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31 July 2009

Mr Elton Humphery
Secretary
Senate Community Affairs Committee
Parliament House
CANBERRA ACT 2600

Dear Mr Humphery

ASMI has reviewed the evidence given at the 8 July hearings on the Therapeutic Goods Amendment Bill, and the submissions sent to the Committee subsequently.

I am pleased to send to you the attached supplementary submission.

If the Committee wishes to examine ASMI further, we will be happy to make ourselves available.

Yours sincerely

Juliet Seifert
Executive Director

Encl.

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

A supplementary submission to the Senate Community Affairs Committee

by the

Australian Self-Medication Industry

July 2009

Table of contents

ATTACHMENTS

THIS SUBMISSION

ASMI has examined the transcript of the Committee's hearings held on 8 July 2009. In the light of the evidence given by the Department of Health and Ageing, we wish to put the following information to the Committee by way of supplementary submission.

We would also like to offer some comments on the supplementary submission by ACCORD and submissions made by some jurisdictions. Apparently these were received subsequent to the Committee's hearings.

CONSULTATION

The Committee received evidence from the Department which purported to rebut ASMI's and others' concerns about the adequacy of the consultative process.

It was said that there had been "three major phases of consultation that the TGA has carried out."[1] These were

- consultations in August and September 2005, resulting in posting on the TGA's website of a document dated 15 December 2005;
- consultations in the development of draft Rules under ANZTPA – 2006; and
- the current consultations, beginning in April 2009 and from which the Bill before the Committee arose, and which, apparently, are still in train.

In regard to this sequence of events, we note as follows.

Relevance of first two rounds

First, the TGA seems to regard the first and second of the above occasions as relevant to the recent round of consultations. We note, however, that

- Both earlier rounds took place while the former Government was in office. It is a well-accepted convention that a change of government brings with it a presumption that unfinished business lapses, unless specifically revived by the incoming Government. That revival cannot be seen as having happened before April this year.
- With the demise of ANZTPA, all concerned were entitled to assume, and did assume, that all bets were off. In a statement following the collapse of

[1] Transcript, 8 July 2009, p. CA32.

ANZTPA, the Parliamentary Secretary made it clear that the Australian Government would be "considering how to garner the benefits of the consultations undertaken … to date."[2]

- When the TGA held consultations in mid-2008 on a range of regulatory reforms, officials specifically declined to indicate what was proposed, or when something would be proposed, about scheduling arrangements.
- A letter from ASMI to the Parliamentary Secretary, dated 12 September 2008, sought information on progress following the Productivity Commission's Report on Chemicals; this letter was never replied to[3].
- No new information or documentation was provided, nor anything posted on the TGA's website, until April 2009.

So far as the public record is concerned, it is fair to say that industry was aware of the 2005 proposals, and the ANZTPA draft Rule. But there was no warrant to assume these were part of a seamless process resulting in the April 2009 proposals and legislation.

ASMI's main concerns not addressed

Secondly, an examination of ASMI's submissions to the 2005 Review,[4] to the ANZTPA Implementation Group[5], and to the TGA in April this year[6] will show that we have maintained a consistent policy in relation to scheduling arrangements. The 15 December 2005 document does not go anywhere near responding to the substantive issues we raised. In our view, it is not a fair comment of the TGA officer to characterize the 15 December document as

> "These are the observations and this is the response".[7]

At the most, the 15 December 2005 website summarised some issues and indicated NCCTG views. There was, for example, no mention of the four principles set out this way in the Executive Summary:

> "ASMI has maintained for some time that:
>
> o The scheduling regime should be the subject of Commonwealth legislation which should "cover the field" under the external affairs power (which allows the Australian Government to enter into the Trans Tasman Treaty);

2 Statement by Sen. the Hon Brett Mason QC 18 July 2007.
3 The letter is reproduced at Attachment 1.
4 Reproduced at Attachment 2.
5 Reproduced at Attachment 3.
6 Reproduced at Attachment 4.
7 Transcript, 8 July 2009, p. CA32.

- The regime should operate transparently under laws clearly defining the criteria to be applied, and it should be seen to be transparent;
- There should be true and complete national uniformity; and
- The regime should follow good regulatory practice, as required by COAG."

Deals not announced

Thirdly, ASMI found out almost by accident that the AHMC had approved the Scheduling Framework as first proposed in 2005. This information appeared in a footnote in the PC's report, which related mainly to chemicals regulation. Contrary to COAG Principles, none of the AHMC, AHMAC, NCCTG or TGA had announced this decision, still less consulted industry about it. As it turned out, little had changed from the 2005 document.

Secrecy of NCCTG

Fourthly, the Department's officials seem to have made it very clear to this Committee that the processes of the NCCTG are separate from those of the TGA and not appropriate for public (or even Parliamentary) scrutiny.[8]

A done deal?

Fifthly, we learned for the first time during the Committee's hearings on 8 July 2009 that the States had put three conditions on their acceptance of the new scheduling arrangements. Mr O'Connor told the Committee:

> "The States and Territories, in agreeing to separate the National Drugs and Poisons Schedule Committee, set out three criteria or provisos for

[8] See Transcript, p. CA32:
"The last round was when we put out, **on behalf of the NCCTG,** the Draft Scheduling Policy Framework and the Draft Standard for the Uniform Scheduling of Medicines and Poisons, **in April this year.** That consultation period **closed at the end of May** and 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.**

CHAIR – were people advised that the form of feedback would be on a website? **Were people advised that that would be how they would get information back?**

Mr Maskell-Knight – Did we do that from last time?

Mr O'Connor – **I cannot recall."** (Emphasis added).

> agreement for the separation. The common secretariat was one, for the need for coordination and cohesiveness between the two committees; the second one was a single schedule policy framework; and the third one was a single poisons standard, which we are trying to deliver through this bill."[9]

And Mr Maskell-Knight had previously said:

> "I think that if the states say 'we want it this way' and the states are responsible for implementing it then that is a pretty compelling argument."[10]

Taken together, these remarks suggest quite strongly that the legislation before the Committee is a *fait accompli* and that the consultation process was never intended to represent a dialogue during which there was any disposition to consider, still less accept, reasoned argument from industry or anyone else. We note, for example, that a central tenet of ACCORD's concerns – separation of medicines and chemicals scheduling – had been vetoed.

This view is further supported by a consideration of the brief submissions the Committee has received from the NT, WA and Tasmania, each of which says little more than "we want it this way."[11]

Not only the Commonwealth should consult

In ASMI's view, the issues which the States have apparently regarded as non-negotiable, and indeed the whole process by which the Scheduling Framework was agreed on, ought to have been the subject of consultation during that process, **not** after everything was cut and dried. The States are as much subject to the COAG Good Regulation Principles as is the Commonwealth. It lays down very clearly the need for a continuous, iterative consultation process.[12] In the present case, this has plainly not been followed.

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9 Transcript 8 July 2009, p. CA37.

10 *Ibid*, p. CA33.

11 See submissions Nos 7, 8 and 9.

12 See COAG*, Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standard-Setting Bodies* (1997), p. 4:

> "The principles of good regulatory practice apply to decisions of Ministerial Councils and intergovernmental standard-setting bodies, however they are constituted, and includes bodies established statutorily or administratively by government to deal with national regulatory problems.
>
> The principles apply to agreements or decisions to be given effect through principal and delegated legislation, administrative directions or other measures which, when implemented, would encourage or force businesses or individuals to pursue their interests in ways they would not otherwise have done (but this does not include purchasing policy or industry assistance schemes)."

"ON-GOING" CONSULTATION

Evidence before this Committee on 8 July established that more consultation processes are in the pipeline:

- providing "a brief rationale for why we are not adopting a particular comment" – not, be it noted, why we **are**.[13]
- a draft cost recovery statement is to be released "later in the year".[14]

This situation is unsatisfactory to industry, and, we would have thought, to the Parliament. Essentially what the Department is saying is – pass the Bill and leave the details to us.

SUBORDINATE INSTRUMENTS

As noted in our earlier submission, there are various legislative instruments which the Bill would authorise. ASMI is concerned that these be developed by transparent processes and that those making them are accountable.

Our submission to the Committee is that the Bill in its present form does not provide these guarantees.

An examination of the Department's evidence on 8 July 2009 does not allay those concerns. The Department said

> "We will continue to consult in exactly the same way."[15]

As we have shown, the consultation about the Scheduling Framework has been conducted on the basis of a done deal unknown to those being consulted. No proposals by industry have been accepted, anyway.

Thus there is little basis to expect that the consultation on statutory instruments the Bill would authorise will be meaningful.

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[13] Transcript 8 July 2009, p. CA33. See also, p. CA35, where it is said that "feedback" will be provided "later this month".

[14] Transcript 8 July 2009, p. CA39.

[15] Transcript 8 July 2009, p. CA37. The remark was made in response to a question about the enumeration of permitted ingredients but has, in our view, general application.

COST RECOVERY

We have referred above to cost recovery. Some time later this year, something may appear setting out who pays, and how much. These questions, and the precise legal underpinning of the charge regime, are of vital interest to industry, and especially the non-prescription medicines sector. We are not in any position to comment on this matter in the absence of any information. We would hope, therefore, that the Senate will not be put in the position of passing "high level" legislation which may authorise the imposition of fees, charges (or perhaps taxes), sight unseen.

LEGAL AND CONSTITUTIONAL ISSUES

ASMI notes that ACCORD has provided to this Committee a legal opinion on various issues raised by the Bill.

The issues identified go to matters more closely relevant to chemicals regulation than therapeutic goods. Nevertheless, we would submit that while these matters warrant close attention by this Committee, their resolution should not be a cause of further delay in necessary reforms to the therapeutic goods regulatory regime.

CONCLUSIONS

In our original submission, ASMI expressed concerns about the consultation process. **This supplementary submission shows that those concerns were justified.**

More important, perhaps, **we continue to press for a true measure of transparency and accountability** in these necessary and long overdue reforms. **We again commend to the Committee the need for amendments to the Bill** along the lines of the suggestions set out in Attachment 4 of our original submission.

Attachment 1

Attachment 2

Attachment 3

Attachment 4

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12 September 2008

Sen the Hon Jan McLucas
Parliamentary Secretary to the Minister for Health and Ageing
Parliament House
CANBERRA ACT 2600

Dear Senator

As you will know, ASMI took a keen interest in the recent briefings which the TGA held to outline proposed reform initiatives. We appreciated the opportunities to be briefed on future intentions.

When questions were raised about the Scheduling processes, we were told that this matter would be the subject of separate, later, consultation. It was said that a report of the Productivity Commission would soon be presented to the Government.

That Report was provided to the Government on 7 August 2008. It is mainly about "Chemicals and Plastics Regulation" but does take up the proposal to split the NDPSC into "poisons" and "medicines" groups.

Industry was consulted about proposed scheduling arrangements within ANZTPA. Our submission dated December 2006 recorded our many concerns with what was proposed – see the attached Executive Summary. In the event, ANZTPA fell through and the reforms originally proposed by Galbally remain unrealised.

If, as the Productivity Commission report proposes, the chemicals committee is to be proceeded with "as soon as feasible", there will need to be parallel arrangements in respect of medicines scheduling.

Industry has a close interest in every aspect of the scheduling process. There are many characteristics of current arrangements which do not measure up to the Government's and COAG's, regulatory reforms. In our view, the opportunity must be taken to achieve substantial modernisation of scheduling processes. Industry will wish to have our views known in detail on the issues.

We therefore ask whether you can indicate what process is to be followed in settling new scheduling arrangements; what timetable is to be followed; and – most importantly – when consultations with industry and other interested parties will take place. We are keen to make a detailed and positive contribution as this matter develops.

