ACCORD

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

ACCORD Supplementary Submission, including independent legal opinion on aspects of the Bill

As a follow-up to our appearance at Committee hearings on this Bill on 8 July, ACCORD Australasia is pleased to provide some supplementary information, including a copy of the independent legal opinion referred in our testimony.

This advice has been obtained from constitutional legal specialist, Mr Ian Cunliffe. Mr Cunliffe's opinion and curriculum vitae are provided as Attachment 1.

This legal opinion supports the general concerns held by our industry with regard to the Bill. Four key conclusions it makes, which we draw to the Committee's attention, are *(our underlining below)*:

1) Extending the reach of the *Therapeutic Goods Act* to chemicals regulation will only exacerbate inherent weaknesses in the constitutional underpinnings of this Act.

2) *"...in light of reasons articulated by the High Court this month in* Pape v Commissioner of Taxation*...it is doubted whether provisions establishing the Advisory Committee on Chemicals Scheduling and empowering the Secretary of the Commonwealth Department of Health and Ageing to create a Schedule of Chemical Substances are Constitutionally valid."*

3) *"The Bill would apparently achieve a scheme for the regulation of chemicals across Australia including implementing industry cost-recovery arrangements. Most of this is invisible in the Bill itself. The substance is apparently to be supplied by a combination of regulations, by State and Territory laws and by extension of existing provisions of the TG Act to the new field of general chemical regulation. While that is (subject to what I have said above) probably lawful, its appropriateness as a legislative technique is doubtful."*

4) *"As ACCORD has submitted, it is not clear at all from the Bill how industry cost-recovery arrangements would be established under the Bill. (Undesirably) in relation to therapeutic goods, cost-recovery arrangements are largely the creation of the TG Regulations...However the therapeutic goods regulatory regime is characterised by requirements that products be registered or listed. Charges are imposed by reference to registration/listing - either initial or continuing. That will presumably not be the case with chemicals - or will it? Has anybody thought it through? If so, why has the proposed approach not been articulated? Or will it be done by regulations devised subsequent to passage of the Bill?"*

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All of the above reinforces our industry's primary policy concerns that the arrangements put in place by this Bill, in relation to *chemicals scheduling*, are inappropriate and represent a retrograde step in terms of the overarching COAG policy goal of creating a more efficient, nationally integrated chemicals regulation system.

The legal opinion highlights potentially significant problems with the implementation of any proposed cost-recovery arrangements.

Namely, that the present system of cost-recovery for therapeutic goods, relies on regulatory definitions, rules and coverage that do not apply under separate Australian law for chemical ingredients.

To elaborate on this further. Chemical ingredients are primarily regulated via the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) under the *Industrial Chemicals (Notification and Assessment) Act 1989.*

The regulatory definitions and rules under the INCA Act adopt a very different framework and approach to those of the *Therapeutic Goods (Charges) Regulations 1990.*

Given this situation, ACCORD doubts that any workable system of TGA cost-recovery for *chemicals scheduling* would be able to be legally underpinned, without resorting to administratively nonsensical approaches, such as having TG regulations pretend that 'chemicals' are 'therapeutic goods', just so that charges can be levied.

It remains our firm hope that band-aid regulatory "fixes" like this are not what the Therapeutic Goods Administration has in mind.

However, in the absence of any details on proposed cost-recovery arrangements, industry continues to remain in the dark on this important matter.

In conclusion, Mr Cunliffe's legal opinion adds further weight to ACCORD's core positions on this Bill.

That is, the arrangements the Bill puts in place for *chemicals scheduling* should be seen only as *interim measures* that are subject to review two years after commencement, as recommended by the Productivity Commission in its 2008 *Chemicals and Plastics Regulation Research Report.*

And that these *interim measures* be eventually replaced by more appropriate federally controlled arrangements, outside the control of the Therapeutic Goods Administration, but still within the Health Department portfolio, in order to better integrate *chemicals scheduling* within a more efficient, nationally integrated system of chemicals regulation.

Arising from our appearance at the Committee hearing on 8 July, there were a small number of additional issues that this supplementary submission will also address.

A question was asked of one of the other industry groups at the hearing regarding the volume of scheduling decision work that currently relates to chemicals, as opposed to medicines.

The answer to this can be found in one of the attachments to ACCORD's previous submission (Attachment 5, pg 6) in the following section, which discusses an assessment recently undertaken by ACCORD staff:

> *"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 substances 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."*

On this basis, these 2008 figures indicate a percentage split of 46 percent medicines, 29 percent agvet chemicals under the control of the Australian Pesticide and Veterinary Medicines Authority (APVMA) and 25 percent other categories of chemicals.

It was also suggested that ACCORD look at the detail of Department of Health and Ageing's submission (which was presented to the Committee by officers of the Therapeutic Goods Administration*).

As stated in our testimony, given the short time that this was available to us, we were not in a position to respond to this on the day of the hearing.

We note the DoHA (TGA) comments under section 2.4 of their submission. But we feel they reflect the 'take it or leave it' attitude commented on in the testimony of one of the other industry groups at the 8 July Hearing.

ACCORD is not disputing what DoHA (TGA) describes as the position of state and territory governments on this matter when it states in its submission "*this approach would be unacceptable to the states and territories*" and "*the states and territories have made it clear through the NCCTG that the single scheduling standard must be retained...*".

Whilst we view such intransigent demands to maintain *status quo* or follow a path of least effort as unhelpful for improving national productivity, they unfortunately do not surprise us.

This does, however, raise an important question. Is DoHA (TGA) a national policy player, in the sense of having a role in developing policy options and trying to bring about arrangements that reflect the Australian Government's policy direction on issues relating to regulatory best practice?

Or is DoHA (TGA) just there to act as a central facilitator to obtain state and territory government input and then to eventually mouthpiece that there is only one feasible option because the 'states want it this way'? *Disappointing*, is the only word to correctly describe this type of federal policy engagement.

The DoHA (TGA) submission's comments relating to ACCORD's position also do not reflect the actual positions put in our 29 May 2009 submission to the TGA/NCCTG public consultation process.

While we have consistently argued for our preferred position of separate legislation for *chemicals scheduling*, we have also proposed administrative alternatives to achieve the policy goal for a more workable separation. These are as follows. They illustrate our industry's pragmatic, flexible approach to providing policy inputs to Australia's governments:

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* *As an aside, the fact that TGA officers who work for a 100% industry cost-recovered regulatory agency are developing, delivering and presenting on what should instead be a Departmental policy responsibility is a concern in itself in terms of best practice governance arrangements implemented since the Uhrig report. Industry would have much more confidence in the quality of policy processes on issues like this if a Department that reports directly in an advisory capacity to the Government via a Minister were undertaking the policy development work. As a contrasting analogy, the federal Treasurer generally charges his department, Treasury, with the task of bringing forward policy proposals and Bills, not the Australian Competition & Consumer Commission nor the Australian Taxation Office.*

"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"*

The DoHA (TGA) submission also, in our view, skips over the foundations of the Productivity Commission's recommendations on scheduling and some of the reservations the Commission raised about the NCCTG/AHMAC proposals which this Bill takes forward.

The relevant sections of the Productivity Commission's report are provided as Attachment 2 for the Committee's reference.

