The Senate

Community Affairs Legislation Committee

Therapeutic Goods Amendment (2009 Measures No. 2) Bill 2009 [Provisions]

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42nd Parliament

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THE INQUIRY

1.1 On 25 June 2009 the Senate, on the recommendation of the Selection of Bills Committee (Report No.10 of 2009), referred the Therapeutic Goods Amendment (2009 Measures No.2) Bill 2009 to the Community Affairs Legislation Committee for inquiry and report by 7 August 2009.

1.2 The Committee received 9 submissions relating to the Bill and these are listed at Appendix 1. The Committee considered the Bill at a public hearing in Canberra on 8 July 2009. Details of the public hearing are referred to in Appendix 2. The submissions and Hansard transcript of evidence may be accessed through the Committee's website at http://www.aph.gov.au/senate_ca.

BACKGROUND

1.3 The National Competition Policy Review of Drugs, Poisons and Controlled Substances was announced in July 1999. The Review, conducted by Ms Rhonda Galbally, examined State and Territory legislation that imposed controls in Australia on supply and use of drugs, poisons and controlled substances against the Principles of National Competition Policy.

1.4 A number of proposals for national uniformity of regulations through legislative reforms were made by the Review, with recommendations for change in the areas of increasing national uniformity, improving efficiency, reducing the level of control where possible, and improving the net benefit to the community as a whole of those controls which rely on professional practice to be effectual.

1.5 The Final Report of the Galbally Review was presented to the Australian Health Ministers' Conference (AHMC) in January 2001. A Working Party of the Australian Health Ministers' Advisory Council prepared a response to the Galbally Review recommendations in April 2003 which was approved by the Council of Australian Governments (COAG) in June 2005. The Working Party had also taken account of the proposal to establish an Australia New Zealand Therapeutic Products Authority (ANZTPA) so that the Review recommendations should be implemented on a trans-Tasman basis.

1.6 The National Coordinating Committee on Therapeutic Goods (NCCTG) oversighted the implementation of the Galbally Review recommendations, most of which were implemented in 2006-07. However, with the suspension of negotiations to

establish the proposed ANZTPA in July 2007, the NCCTG proceeded to implement the remaining Review recommendations on an Australia-only basis.[1]

1.7 A key recommendation from the Galbally Review was to provide separate scheduling arrangements for medicines and chemicals to reflect the different uses and environments in which these substances are made available and used. A 2008 Productivity Commission Research Report on Chemicals and Plastics Regulation supported the Review by recommending that new scheduling arrangements be implemented as soon as feasible.

1.8 The Minister's second reading speech describes the scheduling process:

> Scheduling is a collaborative process involving both the Commonwealth and the states and territories. A committee established under Commonwealth law with state and territory representatives makes decisions that are then implemented through state and territory legislation.
>
> Scheduling is the process by which substances that can be harmful if not used or kept correctly are grouped into categories, known as schedules. Specific requirements are then attached to the schedules under state and territory law regarding supply, availability and oversight of use to support the safe and effective use of these substances. This then has a flow-on effect on the supply, availability and use of medicines and chemicals that contain scheduled substances.
>
> Scheduling decisions are recorded in a document known as the Poisons Standard[2], which brings together the names and details of the substances that have been scheduled and categorises these by schedule. The Poisons Standard is principally used by the states and territories as a tool for regulating public access to and availability of medicines, veterinary, agricultural and domestic chemicals.[3]

THE BILL

1.9 The scheduling amendments in Schedule 1 of the Bill implement the outstanding Review recommendations that were deferred with the suspension of the ANZTPA negotiations. The Explanatory Memorandum notes that 'these amendments reflect extensive consultation with industry and other interested parties'.

1.10 The Bill provides for the replacement of the existing National Drugs and Poisons Scheduling Committee (NDPSC) that makes scheduling decisions with two new expert advisory committees, which will provide recommendations and advice to

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1 Review of drugs, poisons and controlled substances legislation from TGA website at http://www.tga.gov.au/docs/html/rdpdfr.htm accessed 26.6.2009.

2 This is a legislative instrument formally titled the *Standard for the Uniform Scheduling of Drugs and Poisons*.

3 Second Reading speech and Explanatory Memorandum.

the Secretary of the Department of Health and Ageing to inform the Secretary in making scheduling decisions.

1.11 The new Advisory Committee on Medicines Scheduling will be able to provide recommendations and advice about substances used in medicines, while the new Advisory Committee on Chemicals Scheduling will advise on substances such as agricultural, domestic and veterinary chemicals.

1.12 Decisions of the Secretary will then be incorporated into the Poisons Standard. This will be retained as a single complete reference for the scheduling classifications of both medicinal and chemical substances.

