapeutic products agency will be responsible for the Australian-only function of the scheduling of domestic chemicals and agvet products.

This is a matter of concern to the chemicals industry sector as it had not been consulted on this decision nor had any advice been sought by the TGA from industry following the announcement of the joint therapeutic products agency. Industry associations met in May 2005 for a briefing on the proposed scheduling arrangements for the joint agency. Industry advised government observers in attendance that it did not consider that consultation on the proposed scheduling model should occur as part of the consultation on the draft legislation for the joint agency given that the expected consultation period will be only six weeks.

As a consequence of the meeting, relevant industry associations wrote to COAG on 31 May urging its earliest 'sign-off' regarding the recommendations contained in the Galbally Review, specifically in regard to Recommendation 7, but also seeking COAG's agreement to instruct Health Ministers to consult and engage with the relevant sectors of the chemicals industry in the development of a revised scheduling system for domestic and agvet chemicals.

TGA release of Consultation Document for a proposed model for the scheduling of poisons in Australia (Consultation Document)

On 6 July 2005 the TGA released its consultation documents for the proposed models for poisons and medicines scheduling within the trans-Tasman arrangements. Also released for comment is the Scheduling Policy Framework for medicines and poisons. While industry welcomes the release of these important documents as the beginning of the formal consultation process we note with disappointment that no impact assessment and discussion of alternative models was undertaken. Instead, one model was presented as the basis for discussions with stakeholders. Industry was given a further opportunity to raise its concerns with the NCCTG and the Joint Agency Establishment Group (JAEG) within the TGA at a stakeholder consultation in Sydney on 5 August 2005.

Industry concerns with proposed model

The establishment of the joint agency for the regulation of human therapeutic products has little relevance to the system for domestic and agvet chemicals control in Australia.

The TGA's initial proposal as released in December 2004 was essentially the maintenance of the status quo with the exception of the establishment of two

scheduling committees and the application of cost recovery to fund the two committees. The Consultation Document provides more detail on the decision-making process to be adopted by the two scheduling committees indicated that the Managing Director of the joint therapeutic products agency will be the final decision maker, a radical departure from the current decision- making processes.

The joint agency will therefore not only be making regulatory decisions for the Australian and New Zealand governments for human therapeutic products, but will also be administering and making decisions with regard to the Australian-only scheduling system for domestic and agvet chemicals. Under current arrangements, this is the sole prerogative of the states and territories.

Industry is not convinced that the administration of this Australian-only function will be best served through the joint therapeutic products agency. We are pleased that we will now have time to consider in an informed way through the release of the Consultation Document the TGA's proposal. In addition, we will be able to discuss the proposed TGA model with other options as developed by industry with relevant state, territory, Australian Government and New Zealand regulators and their respective policy bodies prior to the release of the draft legislation.

This consultation will enable the chemicals industry to work with government and the community to develop the most effective and cost-efficient regulatory solution, best integrated within the existing Australian chemical control system. It is also important to ensure that reform in this area is consistent with international trends, and not constrained by trans-Tasman political considerations of human therapeutic products.

Industry supports the main thrust of Recommendation 7 of the Galbally Review for changed administrative arrangements for scheduling as we believe that greater efficiencies can be delivered to industry without compromising existing levels of public health and safety.

Industry supports some of the elements of the Consultation Document's proposed model such as:

- processes for the handling of scheduling applications, with decisions being made as part of the public health risk assessment for agvet chemicals;
- development and maintenance of an electronic publication which includes the scheduling of poisons. This publication will be adopted into legislation by the Australian States and Territories;
- requirements for public consultation; and
- processes for the handling of requests for internal review regarding scheduling decisions.

However, industry does not believe that this is the optimal model and we will be seeking better advisory arrangements, the placement of the secretariat outside of the management of the therapeutic products body, streamlined administrative arrangements, decision-making processes to reflect the appropriate jurisdiction and appropriate industry cost recovery arrangements.

Industry does not support an overarching unified scheduling policy framework as outlined in the Consultation Document for medicines and poisons as we believe that the scheduling decisions are based on different outcomes. Medicines scheduling decisions are made in regard to access and availability of scheduled medicines and the level of healthcare intervention while for domestic and agvet chemicals, scheduling

decisions are about risk communication. This represents two different approaches to scheduling decisions. The unified framework approach does not recognise this fundamental difference in decision making and therefore cannot be expected to represent good practice.

Industry does not oppose closer alignment of committee meeting dates to assist the states and territories utilize representational resources more efficiently, but this is a process matter, not a decision which is integral to the decision making processes of the two scheduling committees. These administrative decisions could be considered in the context of the administrative arrangements and should not hinder the development of the best regulatory model to deliver a national chemicals' scheduling model for Australia only functions.

In addition and consistent with the COAG Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standard Setting Bodies (COAG Principles) industry believes that greater efficiencies can be made through changed administrative arrangements to scheduling than those proposed by the TGA. COAG principles require regulatory impact assessment of decisions which affect the way business operates. Minor or administrative decisions do not require impact assessment and while the TGA model may wish to pass off the new arrangements as minor by creating the illusion that the proposed models represent the status quo, we would suggest that an impact assessment and discussion of options is required prior to a final decision being made.

To this end, a number of options have been considered and assessed in light of advantages and disadvantages and cost benefit analysis to industry, government and the community. These options are outlined below. ACCORD welcomes discussion on the models presented as a way of furthering the development of the optimal arrangements for the scheduling of domestic and agvet chemicals in Australia.

Change of name is required

In developing new arrangements, consideration should be given to changing the names of the scheduling committees to better reflect current practices. This has already been done for the Medicines Committee with the change of name from 'drug' to 'medicine'. Similarly, we suggest that a name change be undertaken to replace 'poison' with 'chemical', whereby 'chemical' refers to domestic and agvet chemicals. This reference has been used throughout the rest of the paper.

Objectives of chemicals scheduling

The objectives of the legislation are to protect and promote public health by minimising poisoning, medicinal misadventure and diversion of these substances to the illicit drug market.

The work undertaken in the Galbally Review provides background information to the policy process and objectives of chemicals scheduling in Australia which are to promote and protect the health and safety of humans and animals in relation to the use of drugs, poisons and controlled substances. The Galbally Review was quite specific in its recommendations for a change to administrative arrangements for a separate chemicals scheduling committee. The development of the joint therapeutic products agency has been the catalyst to ensure changes to the current arrangements are undertaken and in place by 1 July 2006.

What is the problem being addressed?

The development of the most efficient and effective scheduling regime for domestic and agvet chemicals for Australia.

Options for scheduling of domestic chemicals

A number of options exist for the most effective and efficient delivery of chemicals scheduling in Australia, these include:

1. Placing the chemicals scheduling arrangements with the chemicals regulator, the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and the agvet scheduling arrangements with the agvet regulator the Australian Pesticides and Veterinary Medicines Agency (APVMA)*;*
2. Placing chemicals' scheduling arrangements with the chemicals regulator, NICNAS;
3. Creating a separate Commonwealth Chemicals' Scheduling Act and Regulations administered by the Australian Government's Department of Health and Ageing (DoHA) through the Office of Chemical Safety (OCS); or
4. Creating a separate Australian only function for chemicals' scheduling under the proposed legislative framework for the Joint Trans Tasman Therapeutic Products Agency.

Option 1 Placing the chemicals scheduling arrangements with the chemicals regulator, the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and agvet scheduling arrangements with the agvet regulator the Australian Pesticides and Veterinary Medicines Agency (APVMA)

Advantages

The scheduling committees would be better qualified to make decisions on their respective substances which should streamline the decision making processes as they will be much better integrated into the control mechanisms for their specific sector. The number of decisions required would be less than the current arrangement whereby the one committee makes decisions for medicines, chemicals and agvet substances. The streamlined decision-making processes should be more responsive to the needs of the relevant industry sectors. Both regulators are well known to the relevant industry sectors, have established contacts with state and territory representatives not only in their respective areas, but also in public health, the environment and worker safety.

Removing relevant sections of the Therapeutic Goods Act and amending existing pieces of legislation for the control of industrial or agvet chemicals should be relatively simple and would be undertaken as part of the consequential amendments in the establishment of the joint therapeutic products agency. This would maintain the Australian only function within the Australian system of regulatory controls for chemicals management. As both regulators are already involved in chemicals' scheduling there will be no loss of efficiency in the transfer of arrangements to the two regulators. Any potential advertising issues for agvet chemicals could be dealt with directly by the Australian Pesticides and Veterinary Medicines Agency (APVMA) through the *Agricultural and Veterinary Chemicals Code Act 1994* and respective Regulations.

The consequential amendments of the joint therapeutic products agency legislation are expected to commence 1 July 2006.

Disadvantages
The primary purpose of the current arrangements is to address public health issues. While NICNAS is within the DoHA, the APVMA is not and this could result in inconsistencies of Australian Government public health decision-making as a result of the two regulators making different decisions. This could add more complexity to the current arrangements. The Standard for the Uniform Scheduling of Medicines and Chemicals (SUSMC) may become three separate publications with separate standards for medicines, domestic chemicals and agvet products.

Required legislative changes
This would require the removal of the Part 6-3 Sections 52A, 52B, 52C, 52D, 52E from the *Therapeutic Goods Act 1989* and Division 3A from the Therapeutic Goods Regulations 1990 and placing these Sections within the *ICNA* and the *Agricultural and Veterinary Chemicals Code Act 1994* and respective Regulations. This would enable the two regulators NICNAS and the APVMA to establish two separate scheduling committees to make decisions about the classification and scheduling of poisonous substances in relation to domestic chemicals and agvet chemicals respectively, taking in total three scheduling committees including the joint therapeutic products agency committee for medicines.

Impact on Business
The scheduling committees will be better informed which should result in better and more timely decision-making. The problems industry face with the inconsistent take up by jurisdictions may not be addressed, and will continue to be a problem. The DoHA will have policy oversight for both medicines and domestic chemicals in the Australian context, while the Department of Agriculture, Fisheries and Forestry (DAFF) will have policy oversight for agvet chemicals.