During the hearing we were also prompted to consider the drafting instruction proposals put forward by the non-prescription medicines industry association, ASMI.

For the most part these appear to be targeted at improving the accountability and transparency of the operation of the scheduling committees. On this basis, the suggestions relating to this aspect would be supported by ACCORD, noting though, that they do not implement our primary recommendation for this Bill. Namely, the establishment of a 2-year review period and the eventual implementation of more appropriate, separate arrangements for *chemicals scheduling.*

We also note that ASMI is proposing a new system of 'data exclusivity' for cases where the applicant certifies that their application for scheduling is 'commercial-in-confidence'. In our testimony we indicated that such as measure may not be appropriate for chemical substances nor fit readily with the ingredient-based chemical regulatory system, as fast-moving consumer goods tend to rely on other forms of intellectual property such as trademarks and brand recognition.

While this proposal has merit for medicines from both and industry and public interest perspective, its implications also need to be considered for chemicals in light of the fact that NICNAS legislation (INCA Act 1989) for the introduction of new chemical ingredients already contains some provisions for confidential listing on the Australian Inventory of Chemical Substances (AICS).

'Data exclusivity' also already exists for agvet chemical active ingredients (which are also subject to *chemicals scheduling*) under the extensive and separate legislative scheme for this category of substance.

The interaction of these existing chemical regulation requirements with any proposal for 'data exclusivity' for scheduling requires investigation and again highlights significant policy flaws in the

proposal not to formally split *chemicals scheduling* from medicines scheduling via separate legislative or administrative arrangements.

This is not to say that ACCORD opposes the concept of 'data exclusivity' for *chemicals scheduling*. But instead to highlight the importance of making sure that scheduling arrangements are properly integrated with the extensive chemicals regulation system already in place. And that this is something this Bill fails to do.

Our final statement in this supplementary submission relates to unresolved concerns regarding lack of accountability for problems arising from the absence of national harmonisation in retail storage requirements for products classified as Schedule 5 and 6 poisons.

Differences in state/territory storage requirements were raised in our testimony and also in response statements by witnesses appearing for DoHA (TGA).

ACCORD recently attempted to raise this matter with the NCCTG (National Coordinating Committee on Therapeutic Goods) following publication in the February 2009 National Drugs and Poisons Schedule Committee Record of Reasons that some jurisdictions were unwilling to amend their current regulations to adopt, reference or recognise the "Draft Code of Practice for National Retail Storage of Schedule 5 and Schedule 6 Products".

Our 26 May letter to NCCTG, the reply received (2 June) and our subsequent ACCORD response (11 June) are included as Attachment 3.

This correspondence chain highlights the major difficulties the chemicals industry faces in gaining traction for ownership of, and action on, problems arising within the existing scheduling system, under the aegis of the Therapeutic Goods Administration.

It is also highly relevant to the arrangements to be put in place by this Bill, as the National Coordinating Committee on Therapeutic Goods (NCCTG) is apparently the decision-making body that will sign off on the regulations following passage of this Bill. ACCORD notes that testimony from another industry body witness at the hearing described NCCTG as a *"...non-accountable committee of officials meeting in secret..."*.

How can industry, the Parliament or the Government have any confidence in the accountability and performance of this body, when it appears there is even confusion over its terms of reference and its roles and responsibilities in relation to scheduling?

Yours sincerely

Bronwyn Capanna
Executive Director, ACCORD Australasia

21 July 2009

cc. Craig Brock, Policy & Public Affairs Director, ACCORD Australasia

ATTACHMENT 1

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Therapeutic Goods Amendment (2009 Measures No.2) Bill 2009

Dear Ms Capanna

You have sought my advice about the *Therapeutic Goods Amendment (2009 Measures No.2) Bill 2009* (**the Bill**) in the context of ACCORD's Submission to the Senate Community Affairs Committee's inquiry into the Bill.

I consider that there are serious problems with the Bill.

The Bill would amend the *Therapeutic Goods Act 1989* (Cth) (the **TG Act**).

Constitutional issues

The Constitutional underpinnings of the TG Act even without the amendments which the Bill would make are problematic. That is a concern, given the importance of the TG Act in the public health administration of Australia. The Bill would extend the TG Act into the realm of regulation of chemicals in a non-medicines context.

The Australian Constitution does not give the Commonwealth Parliament power to make laws with respect to chemicals. Section 6 of the TG Act gives the Act operation in various realms of undoubted Commonwealth legislative competence: things done by corporations; activities in relation to overseas or interstate trade or commerce; under a law of the Commonwealth for pharmaceutical or repatriation benefits; and in relation to the Commonwealth or a Commonwealth authority.

The TG Act does not call in aid other possible realms of Commonwealth legislative competence including the power of the Commonwealth Parliament to make laws under the nationhood power – see for example *Davis v The Commonwealth*[1]. The nature of and likely

[1] (1988) 166 CLR 79.

limits of that power are analysed in Professor Leslie Zines *The High Court and the Constitution*[2].

Most people who refer to the TG Act – including most people who might be involved in the therapeutic goods industry - would not appreciate the limitations to things done by corporations; activities in relation to overseas or interstate trade or commerce; under a law of the Commonwealth for pharmaceutical or repatriation benefits; and in relation to the Commonwealth or a Commonwealth authority. For example, the teeth of the TG Act are in provisions which are expressed to forbid "persons" doing various things[3]. There is no hint of Constitutional limitations in those provisions[4].

The reality is that many activities in relation to therapeutic goods are not caught by the TG Act by reason of those limitations – for example things done by natural persons in intrastate trade.

Extending the reach of the TG Act to the regulation of chemicals generally will exacerbate that problem.

Schedule 1 of the Bill concerns Scheduling of substances. Schedule 1 would establish an Advisory Committee on Chemicals Scheduling[5]. That Committee would make recommendations to the Secretary of the Commonwealth Department of Heath and Ageing in relation to the classification and scheduling of chemical substances[6]. The Secretary – or a delegate[7] - would either amend the current Poisons Schedule[8] or make a new Chemicals Schedule[9]. Those schedules would be given legal force and teeth by the States and Territories.

Especially in light of the reasons articulated by the High Court this month in *Pape v Commissioner of Taxation*[10] about the limitations on the executive power of the Commonwealth it is to be doubted whether the provisions establishing the Advisory Committee on Chemicals Scheduling and empowering the Secretary of the Commonwealth

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[2] 5th edition 2008, at pages 410-417.

[3] For example, s20A.

[4] In contrast for example to s52(1) of the *Trade Practices Act 1974* (Cth) (TPA): "A corporation shall not, in trade or commerce, engage in conduct that is misleading or deceptive or is likely to mislead or deceive." (Section 6 of the TPA gives s52 additional realms of operation – for example in the Territories and in relation to dealings with the Commonwealth).

[5] Proposed s52C.

[6] Proposed s52C(4)(a).

[7] TG Act s57.

[8] Proposed s52D(2)(a).

[9] Proposed s52D(2)(b).

[10] 2009 HCA 23 (7 July 2009). See in particular the judgements of Chief Justice French at paragraphs 96 and 127 and of Justices Gummow, Crennan and Bell at paragraphs 214, 220 and 239.

Department of Heath and Ageing to create a Schedule of Chemical Substances are Constitutionally valid.