1.13 One key element from the existing scheduling arrangements will be retained - the cooperative arrangement the Commonwealth has with the states and territories. This is necessary under the Constitution to achieve scheduling implementation uniformly across all states and territories. Reflecting this important collaborative Commonwealth-state/territory arrangement for scheduling, the advisory committees will include members from the Commonwealth and each of the states and territories as well as other experts to be provided for in the subordinate legislation.

1.14 Transitional provisions will ensure that applications currently under consideration by the NDPSC are able to be transferred across for consideration under the new arrangements and that any recommendations made by that committee will be taken into account by the Secretary. This is intended to ensure a smooth transition to the new arrangements upon their commencement on 1 July 2010. The commencement date will also provide time for the development of supporting subordinate legislation.

1.15 Schedule 2 of the Bill will enable the Secretary to declare purposes for which kinds of medical devices cannot be included in the Australian Register of Therapeutic Goods. Purposes will be precluded where such a use would pose a risk to public health or where it would be otherwise inappropriate.[4]

1.16 Schedule 3 contains a number of amendments including provisions that will:

- enable the TGA to consult with and seek advice from the Gene Technology Regulator about applications for the listing or registration of therapeutic goods that are genetically modified organisms or that contain GMOs;
- clarify inappropriate advertising of therapeutic goods to ensure that appropriate, consistent and accurate information is provided to the public to support the safe and effective use of therapeutic goods; and
- improve the transparency of the requirements for advisory statements on medicine labels by empowering the Minister to specify them in a legislative instrument. These statements assist consumers in choosing the most

4 The Department expands on inappropriate purposes for devices and examples of devices with inappropriate purposes in *Submission* 2, pp.7-8 (DoHA).

appropriate medicine and using it safely and effectively as the medicines these statements apply to are generally those which individuals choose themselves or with the assistance of a pharmacist.

1.17 The Minister's second reading speech advises that:

> The government intends to make further changes to the therapeutic goods regulatory regime later in the year. In particular, we intend to introduce further legislation to give effect to a new framework for the regulation of human cellular and tissue based therapies, as foreshadowed as part of the ANZTPA process.[5]

ISSUES

1.18 There was general support for the principles underlying the Bill, especially the separation of medicines and chemicals scheduling; however the support was conditional. The Complementary Healthcare Council (CHC) noted that many of the amendments 'are long overdue and welcomed by the complementary healthcare industry'. The CHC, 'in general, supports the principles within the Bill however has some concerns relating to several of the proposals'.[6] The Australian Self-Medication Industry (ASMI) similarly considered 'that the Bill represents some important progress and we offer support for it… However, we have serious reservations about the lack of transparency and accountability of the process set out in the Bill.[7] ACCORD also raised a 'number of important questions' that required answers 'before we would be in a position to unequivocally endorse the passage of the Bill as written'.[8]

Consultation

1.19 Industry groups advised that they had been involved in the many processes following the Galbally Review and had provided submissions on the discussion papers produced in recent years. However they were scathing at their treatment and the outcomes. ASMI stated that 'throughout all that time, the Government's consultations have been far from extensive or meaningful' and, in proposing amendments to improve the Bill, commented that 'if we had been consulted in a meaningful way, perhaps some of our proposals might have already been in the Bill'. ASMI provided a list of the occasions that they provided submissions over the past decade and asserted:

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5 This quote and the description of the Bill in this section are extracted from the Minister's second reading speech and *Submission* 2 (DoHA). It should be noted that references in the report are to the submission and evidence from the Department of Health and Ageing (DoHA), and although evidence was given by officers of the Therapeutic Goods Administration, the TGA is a part of the Department.

6 *Submission* 6, p.2 (CHC).

7 *Submission* 1, p.2 (ASMI); also *Committee Hansard* 8.7.09, p.14 (Ms Seifert, ASMI).

8 *Submission* 4, p.3 (ACCORD). ACCORD Australasia is the national industry association for the manufacturers and suppliers of formulated consumer, cosmetic, hygiene and specialty products.