Additional costs would be incurred through the application of cost recovery if the Government appropriation for this activity was not maintained. Where industry is the direct beneficiary e.g. if industry approaches the Chemicals' Scheduling Committee to review a decision or seeks an exemption as opposed to the public interest test, then industry would be expected to pay on a fee for service basis. While this should enable a closer alignment of costs to each of the three specific sectors, the application of cost recovery to maintain the entire scheduling processes for domestic and agvet chemicals would be an additional impost on industry. Given that currently a large amount of the work program is generated by public agencies it would be difficult to see how the total cost could be applied to the chemicals and agvet sector under the Government's current cost recovery policy for which the public is the major beneficiary.

Impact on Government
Under the current arrangements the cost of providing the Secretariat to the National Drugs and Poisons Schedule Committee (NDPSC) is met through Government appropriation to the OCS. The issue of cost recovery has been noted and will be considered as part of further consultations once the scheduling models have been agreed.

The establishment of two separate committees may have some resource implications for state, territory and New Zealand representatives. New Zealand participates in the

scheduling process to improve harmonisation of scheduling decisions between Australia and New Zealand.

Impact on Consumers/community
The scheduling arrangements will not reduce public health and safety levels. However, a more complex system with inconsistencies between domestic and agvet scheduling could increase the cost of some products. Community expectations are for a greater integration for the national system of chemical controls, the proposed Option 1 will not deliver this greater degree of integration.

Recommendation
Given that PIMC has already indicated that it wants to see the two scheduling committees reside within the DoHA, this option is not recommended.

Option 2 Place chemicals' scheduling arrangements with the chemicals regulator, NICNAS.

Advantages
The approach would maintain the existing levels of public health and safety and thus maintain community confidence in the integrity of the scheme. Removing the relevant sections of the Therapeutics Act and placing them within existing pieces of legislation and regulations for the control of industrial chemicals has the attraction of being relatively simple. The advantages are that the Australian only function is undertaken by an entity with Australian jurisdiction for chemicals management. NICNAS is a regulatory assessment scheme for chemical substances and as scheduling decisions are public health assessments made for chemical substances there is an alignment of schedule-decision making with NICNAS's decision-making regarding chemical substances.

The Director of NICNAS would be the final decision maker, thus allowing for a proper appeal process. The Consultation Documents only allows for an appeal against a decision to publish the decision of a scheduling committee in the SUSMC. For chemicals scheduling, the final decision maker would be the independent statutory officer holder, thus enabling for a proper appeal process against the decision, not only the decision to publish.

An important aspect of the Galbally Recommendation 7 was for closer integration of the registration process with the scheduling decision. By placing chemicals scheduling within the ICNA framework, scheduling decisions can be undertaken as part of the assessment process, thus reducing time and cost for industry. In addition, the application of GHS classification criteria relevant to domestic and agvet chemicals can be considered. GHA classification is not relevant for medicines scheduling.

Removing relevant sections of the Therapeutic Goods Act should be relatively simple and would be undertaken as part of the consequential amendments in the establishment of the joint therapeutic goods agency. As NICNAS is part of the OCS and is already involved in chemicals' scheduling there will be no loss of efficiency in the transfer of administrative arrangements to NICNAS.

NICNAS is within the DoHA thereby ensuring consistency in decision making for Australian only public health matters. NICNAS maintains a Memorandum of Understanding (MOU) with the states and territories in regard to information exchange

about new and existing chemicals. The MOU Group has links with state and territory health, environmental and occupational health and safety agencies.

NICNAS is part of the OCS which currently provides the secretariat to the NDPSC. The changed legislative arrangements would therefore not impinge upon the effectiveness of the current arrangements. NICNAS is currently located within the OCS as a regulatory assessment scheme for chemical substances. As scheduling decisions are public health assessments made for chemical substances there is an alignment of scheduling-decisions with NICNAS's assessments regarding chemical substances.

The Director NICNAS is currently the Director OCS. As an Australia only function, the OCS would have a direct relationship with the Department's policy body and assist with the Ministerial appointment process of the scheduling committee members. NICNAS could assume responsibility for the publication of the SUSMC. Any potential advertising issues for agvet chemicals could be dealt with directly by the APVMA through the *Agricultural and Veterinary Chemicals Code Act 1994* and respective Regulations.

Disadvantages
There are no observable disadvantages to the proposed model.

Required legislative changes
Remove the Part 6-3 Sections 52A, 52B, 52C, 52D, 52E from the *Therapeutic Goods Act 1989* and Division 3A from the Therapeutic Goods Regulations 1990 and place it within the ICNA Act and Regulations. This would enable NICNAS to administer a scheduling committee to make decisions about the classification and scheduling of poisonous substances in relation to domestic and agvet chemicals.

Impact on Business
The scheduling committees will be better informed which should result in better and more timely decision-making. Some additional costs may be incurred through the application of cost recovery. Where industry is the direct beneficiary e.g. if industry approaches the scheduling committee to review a decision or seek an exemption as opposed to the public interest test, then industry would be expected to pay. The one scheduling committee dealing with domestic and agvet chemicals would be more cost effective than separate committees run through the two regulatory agencies, thereby reducing costs to industry. The timeliness of decision-making should result in new products getting onto the market more quickly. The DoHA will have policy oversight for public health issues for medicines, domestic and agvet chemicals which will still result in consistency of public health and policy controls for these substances and maintain public confidence in the scheme.

The issue of cost recovery has been noted and will be considered as part of further consultations once the scheduling models have been agreed.

Impact on Government
Under the current arrangements the cost of providing the Secretariat to the NDPSC is met through Government appropriation to the OCS. Some costs for re-scheduling decisions may be able to be recovered through cost recovery and fee for service reducing the cost to Government. The issue of cost recovery has been noted and will

be considered as part of further consultations once the scheduling models have been agreed.

Impact on Consumers/community
The scheduling arrangements will not reduce public health and safety levels. A more simplified and streamlined decision-making processes may result in lower costs for some products and more timely access to new products.

Recommendation
Option 2 is the preferred model. It meets all the criteria set out in Recommendation 7 yet maintains control over the Australia only function of chemicals scheduling. Industry believes that this model has the most to offer as it ensures sovereignty over Australia only functions as well as delivering a system which is more efficient and effective and results in efficiencies to industry without any diminution of public health and safety standards. Option 2 provides for a recognised decision maker for appeals which ensures transparency and integrity in the decision making process. It also enables scheduling decisions to be made during the registration process similar to the process proposed for medicines in the Consultation Documents. This streamlined process has significant benefits for industry and will ensure that public confidence in the integrity of the scheme is maintained.

Option 3 Create a separate Commonwealth Chemicals' Scheduling Act and Regulations administered by the Australian Government's Health portfolio through the OCS.

Advantages
The excising of the relevant sections of the Therapeutics Act and creating a separate piece of Commonwealth legislation has the attraction of being relatively simple. The OCS will be given responsibility for administering the Australian only function which is consistent with its role and function. The OCS has links with state and territory public health, environmental, occupational health and safety agencies as well as the APVMA. The secretariat to the NDPSC is currently located within the OCS therefore there would be no change to the current arrangements. The Director NICNAS is currently the Director OCS ensuing consistency in the application of the Government's public health policies to the scheduling committee's decisions making processes.

Creating a new piece of Commonwealth legislation should be relatively simple and would be undertaken as part of the consequential amendments in the establishment of the joint therapeutic products agency. This would maintain the Australian only function within the Australian system of regulatory controls for chemicals management. As the OCS currently manages poisons' scheduling there will be no changes as a result of the changed legislative arrangements. NICNAS is currently located within the OCS and as a regulatory assessment scheme for chemical substances and as scheduling decisions are public health assessments made for chemical substances there is an alignment of schedule-decision making with NICNAS's decision-making regarding chemical substances.

Any potential advertising issues for agvet chemicals could be dealt with directly by the APVMA through the Agricultural and Veterinary Chemicals Code Act 1994 and respective Regulations.

Disadvantages
There are no observable disadvantages to the proposed model.

Required legislative changes
Remove the legislative function from the *Therapeutic Goods Act 1989* and Regulations as for Options 1 and 2 and create a separate Commonwealth Chemicals' Scheduling Act and Regulations administered within the DoHA through the OCS. This would be part of the consequential amendment process in the establishment of the joint therapeutic products agency.

Impact on Business
The scheduling committees will be better informed which should result in better and more timely decision-making. Some additional costs may be incurred through the application of cost recovery. Where industry is the direct beneficiary e.g. if industry approaches the Chemicals' Scheduling Committee to review a decision or seek an exemption as opposed to the public interest test, then industry would be expected to pay. The one scheduling committee dealing with domestic and agvet chemicals would be more cost effective than separate committees run through the two regulatory agencies, thereby reducing costs to industry.

The issue of cost recovery has been noted and will be considered as part of further consultations once the scheduling models have been agreed.

Impact on Government
Under the current arrangements the cost of providing the Secretariat to the NDPSC is met through Government appropriation to the OCS. The DoHA will have policy oversight for public health issues for medicines, domestic and agvet chemicals which will result in better integration of public health controls for these substances. The issue of cost recovery has been noted and will be considered as part of further consultations once the scheduling models have been agreed.

Impact on Consumers/community
The scheduling arrangements will not reduce public health and safety levels. A more simplified and streamlined decision-making processes may result in lower costs for some products and more timely access to new products.

Recommendation
Option 3 has a number of advantages to recommend it, however it is not as favourable as Option 2. Industry believes that the model has merit in ensuring sovereignty over Australia only functions as well as delivering a system which is more efficient and effective and results in efficiencies to industry without any diminution of public health and safety standards. This option would require a delegated power of decision making and would make the appeal process one step removed from the Delegate who in this instance would need to refer the decision making power to the Office of Chemical Safety. While this model has many close parallels to Option 2, Option 3 is slightly less favoured by industry than Option 2.

Option 4 Create a separate Australian only function for chemicals' scheduling under the proposed legislative framework for the Joint Trans Tasman Therapeutic Products Agency.