Yours sincerely

Juliet Seifert
Executive Director

Attachment 2

Submission to ANZTPA Implementation Group regarding proposed Scheduling arrangements Dec 2006

Executive Summary

- ASMI must reserve its position on the entire proposed scheduling process until complete information (including the policy guidelines) is available.
- ASMI welcomes acceptance of the Galbally proposal to separate "poisons" and "medicines".
- We also welcome the intention that the Authority will take scheduling decisions.
- Trans-Tasman uniformity will not be enhanced by the Commonwealth's unwillingness to "cover the field" – leaving it to the States to give effect to the Schedule – nor by the NZ decision to continue to operate its Misuse of Drugs Act.
- At the very least, all the States/Territories should commit to adoption of the Schedule "by reference".
- We cannot comment on the "Australia only" arrangements, in particular the intended role (if any) for the Office of Chemical Safety.
- ASMI supports the proposal that, in respect of new substances, the initial recommendation may come from expert committees other than the MSC.
- Regarding the constitution of the MSC,
  - there should be no distinction between "nominated" members and others;
  - industry and consumer interests should continue to be able to nominate representatives and have those nominees appointed;
  - persons with expertise in risk/benefit analysis and communications should be added members of the MSC.
- There is a need to clarify what are the points of "decision" as between the Authority, on the one hand, and the expert committees, on the other.
- ASMI welcomes the "Reconsideration" proposals.
- Sponsors must have a statutory right of access to committees and/or the Authority to argue cases in person, especially when it comes to "Reconsideration".
- Provisions for data protection and market exclusivity, especially for "switch" proposals, should be included in the Act(s) or Rules, or both

A Proposed Model for the Scheduling of Medicines

Submission to the

Therapeutic Goods Administration

by

Australian Self-Medication Industry

September 2005

Contents

ATTACHMENTS

1. Industry Commission's Overview on Scheduling
2. Excerpt from ASMI Executive Summary to Galbally review
3. Comparison of Proposed Factors and Current criteria

EXECUTIVE SUMMARY

- **ASMI appreciates the opportunity to comment on the Proposed Model for the Scheduling of Medicines and associated Framework in preparation for the commencement of the Trans-Tasman Agency.**

- **ASMI supports the separation of medicines scheduling from that of poisons.**

- **However, we are very concerned that none of the proposals we have made – over the last ten years – for improvements in the scheduling of medicines arrangements have been taken up.**

- **ASMI has maintained for some time that:**

    - **The scheduling regime should be the subject of Commonwealth legislation which should "cover the field" under the external affairs power (which allows the Australian Government to enter into the Trans-Tasman Treaty);**

    - **The regime should operate transparently under laws clearly defining the criteria to be applied, and it should be seen to be transparent;**

    - **There should be true and complete national uniformity; and**

    - **The regime should follow good regulatory practice, as required by COAG.**

- **ASMI believes that the proposed model will meet none of these tests.**

- **The Australian Government is reported to have made regulatory reform a high priority, but the proposed model will make life more complex and difficult for business than it need be.**

- **We regret, further, that over many years now, those responsible for development of the model did not consult industry as the ideas now presented in the consultation papers were being developed.**

- **ASMI therefore believes that meaningful consultations with industry, based on a range of models and bearing in mind the above principles, should now take place.**

- **ASMI reserves the right to comment further on the Trans-Tasman Agency's scheduling arrangements when the legislation setting it up, and the Rules together with the "Australia only" legislation, can be properly examined.**

RECOMMENDATIONS

- **The scheduling model should be underpinned by legislation which provides extensive cover under the external affairs power.**

- **Ongoing consultation with all stakeholders needs to continue to provide an acceptable, transparent, clearly identifiable and workable legislative Model for scheduling of medicines and poisons.**

- **The legislation should create a model which will operate transparently and in accordance with clearly defined criteria.**

- **Appropriate flowcharts with timelines needs to be provided for all activities related to scheduling and rescheduling of medicines and poisons.**

- **The Medicines Scheduling Committee should be a mix of representation and expertise in specific areas. Appropriate criteria for selection of 'experts' needs to be developed.**

- **The process for appealing decisions needs to be strengthened to allow inclusion of appeals on the merits of a decision.**

- **Certain terminology needs clear definitions and statutory framework to avoid any confusion, for example 'public interest', 'public health benefit', 'substantially safe', 'misused' or 'abused'.**

1 PURPOSE OF THIS SUBMISSION

1.1 The issues

The Australian Self-Medication Industry (ASMI) appreciates the opportunity to comment on these consultation documents:

- *A Proposed Model for the Scheduling of Medicines* – July 2005; and
- *Scheduling Policy Framework for Medicines and Poisons* — July 2005

which were recently published by the TGA.

As well, reference is made to *A Proposed Model for Scheduling of Poisons in Australia* — July 2005.[1]

1.1 Consultation

Perhaps more than any other medicines industry body, ASMI is vitally interested in the way the scheduling system has worked; and in ways it is intended to work in the future.

Ten years ago, ASMI (then PMAA) made strong representations to the Industry Commission (IC) on this matter, among others. Over five years ago, we put submissions to the Galbally Review and to subsequent TGA official reviews of the Galbally Report.

Five years have passed since Dr Galbally reported and almost three since the idea of a Joint Trans-Tasman Agency was first adopted as policy. Throughout all that time, decisions to give effect to reforms, which the IC had found were needed five years before then, have not been taken. And, in the five years since the Galbally report was published, only the most generalised accounts of what might be in prospect have been publicly divulged.

ASMI considers that the proposals contained in the consultation papers that have only now been published would have benefited from closer — but continuous — consultation, over the last five years, with industry. As this submission will show, we have a range of significant concerns with what is now proposed. In our view, the scheme as proposed will need careful re-assessment and substantial revision if it is to be acceptable to industry, whether in Australia or New Zealand.

Our fundamental concern is that those responsible for policy development have not rethought the scheduling system, in the light of the Trans-Tasman developments, with a view to giving effect to modern, best-practice regulatory arrangements. Rather, the proposal is a cut-and-paste of elements of the present system, with all of the features we have — for ten years now — explained were ineffective from industry's viewpoint. The cut-and-paste nature

[1] Referred to below as "Medicines Model"; "Framework", and "Poisons Model" respectively

is exemplified by the apparent intention to have Schedules 2, 3, 4 and 8 for medicines, thus harking back to the days when the NDPSC really saw all medicines as “poisons”.

In short, an important opportunity for reform and modernisation has been passed over.

2 PAST POLICY CONSIDERATION

2.1 ASMI policy

Over the past decade, ASMI's policy on the scheduling process and related issues has been consistent. In brief, we have urged that:

1. The Commonwealth should "cover the field" and legislate for a truly national, truly uniform scheme.

2. The assessment and evaluation procedures should be open and transparent based on scientific risk assessment and cost/benefit principles, as laid down in COAG papers.

3. Industry should be properly represented on the scheduling Committee and the States should not have an effective veto on Committee decisions.

We have also become increasingly concerned that, in its consideration of proposals for advertising of S3 substances, the Committee has taken an unduly conservative approach, which is out of touch with modern market realities.

2.2 Industry Commission

Ten years ago, we made very clear to the Industry Commission our concerns as set out above. The Commission recognised in its Report that the system was in need of significant reform.[2]

The IC's principal findings were that the scheduling process required legislative underpinning and that the Commonwealth should take over the process. It also called for a review of the need for both S2 and S3 schedules.

2.3 1999 Legislation

In 1999, some limited reforms were introduced. The Therapeutic Goods Act was amended by insertion of Part 6-3. Section 52B established the NDPSC and other provisions (including Part 6, Division 3A of the Therapeutic Goods Regulations) laid down detailed procedures and criteria against which the Committee was required to operate. In particular, s. 52E of the Act specified the matters to be taken into account by the NDPSC in reaching scheduling decisions.

2.4 Galbally Review

In 1999, also, PMAA made a comprehensive submission to Dr Galbally's review. A copy of the Executive Summary of our submission is reproduced at Attachment 2.

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[2] Industry Commission, *The Pharmaceutical Industry*, Report No. 51, 3 May 1996, pp 397-417. The Commission's Overview report on scheduling issues is at Attachment 1.

In relation to the scheduling process, we submitted to Dr Galbally that

> "The scheduling process, and the administrative and legislative arrangements for it, is in need of fundamental overhaul. They are complex; they do not deliver national uniformity; they make international harmonisation difficult if not impossible; and they lack accountability and transparency. Parliamentary supervision and appeal rights are very limited. The COAG regulatory principles should be used to guide the necessary reforms".[3]

PMAA also took part in several iterations of consultations with the TGA and committees reporting, as we understand, to AHMAC. Until very recently, however, when the present consultation papers were issued, industry has had no concrete advice as to what the States and the Commonwealth were discussing; or what conclusions they had reached.

2.5 Trans-Tasman Agency

In June 2002, the Discussion Paper called *A Proposal for a Trans-Tasman Agency to Regulate Therapeutic Products* was issued. In the broadest of outline, the paper dealt, at pp. 51-52, with "Proposed [Scheduling] Arrangements under a Joint Agency".[4]

ASMI's response, dated August 2002, said:

> "We note that, in two important areas of policy, the Discussion Paper comes to no final position. These are in relation to the scheduling process, and advertising. Both issues are said to be dependent on the outcome of separate reviews, at least in Australia. These matters require closer definition than the Discussion Paper has provided, before we are able to offer definitive advice on what is proposed."[5]

In relation to scheduling, which ASMI identified as a "principal issue of concern to industry", we noted:

> 2. Scheduling — Under the Constitution, the Parliament can make laws with respect to "external affairs" and also with regard to relations with the islands of the Pacific. The Australian legislation under the treaty must "cover the field" and thus regulate, as all others are, sole traders not trading interstate."[6]

There the matter rested until the consultation papers were issued some three years later.

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[3] PMAA Submission, p.iv
[4] These arrangements are broadly in line with what is now in the consultation papers. Note, however, that there was to be provision to appeal to "an external merits review body". The present papers offer no prospect of such a review.
[5] ASMI, *Responses to questions relating to June 2002 Discussion Paper,* August 2002, p.2
[6] *Ibid, p.3*

2.6 Consultation papers — a lost opportunity

We regret to note that practically none of the proposals this industry has consistently advanced for the past ten years appears to have received any serious consideration by those involved in preparing the present proposal. In particular:

1. Even though the external affairs power would enable the Commonwealth legislation setting up the Trans-Tasman Agency to "cover the field", and even though it is proposed to regulate sole traders by virtue of that power, this obvious and sensible option has not been adopted. No reason is given for this approach.

2. The consequence of relying on States to "adopt into law" the scheduling decisions of the proposed Expert Committee is that true national uniformity will not be achieved. Regulation will thus be more complex than needed, just at a time when the Australian Government is reported to have made lesser, more cost-effective regulation a high priority. (Australian Financial Review, 29 August 2005, pp 1 and 5)

3. The arrangements set out in the consultation papers appear to us to represent a retreat from the (admittedly limited) transparent arrangements ushered in with the 1999 legislation.

4. The Framework, apart from the uncertainty about its legal status, enshrines policy and principles which are not in accord with COAG's regulatory design principles.

We deal with each of these matters below.

3 FUNDAMENTAL POLICY ISSUES

3.1 "Covering the field"

In our submission to Dr Galbally, ASMI said:

> "PMAA has long maintained that, as a matter of Constitutional law, controls over access to medicines could be easily and simply dealt with under an amended and expanded Therapeutic Goods Act. This view is based on advice we commissioned from leading Constitutional lawyer, Mr Denis Rose QC. …. Mr Rose concludes that all matters to do with what is now called scheduling, and all actions of all persons (other than natural persons) in controlling access to medicines are valid subjects of federal legislative power under the Constitution.
>
> This is precisely the position with the matters regulated by the present Therapeutic Goods Act. The Act provides a legislative scheme for the registration or listing of medicines and provides for rules and standards regarding indications, labelling, advertising, GMP, exports and imports, consumer information and so on. The fact that these rules and standards sometimes refer to the provision of the *SUSDP* does not mean the Act and Regulations lack the capacity to prescribe these matters directly. In fact, there is ample scope within the scheme of the Therapeutic Goods Act for it to deal with these matters. It should "cover the field".
>
> PMAA has already proposed a simple regulatory model for controlling access to medicines, involving:
>
> 1 all the matters set out in the *SUSDP* relating to indications, labelling, warning statements, advertising and so on to be decided by the appropriate Evaluation Committee under the Therapeutic Goods Regulations in association with the registration/listing process;
>
> 2 the NDPSC to be re-styled as the Medicines Classification Committee, with the task of classifying medicines in relation to access;
>
> 3 decisions as to access to proceed from a statutory requirement that the Committee must begin from the position that all medicines should be open sale unless the public benefit can be clearly shown, on the basis of risk/benefit analysis, that a more restrictive schedule is justified (and so on up the ladder);
>
> 4 the States/Territories should pass legislation applying the provisions of the Therapeutic Goods Act in relation to these matters (which would operate to control the actions of

corporations) to the actions of natural persons.