As noted above, the TG Act does not call in aid the power of the Commonwealth Parliament to make laws under the nationhood power. The secondary materials to the Bill suggest that the Bill's rationale is that, as the national government, it is appropriate and arguably necessary for the Commonwealth to take the lead in regulation of chemicals. I consider however that the nationhood power will not stretch so far.

I consider that the views expressed in the *Pape* case about what might conveniently be called the implied national power aspect of the executive power in the Constitution[11] are apt also in relation to the extent of, and the limitations to, the legislative power of the Commonwealth Parliament with respect to the implied national power[12].

In the *Pape* case, Chief Justice French referred with approval to the view that under the executive power, the Commonwealth Government could no doubt undertake activities appropriate to a national government. However he referred to "the necessary qualification that the executive power could not, in this way, be given a wide operation effecting a radical transformation in what had hitherto been thought to be the Commonwealth's area of responsibility under the Constitution[13].

Likewise in the *Pape* case, Justices Gummow, Crennan and Bell quoted[14] with apparent approval remarks by Chief Justice Mason and Justices Deane and Gaudron in *Davis v The Commonwealth*[15] that:

> "[T]he existence of Commonwealth executive power in areas beyond the express grants of legislative power will ordinarily be clearest where Commonwealth executive or legislative action involves no real competition with State executive or legislative competence."[16]

Justices Gummow, Crennan and Bell likewise quoted[17] with apparent approval remarks by Justice Brennan in the same case, that determination of whether an enterprise or activity lies within the executive power of the Commonwealth:

> "... invites consideration of the sufficiency of the powers of the States to engage effectively in the enterprise or activity in question and of the need for national action

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[11] See in particular s61 of the Constitution.

[12] References are made to the interrelationship of executive power in the Constitution and the national power in Professor Leslie Zines *The High Court and the Constitution* 5th edition 2008, at page 416 and page 417.

[13] At paragraphs 96.

[14] At paragraph 239.

[15] (1988) 166 CLR 79.

[16] (1988) 166 CLR 79 at 93-94.

[17] At paragraph 239.

(whether unilateral or in co-operation with the States) to secure the contemplated benefit."[18]

Derogation from the Parliament

It might seem remarkable that a Bill as concise as the *Therapeutic Goods Amendment (2009 Measures No.2) Bill 2009* could achieve so much. The Bill would apparently achieve a scheme for the regulation of all chemicals across Australia, including implementing industry cost-recovery arrangements. Most of this is invisible in the Bill itself. The substance is apparently to be supplied by a combination of regulations, by State and Territory laws and by the extension of existing provisions of the TG Act to the new field of general chemical regulation. While that is (subject to what I have said above) probably lawful, its appropriateness as a legislative technique is questionable.

There are a number of reasons why I consider its appropriateness doubtful.

I consider that it is generally undesirable for the Parliament to delegate so much of the substance of law making to regulations, which tend to be less carefully scrutinised than primary legislation.

Most of the TG Act and the various Therapeutic Goods Regulations (the **TG Regulations**) apply only to therapeutic goods. Those provisions will not apply to chemicals which are not therapeutic goods. However a few provisions of the TG Act and the various TG Regulations are expressed in such a way as to apply to chemicals which are not to therapeutic goods. Some at least of those other provisions will not translate very appropriately to the regulation of chemicals which are not therapeutic goods. Examples of that are various parts of the power in the TG Act – s 57 - of the Minister and the Secretary to delegate. Section 57 makes numerous references to therapeutic goods. Those references will not confer the power to delegate in respect of chemicals which are not therapeutic goods. However some aspects of s57 are not confined to therapeutic goods.

Of particular concern is the very broad power to make regulations which is in the TG Act[19]. Although it is not clear from reading the very concise Bill, it will give the executive power to make regulations about chemicals generally. The Bill will permit regulations "convenient to be prescribed for carrying out or giving effect to this Act"[20] in relation to chemicals which are not therapeutic goods. That is a very, very broad power. The Bill will permit regulations specifically which prescribe fees[21]; and which prescribe penalties[22]. How are these powers intended to be used?

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[18] (1988) 166 CLR 79 at 111.

[19] Section 63.

[20] Section 63(1)(b).

[21] Section 63(2)(h).

[22] Section 63(2)(j).

One of the consequences of the legislative approach which the Bill takes is to create the potential to enormously expand the regulatory overburden on the chemicals industry. Is that what the Parliament intends? For example if the Bill is passed, regulations could arguably be made[23] giving officials in the Commonwealth Department of Health and Ageing the power to ban the import and export of all manner of chemicals including chemicals about which there is no health issue[24].

How will industry cost-recovery work?

An example of the wider issue whether the scheme for regulation of therapeutic goods is appropriate for the general regulation of chemicals is the critical, central issue of industry cost-recovery.

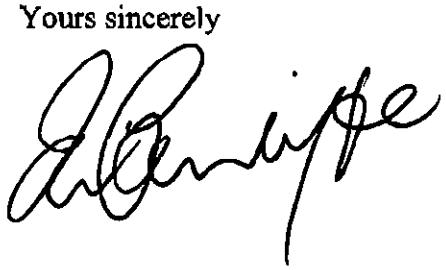
As ACCORD has submitted, it is not at all clear from the Bill how industry cost-recovery arrangements would be established under the Bill. (Undesirably) in relation to therapeutic goods, cost-recovery arrangements are largely the creation of the TG Regulations – specifically of the *Therapeutic Goods (Charges) Regulations 1990*. However the therapeutic goods regulatory regime is characterised by requirements that products be registered or listed. Charges are imposed by reference to registration/listing – either initial or continuing. That will presumably not be the case with chemicals – or will it? Has anybody thought it through? If so, why has the proposed approach not been articulated? Or will it be done by regulations devised subsequent to passage of the Bill?

Who looks for chemical regulation in the TG Act?

I do not doubt that the Commonwealth Parliament is competent, for example, to insert a provision about lighthouses in an Act about postal services; or to insert a provision about railway construction in an Act about copyright. Likewise, subject to what I have said above, I do not doubt that the Commonwealth Parliament is competent to insert provisions about chemical scheduling in an Act about therapeutic goods.

However, there are good reasons why the Parliament should not do so. Who looks for the dos and don'ts of lighthouse regulation in an Act about postal services or aliens?

Yours sincerely



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[23] Under the regulation making power in the TG Act s63(1)(b).

[24] cf TG Act s63(3A) which relates specifically to therapeutic goods.

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On graduation from ANU, Ian was awarded the University's top undergraduate prize, the Tillyard Prize. It is awarded to a student in any faculty graduating with honours who has made the most outstanding contribution to University life. At ANU, Ian was on the Federal Law Review editorial board for four years, and was its editor in 1970.

In 1971, Ian was the associate to Sir Cyril Walsh of the High Court.

In 1972, he did articles at Allen Allen and Hemsley.

In early 1975, Ian was invited to join the secretariat of the Royal Commission on Intelligence and Security, conducted by Justice Hope as its lawyer. He was subsequently elevated to deputy secretary.

Ian then spent nearly a year in the federal Attorney General's Department, working on what was to become the so-called new administrative law package.

After the Hilton Bombing, Justice Hope conducted a further inquiry – the Protective Security Review - into Australia's counter terrorism machinery, laws and policies. He asked Ian to be its deputy secretary.