Advantages
The adoption of this model would essential maintain the status quo in terms of administrative arrangements for scheduling committees, i.e. consecutive meetings, joint decisions on medicines and/or chemicals of common interest, single publication of

scheduling decisions. While it is proposed to establish two committees, one to deal with medicines in the trans-Tasman context and the other to deal with Australia only domestic and agvet chemicals scheduling, this appears to be the only change to the current administrative arrangements. The establishment of the two committees would be managed by the one secretariat with existing NDPSC staff being transferred to the joint therapeutic products agency.

Disadvantages

The focus of the joint therapeutic products agency is on medicines, other matters would be regarded as incidental to the main purpose of the joint agency. Risk assessment methodology for medicines is different to that for domestic and agvet chemicals. While there may be two scheduling committees the proposed administrative arrangements suggest that the jurisdictional representation for both committees would be the same, thereby reducing the opportunity to provide representatives better able to represent the interests for medicines and domestic and agvet chemicals respectively. The decision-making for medicines, domestic and agvet chemicals will rest with the joint therapeutic products agency.

The application of 100% cost recovery would be difficult to justify as most scheduling decisions for domestic and agvet chemicals are in the public interest while for medicines it is generally a request by a company for a reconsideration of decision. The Galbally Review recommends cost recovery by implementing a charge for re-scheduling applications by industry. While industry does not have a problem with this, but we do not believe that this would raise sufficient funds to cover the cost of the NDPSC. Government appropriation would be required to fund the work undertaken in the public interest.

The creation of Australia only functions within a legislative framework to manage therapeutic products in a trans-Tasman context may produce legislative difficulty which can be avoided by creating a Commonwealth only stand alone piece of legislation or inserting the activities into related Australia only legislation. For example, the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) is a document of the AHMAC. In the Consultation Document, the joint therapeutic products agency will have responsibility for the medicines schedule, but as an Australia only function, the joint agency should not be the final decision maker for domestic issues with regard to household, industrial and agvet chemicals. By utilizing web based technologies, industry, government and the community can have access to a unified SUSMC even though responsibility for elements of the document may reside with different agencies. There is no need for co-location of scheduling committees to enable the publication of the SUSMC.

The proposed model in the Consultation Document does not have equal representation of broadly based advisory arrangements. While industry supports Ministerial appointment to the scheduling committees, we do not support the nomination of members to Australia only functions by the Managing Director of the joint agency. This should be done by the Secretary of the DoHA. Industry does not consider this model is sufficiently representative and does not represent best practice stakeholder engagement.

Required legislative changes

Legislative amendment would be part of the process to establish the joint therapeutic products agency and should be in place by 1 July 2006.

Impact on Business
The administration of domestic and agvet chemicals by an agency with a primary focus on medicines may result in less efficient processes for the scheduling of domestic and agvet chemicals. The joint agency will not be a policy body as it will be the regulator for trans-Tasman therapeutic products. The DoHA will have policy oversight for both medicines and domestic chemicals in the Australian context, while the Department of Agriculture, Fisheries and Forestry will have policy oversight for agvet chemicals.

The NCCTG will have policy oversight of the scheduling committees but the flow chart in the Consultation Document has it reporting to the joint therapeutic products agency. This is unacceptable as it should continue to report to AHMAC without the filter of the joint agency, which does not have a policy function, being the regulator of therapeutic products. The policy relationship between the joint agency and the DoHA will need to be managed and this could slow down decision-making and reduce efficiencies to industry.

Impact on Government
There could be a loss of control on Australia only functions and potentially less efficient policy development processes and decision making for domestic and agvet scheduling and related matters. The issue of cost recovery has been noted and will be considered as part of further consultations once the scheduling models have been agreed.

Impact on Consumers/community
The scheduling arrangements will not reduce public health and safety levels. However, the maintenance of the status quo will not deliver the efficiencies industry is expecting which can drive down costs for the consumer and improve market access for new products. Community expectations are for a greater integration for the national system of chemical controls, the proposed trans-Tasman model will not deliver this greater degree of integration.

Recommendation
This model is not recommended as it removes the power of the jurisdictions to be the final decision maker regarding scheduling and makes the joint therapeutic products agency the final decision maker for domestic and agvet chemical scheduling decisions. The joint therapeutic products agency will have a medicines focus, the control of domestic and agvet chemicals will be secondary. The nature of the industry sectors is different to that of medicines and requires a different regulatory response. The publication of Australia only decisions in a joint therapeutic products agency gazette raises issues of sovereignty.

ATTACHMENT A

Proposed Medicines Scheduling Committee and Poisons Scheduling Committee – Functions

The following changes to the *Therapeutic Goods Act 1989* and the Therapeutic Goods Regulations 1990 have been identified as necessary for restructuring the National Drugs and Poisons Schedule Committee into the Medicines Scheduling Committee (MSC) and the Poisons Scheduling Committee (PSC).

THERAPEUTIC GOODS ACT 1989

Amend Section 52C - Functions of the Committee

The proposed functions of the **Medicines Scheduling Committee** are:

(a) to make decisions in relation to the classification and scheduling of medicinal substances; and

(b) to provide technical advice to governments in relation to the legislative restrictions, including restrictions as to accessibility and availability to be imposed in respect of particular medicinal substances; and

(c) to maintain the schedules for medicinal substances in the current Poisons Schedule[1] and

(d) to facilitate the harmonisation between Australia and New Zealand of the legislative provisions relating to the classification and scheduling of medicinal substances; and

(e) to undertake public consultation with respect to matters relating to the classification and scheduling of medicinal substances that are of public health interest or significance; and

(f) to consider any matters referred to it by:

(i) the Minister or Secretary; or

(ii) the subcommittee of the Australian Health Ministers' Advisory Council known as the National Coordinating Committee on Therapeutic Goods;

and report to the Minister, Secretary or subcommittee the results of its consideration; and

(g) any other functions that are prescribed by the regulations.

The proposed functions of the **Poisons Scheduling Committee** are:

[1] Note: the 'Poisons Standard' is currently defined in the *Therapeutic Goods Act, 1989* as referring to the Standard for the Uniform Scheduling of Drugs and Poisons. This definition will need to be amended to refer to the Standard for the Uniform Scheduling of Medicines and Poisons...

(a) to make decisions in relation to the classification and scheduling of poisonous substances, excluding medicinal substances; and

(b) to provide technical advice to governments in relation to:

(i) the legislative restrictions, including restrictions as to accessibility and availability to be imposed in respect of particular poisonous substances; and
(ii) the policies to be adopted with respect to labelling, packaging and advertising of poisons; and

(c) to maintain the schedules for poisonous substances in the current Poisons Schedule; and

(d) to facilitate the harmonisation between Australia and New Zealand of the legislative provisions relating to the classification and scheduling of poisonous substances; and

(e) to undertake public consultation with respect to matters relating to the classification and scheduling of poisonous substances that are of public health interest or significance; and

(f) to consider any matters referred to it by:
(i) the Minister or Secretary; or
(ii) the subcommittee of the Australian Health Ministers' Advisory Council known as the National Coordinating Committee on Therapeutic Goods;

and report to the Minister, Secretary or subcommittee the results of its consideration; and

(g) any other functions that are prescribed by the regulations.

Amend Section 52E - Matters to be taken into account in exercising powers

Matters to be taken into account will be the same for each committee and the same as currently for NDPSC.

THERAPEUTIC GOODS REGULATIONS 1990

Regulation 42ZCD Committee members

Proposed Membership of the Committee **(Medicines Scheduling Committee)**

The Committee comprises each jurisdictional member and other persons appointed by the Minister under this regulation.

The Minister may appoint as a member an expert or a representative.

Each of the following persons is a **representative**:
a) a person nominated by the Therapeutic Goods Administration,

b) a person nominated by an agency of the New Zealand government responsible for regulation of medicines for human use,

c) a person whom the Minister is satisfied represents the pharmaceutical industry,

d) a person whom the Minister is satisfied represents consumers,

e) a person whom the Minister is satisfied represents practicing pharmacists, and

f) a person whom the Minister is satisfied represents practicing complementary medicine practitioners.

Each of the following persons is an **expert**:

a) a medical practitioner expert in clinical pharmacology,

b) an expert in veterinary medicine or pathology,

c) a toxicologist, and

d) an epidemiologist

Proposed Membership of the Committee **(Poisons Scheduling Committee)**

The Committee comprises each jurisdictional member and other persons appointed by the Minister under this regulation.

The Minister may appoint the following experts or representatives.

Each of the following persons is a **representative**:

a) a person nominated by the National Registration Authority,

b) a person nominated by an agency of the New Zealand government responsible for the regulation of agricultural and household chemicals,

c) a person whom the Minister is satisfied represents the chemical industry, and

d) a person whom the Minister is satisfied represents consumers.

Each of the following persons is an **expert**:

a) an expert in occupational health,

b) a toxicologist,

c) an epidemiologist, and

d) an expert in public health (poisonings)

Attachment 4

ACCORD submission on
Draft Standard for the Uniform Scheduling of Medicines and Poisons and
Draft Scheduling Policy Framework
21 August 2007

ACCORD

Advocate for the Consumer, Cosmetic, Hygiene and Specialty Products Industry

Dr David Graham
National Manager
Therapeutic Goods Administration
Department of Health and Ageing
PO Box 100
WODEN ACT 2606

Dear David

Draft Standard for the Uniform Scheduling of Medicines and Poisons and Draft Scheduling Policy Framework

ACCORD provides the following comments in relation to the consultation documents on the Draft Standard for the Uniform Scheduling of Medicines and Poisons (Draft Standard) and Draft Scheduling Policy Framework (Draft Framework).

ACCORD notes the New Zealand Government's announcement that it would not be proceeding with the legislation to establish a joint agency with Australia for the regulation of therapeutic products and that the Australian Government has postponed its plans for the time being to establish the joint agency.

Within this context, ACCORD notes that the Draft Standard and Draft Framework were circulated on the basis of full implementation of the proposed joint agency which now no longer applies at this point in time. ACCORD therefore reserves its right to provide additional comments should further information regarding the status of the joint agency or of these consultation documents be made available.