> Under these arrangements, industry and consumers would have to look to only one set of regulatory arrangements. National uniformity and certainty would be assured. There would be absolutely no diminution in public health benefits. And transaction costs for industry would be significantly reduced."[7]

The position of natural persons no longer provides a valid reason not to adopt this approach. The decision to apply the provisions of the Trans-Tasman Agency legislation to sole traders[8] shows that the TGA must have legal advice to the same effect as Mr Rose's opinion quoted above.

As we shall show below, one of the new arrangements of great concern to us is the way in which the Framework is to be drawn up. It will effectively substitute for the provisions of the Act and Regulations. That is, it is a legislative instrument but will be drawn up in secret by a committee of State and Commonwealth officials (the NCCTG); "approved" or something by the AHMAC (again in secret) and "issued" or something by the Ministerial Council (again in secret).

The secrecy of this process relies on a convention that Commonwealth-State relations are confidential between the parties and that neither the public nor Parliaments have any part to play.

By contrast, reliance on the external affairs power enables the Australian Government, in pursuance of its Treaty responsibilities, to propose legislation to the Australian Parliament, where proper democratic processes are required to be followed.

ASMI does welcome the limited reforms, set out in the consultation papers, for some elements of NDPSC's functions to be assimilated with the Trans-Tasman Agency's product evaluation procedures. However, without access to the proposed Rules, we are in no position to judge how these changes will work.

The fact remains, therefore, that the Rules will, in some way, do no more than authorise (or recognise) the Commonwealth-State arrangements resulting in the compilation of the Framework, thus bypassing the essential legislative processes that are the province of the Parliament.

3.2 The need for true national uniformity

ASMI has been consistently concerned that the present model — which is effectively to be taken over in the Trans-Tasman arrangements —has never delivered true uniformity. The present situation with the States' legislation is anything but uniform. Even those States which have reasonably up-to-date legislation in place clearly leave open to the State Minister to declare minor

[7] *Op.cit,*paras 288-299 (pp56-57

[8] See *TGA News* Issue 47, July 2005. The article states that the States have "agreed to enact legislation complementary to *The Therapeutic Goods Act 1989".* Under the external affairs power, there is no need for such complementary legislation, either to legislate sole traders or to set up (with NZ) a national scheduling scheme.

variations. Usually, these occur for political reasons where there has been agitation over some supposed poisoning incident.

Even if the States do bring down legislation (as footnote 13 on p. 10 of the Medicines Model admits will be needed), past experience shows that such legislation has not been seen as having had high priority. We have no confidence that things will be any better in the future.

Nowhere in the Medicines Model is any reference made to the special Schedule now in Victorian legislation listing Chinese medicines. ASMI has no objection to scheduling of Chinese medicines for practitioner-only dispensing. Nor do we object to a similar category for Western herbalist practitioners. The point is mentioned here because the mere existence of the Victorian Schedule 1 shows just how easy it is to subvert the objective of national uniformity by relying on State legislatures to deliver it.

A more fundamental issue is that the Framework will begin life at a time when the scheduling status of Chinese and Western herbalists is under active consideration in at least two States.[9] Those who prepared the consultation papers would surely have known of these developments, if only because the Expert Committee chaired by Dr Michael Bollen paid a lot of attention to the issue of complementary healthcare practitioners' registration and access to medicines.[10]

3.3 The need for transparency

3.3.1 Criteria for scheduling

ASMI welcomed the 1999 Commonwealth legislation because, for the first time, the procedures for scheduling were set down in statutory form. As well, because the legislation was by the Commonwealth Parliament, the decisions of the NDPSC were open to review under the Administrative Decisions (Judicial Review) Act (C'wlth). Moreover, the NDPSC itself developed a system of publishing its agenda and details of reasons for decisions, which industry has found very helpful.

The criteria which the NDPSC was to apply in taking decisions were also clearly stated in section 52E of the Act.[11] The Committee is required to "take into account" each of the matters listed there; if it did not, or if a proponent thought it had not, clear avenues of appeal have been open, as noted above.

ASMI has not seen any of the draft Rules the Agency is to make. We apprehend

[9] NSW and Western Australia.
[10] *Complementary Medicines in the Australian Health System,* Report to the Parliamentary Secretary, September 2003, Chapter 5. The Government accepted the Committee's recommendations, almost in their entirety. See also the discussion on p.21 of the WA Government's Discussion Paper "The Regulation of Practitioners of Chinese Medicines in Western Australia", June 2005
[11] It is important to note that the "matters to be taken into account" by the NDPSC are in S.52E. They take clear precedence over anything said or implied to the contrary in the NDPSC's Interim Guidelines.

that, in some way, the Rules will "authorise" or "adopt" or apply the Framework. Page 2 of the Medicines Model says only that

> "overarching policy guidance and protocols … are to be developed under [sic] the oversight of the NCCTG …" (p.2)

At best the Rules are to have the status of subordinate legislation but at worst, perhaps not. We have no clear advice yet whether they will be disallowable by either the Australian or New Zealand Parliaments.[12]

And, at best, the Framework is a non-reviewable "guideline" which in part replaces the provisions of the Act and Regulations; in part picks up the NDPSC's Interim Guidelines (which never had any legal standing); and in part inserts some new material. Again, another sign that the new arrangements are a cut-and-paste of old provisions.

For example, on p. 4 of the Framework, a modified (ungrammatical) version of s. 52E is introduced with these words:

> "When considering applications for scheduling of medicines in Australia and New Zealand all relevant information as established under Rule {X} of the Joint Rules is considered, with emphasis given to public health and safety matters. These include:"[13]

We have no way of understanding what this passage is intended to convey.[14] What we do understand, however, is that what was the cornerstone provision by which the NDPSC was required by statute to operate now makes a brief and confusing appearance in a document of dubious legal standing.

3.3.2 Appeals process

We also have concerns about the appeals process on grounds that they will lack transparency. We do not know whether the Trans-Tasman appeals tribunal will have jurisdiction in relation to scheduling decisions, but the consultative papers make no reference to it. We note that this position contrasts with this statement in the 2002 Discussion Paper that:

> "Persons not happy with a scheduling decision could, after internal review, seek recourse to an external merits review body …"[15]

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[12] It is likewise unclear whether the Rules will be a Legislative Instrument for the purposes of the Legislative Instruments Act (C'wlth).

[13] A court would in all likelihood find this whole passage so difficult to construe that it could well find it void of meaning.

[14] We note that

- Former criterion (f) has had "and intended use" added:
- Former criterion (h) now reads "purpose" (sing.);
- A new criterion – "the extent and duration of market exposure outside Australia and New Zealand" – has been added; and
- The final paragraph of old subs.(1) now reads as applying only to (i), rendering the whole passage meaningless.

[15] Discussion Paper, P 51

There is also an ominous passage on p.9 of the Medicines Model, which says that the Agency, on receipt of an appeal (called a "request for internal review"), will make a decision about the appeal only if "the request includes sufficient grounds for warranting an internal review". Such a restriction on appellants' rights is unacceptable. There is no merit appeal process provided for in the Framework or the Model nor is there any appeal process for the actual decision itself, just the process. This is contrary to Government policy for an independent review process for all administrative decisions made by the Australian Government.

3.3.3 How is the Framework drawn up?

There is a very significant lack of transparency in the way in which the Framework is to be drawn up. The process is represented in the consultation papers as no-one's business but the NCCTG. The Committee, as we have already noted, meets in secret and there is no mechanism for the views of industry (or indeed anyone else including the ten Parliaments of New Zealand and Australia) to be taken into account.

We also have significant concerns about the provisions of the Framework as now drafted. These are dealt with further below.

3.3.4 Selection of MSC members

The selection process for the members of the MSC lacks transparency. It is said that

1. the Committee is to have 10-16 members;
2. members are to have "requisite expertise" in certain stated fields;
3. members are appointed by the Ministerial Council but "selected" by the Agency;
4. all States, Territories and New Zealand are to be represented.16

ASMI welcomes the apparent decision that States' veto rights are not to be entrenched. But, if they make up 9 members of a Committee of "10-16", clearly they will have a majority, and perhaps even an absolute majority, and/or quorum. This, combined with the apparently dominant role to be given to the NCCTG, gives us little confidence that the proposed MSC can act, or be seen to act, transparently. The simple fact is that the State nominees are State public servants and are subject to Ministerial and/or senior Departmental direction. Whether they are so directed is beside the point. The Committee cannot be perceived in these circumstances to be operating impartially (that is, free of State Governments' policy priorities) nor transparently.

It is also the case that the decision on who is an "expert" will be made, in secret, by the Agency. There is nowhere in the consultation papers any indication that

[16] Medicines Model, p.3

the convention will be observed that industry's or consumers' representatives will be appointed on request.

3.4 Good regulatory practice

It is with considerable disappointment that we again point out that the arrangements set out in the consultation papers do not follow modern, good regulatory practice. The authors have not done this, despite the fact that all jurisdictions have explicitly subscribed to the COAG's Principles[17]. For example, processes exist for regulatory issues to be referred to committees with relevant expertise; however this does not appear to be the case with advertising where referral to the legislated expert advertising committee is not routinely undertaken. Regulatory decisions without regard given to appropriate expert advice can only be to the detriment of industry viability, a major arm of the National Medicines Policy.

3.4.1 The "cascading principle"

The objective of modern regulation is to put the minimum restriction on economic activity consistent with the public interest. It is the responsibility of the regulator to justify why more regulation, or more onerous regulation, is needed. It is not the proponents' duty to show why less, or less onerous, regulation is appropriate. The whole approach of the Framework is a "top down" rather than "bottom up" approach. This is exemplified by the "cascading principle"[18]. That "principle" flies directly in the face of COAG principles and is bound to result in extreme conservatism in reaching scheduling decisions.[19]

3.4.2 Risk analysis

The scheduling system should be explicitly based on sophisticated techniques of risk/benefit analysis. This principle has been given some prominence in s. 52E, where para (1) (a) requires the NDPSC to consider "the risks **and benefits** associated with the use of the substance." The Framework does not set the principle of risk analysis at the heart of the MSC's responsibilities.[20]

ASMI applauds the reference in the Framework to the need to apply QUM principles in scheduling decisions. As we have said many times before, Australian consumers in the information age are neither children nor fools. All available research shows that people consider very carefully what medicine to take. They read the label and, when they feel the need for it, they seek medical advice. A scheduling system cannot "look after" people as if they were incapable

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[17] COAG, *Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standards Setting Bodies, November 1997.* See also Office of Regulation Review, *A Guide to Regulation, 2nd Edition, 1998*. This latter paper does not apply to State agencies but it does bind Australian Government authorities.

[18] Framework, p.4. See also p.6 in respect of poisons

[19] In the field of advertising, for example the "cascading principle" would seem to require the MSC to start with the proposition that no medicine should ever be advertised. In the Internet age, such a position is at best unrealistic and at worst a danger to public health.

[20] The closest the consultation papers get to endorse a risk analysis approach is in the muddled passage on p.4 of the Framework, discussed in 3.3.1 above.

of acting in their own interests. What it can do is establish a hierarchy of access arrangements, **which the consuming public regards as reasonable,** so that the more "dangerous" a medicine is, the more restrictive the access becomes. This is a "bottom up" system. And it is consistent with established COAG principles.

3.5 Administrative Arrangements

As previously noted, ASMI is content with the proposed arrangements under which the expert committee will recommend Scheduling decisions to the Agency, which will actually decide whether and how the *SUSDP* is to be amended. We are also content for the initial evaluation (in respect of new substances or products proposed for registration) to include an initial evaluation of the appropriate Schedule.

However, when it comes to "poisons" (that is "non-medicines") and the "Australia-only legislation" which is to deal with them, the arrangements appear confusing and, indeed, inadequate.