After the Protective Security Review, Ian headed the Administrative Law Section and then the Legal Section in the Department of Prime Minister and Cabinet.

In 1981, he became Secretary and Director of Research of the Australian Law Reform Commission.

In 1986, Ian was head hunted from the ALRC by Sir Maurice Byers who had been appointed to chair the Australian Constitutional Commission as its chief executive.

Subsequently he became a partner in law firms Blake Dawson Waldron, Dunhill Madden Butler, Deacons and Norton White.

Ian is a member of the Advisory Group to the University of Melbourne's Centre for Comparative Constitutional Studies and of the Melbourne Law School Constitutional Law Discussion Group; and he is the Cunliffe in *Cunliffe v The Commonwealth* (1994) 182 CLR 272, an important Constitutional case establishing the right of Australian citizens to make representations to their governments.

5 Public health

Key points

- Chemical-related risks to public health are subject to numerous regulations — including for poisons and pesticide residues in food — on the grounds that:
  - human health protection is a 'public good' that is underprovided by the private sector.
  - 'information failures' prevent consumers from making fully informed decisions about chemical-related risks to their health.
- Existing regulations generally appear to be effective in achieving their public health goals, but some reforms are warranted to improve that effectiveness and to overcome inefficiencies.
- Distinct regulatory regimes have been established for various public health concerns. There is no case for their amalgamation, but coordination can be improved.
- Poisons scheduling requires different skills and approaches to that of drugs, and so should be undertaken by a separate body:
  - The Australian Health Ministers' Conference should proceed with implementing the draft Australian Health Ministers' Advisory Council reforms to poisons as soon as is feasible
  - Poisons regulatory controls and scheduling decisions should be uniformly adopted, as published in the Standard for the Uniform Scheduling of Medicines and Poisons, by all jurisdictions to remove inconsistencies and duplication.
- Risks associated with chemicals in articles would be managed more effectively and efficiently if, along with the agreed national system of regulation for consumer product safety, there was a formal system of coordination between the national agencies responsible for assessing chemicals and regulating product safety.
- All labelling requirements for cosmetics and toiletries should be administered by a single agency — the Australian Competition and Consumer Commission.
- To prevent the diversion of chemicals into illicit-drug manufacturing, every jurisdiction should adopt the same regulations (and associated risk-based schedule) since current inconsistencies raise costs and could undermine effectiveness.
- Maximum residue limits set by the Australian Pesticides and Veterinary Medicines Authority for domestically grown produce should be included in food standards automatically, to avoid unnecessary duplication and delays.

This chapter investigates the effectiveness and efficiency of regulations used to manage the chemical-related risks that products pose to domestic users and the general public. The areas of health regulation investigated are:

- poisons in formulated products (such as household cleaning chemicals and paints)
- chemicals in consumer articles (such as toys, appliances and furnishings)
- ingredient labelling of cosmetics and toiletries
- diversion of chemicals into illicit-drug manufacturing
- food safety.

All of these areas fall within the broad category of public health, but this is not a sufficient unifying force to lead to a single system of regulation. Rather, distinct regulatory regimes have been established for each area. To some extent, this can be attributed to the regulations having been grafted onto different generic regulatory regimes (detailed in following sections of this chapter).

Governments have recognised that it would be worthwhile to have some degree of coordination between the different areas of public health regulation. As a result, it is common for specific government agencies to play a supporting role across two or more of the abovementioned areas, with this often formalised in regulations or inter-agency agreements (details provided in following sections). However, the lead agency in each area tends to differ. Broadly speaking, primary responsibility for administering the different regimes is as follows:

- health departments — poisons
- consumer-protection agencies — chemicals in consumer articles, and ingredient labelling of cosmetics and toiletries
- law-enforcement bodies — diversion of chemicals into illicit-drug manufacturing
- food regulators — food safety.

The Commission has not found a case for amalgamating the different areas of public health regulation into a single regime. Implementation of the Commission's recommended Standing Committee on Chemicals (chapter 3), in addition to reforms advocated in this chapter, would facilitate an appropriate level of coordination. Opportunities are identified in this chapter to improve policy-oversight mechanisms, decision-making mechanisms and national coordination for poisons scheduling and regulation, consumer-product safety arrangements and illicit-drug precursor controls. Improvements can be achieved through changes in decision-making responsibilities and processes, and stakeholder-input mechanisms.

Finally, this chapter identifies various overlaps and inconsistencies which arise across each area of regulation in their administration and enforcement.

5.1 Poisons scheduling and regulation

The regulatory framework

The Commonwealth, state and territory governments regulate the importation, manufacture, sale and use of poisons. For products containing substances classified as poisons, the poisons have to be identified on the label, with appropriate health and safety warnings, and in many cases be sold in particular types of packaging (requiring child-proof lids for example). Some chemical products are also subject to particular storage requirements, or can be manufactured, sold and used only by licensed parties.

The aims of poisons regulation include the reduction of:

- unintentional poisoning, of which most identified cases are acute poisonings of children
- intentional poisoning, of which most cases are adult suicides or attempted suicides (Galbally 2001).

Underlying the controls is an assumption that without government intervention, firms would not have sufficient incentives to fully inform consumers of the risks of exposure to poisons contained in chemicals, and consumers would be unable to conduct their own assessments of risk without this information. Labels can provide useful information to consumers on the relevant risks, and how to manage that risk. They can also inform emergency personnel of the contents of chemical products, where poisonings have occurred. Packaging requirements act to limit exposure risks to children. Licensing requirements for some high-risk chemicals limit their use to professionals who are adequately trained to manage the risks.

National coordination for poisons scheduling and regulation is provided by the Australian Health Ministers' Conference (AHMC) through one of its subcommittees, the National Coordinating Committee on Therapeutic Goods (NCCTG). The NCCTG's terms of reference are to 'take action necessary to bring about coordination of legislative and administrative controls on therapeutic goods and poisons and to make recommendations to the Australian Health Ministers' Advisory Council [AHMAC, the committee of senior officials underneath the AHMC] as necessary' (TGA 2007c). The NCCTG is comprised of representatives from the Australian Government's Therapeutic Goods Administration (TGA) and

key health authority officials (mostly chief pharmacists). The committee is serviced by the TGA.

National scheduling and regulatory decisions are made by the National Drugs and Poisons Schedule Committee (NDPSC). The Therapeutic Goods Regulations 1990 set out the process the NDPSC must follow. This includes the process for regular scheduling and a provision for urgent scheduling decisions. The NDPSC categorises (or schedules) poisons (and drugs) according to their potential adverse effects on human health, and develops guidelines for their labelling, packaging and other regulatory requirements. In making its scheduling decisions, the NDPSC considers a number of factors, including the poison's purpose, potential for abuse, safety and the need for the substance (Galbally 2001).

Scheduling and rescheduling decisions are made in response to recommendations from the:

- National Industrial Chemical Notification and Assessment Scheme (NICNAS) (following their assessment of new or existing chemicals)
- Office of Chemical Safety (OCS) (often as part of the Australian Pesticides and Veterinary Medicines Authority's (APVMA) agricultural and veterinary (agvet) chemical product assessments)
- approaches from industry or the wider community
- other sources of evidence of a public health concern (TGA 2007b).