ACCORD Australasia is the peak national industry association representing the manufacturers and marketers of formulated consumer, cosmetic, hygiene 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.

Our industry's products play a vital role in:

- keeping our households, workplaces, schools and institutions clean, hygienic and comfortable;
- personal hygiene, grooming and beauty treatments to help us look and feel our best;
- specialised uses that assist production and manufacturing to keep the wheels of commerce and industry turning; and
- maintaining the hygienic and sanitary conditions essential for our food and hospitality industries and our hospitals, medical institutions and public places.

These benefits are essential to safe, healthy living and maintaining the quality lifestyle we all too often take for granted.

With an estimated $10 billion in annual retail product sales, the formulated consumer, cosmetic, hygiene and specialty products industry is a significant part of a prosperous Australian economy. We are a dynamic and growing industry, employing Australians and - through our industrial and institutional sector - supplying products essential for Australian businesses, manufacturing firms, government enterprises, public institutions, farmers and consumers.

Our industry has more than 50 manufacturing operations throughout Australia and New Zealand. Member companies include large global consumer product manufacturers to small dynamic Australian-owned businesses.

A full list of current ACCORD member companies is provided at *Attachment 1.*

GENERAL COMMENTS

ACCORD, on behalf of its member companies, has a specific and direct interest in the Draft Framework and Draft Schedule for chemicals' scheduling. ACCORD is extremely disappointed to note that comments provided to the Therapeutic Goods Administration (TGA) in September 2005 have largely been ignored by the National Coordinating Committee on Therapeutic Goods (NCCTG) and that many of the serious problems and issues identified by ACCORD in the original proposal remain.

Of the original 11 recommendations made by ACCORD in the September 2005 submission to the TGA, we note that only one appears to have been partially accepted.

In an important development the Government has recently announced a significant study into the chemicals and plastics sector by the Productivity Commission (PC). The terms of reference for the study are broad and will look at amongst other matters, the operation of chemicals scheduling in Australia. Given the significant delay by governments to implement Recommendation 7 of the Galbally Review, and industry's waning support due to the apparent lack of commitment to the policy underpinning for the reform process shown by government officials, it is expected that the PC study will take into account industry's concerns with these proposed scheduling arrangements and come to its own view on the best way to proceed.

We note that the Australian Government had intended to introduce a Commonwealth Poisons Bill as a consequential amendment to the joint agency implementation legislation. At one stage, industry would have supported the introduction of the Poisons Bill regardless of progress with the joint agency. However, given the lack of responsiveness by the NCCTG to industry's concerns with the initial Scheduling Framework we can not support any changes to the current system until it has been considered by the PC study and referred to the COAG Ministerial Taskforce for Chemicals and Plastics. Industry sees nothing to be gained from the current approach suggested by the NCCTG, and is indeed, very concerned that the proposals are at variance to current Government policy.

We are pleased to note however, that the Department of Health and Ageing (DoHA) appears to have responded in part to ACCORD's first recommendation regarding using the changes to the scheduling framework as an opportunity for better delivery of chemicals' management in Australia.

Recommendation 1
That the DoHA uses the opportunity provided by the reforms to establish the joint therapeutic products agency to also undertake reforms to deliver a more integrated approach to a national set of controls for chemicals management in Australia.

The role of the Office of Chemical Safety within DoHA appears to have been strengthened by the appointment of a Director to head the Office. While this is a positive step forward towards industry's goal for an integrated chemical control framework in Australia, we remain concerned regarding the possible duplication of chemical policy between the Office of Chemical Safety and the National Industrial Chemical Notification and Assessment Scheme (NICNAS). Indeed, the location of the Office of Chemical Safety and NICNAS within the TGA Group of Regulators is problematic as regulatory agencies such as the TGA (and NICNAS) do not have a role in the development of Government policy, their primary role is to administer legislation.

An outcome of the Australian Government's review of the corporate governance of Commonwealth statutory authorities and office holders (the Uhrig Review) was to improve the performance and get the best from statutory authorities and office holders, and their accountability frameworks. The Government accepted the recommendation that a statement of intent is meant to be provided by the Minister regarding the role of the regulator:

1. *The Government should clarify expectations of statutory authorities by Ministers issuing Statements of Expectations to statutory authorities; by statutory authorities responding with Statements of Intent for approval by Ministers; and by Ministers making public Statements of Expectations and Intent.*
    - *Statements of Expectations would need to take into account the nature of the independence of each statutory authority and may not be necessary where the existing governance framework provides for a comparable arrangement (for example, as is the case in respect of government business enterprises).*
2. *The role of portfolio departments as the principal source of advice to Ministers, should be reinforced by requiring statutory authorities and office holders to provide relevant information to portfolio secretaries in parallel to that information being provided by statutory authorities and office holders to Ministers.*

The Government's response was in August 2004. We are now three years on and yet to see such a statement regarding NICNAS. This is critical in providing transparency to industry as to the role of NICNAS and the Office of Chemical Safety regarding the development of national chemical policy issues and the development of an integrated chemical control framework including scheduling.

In addition, ACCORD raises the question of the role of NCCTG with regard to chemicals scheduling and chemicals policy. The NCCTG is a working group of health officials with a mandate for medicines policy. We continue to have reservations regarding the administrative arrangements and the priority given to the process issues such as convenience of meeting attendance which appears to be driving the Scheduling Framework and Policy.

SPECIFIC COMMENTS

No automatic default to Schedule 7 for chemicals' scheduling

ACCORD is very disappointed to see that the NCCTG is continuing to recommend the automatic default to Schedule 7 for all chemicals in their first assessment. This is by far the most problematic of the NCCTG's recommendations regarding future scheduling processes. We are still to see an impact assessment to justify the reversal of the current scheduling process. Industry is not aware of any demonstrated market failure or risks to public health from the current

approach. The NCCTG is recommending a significant ramping up of regulatory intervention with no justification that that new approach is required or what benefits it will deliver in terms of public health and safety outcomes, improved consumer information or reduced costs to industry.

> ***Recommendation 7***
> *That the TGA and the NCCTG revise its model for chemicals' scheduling classification decisions where a chemical is first assessed as unscheduled in line with the COAG Principles for minimum effective regulation.*

This principle of starting at the highest scheduling level is contrary to the COAG Principle to minimise the impact of regulation:

> '*Working from an initial presumption against new of increased regulation, the overall goal is the effective enforcement of stated objectives. Regulatory measures and instruments should be the minimum required to achieve the pre-determined and desirable outcomes.*' (COAG Principles page 6)

On the basis of the COAG Principles, the starting point for consideration of a scheduling classification should be 'unscheduled' and if proven that scheduling is required the first consideration should be classification against Schedule 5 criteria and then Schedule 6 and so on.

To adopt the NCCTG approach disregards the existing NICNAS process for public health assessment of all new chemicals and referral to the NDPSC for scheduling decisions where appropriate. It could result in the banning of all new chemicals including inert excipients for use in domestic products, regardless of their toxicity, and invoke the plethora of non nationally uniform licensing requirements on these chemicals without any justification.

In considering harmonisation of scheduling decisions, the NCCTG has already adopted the following practice for trans-Tasman harmonisation of scheduling that '*where differences in scheduling exist between Australia and New Zealand that the underlying principle is to harmonise on the less restrictive schedule while giving due consideration to public health and safety issues and/or specific jurisdictional needs*'. Given the current practice by the NDPSC to harmonise on the less restrictive schedule, we do not understand why the Chemicals Scheduling Committee would automatically default to the highest schedule. This is a backward step and cannot be supported.

Nomination process for Chemicals Scheduling Committee

ACCORD continues to remain seriously concerned regarding the nomination process for the Chemicals Scheduling Committee. In our original submission we noted our reservations regarding the appointment process of *experts*. We remain of the view that the proposed appointment process for the Expert Committee is unacceptable. Industry requires assurances that it will be represented by appropriately qualified people recognised by industry as being able to reflect and articulate their interests. It is not appropriate for government to make this decision on behalf of industry. We therefore remain committed to our initial recommendation regarding appointment to the expert committee.

> ***Recommendation 3***
> *That the chemicals industry as represented by ACCORD, Avcare, the APMF and PACIA nominate two members to the Chemicals' Scheduling Committee, one to represent the agvet industry and the other to represent domestic and industrial chemicals.*

Improved consultation mechanisms

With regard to ACCORD's other recommendations it is particularly disappointing to note that in the intervening two years neither the TGA nor the Joint Agency Establishment Group (JAEG)

has provided any feedback to industry in relation to comments provided on the initial consultation documents. The NCCTG has not consulted with industry despite this being one of industry's recommendations regarding the further development of the two documents:

> ***Recommendation 11***
> *That the NCCTG in consultation with industry, develop clear and concise legislative criteria and guidelines for the separate classification of chemicals and medicines.*

Indeed, there is little real incentive for industry to respond to consultation documents given the lack of feedback and recognition of the time and effort industry puts into the process.

Single Scheduling policy framework

Industry does not support an overarching unified scheduling policy framework as outlined in the Consultation Document for medicines and chemicals as we believe that the scheduling decisions are based on different outcomes. Medicines scheduling decisions are made in regard to access and availability of scheduled medicines specifically including the level of healthcare intervention while for domestic and agvet chemicals, scheduling decisions are about risk management and communication through packaging and labelling requirements. This represents two different approaches to scheduling decisions. The unified framework approach does not recognise this fundamental difference in decision making and therefore cannot be expected to represent good practice.

Industry does not oppose closer alignment of committee meeting dates to assist the states and territories utilise representational resources more efficiently, but this is a process matter, not a decision which is integral to the decision making processes of the two scheduling committees. These administrative decisions should not hinder the development of the best regulatory model to deliver a chemicals scheduling model for Australia.

With regard to the Draft Standard we note that the definition of cosmetic on page 12 is no longer accurate with the new definition as passed in the ICNA (Cosmetics) Bill 2007.

