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THERAPEUTIC GOODS AMENDMENT (2009 MEASURES No.2) Bill 2009

A submission to the Senate Community Affairs Committee

by the

Australian Self-Medication Industry

July 2009

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EXECUTIVE SUMMARY

Overall support for the Bill

- As the representative of the Australian non-prescription medicines industry, **ASMI supports the principles in the Bill.**

Self-care

- It is fundamental to our national health policy proposals for **self-care** that people should have the least restrictive access to medicines. A balance must be struck.

Improvements in accountability and transparency

- Our proposals for amendments to the Bill, set out below are designed to make a good Bill better. If we had been consulted in a meaningful way, perhaps some of our proposals might have already been in the Bill.

Improvements in consultation

- Industry does not accept that a take it or leave it approach amounts to meaningful consultation.

Separation of chemicals and medicines scheduling

- This is long overdue.
- We also support the Secretary of the Department of Health and Ageing (or her TGA delegate) as the decision-maker.

Cost recovery

- We await further details before commenting.

Constitution of expert committee

- ASMI expects that the Regulations will **not** continue the State jurisdictions' veto.
- The Committee should have an independent Chair and not an *ex officio* TGA or Health Department official.

Merits and judicial review

- The Bill should be amended to allow for these, at least in the case of individual applicants (s. 52EAA)

NCCTG guidelines – s. 52E(2)

- Ideally the Scheduling Policy Framework – which is plainly legislative in nature – should be a disallowable Legislative Instrument. In lieu of this, ASMI proposes greater transparency and accountability for the NCCTG, with requirements for meaningful consultation.
- We also believe the Act should require guidelines under s. 52E (2) to be consistent with COAG's Good Regulatory Principles.

Medicines Schedule – criteria

- In addition to the matters is to take into account under s. 52E (1), (2) and (3) we propose that the Minister should issue a guideline, by way of disallowable LI, requiring that the matters listed in paras (1) (a)-(f) are carried out consistently with COAG's Principles of Good Regulation in such a way as to ensure modern methodologies are used, including hazard assessment, risk assessment, benefit/cost analyses and probability of adverse events.

Uniform Scheduling

- Section 52AA refers to a "uniform" system but State idiosyncrasies still impose minor (but very costly to industry and therefore consumers) variations.
- It is feasible for the Commonwealth to "cover the field" and legislate in its own right in this matter. Any doubt on this issue was removed by the High Court's decision in the Work Choices case.

Data exclusivity

- ASMI believes the Bill should be amended so that successful individual applicants seeking a commercial-in-confidence favourable scheduling decision should have a brief window of opportunity to develop new markets ahead of competitors who have not invested the time or money that the original applicant did.

Label advisory statements

- ASMI expects there to be full and meaningful consultation on the draft Legislative Instruments to be made under Schedule 3, Part 2 of the Bill.

- We also recommend that the Legislative Instruments must not require labels to be affixed which would be misleading or deceptive, as referred to in s. 25 of the Trade Practices Act.

ABOUT ASMI

Australian Self-Medication Industry (ASMI) represents the interests of Australian manufacturers of non-prescription medicines. We represent both the so-called "over-the-counter" (OTC) sector and the bulk of the "complementary" sector. Annual turnover is about $3bn.

SELF-CARE – RESPONSIBLE SELF-MEDICATION

The products which our members provide to the public are thus self-selected, whether from pharmacies or more generally. ASMI believes strongly in **responsible** self-medication. Thus we look to a strong partnership with government to ensure that the regulatory framework works to protect the public. Equally, however, that framework needs to ensure that beneficial medicines are available to people at least cost and with no more regulatory restrictions than necessary.

Clearly, a balance must be struck. This legislation is about striking the right balance.

At issue are questions going beyond the convenience of ASMI members. An important principle of public health arises.

ASMI has been at the forefront in recent years in developing the concept of **self-care.** This means people taking responsibility for their own health, making better-informed decisions about prevention – first of all – and then treatments. A fuller account of ASMI's self-care policy is at Attachment 1.

Our research shows that people seek information about health and medication from many sources. Increasingly, they see themselves as partners rather than patients.

The Australian Self-Medication Industry has an important role to play in adjusting to these trends. And they are trends which we see the Australian Government supporting, through the work of its agents of reform – the National Health and Hospital Reform Commission, the Preventative Health initiative, the Primary Healthcare Taskforce.

IMPORTANCE OF THIS LEGISLATION

The legislation being considered by the Committee is of fundamental importance to the enhancement of these policy directions. It will determine, by the way it

operates, whether the self-care policies will be advanced, or whether, through an unduly risk-averse approach, it will be stymied.