NDPSC scheduling decisions are published in the Standard Uniform Schedule for Drugs and Poisons (SUSDP) (also published as the 'Poisons Standard', with the most recent being the Poisons Standard 2007 (Cwlth)) (box 5.1). The Commission's terms of reference limit this study to substances in schedules 5, 6 and 7 (other schedules are essentially for pharmaceuticals).

Poisons scheduling and controls set at the national level have little legal authority in Commonwealth law, but play an important role in advising state and territory governments on how poisons should be scheduled and regulated within their jurisdictions. State and territory governments maintain full control over the manufacture, sale and use of poisons in their jurisdictions, and there is no obligation on them to adopt NDPSC recommendations. As will be discussed below, in practice this sometimes means that controls on scheduled substances differ between jurisdictions. However, jurisdictional reporting on departures from the Poisons Standard is now a standing NDPSC agenda item.

Box 5.1 **The Standard for the Uniform Scheduling of Drugs and Poisons**

The Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) (also published as the 'Poisons Standard', with the most recent being the Poisons Standard 2007 (Cwlth)) contains a regularly-updated list of toxic substances, including drugs/medicines, agricultural and veterinary chemicals, domestic chemicals and prohibited substances, grouped into a number of schedules. The schedules are:

- **Schedule 1** — [This schedule is intentionally left blank]
- **Schedule 2** — Pharmacy Medicine …
- **Schedule 3** — Pharmacist Only Medicine …
- **Schedule 4** — Prescription Only Medicine, or Prescription Animal Remedy …
- **Schedule 5** — Caution — Substances with a low potential for causing harm, the extent of which can be reduced through the use of distinctive packaging with strong warnings and safety directions on the label.
- **Schedule 6** — Poison — Substances with a moderate potential for causing harm, the extent of which can be reduced through the use of distinctive packaging with strong warnings and safety directions on the label.
- **Schedule 7** — Dangerous Poison — Substances with a high potential for causing harm at low exposure and which require special precautions during manufacture, handling or use. These poisons should be available only to specialised or authorised users who have the skills necessary to handle them safely. Special regulations restricting their availability, possession, storage or use may apply.
- **Schedule 8** — Controlled Drug …
- **Schedule 9** — Prohibited Substance … (Poisons Standard 2007 (Cwlth), p. vii)

The appendixes to the SUSDP contain requirements for the packaging and labelling of drugs and poisons, which vary depending on the schedule of the substance. The SUSDP also has appendixes containing reduced labelling requirements for paints, tinters and related products that contain certain poisons and lists of chemicals for which greater regulatory controls in manufacture, storage, sale and use are suggested.

Effectiveness and efficiency

The scheduling and regulation of poisons are generally seen to be effective in dealing with the hazards and risks of toxic substances in non-industrial chemical products. The *National Competition Review of Drugs, Poisons and Controlled Substances Legislation* (Galbally 2001) concluded that most of the controls on poisons (and drugs) provided a net benefit to the community. It found that, although death and other adverse health effects continued to occur from exposure to poisons, the problems arising from poisons exposure would be much greater without the controls.

It is not possible to precisely quantify the incidence of poisonings from poisons that are within the scope of this study due to definitional issues with available data. Depending upon the source, some recorded poisonings may be due to exposure to smoke, animal and insect bites and stings, or other unspecified causes. Also, some adverse health effects from chemicals may be recorded under data for burns and corrosion injuries or other data categories. Furthermore, data on poisons-related causes of injury and death are likely to include exposure in workplace, domestic and other environments, thus incorporating adverse effects on humans of chemicals regulated by OHS or other requirements.

However, available data do suggest that death and injury rates from poisons within the scope of the scheduling and regulatory regime are relatively minor compared to those from drugs and other causes. In 2003-04, only 3 per cent of all community injury deaths were due to poisoning by 'other substances' compared to 8 per cent from drugs (Henley et al. 2007). Also, poisonings by non-pharmaceutical substances accounted for less than 1 per cent of total hospitalisations in 2003-04, compared to just over 2 per cent for pharmaceuticals (AIHW 2006).

Child-resistant packaging requirements, outlined in poisons scheduling requirements, have also been effective. The Australian Institute of Health and Welfare's National Injury Surveillance Unit argued that the introduction of child-resistant closures, in the late 1970s and early 1980s, has caused a significant decrease in deaths of young children from poisoning (Cripps and Steel 2006).

Participants in this study raised concerns about the institutional arrangements and decision-making process for poisons scheduling and regulation, inconsistencies in controls between jurisdictions and overlaps with other areas of regulation. Many of these issues were also raised by past reviews, including most recently Galbally (2001). Galbally concluded that, while most of the current controls on poisons (and drugs) provide a net benefit to the community, a number of reforms were needed to increase national uniformity, improve efficiency, reduce the level of control where possible, and improve the net benefit to the community as a whole.

Galbally (2001) made a number of recommendations, including for the:

- NDPSC to be broken into two separate committees — one for drugs (to be renamed medicines) and one for poisons
- NCCTG to develop template legislation that includes all provisions regulating the supply of medicines and poisons, which the states and territories would adopt by reference

- states and territories to automatically adopt all scheduling decisions in the SUSDP by reference and in accordance with timelines developed by the scheduling committees
- APVMA to make decisions regarding the labelling and packaging, and recommend the appropriate scheduling of agvet chemicals as part of the product assessment process
- removal of some jurisdictions' 'extra' regulatory requirements on poisons (over and above those in the SUSDP), such as a requirement for manufacturers and sellers of some poisons to be licensed.

The Commonwealth, state and territory governments released their response to Galbally (2001) in 2005, agreeing to most of the recommendations (AHMAC 2005). One important exception was that they agreed to aim for regulatory uniformity, not through the use of template legislation as recommended by Galbally, but by 'other means'.

AHMAC, through the NCCTG, is currently designing reforms to poisons scheduling and regulation in Australia. In the interests of ongoing consistency and cohesiveness, the NCCTG agreed to a single scheduling policy framework for both medicines and poisons. Key elements of the most recent proposal for changes to poisons scheduling and regulation would:

- split the scheduling committee into two (one for chemicals (poisons) and one for medicines (drugs)) and replace its current membership of representatives with nominated experts
- make the head of the Australian Government Department of Health and Ageing (DOHA) the final decision maker on poisons scheduling decisions, advised by the chemicals (poisons) scheduling committee, with the Department as secretariat
- have the states and territories adopt national scheduling decisions by reference (NCCTG 2007).

Under the AHMAC model there is no commitment to adopt regulatory controls by reference.

The NCCTG would continue to oversee regulatory policy relating to both drugs and poisons.

There are some differences between the agreed scheduling policy framework and that under current arrangements. While the guidelines for classification of substances are largely the same, the proposed framework reflects extensive work on developing scheduling criteria on a schedule by schedule basis. In addition, there

are some changes to the public consultation guidelines. It is expected that the consultation process for poisons would be broadly similar to that proposed for medicines. Under the proposed arrangements, public consultation on the scheduling of a new substance would not routinely occur, although all rescheduling proposals would be the subject of public consultation.