> In every case, Governments have not engaged in any discussion with us and, in many respects, our reasoned arguments have been rejected or ignored without explanation or further discussion.[9]

1.20 ACCORD expressed similar experiences:

> 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.[10]

1.21 Industry groups were also critical of the lack of feedback. ACCORD summed up this criticism stating that:

> A major problem with the consultation processes has been the lack of formal feedback to, or engagement with, chemical industry stakeholder groups. ACCORD has never received any official feedback from the TGA in relation to either our 2005 or 2007 submissions.
>
> 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… 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.[11]

1.22 The Pharmaceutical Society of Australia (PSA) also experienced some difficulty in tracking progress and outcomes of the various consultations, asserting that 'this has been due to lack of feedback on our submissions, long periods where there appears to be low level (or no) activity, ‘low-key’ announcements of outcomes, or follow-up consultations where the outcomes are more or less determined with little or no scope for change.[12]

1.23 The Department's submission constantly reiterated that 'extensive consultation' was undertaken in the development of the Galbally Review recommendations and the proposed scheduling changes and that consultation comments on earlier drafts of documents had 'been taken into account in the development of the latest drafts'. At the hearing, the Department described three main phases in the consultative process and noted that a response to the 2005 consultation was on the website, there was 'not an outcome summary or feedback loop' for the 2006 consultation involving ANZTPA because ANZTPA was not proceeded with and

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9 *Submission* 1, pp.ii, 2 and Attachment 2 (ASMI).

10 *Submission* 4, p.3, emphasis in submission (ACCORD).

11 *Submission* 4, pp.6-7 (ACCORD).

12 *Submission* 3, supplementary submission p.3 (PSA).

in relation to the May 2009 consultation period 'any time soon the NCCTG should be authorising us to put a document on the website saying what people said and what our reaction to that was'.

> Our general proposition is that if people have responded to the call for submissions on the consultation documents we will put a document on the website saying ,'This is what we decided in relation to each of those things,' and saying why.[13]

1.24 Industry clearly does not regard this as a satisfactory approach to consultation by the Department. The Committee is concerned that the issue of consultative processes used by the Department has been the subject of critical comment in a number of recent inquiries. ASMI encapsulated this concern when it said that 'industry does not accept that a take it or leave it approach amounts to meaningful consultation'.

The two Advisory Committees

Administrative framework

1.25 While the intention to separate the medicines and chemicals scheduling committees was supported, there was significant questioning as to whether the planned administrative framework was appropriate. Industry considered that it would be more suitable for the Chemicals Scheduling Committee to be administered by another body where chemical safety evaluation, for substances not intended to be used in therapeutic goods, is conducted as part of their current function.

1.26 The argument is that the TGA's role is to assess and monitor activities to ensure therapeutic goods available in Australia are of an acceptable standard; assessments and evaluation of substances that are not intended for the purpose of therapeutic goods should be the responsibility of another, more relevant, department or body.

1.27 ACCORD especially emphasised this issue stating that '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'. For ACCORD:

> The key problem is that the measures introduced through this bill place chemicals scheduling in the medicines agency, and therefore further away in both a policy and an administrative sense from NICNAS, the Office of Chemical Safety and Environmental Health, the APVMA, the soon-to-be established standing committee on chemicals and the proposed national environmental chemicals bureau. That is why we consider this to be a retrograde step.[14]

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13 *Committee Hansard* 8.7.09, pp.32-33 and *Submission* 2, pp.4-5 (DoHA).

14 *Committee Hansard* 8.7.09, p.25 (Ms Capanna, ACCORD).

1.28 ACCORD indicated that they had recently been advised by government that:

> The legislative approach being adopted through this Bill is preferred because it avoids the need for new state and territory legislation.
>
> 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.
>
> This is conditionally accepted, but still leaves our industry with a dilemma.[15]

1.29 The Department noted that the establishment of two committees while maintaining one Poisons Standard recognised the close relationship between medicines and chemicals, as some substances may be used in both medicinal and chemical products, eg antibiotics, steroids and essential oils. DoHA responded to the ACCORD position in their submission stating that:

> Establishing the two committees under different acts would be problematic as the AHMC agreed model would require both committees to be responsible for amending the same legislative instrument – the Poisons Standard. It would be problematic for two Acts to have responsibility and control over the same instrument. (The states and territories have made it clear through the NCCTG that the single scheduling standard must be retained to allow appropriate reference in their respective legislation).[16]

1.30 Indeed the successful implementation of this scheme relies on the States' continued support as confirmed by the Department at the hearing:

> …it has been very clear from AHMC downwards that the states will only countenance this if they do not have to change their legislation to refer to chemicals and medicines standards.[17]

1.31 ACCORD did not dispute that this was the position of State and Territory governments on this matter, though they viewed 'such intransigent demands to maintain status quo or follow a path of least effort as unhelpful for improving national productivity'. However, ACCORD did dispute the Department's portrayal of their position as reflected in the above quote, advising that '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'.[18]

1.32 ACCORD did respond to the issue of overlap when products could be used in both medicinal and chemical products:

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15 *Submission* 4, p.3 (ACCORD).

16 *Submission* 2, pp.6-7 (DoHA).

17 *Committee Hansard* 8.7.09, p.37 (Mr Maskell-Knight, TGA).

18 *Submission* 4, supplementary submission p.3 (ACCORD).