ASMI SUPPORTS THE LEGISLATION IN PRINCIPLE

Reforms in the scheduling arrangements have been a long time coming. A decade has passed since the Galbally inquiry began. Throughout all that time, the Government's consultations have been far from extensive or meaningful.[1]

Nevertheless, and subject to what is said below, ASMI considers that the Bill represents some important progress and we offer support for it.

In particular, ASMI supports the following basic principles.

- Separation of chemicals and medicines scheduling, but with separate secretariats.
- Decisions arising from expert Committee recommendations to be made by the Secretary of the Department of Health and Ageing (in practice by her delegate in the Therapeutic Goods Administration).

We also have little quarrel with a great deal of what is proposed in a paper known as the *Scheduling Policy Framework*.[2] However, we have serious reservations about the lack of transparency and accountability of the process set out in the Bill. This question is dealt with further below.

COST RECOVERY

We also have concerns about proposals for cost recovery, which are hinted at in para 52EAA (2) (d) of the Bill. However, the paper setting out proposed arrangements has not yet been published (it was promised some time ago) and ASMI is therefore unable to comment in significant detail.

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1 At Attachment 2 is a list of all the occasions over the last decade on which ASMI has made submissions. 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.

Copies of any of the papers referred to in Attachment 2 can be provided to the committee, if desired.

2 We are yet to see the *Scheduling Policy Framework* in its final form. We will reserve our comments, which we believe are constructive, when that document, and the Regulations, are published for comment.

ACCOUNTABILITY AND TRANSPARENCY

Before this legislation was introduced, ASMI – and other industry representatives – asked that an exposure draft be published. As well, we asked that drafts of the proposed regulations and other statutory instruments be similarly published. These requests were not agreed to. But no reasons were provided, and no discussions held with us.

ASMI regrets that the Government did not see its way to meet our requests, because it will be apparent from what is said below that a proper and **meaningful** process of consultation would have resulted in significant improvements to the legislation. As it is, we now ask the Senate Committee to consider our concerns and recommend improvements to the Bill. We propose, as soon as possible, to provide a paper setting out our ideas on drafting instructions for amendments of the Bill. We would like the Committee to propose these to the Senate.

CONSTITUTION OF THE EXPERT COMMITTEE

Sub-section 52B (2) says that the Committee is to be constituted in accordance with the regulations. Sub-s. 52B (3) says that each of the States may nominate one member of the Committee.

But, because the regulations have not been published as an exposure draft, we do not know any more than that about who makes up the Committee. How many members will there be and, of fundamental importance, will the State bureaucrats continue to have a veto over all its decisions?[3]

ASMI considers that the jurisdictional members 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.[4]

We consider it is essential that the regulations do not continue this veto arrangement.

ASMI also believes that the Committee should have an independent Chair – that is, he/she should not be *ex officio* a TGA officer, or an official of the Department of Health and Ageing, of which TGA forms a part.

[3] See Therapeutic Goods Regulation 42ZCR (2).

[4] Evidence was given in the Xenical case that some jurisdictional members had sought and/or been given Ministerial direction as to how they should vote in the NDPSC.

MERITS AND JUDICIAL REVIEW

ASMI has been told that the regulations will allow for decisions of the Secretary to be "reconsidered". However, that reconsideration would be by another TGA official. We believe that the provisions of s. 60 of the Therapeutic Goods Act should be amended so that decisions under Part 6-3, as proposed to be amended, can be appealed, including to the AAT, and under the Judiciary Act.

We ask the Committee to recommend such an amendment.

Alternatively, and as a default position, ASMI's member-companies would be prepared to recommend that decisions taken under s. 52EAA (that is, after consideration of applications by a person to amend the Schedule) be taken to be decisions of an administrative character. Thus they would be appelable under s. 60 and beyond to the AAT. It would also be necessary to make it clear that a decision to refuse an application would be appelable.

LEGISLATIVE INSTRUMENTS

The Legislative Instruments Act is the means by which the Parliament can assure itself that the subordinate legislative powers it confers on the executive are exercised properly. In this, transparency and accountability of the subordinate legislative process are fundamental.

ASMI believes that the arrangements for delegated legislation as set out in the Bill could be greatly improved. In particular, we refer the Committee to

- Item 11 – section 52A (2) – specifying substances; and
- Item 2 – section 52E (2) – directions by a subcommittee of the Australian Health Ministers' Advisory Council (AHMAC); or its sub-committee, to be binding;
- the statement at p. 7 of the EM to the Bill that the Poisons Standard remains a LI exempt from disallowance.