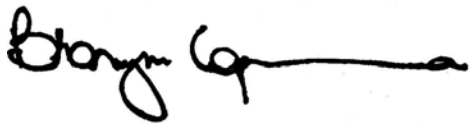
Conclusion and recommendations

ACCORD is very disappointed with the Consultation Documents given that the NCCTG appears not to have taken on board industry's concerns and proposals for reform. For this reason we are resending our original submission for consideration as it is still highly relevant (Attachment 2).

In addition, we strongly recommend that the NCCTG needs to consult more effectively with industry though active engagement and dialogue.

Finally, given the significance of our concerns with the current proposals, ACCORD strongly recommends that no decision regarding changes to Commonwealth/State scheduling decisions regarding chemicals is made until the PC study into chemicals and plastics has been considered by the COAG Ministerial Task Force into Chemicals and Plastics.

Yours sincerely



Bronwyn Capanna
Executive Director
21 August 2007

ACCORD

Advocate for the Consumer, Cosmetic, Hygiene and Specialty Products Industry

Members

Attachment 1

Consumer, Cosmetic and Personal Care:

Advanced Skin Technology Pty Ltd
Alberto Culver Australia
Amway of Australia Pty Ltd
Apisant Pty Ltd
Aroma Science
AVON Products Pty Limited
Baylor Limited
Beiersdorf Australia Ltd
Chanel Australia
Clorox Australia Pty Ltd
Colgate-Palmolive Pty Ltd
Combe International Ltd
Cosmax Prestige Brands Australia Pty Ltd
Coty Australia Pty Limited
Creative Brands Pty Ltd
Dermalogica Pty Ltd
Elizabeth Arden Australia
Emeis Cosmetics Pty Ltd
Estée Lauder Australia
Frostbland Pty Ltd
GlaxoSmithKline Consumer Healthcare
Helios Health & Beauty Pty Ltd
Innoxa Pty Ltd
Johnson & Johnson Pacific
Kao (Australia) Marketing Pty Ltd
Keune Australia
Kimberly Clark Australia
La Biosthetique Australia
La Prairie Group
L'Oreal Australia Pty Ltd
LVMH Perfumes and Cosmetics
Mary Kay Australia Pty Ltd
Nutrimetics Australia
Procter & Gamble Australia Pty Ltd
PZ Cussons Pty Ltd
Reckitt Benckiser
Revlon Australia
Scental Pacific Pty Ltd
Shiseido (Australia) Pty Ltd
Thalgo Australia
The Heat Group Pty Ltd
Tigi Australia Pty Ltd
Trilogy Products
Trimex Pty Ltd
Ultraceuticals
Unilever Australasia
YSL Beaute

Hygiene and Specialty Products

Albright & Wilson (Aust) Ltd
Applied Australia Pty Ltd
BP Castrol Australia Pty Ltd
Callington Haven Pty Ltd
Campbell Brothers Limited
Castle Chemicals Pty Ltd
Chemetall (Australasia) Pty Ltd
Chemform
Ciba Specialty Chemicals
Clariant (Australia) Pty Ltd
Cleveland Chemical Co Pty Ltd
Deb Australia Pty Ltd
Dominant (Australia) Pty Ltd
Ecolab Pty Limited
E Sime & Company Australia Pty Ltd
Henkel Australia Pty Limited
Huntsman Corporation Australia Pty Ltd
Jalco Group Pty Limited
Lab 6 Pty Ltd
Milestone Chemicals Pty Ltd
Novozymes Australia Pty Ltd
Nowra Chemical Manufacturers Pty Ltd
Peerless JAL
Recochem Inc
Rohm and Haas Australia Pty Ltd
Solvay Interox Pty Ltd
Sonitron Australasia Pty Ltd
Sopura Australia Pty Ltd
Tasman Chemicals Pty Ltd
Thor Specialties Pty Limited
True Blue Chemicals Pty Ltd
Whiteley Corporation Pty Ltd

ACCORD

Advocate for the Consumer, Cosmetic, Hygiene and Specialty Products Industry

Associate Members

Specialist Laboratories and Testing

ams Laboratories

Dermatest Pty Ltd

Silliker Microtech Laboratories Pty Ltd

Equipment and Packaging Suppliers

EquipNet Inc.

HydroNova Australia NZ Pty Ltd

SCHÜTZ DSL Group Pty Ltd

Logistics

Star Track Express Pty Ltd

Legal and Business Management

Middletons Lawyers

PricewaterhouseCoopers

Regulatory and Technical Consultants

Archer Emery & Associates

Cintox Australia Pty Ltd

Competitive Advantage

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August 2007

Attachment 2

A new scheduling model for chemicals and medicines

2 September 2005

Contents

Attachment 5

ACCORD submission on
Proposed new arrangements for the scheduling of medicines and poisons
Scheduling Policy Framework and Standard for the Uniform Scheduling of Medicines and Poisons
29 May 2009

ACCORD

Advocate for the Consumer, Cosmetic, Hygiene and Specialty Products Industry

Mr Charles Maskell-Knight
A/G National Director
Therapeutic Goods Administration (TGA)
Department of Health and Ageing
PO Box 100
WODEN ACT 2606

Dear Mr Maskell-Knight

ACCORD is making the following comments in relation to the National Coordinating Committee on Therapeutic Goods (NCCTG) two consultation documents: *Scheduling Policy Framework* (Policy Framework) for Medicines and Poisons and the *Standard for the Uniform Scheduling of Medicines and Poisons*.

We appreciated the meeting with you and your staff from the TGA and the Office of Chemical Safety and Environmental Health (OCSEH) on Friday 22 May 2009 to discuss the two documents. The meeting was very valuable in assisting us to further understand how the proposed new arrangements are intended to operate once implemented.

Having reviewed the documents we remain concerned that the proposed arrangements do not offer any meaningful reform for the chemical products industry, and indeed may be regressive in outcome. The proposed arrangements will not provide for the reform as envisioned by Rhonda Galbally in her *National Competition Review of Drugs, Poisons and Controlled Substances Legislation* 2001 report (the Galbally Report) nor will it achieve the desired effects for improved efficiency and effectiveness for chemicals scheduling as outlined in the Productivity Commission's Research Report into Chemicals and Plastics Regulation (July 2008) (PC research report). Further, while we are yet to see the cost recovery model, our industry is concerned about cost shifting of currently budget funded activity from the taxpayer to industry, even though the tax payer in many instances will be the only identifiable beneficiary.

The net outcome for the chemical products industry is no reform and at a potentially higher cost.

ACCORD has always been concerned with the placement of chemicals scheduling within a therapeutic goods regulatory framework. Chemical products are not therapeutic goods and the scheduling of these products should be undertaken by appropriate experts familiar with the risk management framework for consumer chemicals. Further, we should be able to clearly identify the Chemical Scheduling Committee and scheduling controls as the primary risk management component for these products, rather than submerge it further within the Therapeutic Goods Administration.

One only has to consider some of the comments and misunderstandings arising from the recent OCSEH consultation on implementation of GHS for chemical products, to validate this serious concern.

Medicines scheduling decisions are about access and availability of scheduled medicines and the level of healthcare intervention, integrated within a product registration system, while for consumer chemicals, scheduling decisions are the risk management and communication controls

as specified through concentration limitations, packaging and/or labelling requirements. This represents two very different mechanisms and approaches to scheduling decisions and outcomes. The NCCTG has not in the past, nor has the current consultation document on the Policy Framework recognised this fundamental difference in decision making and associated regulatory systems and therefore the proposed framework cannot be expected to represent good practice.

Many of the concerns we raised in 2005 in response to the consultation document *A new scheduling model for chemicals and medicines* have not been addressed in the latest round of consultation documents and continue to be of concern. In particular, we remain concerned about the:

- scheduling and decision making process for new chemicals
- lack of transparency with notification and appeal mechanisms
- implied automatic default to Schedule 9 for chemical products
- policy role of the NCCTG for consumer chemicals, and
- cost recovery.

We remain disappointed that health ministers have not taken this opportunity for real reform in line with the Productivity Commission's recommendations contained in its reports. These recommendations sought clearer demarcation of responsibility for chemicals scheduling, use of independent expert advice and a greater commitment for national uniformity under the leadership of health ministers.

This would have resulted in a more integrated chemical control framework with Commonwealth policy leadership and oversight. It would have delivered a streamlined approach for the assessment and scheduling of chemicals in Australia but it could also have provided for the national management of chemicals including chemicals of interest from a security or illicit drug manufacture perspective. This opportunity for an integrated control framework should not be squandered.

In developing the new arrangements, consideration has been given to the names of the scheduling committees to better reflect current practices and we are pleased to note that a Chemicals Scheduling Expert Advisory Committee will be established. However, throughout the documents there is confusion regarding the Standard for the Uniform Scheduling of Drugs and Poisons (which is intended to be changed to the Standard for the Uniform Scheduling of Medicines and Poisons to better reflect contemporary terminology), and that of the Poisons Standard. To avoid confusion and while ACCORD supports the adoption of the term *medicines* over *drugs,* we believe that the Schedule should be renamed to the Standard for the Uniform Scheduling of Medicines and Chemicals and referenced consistently. In general we also believe that the term *poisons* should be replaced by the term *chemicals*. Refer also our comments in attachment B.

We note that the Policy Framework makes no reference to embracing the reform principles to improve the regulatory environment for chemicals. There is no mention of COAG's commitment to a seamless national economy and how the proposed framework will contribute to the Government's reform agenda noting that chemicals and plastics were identified as a regulatory *hot spot*. The Policy Framework appears to be written in the absence of any concept of good regulatory practice, reduced compliance burden for industry, improved safety outcomes for the public or increased efficiency and effectiveness of current arrangements. The framework is devoid of any policy context for its proposals. The background notes various reforms but does not respond as to how the proposed arrangements will deliver significant and meaningful long term benefits.