> In my view that is a furphy that has been promulgated to justify a singular committee for some time. Really, what chemicals and medicines scheduling is about is intended use. The committee would routinely specify the intended use: whether it is for a medicine or for chemical or household consumer use. This is clear in the current standard—the differential intended use. So the hazard of a chemical is not going to change regardless of its intended use, but its risk management—what concentrations you would allow as a cosmetic and what concentrations you would allow in therapeutic use—would change depending on the intended use. So it should be the intended use that drives this.[19]

1.33 Some industry groups suggested that chemicals scheduling would more appropriately sit within the Office of Chemical Safety and Environmental Health (OCSEH), because this would better integrate it with the overall chemical management and also keep it within the Department of Health.[20] ACCORD regards chemical scheduling as a public health issue that should be under the Department of Health, just not in the medicines agency. In supporting OCSEH ACCORD noted:

> **Ms Capanna** – Indeed they offer the current secretariat for the National Drugs and Poisons Schedule Committee, recognising that there are elements under the current system, which is joint medicines and chemicals scheduling. The office of chemical safety recognises that and deals with the Therapeutic Goods Administration, NICNAS as the industrial chemicals regulator and indeed the APVMA as the agvet regulator.
>
> **Mr Brock** - Further, it deals with new and emerging issues. It would be looking at issues such as nanotechnology, which is a new issue coming up in the chemicals area; it will be looking at issues of security sensitive chemicals, and that is being run out of the Attorney-General's Department; and it will most likely interact with the environment agencies and the Environment Protection and Heritage Council proposal for a new environmental chemicals bureau. So there is a lot happening in chemicals regulation and, to put this key part of the chemical regulatory framework into the TGA, we think removes a possibility for greater integration and national coordination.[21]

1.34 The Department advised that the OCSEH would be involved, explaining that it was the intention for the delegate for medicines decisions to reside within the TGA while the delegate for chemicals decisions would reside within OCSEH. These administrative arrangements are contained within the Scheduling Policy Framework.

> The expectation is the medicine scheduling power will be devolved to the TGA and the chemical scheduling power will be devolved to the office of chemical safety. The intention is to have a common secretariat for the advisory committees within the TGA. The reason for that is to facilitate

19 *Committee Hansard* 8.7.09, p.26 (Ms Capanna, ACCORD).

20 *Submission* 6, p.3 (CHC) and *Committee Hansard* 8.7.09 p.26 (Ms Capanna, ACCORD).

21 *Committee Hansard* 8.7.09, p.26 (Ms Capanna, Mr Brock, ACCORD).

> exchange of information between the two committees and also, frankly, it will be cheaper for the industry if we have one committee rather than two.[22]

Legal validity

1.35 ACCORD raised the issue of the legal validity of the proposal, arguing that, at a more fundamental level, '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 commissioned independent legal advice from Mr Ian Cunliffe whose opinion supported the general concerns held by industry over the Bill. The legal opinion made four key conclusions:

> 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?"[23]

1.36 ACCORD considered that the legal opinion reinforced the industry's policy concerns 'that the arrangements put in place by this Bill, in relation to chemicals

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22 *Committee Hansard* 8.7.09, pp.32, 37 (Mr Maskell-Knight, TGA)

23 *Submission* 4, supplementary submission p.1 and Attachment 1 (ACCORD).

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'. ACCORD doubted 'that any workable system of TGA cost-recovery for chemicals scheduling would be able to be legally underpinned, without resorting to administratively nonsensical approaches' and concluded that:

> 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.[24]

1.37 The Department responded to the legal validity issue:

> First of all, chemical scheduling already takes place under the Therapeutic Goods Act. The act sets out as one of its objectives in paragraph 4(1)(b) is:
>
> - (b) to provide a framework for the States and Territories to adopt a uniform approach to control the availability and accessibility, and ensure the safe handling, of poisons in Australia.
>
> It then defines a poison as including anything in the poison standard. On that point, I should also say that during the drafting of schedule 1 a number of issues emerged where we sought advice from the Australian Government Solicitor and they did not raise any qualms at all about the legal validity of what we were proposing. The Australian Government Solicitor are not shy about pointing out where they think things are not going to work and they did not have any qualms whatsoever.
>
> I guess the third matter is that the Australian Government Solicitor also observed that having two separate pieces of legislation amending the one poisons standard would raise a whole lot of interesting and novel legal issues and that they did not think that was a very helpful way to proceed.[25]

1.38 The Department thought that the question on legal validity had assumed that the amendments confer power upon the TGA to make chemical scheduling decisions. The Department advised that this is not correct: the amendments in the bill confer power upon the Secretary of the Department, not upon the TGA. The Secretary for administrative convenience may delegate her power to any officer in the Department. As noted earlier it is the intention that scheduling decisions on medicines will be delegated to the TGA; and decisions on chemicals will be delegated to the Office of Chemical Safety.[26]

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24 *Submission* 4, supplementary submission p.2 (ACCORD).