ASMI's members do not have a large stake in manufacture of "poisons" but there are some products now regulated as therapeutic goods but which are scheduled as "poisons". That is, they appear in Schedule 5 or Schedule 6 lists. Among them are

- Hospital-grade disinfectants/antiseptics (e.g. benzalkonium chloride)
- Personal insecticides
- Head lice preparations
- Essential oils
- Mouth washes (e.g. eugenol)
- Methyl salicylate/Oil of wintergreen

The Poisons Model is both part of, but separate from, the Medicines Model. The legal bases from which each derives its authority will be quite different but the same Framework is to operate. The Office of Chemical Safety will perform risk assessments for poisons but it is unclear whether it will be called on to advise similarly in relation to medicines[21]. In any case, the OCS is not created by statute and has no statutory powers or functions.[22]

It appears that the old *SUSDP* (to be known as *SUSMP)* will be a unified document. Indeed the Schedule numbers are not proposed to change, so that the expert poisons committee will deal with Schedule 5 and Schedule 6

[21] What is the position, for example, in relation to "veterinary chemicals" or some of the disinfectant type chemicals regarded as therapeutic goods?
[22] Unless the "Australia-only" legislation rectifies this omission – we have no present way of knowing.

substances. It is proposed that the Joint Agency will have some kind of "dual citizenship", by means of which it will act, in relation to "Australia-only" matters, as if it were still the Therapeutic Goods Administration. The potential for bureaucratic crossed-wires, jurisdictional uncertainties and other confusion is thus quite high. We note [23] that it is anticipated that there may be "particular scheduling issues which impact across medicines and poisons" and that the Agency "may establish a joint working party" in such cases. As well, the Medicines and Poisons expert committees may meet at the same time, or perhaps even together. These proposals further raise concerns about how the whole arrangement will work.

ASMI reserves the right to comment further, once the "Australia only" legislation and the Joint Agency legislation have been published.

[23] Framework, p.9

4 ISSUES WITH THE FRAMEWORK

We have commented above on the unsatisfactory and non-untransparent way in which the Framework is to be drawn up[24]. We now turn to the substance of its provisions.

4.1 What is a "factor"?

It is vital for industry to have a clear set of criteria which decision makers must "take into account" in reaching their decisions. This is why section 52E has been seen as of fundamental importance to industry. Thus we are concerned to learn that s.52E is to be discarded and that "all scheduling decisions should include consideration of a standardised set of 'factors'. These, it appears, are preferred because factors rather than criteria "are contingent, conditional and dependent".[25] On what ? The answer, it seems, is "on each other".

The law on how decision makers should proceed is quite clear. The Administrative Decisions (Judicial Review) Act (C'wlth) requires one to consider all relevant matters and not to consider any that are irrelevant.[26] The Courts have made it clear that a decision-maker cannot pick and choose what to consider. Everything that is relevant must be taken into account.[27] The problem with using "factors" is that they can be applied subjectively and selectively. To use the mathematical image, they can be the lowest common denominator or the highest common factor. Which is it to be and how is it decided? The Framework offers little guidance.

Given that the Framework may not be proposed even to be a legislative instrument (either in fact or in law), ASMI views with some disquiet the proposed recourse to "factors", because of the stated reason that they are "contingent, conditional and dependent". We would much prefer to see the decision makers bound to observe a set of "criteria" or "matters to be taken into account", clearly

[24] See part 3.3.3
[25] Framework, p.3
[26] Administrative Decisions (Judicial Review) Act, s.5
[27] The courts have established quite precise requirements which are incumbent on decision-makers when matters are to be taken into account or had regard to in specified in legislation. See Department of Defence v Fox, Federal Court No. SG 13 of 1996, per O'Loughlin J at 10: "The expression "shall have regard to", which is quite often found in statutory instruments, will always take its meaning from the context in which it appears. Thus the matters to which a decision maker "shall have regard" might be exhaustively listed (Re BHP Petroleum Pty Ltd and Others and Minister for Resources (1993) 30 ALD 173 at 180) or the relevant provisions might be "so generally expressed that it is not possible to say that he is confined to these…..considerations", (Re Hunt; Ex parte Sean Investments Pty Ltd (1979) 53 ALJR 552 at 554 per Mason J). But whether the listed subject matters are or are not exhaustive, they are matters to which regard must be had by the rehabilitation authority and it is essential, to adapt the words of Gibbs CJ in The Queen v Toohey: Ex Parte Meneling Station Pty Ltd (1982) 158 CLR 327 at 333, "to give weight to them as a fundamental element" in making a determination. In my opinion it follows that there would be a failure to "have regard" to nominated matters if the regard was not "adequate" or not "sufficient". The rehabilitation authority would not comply with its statutory obligation if it merely had "token" regard or "nominal" regard to those matters."

set down in a justiciable statutory instrument, as is now the case.

4.2 Definitions

Again, perhaps because the Framework has been conceived as a "policy" document, very few of the terms used in the "factors" are defined. Thus the expressions used are open to subjective interpretation. See also part 4.5 below.

4.3 Veterinary Medicines or Chemicals

Page 3 of the Framework refers to the medicine scheduling arrangements to relate to "medicines for human use". However, on Page 13, the "Proposed factors for prescription **and veterinary chemicals**" are set out. This dual approach was well understood under the old arrangements. It is, however, by no means clear how the Agency, which is to deal with therapeutic products for human use, will fulfil this role under the new arrangements.[28] At the very least, the consultation papers should have dealt with this anomaly. They should have explained how it was that "veterinary chemicals" turn up in Schedule 4 and in Schedule 8.

As well, there is a need to explain the differences between veterinary **medicines** and (as appears on p.13 of the Framework) veterinary **chemicals.** The latter, of course, can also be S5, S6 or S7 or S8 poisons".

4.4 Number of Schedules

Ever since the days of the Industry Commission enquiry and during our interface with the Galbally enquiry, ASMI has urged that serious consideration be given to whether the Schedule 2 and Schedule 3 classifications ought to be merged into one "Pharmacy Only" category. Australia, Canada and New Zealand are the only countries to maintain the present distinctions.

The Galbally Report considered that the issue deserved further consideration. In the five years since, ASMI has received no consultation papers on this matter and the Framework suggests that the issue is off the agenda of those who drafted it. In any event, it is not referred to.

We are aware [29] that the Department of Health and Ageing and the Pharmacy Guild of Australia funded some research by Professor S I Benrimoj of the University of Sydney which appears to address aspects of this matter. ASMI was not consulted during the course of the research and we have not been provided with access to the report with only a media release issued which appears to support the cost-benefit of pharmacy intervention in the distribution of over the counter medicines.

ASMI considers that this issue deserves thoughtful and careful consideration and that the issues ought not to be foreclosed or ignored in the issue of the consultation papers. If indeed the regulators consider the issue to be off the

[28] A *Proposal for a Trans-Tasman Agency to Regulate Therapeutic Products*, June 2002, p.10
[29] See the Pharmacy Guild's website at http://beta.guild.org.au/research/project_display.asp

agenda, they should say so.

4.5 Proposed Factors

At Attachment 3, we present a point-by-point commentary on the "factors" as listed on pp 10-20 of the Framework.

As already noted, many expressions appear in this section of the Framework as if their meaning is perfectly clear. Put another way, the proponent and the regulator may very well dispute the meaning to be given to phrases like "quality use of medicines"; "pharmacy trained personnel"; "substantially safe"; "misused"; abused"; "illicitly used"; "normal therapeutic dosage"; "pharmacist intervention"; "manageable"; "pharmacist-consumer dialogue"; "adjunctive therapy"; "serious"; "severe"; "toxic dose"; "normal clinical conditions"; "unanticipated effects"; and so on. Every one of these expressions could well be the subject of technical and semantic argument. Without a statutory framework which includes definitions of key expressions the scope for argument into the future is considerable.

We also have considerable concerns about the subjective (but absolutist) nature of the qualification in Factor 3 in the Schedule 2 list. It appears to be the intention that any medicine that is not "unlikely to be misused, abused or illicitly used" may not be Schedule 2, "irrespective of any other applicable factors". How are the three "unlikely" matters to be determined?

Who is to say in what way a "normal therapeutic dosage level" may not be "misused". Does "illicit" include potential offences of improperly exporting a medicine overseas? With a "top down" view of scheduling decisions, this caveat has the potential to restrict access to quite a few substances which are found in useful self-medication products.

4.6 Timelines

The consultation documents do not provide timeframes for decision making or implementation processes so it is unclear how the Committees will operate, how often they will meet or statutory timeframes around decisions**.** It would be of benefit to industry if a flow chart was provided for all scheduling and rescheduling decisions which include time frames for decision points.

4.7 Commercial-in-Confidence information

We also have concerns about information that is to be considered commercial-in-confidence and note that it is accepted that sales data, product formulation details and manufacturing processes are considered commercial in confidence. While an opportunity exists for an applicant to justify any other commercial in confidence material contained in their application, it is considered that this list should be extended to cover other information such as labelling, in-house unpublished clinical data, market research data, without the need for justification.

Attachment 1

Attachment 2

Attachment 3

COMPARISON OF PROPOSED FACTORS FOR SCHEDULING WITH PREVIOUS CLASSIFICATION CRITERIA

UNSCHEDULED

CONSULTATION DOCUMENT	INTERIM GUIDELINES	COMMENTS
1. The quality use of the medicine can be achieved through consumer self diagnosis, treatment and management *The medicine is used to either maintain or enhance health, or for the treatment of minor ailments or symptoms of medical conditions, which are capable of being diagnosed, managed and monitored by the consumer*	No criteria in current guidelines	Refers to 'minor' ailments with no definition provided about what a 'minor' ailment might be. Consider adding 'prevention' to criteria. Suggest rewording the criteria to: "The quality use of the medicine can be achieved through consumer self diagnosis, either for the prevention or treatment or management. *The medicine is used to either maintain or enhance health, or for the prevention or treatment of ailments or symptoms of medical conditions, which are capable of being diagnosed, managed and monitored by the consumer"*
2. The safe use of the medicine is well established		It could be argued that is unnecessary as point 1 covers the 'quality use' which includes safe use
3. The use of the medicine at normal therapeutic dosage levels is rarely known to produce dependency or is unlikely to be misused, abused or illicitly used		Any medicine can be 'misused' i.e. taken in higher or lower doses than recommended, so when taken at 'normal therapeutic dosages is unlikely to be 'misused'. It is considered to be more appropriate to use the term 'established' rather than 'normal'. In addition, clear definitions of terminology (i.e. misused, abused, dependency,) are required to avoid decisions based on subjective views. Suggested rewording: "The use of the medicine at established therapeutic dose levels …….. used"

4. The risk profile of the medicine is low and well defined. The risks are identifiable by appropriate packaging and labelling and are manageable by consumers through appropriate packaging and labelling and any consumer medicine information provided		The term 'consumer medicine information' is specific to the regulatory requirement for S3, S4 and S8 medicines. Suggest this be changed to read "…other information provided".
5. The use of the medicine at normal therapeutic dosage levels is not likely to mask the symptoms or delay diagnosis of a serious condition		This criterion is accepted with the substitution of 'established' for 'normal'. That is, " …. established therapeutic dosage levels …."