Under the AHMAC model, for chemicals (poisons) scheduling and rescheduling decisions, the Chemicals Scheduling Committee (CSC) would assess the evidence and send their scheduling recommendation to DOHA for a final decision. The CSC would be made up of appointed experts: one nominated expert member from each state and territory; one nominated expert member from each of OCS, NICNAS and APVMA; and OCS nominated members with professional expertise. The OCS nominated expert members would include professional expertise in areas such as toxicology, consumer and industry issues. Scheduling decisions made by DOHA would be communicated to stakeholders via an electronic register, the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), which would be administered by the TGA (NCCTG 2007).

While industry (for example, ACCORD Australasia, sub. 42; PACIA 2005; 2007b) supported Galbally's recommendations, it has expressed concern about the direction of, and processes followed, in reforms since that time. Industry concerns included that the states and territories had not made a commitment to uniformity in poisons scheduling and regulation, and proper regulation impact assessment and consultative processes had not been followed. Governments had only consulted on one reform option and no regulation impact statement (RIS) had been prepared to assess the impacts of the proposed reforms. Governments had also only started to consult late in the process after the drafting process for legislation had already begun.

The case for the reform of the administration of drugs and poisons regulation

Reviews dating as far back as 1954 have recommended that poisons and drugs be scheduled and regulated separately,[1] citing the efficiency gains in splitting up decision making responsibility between the two areas, differences in the risk profiles associated with each area and the different decision-making paradigms required (Galbally 2001; IC 1996b).

[1] The National Health and Medical Research Council first recommended that national standards for regulating drugs, poisons and foods be developed in 1954, with the intention that these areas be regulated separately (Galbally 2001). Subsequent moves to develop national standards created separate regulation for foods, but drugs and poisons continued to be regulated together.

Regulatory controls and scheduling decisions in the areas of drugs and poisons require different approaches, and having them under the same framework has the potential to lead to less effective and efficient outcomes than if they were regulated separately. As stated by ACCORD Australasia:

> 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 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. (sub. 42, p. 23)

The membership of the current NDPSC includes individuals who have a background in either drugs *or* poisons, and consideration of therapeutic substances is seen to dominate (SA Government sub. DR110). Membership is based on representation from government (the Commonwealth, states and territories), industry and consumers. All members vote on scheduling decisions (though the vote is only passed if a majority of the committee is also a majority of jurisdictional representatives).[2] The NDPSC is large in membership, and where member experience and expertise is in either drugs or poisons, scheduling decisions are not always cost-effective in the use of member time and expertise. The NDPSC process has been criticised as slow and cumbersome due to the long consultation process, and the fact that it meets just three times a year means scheduling decisions are delayed (Galbally 2001). As discussed in chapter 3, best-practice arrangements for a standard-setting body are for decisions on technical standards such as scheduling decisions to be made by independent experts who are informed by public consultation processes and are required to act in the public interest. On matters of policy significance, decisions would be made ultimately by the relevant Ministerial Council.

The Commission considers that there is an overwhelming case for responsibility for the scheduling process of drugs to be separated from that of poisons. This would allow stronger focus on poisons assessments and encourage greater efficiency and more detailed consultation. The AHMAC model does not have all of the features the Commission considers appropriate, but it is an improvement over current arrangements. While the proposed CSC would retain representative membership, this would no longer be a concern given its advisory only nature.

The NCCTG should continue to have responsibility for the overall design of schedules and attached appendixes, and be overseen by the AHMAC. The CSC

2 *Therapeutic Goods Act 1989*, part 6, division 3A, subdivision 4.

should make scheduling recommendations within the scheduling framework developed by the NCCTG.

The Commission considers this should be supported by a strong intergovernmental agreement (IGA) that sets out the institutional arrangements and regulatory processes. In order to ensure consistency, states and territories should adopt scheduling decisions by reference, as proposed by AHMAC. To achieve uniform regulatory outcomes nationally, jurisdictions would also need to implement consistent schedule-based poisons controls across Australia. The Commission considers the jurisdictions should adopt poisons regulatory controls by reference.

Any amendments to the overall design of the schedules, or attached appendixes, undertaken by the NCCTG in the Standard, 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, and the CSC should be charged with the responsibility to determine whether a RIS should be undertaken.

Where decisions need to be made quickly in an emergency, the Secretary of DOHA should be empowered to make some decisions out of session, with limited or no consultation. Such a provision would require strict criteria to identify what constitutes an 'emergency' and the decision would need to be reviewed, following the normal advisory and consultation processes, as soon as practicable.

In negotiating the proposed reforms to medicines and chemicals scheduling, the NCCTG agreed to a single secretariat to support both the chemicals and medicines committees, as well as a single scheduling Standard. Coordination between the new scheduling committees would be provided by the single secretariat, and would enable appropriate handling of those substances classified as both drugs and chemicals. Where there are scheduling issues that potentially impact across the medicines and chemicals divide, meetings of the medicines and chemicals committees may be run over consecutive meeting days to facilitate consultation (NCCTG 2007).

The Commission considers that scheduling decisions could have been left to the CSC rather than with the Secretary of DOHA — however, this would only have been appropriate if the committee was not representational. On balance the Commission considers that the AHMAC model should be implemented at the earliest possible time, but that a post implementation review of its effectiveness and efficiency should be undertaken as soon as is practicable. Among other things this review should analyse any DOHA decisions that depart from recommendations by

the CSC, the reasons for these and the subsequent actions of individual jurisdictions in implementing the DOHA decisions.

Inconsistencies in the controls on poisons between jurisdictions

Inconsistencies exist in the regulations applying to poisons between jurisdictions, creating costs for firms operating across borders and, ultimately, consumers. While most jurisdictions adopt Part 4 of the SUSDP by reference, the remainder of the Poisons Standard is adopted inconsistently by the jurisdictions, if at all. The differences include retail storage requirements for schedule 5 and 6 poisons, controls on the sale and use of schedule 7 poisons, and inconsistent implementation of Appendix I of the SUSDP (the Uniform Paint Standard) (ACCORD Australasia, sub. 42; APMF, sub. 8; TGA 2007a). There are also inconsistencies between jurisdictions in the scope of their controls on schedule 7 poisons (which in some cases apply to both domestic and industrial use) (ACCORD Australasia, sub. 42). This last issue will be discussed later in this section.

One example is the inconsistency in retail storage controls on schedule 5 and 6 poisons between jurisdictions (ACCORD Australasia, sub. 42). Each jurisdiction takes a different approach in this area, with quite prescriptive requirements applying in New South Wales[3] and South Australia,[4] and either more general or no requirements applying in other jurisdictions (South Australia is currently implementing a number of initiatives including removal of licensing requirements for manufacturers and wholesalers of Schedule 5 and 6 substances (South Australian Government, sub. DR110)).

These differences may create unnecessary costs for chemicals manufacturers, distributors and retailers that operate across borders:

> For example the retail storage requirements for Schedule 5 poisons differ across all jurisdictions, yet this controls the way a large number of consumer products are managed in Australia. The lack of consistency has recently encouraged retailers to attempt to impose their own conditions across Australia which is potentially more onerous than that arising out of some of the legislation. (ACCORD Australasia, sub. 42, p. 24)

Some national retailers with some degree of market power seek to simplify their supply chain management by requiring their suppliers to always meet the most stringent regulatory requirements among all jurisdictions. These costs are likely to be passed on to consumers. A more efficient outcome would be achieved if controls

3 Poisons and Therapeutic Goods Regulation 2002 (NSW), part 2, Division 2, clause 12.

4 Controlled Substances (Poisons) Regulations 1996 (SA), section 25.

were uniform in all jurisdictions, and set at a level commensurate with the relevant risks. One option would be to set performance-based standards that these chemicals be kept out of the reach of children, allowing firms to find the most cost-effective way in which these requirements could be met.