25 *Committee Hansard* 8.7.09, p.32 (Mr Maskell-Knight, TGA).

26 *Submission* 2, additional information dated 31.7.09, p.1 (DoHA).

Constitution of the Advisory Committees

1.39 The Bill provides that the Advisory Committees will be constituted in accordance with the regulations and that the Commonwealth, each State and Territory are each entitled to nominate a member. It was proposed that a representative from the industry sector should be on the Committees. The CHC argued that to ensure that substances used in complementary medicines are assessed and evaluated appropriately, there should be appropriate complementary medicine representation and expertise on the Medicines Scheduling Committee.[27]

1.40 ASMI also raised questions about the likely membership of the Medicines Scheduling Committee, and, of fundamental importance, whether State bureaucrats would continue to have a power of veto over all its decisions. ASMI considered:

> That the jurisdictional members [of the current committee] have displayed an unduly risk-averse approach to issues before them and have, on occasion, voted in accordance with State-specific Ministerial priorities as directed by them.
>
> We consider it is essential that the regulations do not continue this veto arrangement.[28]

1.41 ASMI also believed that the Committee should have an independent Chair, that is not be ex officio a TGA officer, or an official of the Department of Health and Ageing. They explained that expertise was needed at the committee table and that was currently lacking. It 'is not to say TGA does not have competence in this area; it is simply to say there are other skills that good governance would demand be part of the process'.[29]

1.42 ACCORD raised similar issues on the membership of the Chemicals Scheduling Committee. They questioned what provisions would ensure that the States and Territories nominate members with appropriate expertise to ensure the scientific integrity of the Chemicals Committee's decisions and why the membership provisions remained silent on other key member bodies with both a role and expertise in chemicals regulation for public health - NICNAS, APVMA and DoHA's Office of Chemical Safety and Environmental Health.[30]

1.43 The Department explained the expertise that it envisaged for the Committees, focussing on CHC's comment of complementary medicines expertise on the Medical Scheduling Committee:

> We want to have an expert committee. The sorts of things we want the secretary to be advised about are things like toxicology and pharmakinetics.

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27 *Submission* 6, pp.3-4 (CHC).

28 *Submission* 1, p.3 (ASMI).

29 *Committee Hansard* 8.7.09, p.15 (Ms Seifert, ASMI).

30 *Submission* 4, p.5 (ACCORD).

> The toxicology of complementary medicines is the same as the toxicology of anything else, and so is the pharmakinetics, so we do not see this committee as one to have complementary medicine expertise, over-the-counter expertise, prescription medicine expertise and so on… So it is more about scientific expertise that would cover a whole range of medicines. That is what we see the committee membership being.[31]

Use of terms 'Medicines' and 'Chemicals'

1.44 The PSA noted that the draft Scheduling Policy Framework used the terms 'medicines' and 'poisons', though the Bill used the term 'chemicals' in place of 'poisons'. They regarded this as 'somewhat confusing' and inconsistent use of terminology.[32]

1.45 The Department clarified this change in terminology, advising that:

> The term ‘chemicals’ is used in relation to the title of the advisory committee, and that title was chosen because our colleagues from ACCORD and others expressed concern that we were referring to their products as being poisons rather than chemicals. In terms of the poisons standard, it is still the poisons standard, as it always has been…[The explanatory memorandum] uses the term ‘chemicals’ when it is referring to the chemicals committee and it uses the word ‘poisons’ when it is referring to the poisons standard or, indeed, the generic group of things that are medicines and chemicals.[33]

National uniformity

1.46 A major and ongoing issue of concern for industry groups has been the variability in the implementation of scheduling and other related matters in the States and Territories following a decision or recommendation made at a national level.

1.47 ASMI argued 'that the 'uniform' scheduling system is only almost uniform'. They considered that this is because the States have often not quite legislated in accordance with the 'uniform' Schedule. These variations are regarded as small and idiosyncratic and, in ASMI's view, not based on sound principles. However, it was argued that these small variations are costly and time-consuming for industry and contribute to situations which are not conducive for the promotion of quality use of medicines principles.

1.48 ASMI noted that section 52AA of the Bill promises “a uniform system in Australia” but the Scheduling Framework paper makes it clear that each State and Territory will continue to reserve its position. PSA believed that continuing to allow

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31 *Committee Hansard* 9.7.09, pp.41-42 (Mr Maskell-Knight, TGA).

32 *Submission* 3, pp.1-2 (PSA).