SCHEDULE 2

CONSULTATION DOCUMENT	INTERIM GUIDELINES	COMMENTS
1. The quality use of the medicine can be achieved by labelling, packaging and/or consumer medicine information; however access to advice from pharmacy trained personnel is available to maximize the safe use of the medicine. *The medicine is for minor ailments or symptoms that can easily be recognized and managed by the consumer without the need for medical intervention. However the availability of a pharmacist supports the consumer in selecting the appropriate medicine, where necessary.*	Schedule 2 poisons are substances or preparations for therapeutic use – • Which are substantially safe in use but where advice or counselling is available if necessary • For minor ailments or symptoms which – • can be easily recognized by the consumer • do not require medical diagnosis or management	Refers to 'minor' ailments with no definition provided about what a 'minor' ailment might be. The term 'consumer medicine information' is specific to the regulatory requirement for S3, S4 and S8 medicines. Suggest this be changed to read "…<u>other information</u> provided".
2. The use of the medicine is substantially safe and the potential for harm from inappropriate use is low.	The medicine or preparation in normal use should have the following characteristics – • suitability for self treatment of a minor ailment or symptom capable of being monitored by the consumer • Extremely low abuse potential • Low potential for harm from inappropriate use • Low or well characterized incidence of adverse effects or side-effects, and contra-indications for which advice or counselling is available • Only minor or well-characterized interactions with commonly used substances or food for which advice or counselling is available • A wide therapeutic index	Accept

	• Low risk of masking a serious disease • Low risk of compromising medical management of a disease	
3. The use of the medicine at normal therapeutic dosage levels is unlikely to produce dependency and the medicine is unlikely to be misused, abused or illicitly used. *Medicines which do not meet this factor are not suitable to be classified as Schedule 2 Pharmacy Medicines, irrespective of any other applicable factors*	The ailment or symptom(s) to be treated should – • Not require ongoing or close medical diagnosis or management • Be easily recognized by the consumer • Be amenable to short term treatment; or • Be capable of being monitored and self managed by the consumer with advice and counselling if necessary.	Any medicine can be 'misused' i.e. taken in higher or lower doses than recommended, so when taken at 'normal therapeutic dosages is unlikely to be 'misused'. It is considered to be more appropriate to use the term 'established' rather than 'normal'. In addition, clear definitions of terminology (i.e. misused, abused, dependency,) are required to avoid decisions based on subjective views. Suggested rewording: "The use of the medicine at established therapeutic dose levels …….. used". In addition, we don't agree with the proposed qualifier as it is too absolute in terms. Refer to Point 4.1 of our response regarding relevance of material to be taken into account.
4. The risk profile of the medicine is low and well defined. The risks are identifiable by appropriate packaging and labelling and are manageable by consumers through appropriate packaging and labelling and any consumer medicine information provided		The term 'consumer medicine information' is specific to the regulatory requirement for S3, S4 and S8 medicines. Suggest this be changed to read "…other information provided"
5. The use of the medicine at normal therapeutic dosage levels is not likely to mask the symptoms or delay diagnosis of a serious condition		This criterion is accepted with the substitution of 'established' for 'normal'. That is, " …. established therapeutic dosage levels …."

SCHEDULE 3

CONSULTATION DOCUMENT	CURRENT GUIDELINES	COMMENT
1. The medicine is substantially safe but pharmacist intervention is required to ensure the quality use of the medicine. *The consumer can identify the ailments or symptoms that the medicine is used for but counselling and verification by a pharmacist is required. Pharmacist-consumer dialogue is necessary to reinforce and/or expand on aspects of the use of the medicine.*	Schedule 3 poisons are substances or preparations for therapeutic use – • Which are substantially safe in use but require professional advice or counselling by a pharmacist • The use of which requires pharmacist advice, a management or monitoring • Which are for ailments or symptoms which- • Can be identified by the consumer and verified by a pharmacist • Do not require medical diagnosis or only require initial medical diagnosis and do not require close medical management	Accept
2. The use of the medicine at normal therapeutic dosages is not expected to product dependency. Where there is a risk of misuse, abuse or illicit use identified, the risk can be minimized by monitoring by a pharmacist.	The medicine or preparation in normal use should have the following characteristics – • Low abuse potential • Low potential for harm from inappropriate use • Low incidence of adverse effects or side-effects, which are likely to require medical intervention • Only interactions with commonly used medicines or food which can be managed by a pharmacist • A medium to wide therapeutic index	This criterion is accepted with the substitution of 'established' for 'normal'. That is, " …. <u>established</u> therapeutic dosage levels …."

	• The risk of masking a serious disease or compromising medical management of a disease can be managed by a pharmacist • Only contraindications that can be dealt with by a pharmacist • Safety in use with counseling (sic) by a pharmacist.	
3. The risk profile of the medicine is well defined and the risk factors for adverse effects and interactions are known, identifiable and manageable by a pharmacist.	The ailment or symptom(s) to be treated should – • Not require close medical management or direct supervision by a doctor • Be easily recognized with assistance from a pharmacist • Be amenable to short term treatment or capable of being monitored by the consumer with assistance from a pharmacist	
4. The medicine is intended for recurrent or subsequent treatment of a chronic condition. Pharmacist intervention is required to monitor safe use of the medicine following recommendation by a medical practitioner *The consumer may not be able to self-monitor the safe ongoing use of the medicine. The condition does not require medical diagnosis or only requires initial medical diagnosis, and the consumer does not require close medical management.*		Suggest the following "The medicine <u>may be</u> intended …. following recommendation by a medical practitioner or <u>a pharmacist</u>". *The condition <u>may not</u>* ….. close medical management
5. The use of the medicine at normal therapeutic dosage levels may mask the symptoms or delay diagnosis of a serious condition		This criterion is accepted with the substitution of 'established' for 'normal'. That is, " …. <u>established</u> therapeutic dosage levels …."

SCHEDULE 4

Consultation document identifies proposed factors for prescription medicines and veterinary chemicals

CONSULTATION DOCUMENT	CURRENT GUIDELINES	COMMENTS
.The ailments or symptoms that the medicine is used for require medical, veterinary or dental intervention *Diagnosis, management or monitoring of the medical condition is such that it requires medical, veterinary or dental intervention before the medicine is used.*	Schedule 4 poisons are substances and preparations for therapeutic use – • The use of which requires professional medical, veterinary or dental management or monitoring • Which are for ailments or symptoms that require professional medical, veterinary or dental diagnosis or management • The safety or efficacy of which may require further evaluation • Which are new therapeutic substances	Accept
2. The use of the medicine/veterinary chemical requires adjunctive therapy or evaluation *Adjunctive therapy could include other medicines, non-pharmacological measures or specialized medicine delivery devices. Evaluation could include laboratory tests or additional clinical assessments*	A medicine or preparation may be classified as a Schedule 4 poison if: • It has low to moderate abuse potential • Its use may produce serious side effects • It has a narrow Therapeutic index • Its use requires professional medical, veterinary or dental management or monitoring • Its activity, safety, efficacy or side effects require further evaluation dealt with by a pharmacist	Accept
3. The use of the medicine/veterinary chemical at normal therapeutic dosage levels, may produce dependency but has a low	The ailment or symptom(s) it is used for requires professional medical, veterinary or dental diagnosis,	Accept

propensity for misuse, abuse or illicit use. *Control of access and duration of therapy by a medical, veterinary or dental practitioner is required.*	management or monitoring.	
4. The seriousness, severity and frequency of adverse effects are such that monitoring or intervention by a medical, veterinary or dental practitioner is required to minimize the risk of using the medicine/veterinary chemical.		Accept
5. The margin of safety between the therapeutic and toxic dose of the medicine/veterinary chemical is such that it requires medical, veterinary or dental intervention to minimize the risk of using the medicine/veterinary chemical		How is the margin to be defined? Otherwise this factor becomes no more than a self-fulfilling prophecy
6. The seriousness or severity and frequency of the interactions of the medicine/veterinary chemical (medicine-medicine, medicine-food or medicine-disease) are such that monitoring or intervention is required by a medical, veterinary or dental practitioner		How is the 'seriousness' to be defined? Otherwise this factor becomes no more than a self-fulfilling prophecy
7. The use of the medicine/veterinary chemical has contributed to, or is likely to contribute to, communal harm *For example the development of resistant strains of microorganisms. Appropriate use, and/or the decision to continue treatment, requires evaluation by a medical, veterinary or dental practitioner*		New statement. Does this imply that no antibiotics (for example) will ever become S3 or S2? How is "communal harm" to be defined?
8. The experience of the use of the medicine/veterinary chemical under normal clinical conditions is limited *Unexpected effects of the medicine/veterinary chemical may only become evident after widespread use by a medical, veterinary or dental practitioner. Close monitoring of the patient is required by a medical, veterinary or dental practitioner to monitor*		Accept.

for unanticipated effects.		

There is a need to define and clarify what a “veterinary chemical” is. While the issue is not of direct interest to ASMI, we consider that all “veterinary products” – whether S2, S3, S4, S5 or S6, should fall within the Poisons Scheme.

SCHEDULE 8

CONSULTATION DOCUMENT	CURRENT GUIDELINES	COMMENT
1.The medicine/veterinary chemical contains a substance included in Schedule I or II of the *United Nations Single Convention on Narcotic Drugs* 1961 or in Schedule II or III of the *United Nations Convention on Psychotropic Substances 1971*	Schedule 8 poisons are substances and preparations for therapeutic use (i.e. medicines) • Which are dependence producing • Which are likely to be abused or misused	Accept
2. The medicine/veterinary chemical has an established therapeutic value but its use, at normal therapeutic dosage levels, is recognized to produce dependency and has a high propensity for misuse, abuse or illicit use.	A substance or preparation will be classified as a Schedule 8 poison if it: • Is included in Schedule I or II of the WHO Single Convention on Narcotic medicines • Is included in Schedule II or III of the WHO Convention on Psychotropic Substances • Is likely to present a substantial risk of abuse, dependence or misuse for illegal purposes	Accept
3. The medicine/veterinary chemical contains a substance that by reason of its novelty or properties could substantially increase the risk of producing dependency, misuse, abuse or illicit use.		Accept

SCHEDULING OF THERAPEUTIC SUBSTANCES

Submission to ANZTPA Implementation Group regarding proposed Scheduling arrangements

by

Australian Self-Medication Industry

AUSTRALIAN SELF-MEDICATION INDUSTRY

BETTER HEALTH THROUGH RESPONSIBLE SELF-CARE

December 2006

Contents

Executive Summary

- ASMI must reserve its position on the entire proposed scheduling process until complete information (including the policy guidelines) is available.
- ASMI welcomes acceptance of the Galbally proposal to separate "poisons" and "medicines".
- We also welcome the intention that the Authority will take scheduling decisions.
- Trans-Tasman uniformity will not be enhanced by the Commonwealth's unwillingness to "cover the field" – leaving it to the States to give effect to the Schedule – nor by the NZ decision to continue to operate its Misuse of Drugs Act.
- At the very least, all the States/Territories should commit to adoption of the Schedule "by reference".
- We cannot comment on the "Australia only" arrangements, in particular the intended role (if any) for the Office of Chemical Safety.
- ASMI supports the proposal that, in respect of new substances, the initial recommendation may come from expert committees other than the MSC.
- Regarding the constitution of the MSC,
  - there should be no distinction between "nominated" members and others;
  - industry and consumer interests should continue to be able to nominate representatives and have those nominees appointed;
  - persons with expertise in risk/benefit analysis and communications should be added members of the MSC.
- There is a need to clarify what are the points of "decision" as between the Authority, on the one hand, and the expert committees, on the other.
- ASMI welcomes the "Reconsideration" proposals.
- Sponsors must have a statutory right of access to committees and/or the Authority to argue cases in person, especially when it comes to "Reconsideration".
- Provisions for data protection and market exclusivity, especially for "switch" proposals, should be included in the Act(s) or Rules, or both
- Rule 10.09 (1) (b) – assessing risk/benefit – should be the fundamental and overriding criterion for all scheduling decisions and the MSC should include persons with expertise in risk/benefit analysis.
- It is essential that the "relevant guidelines":
  - are made by a publicly accountable, transparent process;
  - are a Legislative Instrument or similar, subject to disallowance in whole or in part; and

  - are consistent with modern regulatory principles, as directed by COAG.

- The advertising of scheduled medicines should be regulated under the Advertising Rules and not by the equivalent of Appendix H of SUSDP.

1. Introduction

ASMI appreciates the opportunity to comment on the following two consultation papers, which outline proposed arrangements for scheduling of therapeutic substances:

- Extracts from draft Administration and Interpretation Rule relating to the scheduling of therapeutic substances ("Rules"); and
- Plain English Guide to the Arrangements ("Guide").

It has been difficult for industry to reach settled views on the matters set out in the above two papers, because together they do not give a complete picture of the way the scheduling arrangements are intended to work. Two documents which are critical to getting a full picture are:

- the proposed legislation – which has not been published in either Australia or NZ at the time this submission was prepared; and
- the "Policy Framework", which is not intended to be provided for consultation until the first quarter of 2007.[1]

As well, and in part because not all information is yet available, various questions have arisen in our minds after close study of the consultation papers. In any case, however, **ASMI must therefore reserve its position on the entire scheduling process** as proposed in the consultation papers, until we have had an opportunity to also consider:

- the draft NZ and Australian Bills; and
- the draft "Policy Framework".