SUBSTANCES TO BE SCHEDULED

ASMI does not object to this provision. However, we believe it should be the subject of **meaningful** (that is interactive and iterative) consultation with industry.

We ask the Committee to so recommend.

DIRECTIONS BY AHMAC OR ITS SUB-COMMITTEE

ASMI has very strong concerns about this provision.

First, what is the "sub-committee" referred to in s. 52 (2)? It is more generally known as the National Coordinating Committee on Therapeutic Goods – NCCTG.

The sum total of what is known about the NCCTG appears on the TGA's website[5] is reproduced at Attachment 3. The Committee will note that

- the NCCTG is not established by, or otherwise recognised in any other, statute;
- It meets in secret and no minutes or records of its discussions are published;
- its members are appointed by non-statutory processes;
- and being officials, they are subject to ministerial direction by their ministers and/or bureaucratic superiors.

ASMI submits that a non-elected body, whose processes are not transparent, and whose members are not publicly accountable is an inappropriate body to issue binding policy directions under s. 52E (2), particular as the directions as set out in the *Scheduling Policy Framework*, are not proposed to be issued as a Legislative Instrument.

The Scheduling Policy Framework is clearly of a legislative character. Ideally, it should be issued as an LI and be subject to disallowance processes. Because, however, the document is said to represent policies decided on jointly by Commonwealth and State jurisdictions, ASMI understands there could be difficulties in following this course.

We therefore propose the following default position. The Bill should be amended to

- require that the AHMC and NCCTG publish the minutes of those parts of their meetings where the directions proposed to be issued under s. 52E(2);
- require that any directions must be consistent with the COAG Principles of Good Regulation; and
- require that the NCCTG ensure that there are meaningful (that is, interactive) consultations with industry and other interested parties in the development of any directions.

[5] www.tga.gov.au/docs/html/ncctg.htm

MEDICINES SCHEDULE – matters to be taken into account

ASMI accepts that the matters set out in s. 52E (1) are appropriate, subject to two conditions:

First, we have argued above that the guidelines issued under sub-section 52E(2) should be a Legislative Instrument, or failing that, at least be required to be consistent with COAG Principles. Considering that all Commonwealth and State jurisdictions have signed up to these, there ought be no difficulty in accepting this proposal.

Second, however, we propose that the Minister be required to lay down, by LI, guidelines which both the Committee and the Secretary would have to observe in the application of the scheduling criteria set out in s. 52E (1).

The LI we propose would require scheduling decisions to be taken after hazard assessment, risk assessments, benefit/cost analysis and probability studies to quantify adverse events, had been conducted and having regard to their findings. All these would be required to be consistent with the relevant COAG Principles which recommend, indeed mandate, these approaches in all modern regulatory systems.

ASMI makes this important recommendation, because we do not believe these modern, scientific techniques have been applied by the NDPSC with sufficient rigour. We have never believed that it is enough to identify the "hazard" a medicine presents. The risk must then be measured (as s. 52E (1) (a) is to require), using sophisticated probability techniques.

This approach is especially necessary under the new arrangements for applications – usually submitted by individual companies – for down-scheduling of substances. Only by a policy which is open to "switching" will the public health benefits under our self-care policies be realised.

We consider that the Regulations relating to the constitution of the Committee must include persons qualified in these disciplines among its members.

MEDICINES SCHEDULE – appeals relating to individual applications

ASMI accepts that the Schedule itself should remain as a LI exempt from disallowance. However, we do not accept the argument that individual decisions should, for that reason, not be appelable.[6]

As noted above, it seems to us that, if individual companies can apply for scheduling decisions and these can be "reviewed", then those decisions can

[6] See paras 4-5 on p. 7 of the EM,

likewise be appealed, under s. 60, all the way to the AAT. It seems to us, also, that decisions must be open to judicial review.

We ask the Committee to recommend amendments to the Bill to meet all the above concerns about the Medicines Schedule.

Although the argument can be made that the action of amending the Medicines Standard is quasi legislative in character, the process of taking a decision to change the schedule status of a particular item is administrative. This is seen from the Administrative Decisions (Judicial Review) Act 1977 (Cth) **(AD(JR) Act).** Although that Act is confined to the review of "decisions of an administrative character",[7] the Act specifies as follows:

> "In this Act, a reference to the making of a decision includes a reference to:
>
> (a) making, suspending, revoking or refusing to make an order, award of determination;
>
> …
>
> (b) doing or refusing to do any other act or thing."[8]

The AD(JR) Act also allows for the judicial review of conduct engaged in for the purpose of making a decision.[9] The Act provides:

> "A reference in this Act to conduct engaged in for the purpose of making a decision includes a reference to the doing of any act or thing preparatory to the making of the decision, including the taking of evidence or the holding of an inquiry or investigation".[10]

Of course, to have standing to appeal a decision, whether to the Administrative Appeals Tribunal or to obtain judicial review by the courts, one has to have standing to bring the appeal or application. Only a person whose interests are particularly affected by a decision has such standing.[11] This would be the case with applications by individuals.