33 *Committee Hansard* 8.7.09, pp.35-36 (Mr Maskell-Knight, TGA).

such flexibility has the potential to significantly undermine the principles of quality use of medicines across Australia.[34]

1.49 The industry groups were strongly of the view that as a highest priority the Commonwealth must ensure that uniformity in scheduling was complete across all jurisdictions.

Powers of Secretary

1.50 The PSA noted that the revised list of factors which the Secretary must take into account in exercising powers, subsection 52E(1), no longer includes the safety of a substance, the patterns of use of a substance and the need for (access to) a substance. The PSA commented:

> It is PSA's belief that these three factors, in addition to those already proposed, are all fundamental considerations in the decision-making process for the scheduling of a substance and therefore warrant their explicit inclusion. The three issues referred to above are also mentioned in the Scheduling Policy Framework as factors to be considered in a scheduling decision and therefore their inclusion in the Bill will promote consistency with the Framework.[35]

1.51 The Department advised that when the subsection was redrafted, addressing the factors became repetitive:

> What we are now saying is that we must have regard to the risks and benefits of use; the purposes and extent of use; toxicity, dosage formulation, labelling, packaging and presentation; the abuse potential; and anything else. The PSA are saying that we should have regard to: safety—our view is that 'the risks and benefits' covers that; the patterns of use—our view is that 'the purposes for which a substance is to be used and the extent of use' effectively covers that; and the need for access to a substance—again, that comes under 'the purposes for which a substance is to be used'. So we think those criteria are actually covered.[36]

1.52 ASMI believed 'that the arrangements for delegated legislation as set out in the Bill could be greatly improved', though it was particularly concerned that subsection 52E(2) provided that the Secretary 'must comply' with any guidelines of AHMAC or its subcommittee, the National Coordinating Committee on Therapeutic Goods (NCCTG). ASMI submitted that as a non-elected body, whose processes are not transparent, and whose members are not publicly accountable, this subcommittee was an inappropriate body to issue binding policy directions under ss 52E(2),

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34 *Submission* 1, pp.7-8 (ASMI) and *Submission* 3, supplementary submission pp.1-2 (PSA).

35 *Submission* 3, p.2 (PSA); also *Committee Hansard* 8.7.09, pp.22-23 (Dr Sorimachi, PSA).

36 *Committee Hansard* 8.7.09, p.40 (Mr Maskell-Knight, TGA).

particularly as the directions as set out in the Scheduling Policy Framework are not proposed to be issued as a Legislative Instrument.[37]

1.53 The Department responded to these concerns that the NCCTG was not transparent or accountable:

> Firstly, it is no different to what happens now…It is not making a change. Secondly, the secret guidelines are the ones we have just been consulting on. If they were really going to be secret we would not have. Thirdly, for the most of the last three months I [Mr Maskell-Knight] have, for my sins, been the acting chair of the [NCCTG]. In that capacity I have received two requests for the committee to give guidance to the National Drugs and Poisons Scheduling Committee, and they have both been from industry saying, 'Why won't you tell the National Drugs and Poisons Scheduling Committee to do what industry wants?' So there is a capacity for it to be a double-edged sword, I would argue.[38]

1.54 ASMI provided drafting instructions for proposed amendments (reproduced at Appendix 3) to address these issues and others referred to in this report thereby improving the Bill. They believed that the proposed amendments were 'consistent with modern principles of transparency and accountability in regulatory design'.[39]

1.55 ACCORD commented on the proposed amendments indicating that 'for the most part these appear to be targeted at improving the accountability and transparency of the operation of the scheduling committees' and that on this basis, 'the suggestions relating to this aspect would be supported by ACCORD'. However, they also reiterated their recommendation for a 2-year review and the eventual implementation of more appropriate, separate arrangements for chemicals scheduling.[40]

1.56 The Department advised that they were willing to consider ASMI's proposals, though some may not require a legislative response:

> I think there are some issues with the drafting of a number of [the ASMI proposed amendments] and I do not think they necessarily require legislation. But there are some issues in there that we will think about.[41]

Cost recovery

1.57 Industry groups also raised concerns about the cost recovery proposals. The CHC was concerned as to whether the complementary medicines industry was going to be required to pay for chemical scheduling now separately to medicine scheduling, especially as their existing fees and charges paid to the TGA have significantly

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37 *Submission* 1, p.5 (ASMI).

38 *Committee Hansard* 8.7.09, p.40 (Mr Maskell-Knight, TGA).

39 *Submission* 1, p.9 and Attachment 4 (ASMI).

40 *Submission* 4, supplementary submission p.4 (ACCORD).