Against this background, we offer our comments at this stage on the following issues in subsequent sections of this submission.

- Constitution of Medicines Scheduling Committee (MSC).
- Uniform Schedule.
- Commercial-in-confidence issues.
- "Policy Framework".

ASMI therefore welcomes and supports

- the acceptance of the Galbally recommendation for a separation of the "medicines" and "poisons" scheduling processes into two separate systems;
- the intention that the Authority itself will actually take responsibility for scheduling decisions.

[1] Guide, p. 4. We take this to be the same as the "relevant policy guidelines" defined in Rule 10.02 (1).

With regard to the proposed separation of drugs and poisons into two committees, we note that the so-called "Australia-only" arrangements are yet to be announced. Depending on how these arrangements are made, ASMI may need to comment further. One issue that remains for clarification, for example, is the administrative and legal relationship between the Office of Chemical Safety (OCS) and the MSC and ANZTPA.

2. Constitution of the MSC

2.1 Membership

ASMI is pleased to note that industry and consumer interests are to be represented on the committee.

We also support the principle, implicit in the Rules, that each member's vote is of equal value. That is, the NDPSC requirement for decisions to be supported by a majority of jurisdictional members has been removed.

It remains the case, however, that "nominated" members (being jurisdictions' representatives) will form a majority of the total membership and thus in a position to exercise a de facto veto. It is therefore essential for the Rules to provide expressly that the "nominated" members are not subject to direction, by the jurisdictions who nominated them, in the exercise of their Committee functions.

We also believe that there is no case for Committee members to be divided into two classes – those who are "nominated" and those who are not. In this respect, ASMI calls on the Authority to acknowledge that **the traditional arrangements under which industry and consumer interests may "nominate" their Committee members** will continue. Also, that as a matter of convention, those nominations will be accepted.

2.2 Range of expertise

One area of expertise where, in our view, the NDPSC has had inadequate representation, is in risk/benefit analysis and communications. We urge that this field of expertise be added, and that ANZTPA ensure there is adequate representation of it as the MSC is assembled.

The fundamental task of the MSC will be to **balance risk and public benefit**. Whether the issue is medicines, road or air safety, building codes or any other human activity, the principles are the same. The application of Rule 10.09 (1) (b) – in our view the most important principle in scheduling – will be greatly assisted if relevant expertise is available to the Committee.

3. The need for uniformity

3.1 Trans-Tasman scheme should have uniform application

Industry considers it **essential that scheduling regulations will be absolutely uniform in all parts of Australia and NZ**. Even slight variations as between States, or as between Australia and NZ, create potentially large costs for industry. The supposed benefits of local, subtle, departures for so-called "special" or "local" situations are not apparent to industry. And such

benefits have to be traded off against the additional costs – initially to industry but likely to be passed on to consumers – that are inevitably involved.

Together, the retention of a State/Territory discretion to "adopt" or not, or to vary, scheduling "recommendations", and NZ's excision of Authority jurisdiction over some classes of medicines, are of concern. These two decisions amount to significant retreat from the principle of a uniform Trans-Tasman scheme.

3.2 Variations between Australian jurisdictions

Industry views with concern, therefore, that it has apparently been decided that the Australian legislation should not "cover the field", even though there is ample Constitutional competence for the Australian Parliament to do so. ASMI is further concerned that the consultation papers do not even indicate whether, as Galbally recommended, the States/Territories will all legislate to adopt the Schedule, as decided by the Authority, "by reference". Any other arrangement is not acceptable to industry and cannot be justified on grounds of good regulatory practice.

An issue that must be addressed is the existence, in Victoria alone, of a Schedule 1 to include certain Chinese medicines. Will this Schedule be part of what the Authority will issue or approve as "the Schedule"? Will it be included in the authorised electronic copy?[2]

Alternatively, is the Victorian Schedule 1 to be regarded as "other matters" under Rule 10.04 (7)?

3.3 NZ departure from the Treaty

Equally, we are concerned at a decision which has been taken by the NZ Government apparently subsequent to its accession to the Treaty, that

> "New Zealand has proposed only to recognise recommendations for scheduling [of S2, S3 and S4]. The NZ Misuse of Drugs Act 1975 will continue to apply …"[3]

Because the NZ Misuse of Drugs Act relates to some medicines now scheduled other than S8 and S9, this decision will require a great deal of complex double-doing for industry, especially when it comes to labelling. In our view, this departure from the ANZTPA scheme is such that the provisions of Article 12 of the Treaty should operate. We are not convinced that there are "exceptional public health, safety, third country trade, environmental or cultural factors"[4] that justify the imposition on Australian and NZ industry and consumers of the extra costs and complexities represented by this intended arrangement.

3.4 ASMI's proposals

We recommend that

- the Australian legislation should "cover the field" (by virtue of the external affairs and corporations powers) with the Schedule being one more Rule or Order of ANZTPA like all the others;

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[2] Rule 10.4 (4).

[3] Guide, p. 5.

[4] Treaty, Art. 12 (2) (a).

- failing that, the Schedule should be adopted "by reference" into every jurisdiction's regulatory arrangements;[5]
- the NZ Misuse of Drugs Act be applied only in respect of S8 and S9 substances, so as to avoid the need for dual labelling or signal headings on S2, S3 and S4 (and S5 or S6 if applicable).

4. Commercial-in-confidence issues

4.1 Rule 10.03

For industry, the regulatory regime must provide a level playing field, so that firms can compete for market on a basis of equality. One element in that competition relates to scheduling decisions. Because those decisions determine point of sale and the degree of difficulty of access by consumers to a product, they are of great significance to individual companies.

These issues are of particular importance in the case of re-scheduling decisions – known as "switch".

Often, firms will spend a great deal of time and money mounting a case for rescheduling. This effort may very well include a new range of clinical investigations, the compilation of safety data, market research and the like. Products may also be reformulated, new routes of administration proposed, or other technical or clinical improvements. All this effort represents valuable proprietory information and, the firm expects, a means to secure market advantage.

It is therefore of great importance to ASMI's member-companies that the Rules relating to the MSC's and Authority's access to and use or reliance on, commercial-in-confidence information are clear. As well, they must be applied in accordance with guidelines that are consistently and impartially applied, and seen to be so.

Proposed Rule 10.03 appears to leave it up to the Authority to be "satisfied" or not "that the information is commercial-in-confidence". However –

- nothing in the Rules sets out what principles the Authority must follow, whom it must or may consult, or what procedural fairness requirements it must follow;
- there appears to be no provision for guidelines[6] to be issued to assist industry and the Authority in deciding what is, or should be, commercial-in-confidence; and
- Rule 10.03 does not in express terms apply to the MSC. (It can be inferred that the MSC, as a creature of ANZTPA, is covered by Rule 10.03 but it would be better if that were said in terms).

ASMI recommends that the issues set out above be clarified and that guidelines for the handling of commercial-in-confidence material be issued as soon as possible.

[5] Subject to clarification regarding Victoria's Schedule 1 – see 3.2 above.

[6] For example, similar to those now contained in the NDPSC's Interim Guidelines.

In our view, matters that should certainly be regarded as commercial-in-confidence include:

- sales data;
- formulation details;
- manufacturing processes; and
- unpublished proprietary information such as research, market survey or similar data.

Until these measures are taken, **ASMI is not satisfied that arrangements for protection of commercial-in-confidence information are adequately dealt with in the Rules.**

4.2 Data protection and market exclusivity

In February 2006, ASMI issued its *Position Paper on Data Protection and Market Exclusivity for Non-Prescription, Complementary and OTC Medicines*. This is reproduced at Attachment 1. At section 2.2.1, ASMI argues that "switch" decisions should be accompanied by at least a period of market exclusivity and data protection for the successful applicant. This is not provided for in the draft Rules, but should be. Alternatively, the matter can be provided for in the draft legislation by extension of the principles in s. 25A of the Therapeutic Goods Act.

ASMI looks forward to working with ANZTPA to advance this important policy. We will also be making representations to the Australian Government and Parliament when the Australian legislation is under consideration.

As the *Review of intellectual property legislation under the Competition Principles Agreement* recently noted –

> "… harm to competition should not, and cannot, be inferred from the mere existence of an exclusive right, such as those conferred by the intellectual property laws. Incumbent firms whose intellectual property benefits from protection may be subject to rivalry from numerous sources, including from other firms supplying differentiated but substitutable products. Perhaps more importantly, they may also be subject to the threat of their product being superseded by technologically superior versions. The very protection an incumbent firm enjoys may provide the incentive for its rivals to invest in developing these alternatives – so that the intellectual property protection, rather than undermining contestability, stimulates and channels it in directions that are usually socially beneficial".[7]

5. Principles of scheduling

5.1 Complete information is not yet available

As already pointed out, we do not yet have enough information to get a full picture of

- how the scheduling process will work (in particular, the intended procedural relationships between the Authority, the MSC, the States and NZ and the OCS); and
- what policy principles will apply (in particular, how Rule 10.09 may be modified or interpreted by the guidelines) and their relative legal force.

[7] Review of Intellectual Property Legislation Under The Competition Principles Agreement, 2000, Intellectual Property and Competition Review Committee, Commonwealth of Australia.

ASMI must therefore reserve its position in relation to these matters until the missing information has been provided and considered. The following matters should be read against that background.

5.2 The scheduling process

As we understand the consultation papers, for a substance to be scheduled (or rescheduled), there are three levels of consideration:

- The MSC or other expert committees consider applications and make "recommendations" to the Authority (in most cases new substances will be scheduled on other expert committees' recommendations – unless public consultation is decided on by the Authority – and rescheduling by the MSC);
- The Authority adopts or approves those recommendations or not, as approved, and these become "the Schedule".
- However, the Schedule is not "given effect to" unless and until State, Territory and NZ jurisdictions do so (by processes unknown to us but assumed to be similar to the present State-based legislation).

There is also the question of the role (if any) to be played in the future by the (Australian) Office of Chemical Safety (OCS). The OCS' website describes one of its functions as to act as the NDPSC's secretariat. It is also well-known that the OCS regularly provides NDPSC with assessments or evaluations on which the NDPSC relies (in the legal sense) in reaching some scheduling decisions. **ASMI seeks clarification as to how this relationship will operate when ANZTPA takes over**.

The MSC is described as an "expert committee". As noted, there are some changes in its makeup, compared with that of the NDPSC, which to date has been the final point of decision before "adoption" of *SUSDP* by the States. Now, however, the intention is that the MSC will be one among several who may make recommendations, which in all cases the Authority is to approve. By definition, the Authority may also **not** accept the recommendations from whatever source, or may vary them.

It is also the case that, whatever decision the Authority takes, it is still to be "given effect" by legislation of the various jurisdictions.

Setting aside for the moment issues that arise depending on whether the Authority *qua* Authority, or a delegate, will do the approving of the MSC's recommendations, the immediate issue is the need to identify more clearly who is actually taking "decisions", being decisions which presumably are to be reviewable and/or appealable. That is, at what point(s) in the process are these review options to be available to sponsors?

It is apparently left to the Authority to decide whether public consultation is to be undertaken other than in rescheduling cases. ASMI submits that in other cases, the sponsor should be able to propose public consultation and the Authority required to agree to do this.

It cannot be assumed, and the Rules as drafted do not so assume, that the Authority's role is merely to rubber-stamp MSC decisions. Indeed, the decisions appear to be expressed in the Rules as being taken by the Authority. Nevertheless, if the MSC or the other expert committees are to "stand in the shoes" of the NDPSC, it will be that Committee which

actually decides each issue, or at least decides its recommendations on each issue. Certainly that seems to be the case with issues which are deemed to require public consultation.

Either way, industry needs to be clear on the administrative law principles surrounding each of the three stages in the process listed above. In our view, a decision by the MSC or another expert committee is, and should be expressed to be, a decision under an enactment and thus reviewable under whatever the legislation establishes as the equivalent of the Administrative Decisions Judicial Review. Likewise appealable under whatever is to be the equivalent of s. 60 of the Therapeutic Goods Act. (This issue is separate from the "Reconsideration" arrangements set out in Div. 10.05 of the Rules).