The Commission is of the view that the nature of the risks from poisons warrants a nationally-uniform approach. The risks of adverse health effects from exposure to poisons in the domestic, public space, or agricultural environment are unlikely to vary according to jurisdiction. Variations from the agreed national standards in this area are likely to impede interstate trade and increase costs to business and consumers, with little offsetting benefit in public health outcomes.

The Commission notes that, at COAG's meeting of 3 July 2008, there was agreement to implement the national harmonisation of poisons scheduling regulation and mutual recognition of decisions, as well as uniform implementation of scheduling of poisons by states and territories. COAG directed the Ministerial Taskforce on Chemicals and Plastics to present recommendations to the October 2008 meeting for endorsement by the December 2008 COAG meeting.

The Commission is of the view that notwithstanding the mutual recognition of decisions as agreed to by COAG, state and territory governments should continue to report any variations to nationally-agreed poisons scheduling or regulatory decisions to the Australian Health Ministers' Conference and include a statement of reasons for the variations.

RECOMMENDATION 5.1

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 Ministers' 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.***

State and territory governments should:

- ***adopt poisons scheduling decisions made by the Department of Health and Ageing directly by reference, as published in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)***
- ***uniformly adopt regulatory controls for poisons through either a template or model approach, as published in the SUSMP***
- ***continue to report any variations to nationally-agreed poisons scheduling or regulatory decisions at the state and territory level to the Australian Health Ministers' Conference, and include a statement of reasons for the variations.***

Overlaps between poisons controls and workplace substances regulation

ACCORD Australasia (sub. 42) noted two examples where controls on Schedule 7 poisons were inadvertently applied to industrial users in some jurisdictions, despite the relevant hazards being adequately addressed by OHS regulations. One example was the scheduling of HF (Hydrofluoric Acid), and while the intention was to ensure that products containing a concentration of more than 1.0% HF were not available for domestic use, in general it had the unintended consequence of requiring bona-fide industrial users (e.g. welders) to seek certain authorities/licenses. Another example related to Methylcyclopentadienyl Manganese Tricarbonyl (MMT), where the same in-principle issues arose.

This overlap between domestic poisons controls and those on workplace substances could impose unnecessary costs on firms that have to meet additional requirements, with little benefit to public health (or occupational health and safety) outcomes. It also imposes unnecessary costs on governments administering poisons controls that apply to both industrial and domestic uses. The intent of poisons controls is to protect public health by managing the risks from chemicals in domestic use. Occupational health risks are best dealt with through the existing regulatory framework for occupational health and safety.

ACCORD Australasia (sub. 42) was concerned that despite governments having recognised this as an issue, more regulatory reform was needed to better delineate between controls on domestic poisons and workplace substances. It noted that New South Wales has dealt with this by amending its poisons regulations to exclude schedule 7 substances with an industrial purpose. However, industrial users of schedule 7 poisons in Western Australia and the Northern Territory still need to obtain approval from their jurisdiction's health department.

However, concerns were raised that exempting authorised users of poisons in the industrial environment from poisons controls could result in a regulatory gap such as in relation to atypical workplaces (SA Government, sub. DR110). For example, in WA poisons regulations pick up a gap left by workplace regulations that do not cover small workplaces. In most cases, poisons controls are not needed in the industrial environment as workplace regulations are adequate. However, there are some particularly hazardous substances, such as cyanides, where it would be appropriate to limit access to those poisons. Workplace hazardous substances regulations do not provide such controls.

RECOMMENDATION 5.3

Where a poison is adequately covered under workplace substances regulations and there is demonstrated compliance with those regulations, state and territory governments should exempt those users from poisons controls.

5.2 Controls on chemicals in consumer articles

The regulatory framework

Some chemicals contained in consumer articles (such as toys, electronic appliances, furniture or carpets) may pose health and safety risks to certain consumers if they are released from articles after purchase. These risks are sometimes immediately obvious and can be easily traced back to the use of, or close proximity to, the article. However, other risks may take a longer time to become apparent, or may arise from cumulative exposure.

Although firms face a number of incentives to supply safe articles — including market incentives, the threat of adverse media publicity, legal liability and ethical considerations — the effectiveness of these mechanisms may be reduced where:

- suppliers know more than consumers about the hazards of a product, and find it in their interest to withhold some of that information for commercial advantage
- suppliers do not have a strong or long-term commitment to particular product types and markets, and so have less need to maintain the long-term patronage of customers
- both suppliers and consumers do not have full knowledge of the hazardous characteristics of the products because the hazardous characteristics of the chemicals contained in them have not been assessed.

ATTACHMENT 3

ACCORD

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

Mr Charles Maskell-Knight
A/g Chair
National Coordinating Committee on Therapeutic Goods (NCCTG)
Therapeutic Goods Administration
Department of Health and Ageing
PO Box 100
WODEN ACT 2606

Dear Charles

Thank you for your letter of 2 June 2009 responding to our request for the NCCTG to provide policy guidance to the NDPSC to nationally harmonise retail storage requirements for Schedule 5 and 6 poisons.

We are somewhat confused however, regarding the suggestion that the role of the NCCTG is limited to providing *guidelines to the NDPSC on matters to be taken into account when the NDPSC is considering amendments to the Poisons Schedule.*

On the TGA's website the Terms of Reference for the NCCTG are listed, and include for example:

(a) to promote coordinated and harmonised approach to the regulation and controls over therapeutic goods and poisons; and
(b) to provide policy guidance to the National Drugs and Poisons Schedule Committee

Notwithstanding, we understand that the details of the draft Code and its mechanism of adoption were discussed at NCCTG's last meeting. We are pleased that this matter appears to be proceeding, and we look forward to receiving the outcomes of the discussion, and as necessary, future engagement with the NCCTG on this important matter for our industry.

Yours sincerely

Bronwyn Capanna
Executive Director

11 June 2009

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Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Ms Bronwyn Capanna
Executive Director
ACCORD Australasia Limited
PO Box 290
BROADWAY NSW 2007

Dear Ms Capanna

Thank you for your letter of 26 May 2009 requesting that the National Coordinating Committee on Therapeutic Goods (NCCTG) provide policy guidance to the National Drugs and Poisons Schedule Committee (NDPSC) to direct the NDPSC to revise and finalise the *Draft Code of Practice be for National Retail Storage of Schedule 5 and Schedule 6 Products* to limit the Code to Schedule 6 products only and for all states and territories to recognise/implement the Code.

The role of the NCCTG, as prescribed in the *Therapeutic Goods Act 1989,* is to provide guidelines to the NDPSC on the matters to be taken into account when the NDPSC is considering an amendment to the Poisons Standard. The NCCTG's guidelines relate to the framework within which the NDPSC makes scheduling decisions and not to the content of individual scheduling decisions. The NCCTG is not empowered to direct the NDPSC to make a particular decision, such as to amend Part 3 or add a new Appendix to the Poisons Standard, nor is the NCCTG able to require states and territories to make legislative changes, either directly or via the NDPSC.