ACCORD believes that the Policy Framework can be improved upon to deliver a structure which is more in line with the PC's proposal and hence deliver significantly more benefits. Such a Framework would include the following elements:

- The Secretariat would remain in OCSEH – there is no policy nor cost benefit analysis to demonstrate why change is required
- The decision maker would be the Secretary of the Department or delegated decision-maker
- The Medicines Scheduling Expert Advisory Committee would be managed by the TGA
- The Chemicals Expert Advisory Committee would be managed by OCSEH and would be an independent expert body providing risk management advice to the Secretary or delegated decision maker regarding chemical scheduling decisions
- The OCSEH would provide services to the TGA under a service level agreement
- All costing would be activity based, transparent and where the public is the identified beneficiary, governments would contribute to the costs
- The TGA and OCSEH would independently manage decisions of its experts committees
- The Poisons Schedule would be separated into a Medicines Schedule and a Chemicals Schedule, and
- Schedule 7 products would be automatically referred to Safe Work Australia and treated as a workplace safety matter and not be subject to any control of use through state and territory health officials in line with the PC Recommendation 5.3.

As an absolute minimum the proposed arrangements in the NCCTG Policy Framework should deliver the following:

1. the Schedule should be renamed to the Standard for the Uniform Scheduling of Medicines and Chemicals and that the terms *substances and/or chemicals replaces poisons*;
2. the policy oversight for chemical products be undertaken by the OCSEH in consultation with relevant Commonwealth, state and territory bodies responsible for the risk management of chemicals;
3. the Policy Framework should adopt enhanced accountability measures which includes public reporting on variations to scheduling decisions, annual reporting to health ministers (AHMC) and a reporting line be established between AHMC and the Standing Committee on Chemicals for scheduling matters.

We have provided specific comments in relation to the *Proposed Scheduling Policy Framework* at Attachment A and the *Proposed Standard for the Uniform Scheduling of Medicines and Poisons* at Attachment B.

Should you have any questions in relation to the issues raised in our submission, the contact officer is Ms Dusanka Sabic, Regulatory Reform Director who can be contacted on 02 9281 2322 or by email dsabic@accord.asn.au

We look forward to working with staff of the Department of Health and Ageing and NCCTG further in bringing forward a tangible reform process for the uniform scheduling of chemicals.

Yours sincerely

Bronwyn Capanna
Executive Director

29 May 2009

ATTACHMENT A

Specific comments on the NCCTG consultation document *Scheduling Policy Framework for Medicines and Poisons:*

1 Introduction

ACCORD disputes that there is a high degree of scheduling and consequential uniformity for controls on chemical products across Australian states and territories. There is nothing in the proposed new arrangements which will lead to improved national adoption of scheduling decisions and their subsequent controls.

The PC research report provides detailed comments on inconsistencies in the controls on chemicals between jurisdictions (pp103, 104) and made a number of recommendations to overcome this problem. We find it disturbing that the jurisdictions continue to suggest uniformity and commitment to a national approach exists. One only has to go to the most recent Record of Reason (February 2009) to see that this is simply not true.

The NDPSC has been working towards the national harmonisation of the requirements for the retail storage of Schedule 5 and Schedule 6 poisons by working on a *Draft Code of Practice for National Retail Storage of Schedule 5 and Schedule 6 Products* (the Draft Code). Progress on this issue has been slow and laboured due to current differences between the states and territories which can range from quite prescriptive in NSW to no requirements in Victoria.

The February 2009 NDPSC meeting Record of Reasons indicated that some jurisdictions believed the Draft Code too stringent while others believed it to be not stringent enough compared to their existing requirements. The Record of Reasons also indicated that some jurisdictions were unwilling to amend their current state regulations to adopt the Draft Code once it was finalised. We see little evidence in this very recent post COAG agreement to the PC recommendations on its chemical study that there is any enhanced commitment to national uniformity or consistency of approach in scheduling outcomes.

3 Key Aspects

Scheduling Policy

We question the single point of reference for scheduling policy through the NCCTG – a therapeutics based committee. The regulation of chemical products and hence scheduling decisions and outcomes differ substantially from that of therapeutic goods regulation. Placing consumer chemicals scheduling within a therapeutic goods agency and providing policy over sight by a therapeutic goods committee is not reform of chemicals scheduling.

The PC in its study of chemicals and plastics argued for clearer demarcation of medicines from chemicals, *The Commission considers that there is an overwhelming case for responsibility for the scheduling process of drugs to be separated from that of poisons (p101)*. Further, it went on, *The Commission considers that scheduling decisions could be left to the CSC rather than the Secretary of DoHA – however, this would only have been appropriate if the committee was not representational (p102).* The PC recognised the opportunity for genuine reform with the separation of the scheduling committees and the appointment of an expert based decision making scheduling body. We therefore recommend that policy oversight for consumer chemicals

be undertaken by the OCSEH in consultation with relevant Commonwealth, state and territory bodies responsible for the risk management of chemicals.

Decision maker
We support the Secretary of the Department (or delegated decision maker) to make scheduling decisions for new chemical entities. This can provide flexibility and improve timeliness for some scheduling decisions for new chemicals in relation to the agvet sector which is a product based registration scheme. For new industrial chemicals, the system differs slightly and the introducer of a new chemical may not be the only affected party under a proposed scheduling decision. For example, while the chemical entity may not appear on the Australian Inventory of Chemical Substances (AICS) it may be in use through a variety of other mechanisms such as exemptions or permit categories depending on volume or use.

Under the current arrangements only the introducer will be consulted and given an opportunity to comment on the draft decision prior to the delegate making a final decision.

While there is no appeal mechanism to the Delegate's decision, we note there are opportunities for seeking reconsideration to a decision. Also in relation to the assessment of industrial chemicals, the decision of the Director, NICNAS is open to an administrative appeal. Therefore a range of appeal mechanisms do exist within existing arrangements for the assessment of industrial and agvet chemicals. These need to be taken into account in the decision making process for scheduling, and, as they may not be well understood by all stakeholders need to be clarified within the new framework.

ACCORD is concerned with the proposal that NICNAS makes recommendations direct to the delegate for scheduling. NICNAS is a notification and assessment body, without significant experience in relation to scheduling matters. Further, this is contrary to the PC recommendation regarding the future role of NICNAS as a scientific assessment body (Recommendation 4.3) which has been agreed to by COAG. In its draft report the PC makes the following observation*:*

> *While NICNAS already conducts its own toxicology assessments and provides poisons scheduling recommendations to the NDPSC, giving it risk management powers would distract it from its role as a hazard and risk assessment body, and would create potential for regulatory conflicts and overlaps to occur (p107).*

Expert Advisory Committees
ACCORD notes the appointment of the Expert Advisory Committees and provides detailed comments on this under Part 5 – Scheduling Expert Advisory Committees.

The Poisons Standard
ACCORD notes that the SUSMP will be considered a Legislative Instrument for the purposes of the Legislative Instruments Act 2003 (LIA). While ACCORD supports this, the problem remains regarding the affected parties for new chemicals having been identified and consulted with prior to the delegate making a final decision. As noted above, ACCORD also supports the development of two distinct poisons schedules – one for medicines and the other for chemicals.

Implementation and accountability
ACCORD notes the NCCTG commitment to the principle of national uniformity. However, there has been little to demonstrate that the principle is being implemented. The PC noted that the states and territories should adopt poisons scheduling decisions by direct reference and that they should be uniformly adopted either through template or model approach. The PC notes inter alia that … *state and territory governments should continue to report any variations to nationally-agreed poisons scheduling or regulatory decisions at the state or territory level to the Australian Health Ministers' Conference*, *and include a statement of reasons for the variations (Rec 5.2).*

ACCORD recommends that the Policy Framework adopts these enhanced accountability measures as proposed by the PC which includes public reports on variations to scheduling decisions.

The NCCTG should be accountable to the health ministers who are in turn accountable to the Standing Committee on Chemicals for reporting on scheduling matters and implementation of PC and COAG decisions. The disclosure and justification of variances to implementation of scheduling decisions should be available for public scrutiny.

Costs
The issue of cost recovery is an important one for industry. ACCORD notes that it is intended to fully recover the costs of scheduling of chemicals from the relevant industry sectors and that a CRIS is being prepared.

The Commonwealth Government adopted a formal cost recovery policy in 2002 to improve consistency, transparency and accountability of the Commonwealth's cost recovery arrangements and to promote the efficient use of resources. Cost recovery encompasses fees and charges related to the provision of government goods and services (including regulation) to the private and other non-government sectors. Costs should reflect the fee for the service and should not include those services provided in the public interest.

ACCORD supports the Government's cost recovery policy and as an industry association, has acted responsibly in assisting the Government bed down its policy and gain general acceptance for it by our members. As a matter of principle, we believe that under the current economic conditions it is appropriate to review the Government's cost recovery policy with a view to reducing the cost burden on industry.

However, in relation to fees and charges for scheduling, new substances could be included as part of the assessment registration process for domestic, industrial and agvet chemicals. This however does present problems for industrial chemicals where the introducer may not be the only one using the chemical, resulting in *free riders*. If a company has put forward a submission for a rescheduling decision, then it would expect to pay, on a fee for service basis using activity based costing, for the cost of that decision. ACCORD believes that where a scheduling or rescheduling decision has been brought to the Chemicals' Scheduling Committee's attention by State, Territory and/or Federal Government agencies, that Government appropriation would be used to support this process as these would be done in the public interest.

In our review of the medicines and chemicals that have been considered by the NDPSC in 2008, 32 (out of 69 substances) were medicines, 20 were referred to the NDPSC by the APVMA and 17 were "other agricultural/veterinary, industrial and domestic chemicals". All of the 17 substance were existing chemicals that did not go through the NICNAS new chemical notification processes. From the Record of Reasons it also appears that most of these 17 were referred to the NDPSC by itself as a result of previous decisions or minor administrative requirements for re-aligning previous decisions with appendices or schedules. From this cursory analysis it appears difficult to understand how the chemical industry is going to equitably contribute costs towards chemical scheduling processes in line with the governments cost recovery principles.

4 The Scheduling process

Scheduling

ACCORD has highlighted some of the unintended consequences of the proposed scheduling process for new chemicals above.

Rescheduling
The PC made a number of recommendations regarding amendments to the schedule of appendices. It noted that *the NCCTG should require the preparation of a COAG RIS where they are not minor or machinery in nature. As well some scheduling advice by the CSC, particularly where schedule 7 substances are concerned, would meet the requirements for undertaking a RIS p102).* We do not see any discussion of RIS analysis in the NCCTG Policy Framework as part of scheduling, rescheduling or the public consultation process.