Alternatively, if the view is taken that the expert committees are no worse than that and do not take decisions, the process for Authority consideration of its recommendations, including the need for procedural fairness, needs much greater elaboration.

In particular, there is a need to establish in the Rules who has a right to be heard (in person) before an expert committee (including the MSC) and/or the Authority and/or the Reconsideration process. ASMI believes this right is fundamental to procedural fairness in all cases.

In the absence of the draft Bills, we cannot reach a definitive view on this matter. It is of such basic importance to our members, however, that **ASMI must reserve its position until these issues are clarified.**

In our view, the Acts or Rules should provide that, if the Authority is minded to do other than adopt a MSC or other expert committee recommendation in full, the process of Authority deliberation should provide for all the elements of procedural fairness that presumably will apply to the initial consideration of the issues by the MSC or other expert committee.

5.3 Division 10.05 – Reconsideration

Access to this process will be welcomed by sponsors. We note, however, that it is no substitute for access to independent merits review (under Australian conditions, via the AAT) or procedural fairness review (corresponding to Australian ADJR). **ASMI must reserve its position on this matter until the legislation details are known.**

As already noted, we believe it to be important that sponsors have, as of right, the ability to appear in person during reconsideration procedures.

5.4 Policy principles on scheduling

We note that Rule 10.09 (1) takes over the matters to be taken into account as set out in s. 52E of the Therapeutic Goods Act. ASMI considers that the fundamental and most important matter that should be taken into account, indeed the guiding principle is 10.09 (1) (b) – "the risks and benefits associated with the use of the substance". Each of paras (a) and (c) – (i) are better seen as determinants of para (b).

We propose, therefore, that Rule 10.09 (1) (b) should be set above the other paragraphs as the single binding consideration, with "matters to be taken into account" as set out in those other paragraphs. This approach fits in with our view that the MSC should be strengthened by addition of risk-benefit expertise (see section 2.2 above). But, importantly, it reflects the true and central purpose in the scheduling operation.

5.5 "Relevant guidelines"

Rule 10.09 (2) will require "the Authority" (and presumably the MSC) to comply with the "relevant guidelines". These have not been published, so we do not know what they are. What we do know is that they are intended to be made by the NCCTG.

It is objectionable in principle that these mandatory guidelines will be drawn up by a body which

- consists entirely of officials who are subject to direction within their respective jurisdictions;
- is not established by statute;
- may take decisions which may not be open to judicial review, or Parliamentary scrutiny (including the power to disallow, in whole or in part) the guidelines;
- conducts its deliberations in a non-transparent process; or
- allows no public participation in those deliberations (e.g, by inviting and having regard to submissions, publication of consultation drafts or draft decisions).

It is also objectionable in principle that the Authority is apparently to be bound by the guidelines in such a way that the matters to be taken into account in Rule 10.09 (1) may be qualified or, indeed, rendered irrelevant or inapplicable.

This arrangement flies in the face of all the provisions of the Legislative Instruments Act (C'wth), which was expressly designed to avoid objectionable arrangements of this kind.

ASMI therefore reserves its position with respect to the manner of making of the guidelines and recommends that the Rules ensure that **the process is transparent, accountable and in keeping with the principles of the Legislative Instruments Act.**

We do not know what the guidelines may contain but we apprehend they may be based on the NDPSC's "Interim Guidelines". In principle, these are unduly risk averse and are based on an approach to scheduling which is not consistent with COAG regulatory principles. ASMI trusts that, in the preparation of the guidelines, the opportunity will be taken to ensure that, consistent with the principles in Rule 10.09 (1), a risk-benefit approach will be adopted.

5.6 "Other matters" – advertising of Scheduled products

The intention of Rule 10.04 (7) is not clear, even when the "Example" in the note is considered.

Under the current arrangements, the advertising of S3 products is permitted or not by whether the product is admitted to Appendix H of SUSDP. ASMI has always believed that an expert committee on "drugs and poisons" is not the place for regulation of advertising of medicines. Rather the proposed Advertising Rules and the attendant co-regulatory arrangements should apply to all medicines.

It is not clear whether, in some way, the MSC will retain the responsibility NDPSC has had for regulation of advertising of S3 products. Or whether the "Policy Framework" will include something along the lines of the NCCTG's Advertising Guidelines. Industry strongly believes **these matters are best left to the general regulatory regime on advertising of**

medicines. It is our understanding that this is to be the case, but we seek explicit confirmation of this understanding.

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SCHEDULING - REVISED ARRANGEMENTS

A submission to the Therapeutic Goods Administration

by the

Australian Self-Medication Industry

May 2009

Table of contents

ATTACHMENTS

EXECUTIVE SUMMARY

Overall support

- ASMI supports many of the proposed changes to the scheduling system.

Consultation

- However, we wish to reserve our position on several fundamental aspects, until the full legislative picture can be seen.

- We therefore request that complete details of the scheme be published as an exposure draft for full public consultation.

- We also ask that industry be fully engaged in further discussions to clarify areas of concern.

"Covering the field"

- ASMI believes that there is adequate Commonwealth power for legislation on scheduling to "cover the field". Doing so will deliver Australia-wide uniformity.

Accountability

- ASMI considers that the COAG Principles on Good Regulation should apply to all aspects of the scheduling framework and processes.

- ASMI therefore believes that more can be done to ensure accountability and transparency in the process. In particular –
  - legislative instruments (except the proposed SUSMP) should be disallowable by the Parliament;
  - the full range of merits and judicial review processes under Commonwealth law must be available for aggrieved persons to challenge decisions;
  - the Government's general FOI reforms should apply to all scheduling processes, subject to proper protection of commercial-in-confidence matters.

Supporting new processes

- ASMI supports these proposed changes:
  - the decision-maker to be DOHA (delegated to the TGA);
  - new substances scheduled as part of the evaluation process;

- the proposed "factors" for classification (subject to the continuance in legislation of criteria as now set out in sub-s. 52E (1));
- maximum publication of decisions and proceedings, without compromising commercial-in-confidence arrangements that would negatively impact on industry viability.

MSEAC

- ASMI believes it is essential that the proposed expert committee is required by legislation to adopt a risk/benefit approach consistent with COAG principles. Hence, we believe the expertise for the committee should include expertise in risk/benefit analysis and consumer communications.
- The Chair of MSEAC should not be a TGA official but an independent person.

Cost recovery

- ASMI reserves its position on the proposals for cost recovery until the CRIS is available. In principle, we see a difficulty in charging individual sponsors for what are said to be decisions which are legislative in character.

Advertising

- In relation to advertising, ASMI welcomes the decision to phase out Appendix H. New rules for advertising S3 substances should be drawn up by the TGCC, consulting NCCTG as appropriate.

Data protection

- ASMI believes the legislation should provide for a window of opportunity free from competition, if the original sponsor has borne the expense and risk of securing a re-scheduling decision.

1. INTRODUCTION

In April 2009, the TGA published on its website several documents[1] which together set out the Government's proposals for changes to the Scheduling arrangements. Comments on the proposals were invited. This submission sets out the views of ASMI on what is proposed.

For the reasons set out below, ASMI trusts that the Government will ensure there is more consultation before these proposals assume final legislative shape.

2. THE REFORM PROCESS

2.1 Past proposals

As the Scheduling Policy Framework (SPF) notes, these proposals arise out of the 1999 Galbally Review. Then the proposals went into abeyance until the ANZTPA changes were mooted. With the collapse of ANZTPA in July 2007, there has been another delay until, in April 2009, the present proposals were published.

2.2 ASMI's position and response to ASMI's position

At several stages throughout this ten year process industry has made considered and detailed responses to the various policy proposals. A checklist of all our submissions on this matter over the last decade is at Attachment 1. It will be seen that ASMI has taken a consistent position over the years.

However, there has been very little opportunity for a considered exchange of views. As successive drafts have appeared there has been no indication that our proposals have had any consideration, or if they have, any indication why they have been set aside without acknowledgement.

In our view there remain several issues needing further clarification and consequently ASMI wishes to reserve its position on some of the issues dealt with below.

[1] The documents under review are:
- *Scheduling Policy Framework for Medicines and Poisons* (SPF")
- Draft *SUSMP ("SUSMP")*
- Table of changes from SUSDP to SUSMP ("Table of changes")
- Flow chart of proposed processes ("Flow chart").

2.3 The full picture

There are quite a number of the present proposals with which ASMI is in agreement. In particular:

- We support the proposed separation of medicines and poisons into two decision-making streams, and supported by a single secretariat.
- We also support the proposal to make the decision maker the Secretary of DOHA or their delegate.
- We agree with the proposal to include S3 advertising controls within the general scheme of controls under Part 5-1 of the Act.

However, our support for other proposals is contingent on a better understanding of what is proposed and how it will work. In respect of all these matters, ASMI sincerely hopes that there would be an opportunity to discuss the issues raised below.

The two consultation documents (SPF and the SUSMP) do not constitute a complete picture of the proposed new scheduling arrangements. The legislative base and authority for these documents – amendments to Part 6-3 of the Therapeutic Goods Act and new Regulations (presumably amending Div. 3A) - are not apparent.

We note from the consultation papers that, broadly speaking, the following entities are intended to exercise powers and functions as shown:

- NCCTG – policy advices
- Department of Health and Ageing – decision maker
- TGA – decision maker as delegate of the Secretary DOHA
- Expert committees – advisory to the decision maker
- State/Territory jurisdictions (adoption by reference or other legislative process)

It is, however, not possible to determine with any certainty what the nature of these powers and functions will be. This difficulty arises from the fact that all of these matters are set out as general propositions, without the hard edge of actual draft legislation.

Industry wishes to know how the executive powers are to be accountable, both to the Parliament and by means of merits and judicial review. Likewise, we are concerned to know how all aspects of the SPF are to be transparent.

We urge the Government to make the proposed legislation, including all subordinate legislation, publicly available by way of exposure drafts so that all stakeholders have an opportunity to put fully informed views.

ASMI stands ready to work constructively with the Government to advance the reform of the scheduling system.[2]

3. COMMENTS ON THE PROPOSED SCHEME

3.1 Committee structure and procedures

3.2.1 Separation of medicines and poisons

ASMI supports the proposed separation into two expert committees, and supported by a single secretariat. ASMI understands this separation to require complete separation (not merely in name) in respect of all aspects of the functioning of the committees. Likewise, the membership of the committees should not overlap.

3.2.2 Decision-making process

ASMI supports the proposal that the decision-maker will be the TGA (under delegation from the Secretary) on the recommendation of the MSEAC.

Likewise, we support the proposed procedure under which new substances will usually be scheduled by the TGA as part of the registration evaluation process.

We accept that the TGA may refer certain matters to the MSEAC. However, we do not understand what the process of discretionary referral to "any other relevant committee/s" may entail. We assume that the MEC, CMEC or ADEC may be in mind, or perhaps the Therapeutic Goods Advertising Code Council.

ASMI **requests more information be published on this point,** perhaps with guiding principles for such referrals.

3.2.3 MSEAC membership

ASMI recommends that the range of expertise for membership be expanded to include:

- risk/benefit analysis
- cost/benefit regulatory analysis
- consumer behaviour
- consumer communications

[2] The COAG's *Best Practice Regulation* stipulates Principle 7 as "consulting **effectively** with affected key stakeholders at **all** stages of the regulatory cycle" – see p. 4.

In industry's view, the scheduling process would be greatly enhanced by including expertise on risk assessment and the related discipline of cost-benefit analysis. *Rethinking Regulation* found those skills to be central to good regulation.[3] Likewise, the *Best Practice Regulation Handbook*[4] makes clear that, "if the aim of regulation is to address a hazard, risk analysis should be conducted …". As well, the COAG *Principles of Best Practice Regulation*, which the Introduction makes clear apply to bodies such as those dealing with scheduling,[5] also stresses the fundamental importance, not merely of hazard identification, but of risk analysis as well.[6]

Thus we consider that the proposed Medicines Scheduling Expert Advisory Committee (MSEAC) would be strengthened, in line with COAG's requirements, if expert risk analysts were included in the membership. The Committee would also benefit from members who had closer experience of consumer behaviour in the marketplace, and of the effects of communication.