UNIFORM SCHEDULING

For many years now, **ASMI has been most concerned that the "uniform" scheduling system is only almost uniform.** This is because the States have

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7 See the definition of ***decision to which this Act applies*** in s. 3(1) of the AD(JR) Act. There is no such restriction for judicial review cases brought under s. 39B of the *Judiciary Act 1903* (Cth) and the Australian Constitution.

8 s. 3(2) of the AD(JR) Act.

9 s. 6(1) of the AD(JR) Act.

10 s. 3(5) of the AD(JR) Act.

11 ss. 5(1) and 6(1) of the AD(JR) Act and s. 27 of the *Administrative Appeals Tribunal Act 1975* (Cth).

often not quite legislated in accordance with the "uniform" Schedule. These variations are small and idiosyncratic and, in our view, not based on sound principles. These small variations are costly and time-consuming for industry.

We have long pressed for a truly uniform system. We note that s. 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.

It is for this reason that ASMI has consistently pressed for poisons legislation to "cover the field". In our view, there is ample Commonwealth power to do so. We do not accept the assertion in the Parliamentary Secretary's Second Reading Speech that "the cooperative arrangement we have with the States … is **necessary** under the Constitution to achieve scheduling implementation uniformly" (emphasis added).

The decision of the High Court in the WorkChoices Case[12] would both enable the Commonwealth, for practical purposes, to cover the field regarding poisons; and gives it negotiating leverage to ensure that the States and Territories do take the necessary steps to ensure full uniformity across Australia. In our view, at the very least, the Commonwealth must ensure uniformity is complete across all jurisdictions.

DATA EXCLUSIVITY

Our member' companies often invest a great deal of time and money in putting proposals to the NDPSC for down-scheduling of substances they either intend to include in medicines they already make and/or sell, or to purvey in new, innovative, formulations.

A favourable decision is of some considerable commercial advantage to the applicant. However, since it is the **substance** and not the therapeutic good, which is the subject of the decision, any other person can free-ride on the decision, as soon as it is announced.

ASMI has for some time argued that there should be provision in the legislation for successful applicants who have made commercial-in-confidence proposals to have the advantage of a brief window of opportunity to exploit that success, ahead of their commercial rivals. A period of no less than six, nor more than twelve, months is considered reasonable.

We recommend that the Committee propose an amendment to s. 52EAA to allow the Secretary to grant this window of opportunity to successful applicants where the Secretary is satisfied that either or both:

[12] *New South Wales v Commonwealth* (2006) 231 ALR 1.

- the proponent's product will enhance and encourage innovation in the Australian industry; or
- the proponent's product proposed for down-scheduling represents a large or significant investment by the company concerned.

SCHEDULE 3, PART 2 OF THE BILL

Although not related to scheduling, the proposed amendments to s. 3 (5) of the Act call for some comment.

It appears that the document issued by the TGA now known as Required Advisory Statements on Medicine Labels (RASML) is to be the subject of a LI, we trust disallowable.

ASMI expects that there will be full and meaningful consultation on the LI before it is issued.

We also propose that a sub-s. 3 (5c) be added to require that the LI 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 s. 52 of the Trade Practices Act.

AMENDMENTS TO THE BILL

With the objective of assisting the Committee, we have set out, at Attachment 4, drafting instructions illustrative of the various amendments we have proposed in this Submission. We would be happy to discuss these further in detail with the Committee, or indeed the Government.

CONCLUSIONS

In this submission, our intention has been to propose to the Committee ways in which this legislation can be improved. **Those improvements, we believe, are consistent with modern principles of transparency and accountability in regulatory design.** They are not intended to be critical of the good work officials have done in the past and, which, we don't doubt, they will continue to do.

The principles of transparency and accountability, to which we have drawn attention, are said by the present Government to be fundamental to its regulatory policy approach. Likewise, our understanding of the Senate's traditional approach to legislation is that there is a concern to see these principles upheld in measures that come before it.

We trust, therefore, that our recommendations will be seen as **efforts to make a good bill better.**