41 *Committee Hansard* 8.7.09, p.34 (Mr Maskell-Knight, TGA).

increased.[42] However, as ASMI noted, the paper setting out proposed arrangements has not yet been published and it is therefore unable to comment in significant detail.[43]

1.58 The Department confirmed that the current intention is to release a draft cost recovery impact statement that will spell out a schedule of fees for products listed under both the medicines and chemicals schedules. The Department explained that:

> The Therapeutic Goods Administration works on cost recovery at the moment. There were suggestions that we do not want to be cross-subsidising chemicals and so on. We do our very best to make sure that each activity we undertake is covered by the fees we charge for that particular activity. We have greater or lesser success with that, but those greater or lesser successes are at the margin. We certainly do not intend that the chemical industry will be getting a free ride from the therapeutic goods industry, nor do we want the chemical industry to be paying more than its fair share.[44]

Advertising offences for inappropriate advertising

1.59 Industry recognised that inappropriate advertising of therapeutic goods is of great concern, particularly in relation to accurate information being provided to consumers. The proposed amendment in Schedule 3 will mean that offence provisions can be applied to any persons found to be inappropriately advertising a therapeutic good, not just sponsors as is the case now.

1.60 The CHC acknowledged this amendment will deter sponsors from recruiting other persons to inappropriately advertise a product on their behalf, knowing that they cannot be penalised. However, the CHC sought further clarification as to how and when this provision would apply as they believed there may be certain scenarios where this may be difficult to administer, eg there may be scenarios where advertisements are published in good faith but are subsequently considered to be an offence under the Act. The CHC also sought clarification of a defence for an offence under this section and suggested that if the current wording in the proposal is to remain, a defence should be included to cover any scenarios where an advertisement is published in good faith.[45]

1.61 The CHC noted that it is currently working on an Advertising Reform proposal; and that advertising had been identified by the previous Parliamentary Secretary for Health and Ageing as an area requiring overall review, to which the industry agrees. The CHC understood that the TGA is also looking at advertising reform and suggested that any changes to the Act relating to advertising be postponed

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42 *Committee Hansard* 8.7.09, p.3 (Dr Morrow, Ms Roberts, CHC)

43 *Submission* 1, p.2 (ASMI).

44 *Committee Hansard* 8.7.09, p.41 (Mr Maskell-Knight, TGA).

45 *Submission* 6, p.4 (CHC).

until that review has been completed.[46] ASMI did not support this suggestion, commenting that 'as part of a proper review of advertising, it may come up again to be looked at, but it should not hold up the passage of this work'.[47]

1.62 The Department confirmed that that they are 'working towards producing a consultation document about how we think the advertising regime can be simplified and improved' though that process should not delay this amendment.

> …I think that this is a discrete problem that we have at the moment and that we should not wait 12 months to fix it up. If you go online, Senator, you will be able to find lots of online pharmacies bruiting products completely outside the indications that are on the register for them. At the moment there is no provision—there is nothing we can point to—that says, 'Thou shalt not do this because it is a criminal offence.'[48]

1.63 In relation to CHC's concern about advertising in good faith, the Department did not consider that this was an issue because the DPP was highly unlikely to form the view that it was in the public interest to prosecute someone for publishing in the scenario provided and even if that were to happen, the prosecuted person could use as a defence section 9.1 of the Criminal Code Act relating to acting in a mistaken belief about or are ignorant of particular facts.[49]

Advisory statements for medicines

1.64 The CHC referred to the amendments in Schedule 3, Part 2 of the Bill relating to advisory statements for medicines and sought clarification as to whether this proposal intends to alter the current process for establishing these statements and whether the complementary medicine industry will continue to be included in such consultations. The CHC indicated that it 'supports the requirement of advisory statements (where needed) for medicines, including complementary medicines, to inform consumers and raise awareness; however the CHC would like reassurance that the processes in establishing these will be done in full consultation with the complementary medicines industry'.[50]

1.65 ASMI also expected that there would be 'full and meaningful' consultation on the legislative instrument to be made under these amendments. ASMI proposed that a new sub-section 3(5C) be added to ensure that the legislative instrument 'must not require sponsors of the therapeutic goods to affix labels if the information would be misleading or deceptive, as those terms are used in s52 of the Trade Practices Act'.[51]

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46 *Committee Hansard* 8.7.09, pp.5, 7 (Dr Morrow, CHC).

47 *Committee Hansard* 8.7.09, p.11 (Ms Seifert, ASMI).

48 *Committee Hansard* 8.7.09, p.39 (Mr Maskell-Knight, TGA).

49 *Committee Hansard* 8.7.09, p.39 (Mr Maskell-Knight, TGA).

50 *Submission* 6, pp.4-5 (CHC).

51 *Submission* 1, p.8 (ASMI).