Public consultation
ACCORD understands that the current public consultation process for rescheduling decisions will be maintained. The issue of public consultation for new industrial chemicals which are not bound by confidentiality provisions requires consideration.

Date of decision
The Consultation Document while containing a flow chart of the decision making process for scheduling and rescheduling decisions, did not provide any time frames for decision making processes. It is unclear how the Committees will operate, when they will meet and what are the statutory time frames around the meetings to get decisions. The NCCTG will need to provide more detail around these issues to enhance transparency of the new arrangements as exists with current arrangements. While we understand that there will be improved timeliness for decisions effecting new chemicals and whilst this is appreciated, all stakeholders are require to be informed as to how the new processes will work.

5 Scheduling Expert Committees

Introduction
ACCORD does not support the establishment of the Chemicals Scheduling Expert Advisory Committee under the Therapeutic Goods Act. As advised previously, we see this as a further blurring of responsibility for chemicals management within the health portfolio and is the antithesis of what is the proposed outcome for chemicals regulation and management following the PC report and recommendations.

Responsibilities of the Committees
ACCORD notes the responsibilities of each of the Scheduling Committees as outlined in the table on pp6 and 7 of the Policy Framework. ACCORD is concerned with the emphasis of scheduling a new substance that may meet the criteria for inclusion in Schedule 7. ACCORD did not accept the NCCTG's proposal for automatic default to Schedule 7 for all chemicals in their first assessment as outlined in the 2005 consultation paper and we do not support the inference that Schedule 9 will be the commencement for consideration of scheduling for new chemicals now. Further, we note that in Chapter 3 it is now proposed that … *For poisons, a substance is first assessed using factors for Schedule 9(p19).*

This principle of starting at the highest scheduling level is contrary to the COAG Principle to minimise the impact of regulation - ' '*Working from an initial presumption against new of increased regulation, the overall goal is the effective enforcement of stated objectives. Regulatory measures and instruments should be the minimum required to achieve the pre-determined and desirable outcomes.*'

On the basis of the COAG Principles, the starting point for consideration of a scheduling classification should be 'unscheduled' and if proven that scheduling is required, the first consideration should be classification against Schedule 5 criteria. Rather than the adoption of the proposed 'cascading principle', the 'escalating' principle should be put in place.

In considering harmonisation of scheduling decisions, the NCCTG has already adopted the following practice for trans-Tasman harmonisation of scheduling that '*where differences in scheduling exist between Australia and New Zealand that the underlying principle is to harmonise on the less restrictive schedule while giving due consideration to public health and safety issues and/or specific jurisdictional needs*'. Given the current practice by the NDPSC to harmonise on the less restrictive schedule, we do not understand why the Scheduling Committees would automatically default to the highest schedule.

Membership
ACCORD has reservations about the appointment process of experts to the proposed Chemicals' Scheduling Expert Advisory Committee and in particular the rather novel concept of *two classes of experts*. In line with the PC's original observation regarding an expert decision making process, while ACCORD supports the Secretary of the Department as the decision maker, we nonetheless consider that the Delegate should be informed by an expert advisory body which is independent of jurisdictional interest. We note that the current proposal for eleven but not more than fifteen members, once the jurisdictions are taken into account, the regulators given a role the opportunity for experts such as toxicologists, clinical child health experts, industry and consumer to participate is extremely limited. It is difficult to justify the Committee as expert when in fact a prerequisite for membership is jurisdictional representation.

Voting
The quorum for meetings requires further defining as two thirds of committee members under the current proposal could represent the jurisdictions only. The quorum should be proportionally based to ensure all interests are represented.

Secretariat

We note the proposed move of the Secretariat to the TGA. To date, the Secretariat has worked efficiently within the OCSEH and we are unsure as to why a move is necessary. The OCSEH could put in place a service level agreement with the TGA regarding fees and charges for work in relation to medicines scheduling. Maintenance of the status quo with regard to the placement of the Secretariat in the OCSEH could provide additional confidence and clarity to the chemical industry regarding the relevance and independence of its operations.

Chapter 3 Classification of medicines and poisons – general

ACCORD notes the concept of including consideration of a standardised set of factors rather than criteria. We do not oppose this approach in principle. However, we do not support the automatic default to Schedule 9 for poisons as we have already outlined earlier in our submission.

Principles of Scheduling
We note that the Principles indicate that Schedules 5 and 6 can be applied to medicinal substances intended for human therapeutic use (p18). ACCORD is under the impression that this practice has been recently changed and that all medicines which had been Scheduled 5 and 6 have been rescheduled to Schedule 2. We seek clarification on this point.

Chapter 4: The scheduling factors

Without complete separation of the medicines and chemicals schedules, intended scheduling of medicines can inadvertently capture chemicals with legitimate industrial uses. The most recent example of this is guanidine, where the Schedule 4 entry of guanidine had always prevented the use of guanidine salts in hair and skin care products. Guanidine carbonate is a commonly used salt in hair straightening treatments. This inadvertent ban of guanidine in cosmetic ingredients has only been addressed recently, although guanidine containing products have been available in other economies such as the EU for years.

The OCSEH has recently completed its consultation on a discussion paper on the adoption of GHS for domestic and consumer chemicals. Within the discussion paper, there was an extensive analysis of the health hazard classification criteria. We would support waiting for the final outcome of the consultation before making decisions on the proposed factors for scheduling products. This would allow clear communication of the risk assessment process, based on a published set of classification criteria. We note that points 1 and 2 of the proposed factors for Schedule 5, 6 and 7 all relate to classification criteria.

The factors that must be considered for scheduling should be divided into classification factors and risk-assessment factors. With the proposed "cascade down" scheduling principle starting from Schedule 7 and the literal reading of the proposed factors for schedule 5, we believe most, if not all chemicals will be at least Schedule 5.

Chapter 5: Guidelines for application and information requirements

We note that the proposal for scheduling and rescheduling decisions is largely based on existing processes. However, with regard to the request for advice to NICNAS by the Department, we assume that this will be on a fee for service basis and that NICNAS will recover costs from the Department for this technical expertise.

Chapter 6: Guidelines for public consultation – general

ACCORD does not support that all scheduling information be published on the TGA website. For medicines matters this is quite appropriate but consumer chemicals information should be published on the Department's website though the OCSEH. This re-enforces the distinct separation of the two processes and the differences between medicines and consumer chemicals.

While the public consultation guidelines appear to reflect current practices we believe that the process needs to be made transparent for all stakeholders including the general public. We are uncertain as to what is meant by the statement … *Provided that a submission is* ***directly relevance*** *to the matter for consideration.* We assume that guidance will be provided around what is meant by directly relevant.

With regard to new substances ACCORD does not have any in-principle disagreement with the approach proposed apart from the issue already raised in relation to new industrial chemicals. However, we believe mechanisms exist which can provide the flexibility to improve the timeliness for scheduling of new substances while also ensuring that all relevant stakeholders are engaged in the process.

ATTACHMENT B

Specific comments on the NCCTG consultation document Standard for the Uniform *Scheduling of Medicines and Poisons.*

General Comments

ACCORD has already advised that we would prefer to see two Schedules as part of the reform process with a clear distinction for chemical products to that of medicines as well renaming the SUSMP to the Standard for the Uniform Scheduling of Medicines and Chemicals.

We are very disappointed with what appears to be a poor review in the first instance of a revised Schedule. There are many inconsistencies in terminology throughout the document, for example the term *drug* continues to be used and *poisons* is used inconsistently. We recommend that *poisons* be replaced by the term *substance* and/or *chemical* throughout the document.

Specific Comments

Introduction

We do not support the term *unregistered poison* as this implies that there are no controls for these substances particularly for chemical products which are subject to the industrial chemicals regulatory framework, trade practices and product liability provisions therein, ingredient disclosure where relevant as well as a range of other legislative requirements including scheduling. The term unregistered poisons diminishes the importance of the numerous regulatory controls exerted by other Commonwealth, state and territory legislation to manage the risks of these products within a risk management framework. To apply the term unregistered poisons implies that the NCCTG is unaware of this extensive range of controls for products which are not necessarily subject to a product registration scheme.

Further, the reference to requirements for labelling of containers as outlined on p6 for Schedule 5 & 6 products should be removed as there is a clear distinction between workplace and consumer controls and the reference in the SUSMP only serves to create confusion rather than clarity regarding existing control measures.

In another example under labelling requirements, Schedule 5 & 6 chemical products are not subject to the labelling requirements for containers and other controls as outlined on p4. In our comments on Chapter 3, Principles of Scheduling we have sought clarification regarding Schedule 5 & 6 therapeutic goods reclassified to Schedule 3 medicines. We have sought clarification on this point.

Classification

ACCORD has already outlined our concerns with the labelling classification and criteria in ATTACHMENT A of this document.

Part 2 – Labels and Containers

Addition of new provisions 13A

ACCORD suggests extending the labelling exemption in (2) to apply to packaging as well as the labelling provisions as outlined in the Table of Changes from SUSDP to SUSMP p7.