Notwithstanding the above, your statements in support of national uniformity of requirements for poisons are appreciated and will be brought to the attention of the NCCTG.

Yours sincerely

Charles Maskell-Knight
Acting Chairman, National Coordinating Committee on Therapeutic Goods
Acting National Manager, Therapeutic Goods Administration
2 June 2009

ACCORD

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

Mr Charles Maskell-Knight
Acting Chair
National Coordinating Committee on Therapeutic Goods
Therapeutic Goods Administration
Department of Health and Ageing
PO Box 100
WODEN ACT 2606

Dear Charles

ACCORD is writing to request that the National Coordinating Committee on Therapeutic Goods (NCCTG) provides policy guidance to the National Drugs and Poisons Schedule Committee (NDPSC) and the relevant state and territory authorities on the implementation of regulations to nationally harmonise retail storage of Schedule 5 and Schedule 6 poisons based on the *Draft Code of Practice for National Retail Storage of Schedule 5 and Schedule 6 Products* (the Draft Code).

We are aware that the NDPSC has been working towards national uniformity of requirements for the retail storage of Schedule 5 and Schedule 6 poisons by working on the Draft Code. We are also aware that progress on this issue has been slow and laboured due to current differences between the states and territories.

ACCORD was extremely disappointed to learn from jurisdictional responses to the Draft Code in the Record of Reasons of the February 2009 NDPSC meeting, that some jurisdictions were unwilling to amend their current regulations to adopt, reference or recognise the Draft Code once it is finalised. Meaningful national uniformity can only be reached if all states and territories agree to recognise the Draft Code as a regulatory and/or compliance instrument.

The responses at the NDPSC meeting are all the more disappointing given the recommendations regarding poisons scheduling by the Productivity Commission in its Research Report *Chemicals and Plastics Regulation* (July 2008) and our understanding that COAG has endorsed the PC's findings. The PC states inter alia:

> *State and territory governments should:*
> - *uniformly adopt regulatory controls for poisons through either a template or model approach, as published in the SUSMP (Recommendation 5.2)*

It is ACCORD's position that a template approach should be used by the states and territories. In this instance, the Draft Code should be included in the SUSDP and subsequently be referenced or included within the jurisdictions' legislative instruments.

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ACCORD

The February 2009 NDPSC meeting Record of Reasons indicated that some jurisdictions believed the Draft Code too stringent while some believed it to be not stringent enough compared to their existing requirements.

Based on the lack of tangible evidence of an existing safety issue, it has been ACCORD's view all along that the minimum effective requirements from the current state and territory regulations should be accepted nationally. Given that currently some states and territories have no requirements for the retail storage of Schedule 5 and Schedule 6 products, ACCORD does not believe there is a demonstrated need to introduce special storage requirements for retail storage of both Schedule 5 and Schedule 6 products. This is consistent with the COAG Principles of Best Practice Regulations.

However, given expressed concerns of some jurisdictions, the need for certainty and predictability for both manufacturers and retailers, and a timely resolution of this issue, ACCORD supports as a pragmatic solution the adoption of the Draft Code modified for relevance to Schedule 6 products only.

ACCORD urges the NCCTG to provide guidance to the NDPSC on the adoption of minimum effective regulation by actively encouraging the finalisation of the Draft Code for Schedule 6 products only. We also urge the NCCTG to promote the timely recognition/implementation of nationally uniform requirements for retail storage of Schedule 6 products based on the Draft Code by all states and territories.

If you or any of your staff require any clarification on any of the matters raised in this letter, please contact our Science and Technical Manager, Catherine Oh at coh@accord.asn.au or (02) 9281 2322

Yours sincerely

Bronwyn Capanna
Executive Director

26 May 2009

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

National Coordinating Committee on Therapeutic Goods (NCCTG)

The National Coordinating Committee on Therapeutic Goods (NCCTG) was established by Order of the Federal Executive Council on 17 March 1971. The 1971 Order was revoked in October 1986 to facilitate the establishment of NCCTG as a committee of the Australian Health Ministers' Advisory Council (AHMAC).

NCCTG terms of reference

The Terms of Reference of the NCCTG are:

a. to promote a coordinated and harmonised approach to the regulation and controls over therapeutic goods and poisons

b. to provide policy guidance to the National Drugs and Poisons Schedule Committee

c. to contribute to projects relevant to the regulation and control of therapeutic goods and poisons

d. to share knowledge on emerging and important matters relevant to the regulation of therapeutic goods and poisons

e. to report and make recommendations to the Australian Health Ministers' Advisory Council, via the Clinical/Technical and Ethical Principal Committee, as necessary.

NCCTG servicing

The Committee is serviced by the Therapeutic Goods Administration, a Division of the Australian Government Department of Health and Ageing.

NCCTG membership

The Committee is chaired by the National Manager of the Therapeutic Goods Administration and there is one other Australian Government appointed member (Branch Director of the Office of Devices, Blood and Tissues of the Therapeutic Goods Administration). One member from each State and Territory health authority is appointed by the relevant Minister responsible for the health portfolio of that State or Territory. One member is nominated by the New Zealand Ministry of Health. A delegate may attend meetings in the absence of a member. At the discretion of the chair, a member may invite an observer.

Member terms

There are no fixed terms for members. Neither sitting fees nor any other benefits are paid to members. Members receive fares and travelling allowance for attending meetings from their various health authorities.

NCCTG Members

Dr Rohan Hammett (Chair)
National Manager
Therapeutic Goods Administration

Dr Larry Kelly

Office Head, Office of Devices, Blood and Tissues
Therapeutic Goods Administration

Mr Bruce Battye (Acting Member)
Acting Chief Pharmacist
NSW Health Department

Mr Andrew Petrie
Director, Medicines Infrastructure & Support
Queensland Health

Mr Keith Moyle
Manager, Drugs and Poisons Section
Department of Human Services, Victoria

Mr Murray Patterson
Chief Pharmacist
Department of Health, Western Australia

Ms Mary Sharpe (Acting Member)
Chief Pharmacist
Department of Health and Human Services, Tasmania

Ms Elizabeth Hender (Acting Member)
Pharmaceutical Services
Drug and Alcohol Services, South Australia (DASSA)

Ms Gay Lavery (Acting Member)
Poisons Control
Department of Health and Families, Northern Territory

Ms Jane Strang
Chief Pharmacist
ACT Health

Dr Susan Martindale
Medsafe
Ministry of Health, New Zealand

Mr P K Harrison (Secretary)
Office of Devices, Blood and Tissues
Therapeutic Goods Administration
Tel 02 6232 8636
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NCCTG reports & reviews

- A discussion paper on regulation of extemporaneously prepared medicines in non-hospital pharmacies
  <http://www.tga.gov.au/meds/extempcomp2.htm>
  April 2008
- Review of the need for further regulation of extemporaneous compounding
  <http://www.tga.gov.au/meds/extempcomp.htm>
  September 2005
- Report to Health Ministers on a cost-benefit analysis of pharmacist only (S3) and pharmacy medicines (S2) and risk-based evaluation of the standards
  <http://www.tga.gov.au/meds/s2s3report.htm>
  August 2005