1.66 In response to these issues relating to advisory statements the Department provided the reassurance that was sought, confirming that 'they will be disallowable', adding that 'the Legislative Instruments Act mandates you must consult on legislative instruments, and we do consult on [Required Advisory Statements for Medicine Labels] at the moment. We will continue to consult in exactly the same way.'[52]

CONCLUSION

1.67 As is becoming common in recent times the Committee has once again been asked to inquire into a Bill which provides for much of the detail on its operation and administration to be outlined in yet to be drafted legislative instruments. This Bill does not commence until 1 July 2010 specifically to enable time for the associated regulations to be drafted. The Department has indicated that certain regulations and guidelines will be released in draft format and that industry will be involved prior to their finalisation.

1.68 The Committee considers that there remains a need for the Department and industry to work constructively together through a number of areas where industry raised concerns, and which will be the subject of legislative instruments, including membership and expertise on the Scheduling Committees, chemicals scheduling, appeal and review of decisions by the Secretary, cost recovery and the publication of advisory statements.

1.69 The Committee is mindful of the Minister's comment in the second reading speech that further changes to the therapeutic goods regulatory regime will be made later in the year which reinforces the importance for government and industry to work constructively together.

1.70 The Committee notes that the Department indicated that it considered that some of the ASMI proposals for improved transparency and accountability did not require a legislative response and that the other proposals would be considered. The Committee requests that the Department provide both the Committee and ASMI with feedback as to what actions it takes on these proposals together with an explanation of its decisions.

1.71 The Committee heard from all sectors of industry that they had issues with the Department's previous approach to consultation. It was not that there had been a lack of consultation, rather that it lacked meaningful feedback to explain why decisions had been reached and whether their proposals had been considered and rejected or simply ignored. While expressing certain cynicism as to the likelihood of continuing in this manner, the industry groups emphasised that they still wished to engage and work with the Department to ensure the best possible outcomes not just for these scheduling amendments but for the regulation of therapeutic products, medicines and chemicals in general.

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52 *Committee Hansard* 8.7.09, p.38 (Mr Maskell-Knight, TGA).

1.72 The Committee has concluded that the government should give a commitment that it will undertake the further consultation as foreshadowed with industry in a renewed sprit of openness and cooperation that will provide meaningful feedback to the proposals, issues and general concerns held by industry to ensure that the new system when fully implemented is supported by all parties and is totally transparent and accountable.

1.73 The bottom line with these changes to scheduling and related matters is to reduce risk and improve public health outcomes for the whole nation. The Committee supports the Bill and considers that it should be passed without delay to ensure that the maximum amount of time is available for the drafting and consultative processes that will be required in the production of the associated legislative instruments.

Recommendation

1.74 The Committee recommends that, subject to an undertaking by government to actively pursue the issues raised in the Conclusion to implement this new system, the Therapeutic Goods Amendment (2009 Measures No.2) Bill 2009 be passed.

Senator Claire Moore
Chair

August 2009

APPENDIX 1

Submissions received by the Committee

1 Australian Self Medication Industry

Supplementary information

- Supplementary submission dated 31.7.09

2 Department of Health and Ageing

Supplementary information

- Response to questions arising from hearing 8.7.09, dated 30.7.09

3 Pharmaceutical Society of Australia

Supplementary information

- Supplementary submission dated 13.7.09

4 ACCORD Australasia Limited

Supplementary information

- Supplementary submission dated 21.7.09

5 Plastics and Chemical Industries Association (PACIA)

6 Complementary Healthcare Council of Australia

7 Tasmanian Government

8 Western Australian Department of Health

9 Northern Territory Department of Health and Families

APPENDIX 2

Public Hearing

Wednesday, 8 July 2009
Parliament House, Canberra

Committee Members in attendance

Senator Claire Moore (Chair)
Senator Judith Adams
Senator Sue Boyce
Senator Mark Furner

Witnesses

Complementary Healthcare Council of Australia

Dr Wendy Morrow Executive Director

Ms Kristy Roberts, Scientific and Technical Manager

Australian Self Medication Industry

Ms Juliet Seifert, Executive Director

Mr George Brownbill, Consultant

Pharmaceutical Society of Australia

Ms Kay Sorimachi, Director, Policy and Regulatory Affairs

Mr Grant Martin, Director, Professional Services

Accord Australasia Ltd

Ms Bronwyn Capanna, Executive Director

Mr Craig Brock, Policy and Public Affairs Director

Department of Health and Ageing

Mr Charles Maskell-Knight, Principal Advisor, Regulatory Reform, Therapeutic Goods Administration

Mr Michael O'Connor, Director, Parliamentary and Regulatory Operations Section, Therapeutic Goods Administration