Attachment 6

Extract from Department of Health and Ageing's Annual Regulatory Plan 2007-08

Title	**Legislative change to implement a revised scheduling framework**
Description of issue	Changes are required to the *Therapeutic Goods Act 1989* and the *Therapeutic Goods Regulations 1990* to implement one of the recommendations of the *National Competition Policy Review of Drugs and Poisons and Controlled Substances Legislation* (the 'Galbally Review'), namely that the National Drugs and Poisons Schedule Committee be disbanded and replaced with two separate committees – the Medicines Scheduling Committee and the Chemicals Scheduling Committee.
Consultation opportunities	The proposed scheduling model was developed in close consultation with the National Coordinating Committee on Therapeutic Goods. Widespread consultation on the proposed scheduling model occurred with face-to-face stakeholder meetings in August 2005 and in November 2006 (medicines only) following the release of the relevant draft Australia New Zealand Therapeutic Products Regulatory Scheme legislation. Stakeholder consultation on other aspects of the proposed scheduling model including the *Standard for the Uniform Scheduling of Medicines and Poisons* and the Scheduling Policy Framework has also occurred.
Expected timetable	It was intended to implement the proposed scheduling arrangements with the commencement of the trans-Tasman therapeutic products regulatory scheme. Due to the decision in July 2007 to postpone negotiations on the establishment of the trans-Tasman therapeutic products regulatory scheme, work to adapt the scheduling framework in Australia is being reviewed.
Contact details	Mick O'Connor Executive Support Therapeutic Goods Administration Ph: (02) 6232 8197 Email: mick.o'connor@tga.gov.au
Date last modified	July 2008

Title	**National Health Amendment (Pharmaceutical and Other Benefits – Cost Recovery) Bill 2007**
Description of issue	The amendments in this Bill are required to implement a 2008-09 Budget measure for cost recovery of processes relating to evaluating and pricing medicines, vaccines and other products for listing on the Pharmaceutical Benefits Scheme and National Immunisation Programme. Fees will be charged to sponsors (generally, the pharmaceutical industry) who bring submissions for listing products to the Pharmaceutical Benefits Advisory Committee for consideration. Details of the cost recovery scheme, including a schedule of fees, will be specified in regulations.
Consultation opportunities	Rounds of consultation with the pharmaceutical industry and other key stakeholders occurred in November 2005, June 2006 and May 2007. Further consultations occurred following the announcement of this measure in the 2008 Budget and will continue prior to implementation. The Department has established an ongoing consultative forum on cost recovery with Medicines Australia and Generic Medicines Industry Australia.
Expected timetable	The Bill is before Parliament. On 18 June 2008, the Senate voted to refer the Bill to the Senate Community Affairs Committee for an inquiry, to report 'not before' 18 August 2008. Commencement of fees is subject to Parliamentary approval.
Contact details	Diana MacDonell Pharmaceutical Evaluation Branch Department of Health and Ageing Ph: (02) 6289 7085 Email: diana.macdonell@health.gov.au
Date last modified	3 July 2008

Attachment 7

Joint industry letter to then Prime Minister Howard

"Business Regulation Reform - a nationally integrated chemical control framework"
19 April 2005

The Hon John Howard, MP
Prime Minister
House of Representatives
Parliament House
CANBERRA ACT 2600

Facsimile 026273 4100 (2 pages)

Dear Prime Minister

Business Regulation Reform – a nationally integrated chemical control framework

As the major industry associations representing the industrial, agricultural, domestic and specialty chemicals and paint industries, we are writing to you about a regulatory reform priority for the nation's $24B chemicals industry. This industry is vital to Australia's international competitiveness in a range of sectors from agriculture to minerals to manufacturing, and to the health and wellbeing of all Australians.

Industry has valued the opportunity to work closely with your Government through Minister Macfarlane and his colleagues on the development of the Chemicals and Plastics Industry Action Agenda. We particularly welcomed the decision in this year's Budget to remove the 3% duty on tariff concession orders. We also welcome the in-principle support for a comprehensive review by the Productivity Commission of the regulatory frameworks governing the chemicals sector and we await with great anticipation your Government's formal response to the Final Report of the Chemicals and Plastics Leadership Group.

Given this positive experience to date, the industry is concerned that a short-term decision about regulatory frameworks arising from the Galbally Review may undermine the potential for Australia to achieve more efficient, effective and integrated regulatory controls for chemicals.

On 31 May 2005 we wrote to you and other members of the Council of Australian Governments (COAG) urging your earliest sign-off regarding the recommendations contained in the Galbally Review, specifically in regard to Recommendation 7 and the separation of medicines and chemicals scheduling. We also sought COAG's agreement to instruct Health Ministers to consult and engage with the chemicals industry in the development of any revised scheduling system.

As a consequence of COAG's positive intervention, the chemical industry has now been engaged in consultations with the National Co-ordinating Committee on Therapeutic Products (NCCTG) and the Joint Agency Establishment Group (JAEG) within the Therapeutic Goods Administration (TGA).

The chemical industry is concerned about the model being proposed under the Joint trans-Tasman Therapeutic Products Agency. We would like to see the development of the best model which will serve Australia's needs now and into the future. We do not see how the Australian chemical industry or the regulation thereof will benefit from decisions regarding the scheduling of chemicals being made by a bi-national medicines and medical devices agency.

The implementation of the Galbally Recommendation 7 regarding the separation of scheduling of medicines and chemicals provides an excellent opportunity to look at how best to develop an improved integrated chemical management framework for Australia. This cannot be achieved by placing Australia's premier chemicals regulator, the National Industrial Chemicals Notification and

Assessment Scheme (NICNAS) and the Office of Chemical Safety (OCS) within the auspices of the Joint trans-Tasman Therapeutic Products Agency.

The industry believes a more integrated chemical control framework still within the aegis of the Department of Health and Ageing (but separate from a Joint trans-Tasman Therapeutic Products Agency) will not only deliver a streamlined mechanism for the assessment and scheduling of chemicals in Australia, but could also provide an improved approach to the management of chemicals of interest from a national security perspective and/or illicit diversion.

We believe that this approach would deliver at a national and strategic level, enhanced policy development, and more efficient, effective and streamlined regulatory controls.

The chemicals industry will continue to work with the NCCTG and the Department of Health and Ageing on the development of a chemical scheduling framework which meets the needs of the states and territories and industry, but importantly, one that does not inhibit future reform to enable the development of a proper integrated chemical control framework for Australia.

We believe this can be achieved with the OCS, NICNAS and chemicals scheduling legislation being sited outside the Joint trans-Tasman Therapeutic Products Agency and within the aegis the Department of Health and Ageing.

We seek your support in pursuing this approach and indeed continuing the momentum for responsible regulatory reform initiated by your Government through the Chemicals and Plastics Industry Action Agenda.

Yours sincerely

Bronwyn Capanna
Executive Director
ACCORD

Michael Hambrook
Executive Director
APMF

Claude Gauchat
Executive Director
Avcare

Michael Catchpole
Chief Executive
PACIA

19 August 2005

Attachment 8

Extract from recent CHOICE magazine article
on cosmetics safety

Focus chemicals and where you'll find them

As a starting point, we used a database compiled by the US-based Environmental Working Group (EWG) which uses government databases and peer-reviewed literature to assess more than 8000 ingredients and 40,000 products for safety. Ingredients are rated from one to 10, where one is low hazard and 10 is high-hazard. Most of the substances we looked at are rated 10 out of 10. Others are included because they have been banned in certain countries. After identifying brands and products known to contain these chemicals, we hit the shops.

On the upside, we found many of the major international brands no longer contain any of the more dubious ingredients – formulations have changed since the EWG database was last updated. In the globalised marketplace, there's little sense in producing different formulations such that a banned or restricted chemical is used in products to be sold in countries that allow it, but not others. As a result, the once-common dibutyl phthalate, toluene, butylated hydroxyanisole and petroleum distillates have all but disappeared from big brand nail polishes, lipsticks and mascaras.

However, beyond these international brands the findings were less reassuring. As well as supermarkets, department stores and chemists, we looked in ethnic grocers and two-dollar shops and found examples of cosmetics made in Australia, Asia and the Middle East that contain chemicals banned or restricted elsewhere. Of concern, too, was the number of products without ingredients listed, particularly skin whiteners, henna for tattoos and certain eye make-up products that are sometimes found to contain heavy metals (lead and mercury) or other problem chemicals.

Did you know

Labelling laws All cosmetic products must be labelled with ingredients so consumers can check for allergens or other ingredients to which they may react. The listing must appear either on the product packaging, or on pamphlets or display panels near the product at point of sale. Premium products often come with lots of packaging, so labelling is fairly straightforward. Cheaper products available in supermarkets are usually blister-packed on cardboard, which allows room for ingredient information. In chain department stores such as Target, Kmart and Priceline, where products are sold without additional packaging, you'll find pamphlets or cards listing ingredients near the products. It's difficult, for example, to legibly print all the ingredients onto a tube of lipstick). In bargain stores and two-dollar shops, you may not always find any sort of labelling at all.

Who regulates cosmetics?

Cosmetics sold in Australia are regulated by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), a division of the Department of Health and Ageing. Its role is to assess the safety of chemicals new to Australia and existing chemicals if reason for concern arises. Anyone importing or manufacturing cosmetic ingredients or products must be registered with NICNAS. Products must comply with certain legislative requirements, including labelling of ingredients, which is overseen by the Australian Competition & Consumer Commission (see Did You Know?, below).

International bodies with a say in cosmetics formulation and regulation include the **Cosmetic Ingredient Review (CIR)**, a US-based panel that reviews and assesses cosmetic ingredients and publishes the findings in peer-reviewed scientific literature. It's supported by the Food and Drug Administration and funded by industry, but has no regulatory clout. California has a law, **Proposition 65**, under which known carcinogens and other dangerous substances must be listed on products containing them, along with a warning label, making them rather unattractive for consumers. Cosmetics in Europe must comply with the **Cosmetics Directive**, overseen by a panel of independent experts. **Health Canada** publishes a hotlist of ingredients that are banned or restricted in cosmetics. The Ministry of Health and Welfare in Japan has established the **Standards for Cosmetics**, which lists banned and restricted ingredients.

Putting chemicals in perspective

Almost all cancers can be attributed to known carcinogens and carcinogenic lifestyles, such as tobacco, alcohol, sun, excessive red and processed meats, lack of fruit and vegetables, obesity, bacteria, viruses and lack of exercise.

Yet with so many people getting cancer these days, not to mention the apparent increase in fertility problems, allergies, attention deficit hyperactivity disorder, chronic fatigue syndrome and other modern-day maladies, you can't help but wonder about man-made chemicals in our food. >

Many chemicals used in cosmetics can be dangerous under certain conditions, which is why it's important to put them in perspective.

Nail hardeners
Some contain dibutyl phthalate (DBP) – banned in Europe as an endocrine disrupting chemical.

Nail polish
Some contain toluene – considered unsafe for use in cosmetics by the International Fragrance Association, because of its liver toxicity risk.