Under current arrangements, industry has been represented on the NDPSC by way of a nomination put forward by industry. Given the fact that the proposed scheme makes provision for two classes of experts, **ASMI recommends that this practice of a nominated industry member should continue.**

ASMI strongly believes that **the MSEAC Chair should be an independent person and not a TGA officer**. This is considered important as the TGA is intended to be the decision-maker on the recommendations of the MSEAC.[7]

3.2.4 Public health and safety – urgent scheduling

On p. 4, the SPF says that substances can be referred for scheduling decision "where it is in the interests of public health and safety".[8] The same expression is used in relation to urgent scheduling.[9] **ASMI recommends that this expression be defined by reference to objective criteria** in the Act or legislative instrument. A distinction is drawn, under s. 30 of the Act, between cancellation options, depending on whether para 30 (1) (a) applies, or not. It is in the interests of proper process that a similar distinction be drawn in the present case.

3 *Report of the Taskforce on Reducing Regulatory Burdens on Business*, January 2006, p. 149.
4 p. 81.
5 p. 3.
6 Appendix B.
7 It would be even more problematic if a provision such as sub-Reg. 42 ZCR (5) were to be retained – in effect giving the TGA a deliberative and a casting vote and a decision-making discretion.
8 SPF, p. 4.
9 SPF, p. 5.

3.3 Cost recovery

It is said that "the costs associated with scheduling of medicines … will be fully recovered from the relevant industry sectors".[10] This represents a new policy decision, but it is not clear how this will be applied in practice in a range of different circumstances.

Scheduling of medicines (and poisons) in Australia is substance based rather than product based. Consequently, all therapeutic goods containing a particular substance are scheduled. This means that each decision will benefit or disbenefit all sponsors whose products are in competition with each other. Indeed, one sponsor may have sought a scheduling decision while others may not wish its acceptance at all.

In these circumstances, who pays? It may be said that the applicant pays, so that others enjoy a "free ride". If all concerned are asked to pay ("the relevant sector"), those who did not apply for the decision, or opposed it, would arguably also be made liable.

It is to be anticipated that there would be cases where a sponsor(s) may not initiate a scheduling process.[11] Again, it is not clear who will be responsible for the costs. As well, in the case of new substances which are to be scheduled by the TGA as part of the evaluation process, will the evaluation fees include a new element regarding Schedule decisions?

We note that a CRIS is to be published but at the time of lodging this submission its details are not known. **ASMI wishes to reserve its position until the CRIS has been published** and we have had a chance to examine it, along with further information which may clarify the issues set out above.

3.4 Classification of medicines - Factors

3.4.1 Factors in Scheduling classifications

The passage on p. 17 of the SPF argues that "Factors rather than criteria are considered to be more appropriate assessment tools". ASMI supports the theoretical framework set out on p. 17 of the SPF, as it gives assessors (including the MSEAC and the decision maker) a sensible approach. In particular, we commend the list of questions about "hazard", which, if rigorously applied and required to be followed by virtue of statutory provisions, may well lead to robust risk analyses.

[10] SPF, p. 4.
[11] See SPF, p. 4.

However, we are of the view that **these factors should have legal underpinning and that legal underpinning should ensure that the decisions are open to merits and judicial review.**

3.4.2 Criteria

Under the present scheme, the NDPSC is bound to have regard to each of the criteria set out in s. 52E of the Act. These provisions are seen by industry as an important control on the exercise of executive power.

We do not know what is intended to be included in the Act as proposed to be amended. In our view, it is fundamentally important that the criteria are in the Act to ensure that the MSEAC and the decision maker are bound to have regard to these criteria.

Sub-section 52E (2) requires the Committee to comply with "any guidelines" of the NCCTG. Again, it is not clear how this will work under the new scheme. ASMI contends that if the SPF and "any guidance" are intended to have equal standing with the law, this should be achieved by way of a disallowable legislative instrument and/or by incorporation into the Act.

3.4.3 The "cascading principle"

The SPF describes at pp. 18-19 "the model for making scheduling decisions embodies a cascading principle". The approach set out there is in our opinion not consistent with regulatory practice as it has been expressed in COAG documents.

Accordingly, industry suggests that the cascade should be bottom up, not top down. A level of minimum effective regulation will be achieved by starting with the least restrictive level and proceeding to higher levels of restriction through a hierarchical process of justification for the levels of restriction deemed necessary to ensure public health and safety.

3.4.4 Factors for scheduling

In general, ASMI supports the characterisations of the "factors" for each Schedule as set out in Chapter 4 of the SPF. It appears that these vary little from the present guidance principles. It is essential that at all times, hazard identification and risk/benefit analysis be separated as elements in the decision making process.

3.5 Advertising of S3 substances

We note that use of Appendix H will be "phased out" and "replaced by legislation under the Act"[12]. This suggests that there would be some kind of special subordinate legislation which would perpetuate Appendix H, perhaps under another name.

ASMI supports the proposal that decisions in relation to advertising will be made by the Secretary, thus clearly separating it from recommendations in relation to scheduling made by the MSEAC.

However, we would like to propose an alternative regulatory approach to advertising decisions which would be consistent with COAG principles. We suggest that Appendix H (or its substitute) should become a "negative" list, i.e. listing substances, advertising of which would not be in the public interest. This approach would require the regulator (decision-maker) to commence with the least restrictive position and it would place the onus on the regulator to justify increasing levels of regulatory restrictions.

To achieve effective separation between scheduling and advertising decisions we also suggest that the Therapeutic Goods Advertising Code Council should have responsibility for developing a set of public interest criteria to determine which substances should not be permitted to be advertised, consulting NCCTG as appropriate.

Finally, it is not clear how the proposed changeover is intended to be phased out and in. What is the timetable? What legal or administrative processes will be followed? ASMI is looking forward to receiving further details to clarify these matters.

3.6 Mandatory Recording Requirements

ASMI provisionally supports the proposal to implement a mechanism to ensure uniformity in mandatory recording requirements to address specific issues such as "illicit diversion" or "resale for misuse". However, **ASMI wishes to reserve its final position on this proposal, pending the release for public consultation of the criteria that will determine inclusion of substances in proposed Appendix N.**

[12] SPF, p. 14.

4. THE LEGISLATIVE BASE

4.1 Proposed replacement arrangements

Page 11 of the SPF says that the Act will set down "procedures for the decision-maker". However, the two expert advisory committees are to be established "under" (not by force of) the Act, while their procedures are intended to be dealt with in the Regulations **and** the SPF.[13]

It is further said that the decision maker "will be required to take into account the relevant matters specified in the Act, the Regulations and **subsequently** the regulatory principles, processes and guidelines set out in the SPF"; and that "the decision-maker **must** comply with the SPF".[14]

It is not stated whether the SPF will be legislative in character. We infer that the intention is that a provision similar to the present sub-s. 52E (2) of the Act is intended to delegate "responsibility for overarching policy principles, guidance and protocols on scheduling (including procedural guidelines)" to the NCCTG.

It seems that none of this will be contained in the Act, nor in a Regulation made under the Act, nor in a legislative instrument disallowable by the Parliament.

We consider that **the legislation to be introduced should at least establish and confer Parliamentary authority on the NCCTG to adopt the role of delegated legislator proposed for it and to ensure that its constitution and procedures are appropriately transparent and accountable.**

What is said above has implications for the merits review and judicial review proposals under the new scheme. As well, issues about transparency and FOI, balanced against commercial-in-confidence issues, require attention. These are dealt with in the relevant sections below.[15]

ASMI accepts that some of the inferences drawn above may be disproved, or our concerns mitigated, once the complete package of legislative instruments is known. At this stage, however, we can only go by what is published. Given the importance of these matters, **we urge the Government to publish exposure drafts of the Bill, Regulations and the SPF in their intended final forms.**

At this stage, therefore, ASMI reserves its position in relation to the basic legislative structures.

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13 SPF, p. 11.
14 SPF, p. 3, emphases added. It is unclear what "subsequently" means. Subsequent to what?
15 See Section 5 and Section 6.

We note that the SUSMP is considered to be "legislative in character" and as such it will be a legislative instrument for the purposes of the LIA. ASMI does not have any objection to the proposal that it will not be disallowable "to ensure certainty in the continuing application of state and territory laws."[16]

4.2 Uniformity and "covering the field"

ASMI's member-companies have always been concerned about variations in relation to schedule entries in SUSDP when they come to be adopted by State legislatures. ASMI is therefore pleased to note:

> "As the NCCTG is committed to the principle of national uniformity, any decision to depart from a scheduling entry in the SUSMP will need to be fully justified in an annual report to the NCCTG".

ASMI requests that details of the measures to give effect to this commitment be released for public consultation. The details need to provide answers to questions like: How will this process work? Will the "full justification" be published? Will the NCCTG's annual report be published? Can a party appeal a decision to vary or not to vary a schedule?

Notwithstanding the above, ASMI would like to propose an alternative approach to achieve uniformity. We submit that to achieve uniformity **the simpler and preferable way to proceed to introduce the proposed scheduling reforms would be by simple amendment of the Therapeutic Goods Act to "cover the field".** Existing sections 6 and 9 of the Act would then operate to allow development of a scheme covering this aspect of marketing approval for therapeutic goods.

5. APPEALS – MERITS AND JUDICIAL REVIEW

5.1 Limitation to appeal options

In our view, the provisions for appeal against scheduling decisions ought to be aligned with the general principles of Commonwealth administrative law. Thus, we object strongly to proposals

- to oust the jurisdiction of the courts under ADJR;
- to allow only a limited access to in-house "reconsideration" of decisions; and
- presumably – although this is not stated in terms – to oust the jurisdiction of the AAT to hear merits appeals (and perhaps also – again not stated – access to s. 60 processes).

[16] SPF, p. 3.

Again, being mindful of COAG Principles, we do not believe there is any justification for these severe limitations of appeal and review rights.

ASMI needs to reserve its position on these matters and requests an opportunity for further discussion to reach agreement on proposals that would be accountable, comprehensive and transparent.

5.2 Scheduling decisions "legislative in character"

It is said that scheduling decisions are "legislative in character" and the SUSMP (but, it seems, not the SPF) will be tabled in Parliament under the Legislative Instruments Act. At the same time, however, it is well-known that scheduling decisions relate to particular substances and that sponsors seek, in effect, a "decision under an enactment", as that expression is used in the ADJR Act.

The essential truth of this characterization appears from the proposals relating to rights to "reconsideration", which relate to individual cases or sponsors. Also, the proposal to recover costs seems to be premised on individual cases as the basis for amendments of the SUSMP.

5.3 Appeal rights should not be restricted

Either way, it is submitted that sponsors or other aggrieved persons ought not be denied access to the full range of merits and judicial review that the law allows. This is particularly necessary because of the proposal not to permit disallowance of the SUSMP.

5.4 "Reconsideration" of decisions

ASMI accepts the "reconsideration" as a second-best arrangement, in the absence of full access to appeal rights. Ideally, the "reconsideration" should be the initial right to internal review, as under s. 60.

ASMI would appreciate clarification as to whether the intention is to allow s. 60 appeals, or whether the "reconsideration" option is regarded as in substitution.

In our view, it is essential that the person delegated to hear a reconsideration application is independent of the scheduling processes up to that point.

5.5 Date of effect of decisions

It is stated on p.6 of the SPF that "all other scheduling decisions would come into effect no more than 6 months after the decision was made unless otherwise

specified". ASMI understands this to mean that the 6 month period will not be necessarily the norm and that adequate provision will be made to allow consideration on a case-by-case basis. This is of particular commercial relevance in those instances where changes in scheduling are not resulting from sponsor initiated applications.

6. CONFIDENTIALITY

6.1 Issues for consideration

On the one hand, ASMI supports the proposal to ensure greater transparency. On the other, however, **our member-companies see a need to ensure that commercial-in-confidence information is properly protected.**

A further issue, which can be conveniently considered here, is the issue of data protection. Put another way, our member-companies are concerned to ensure that the regulatory processes do not extend "free rides" to competitors who have not made the outlays of time and money to secure a commercially favourable (e.g. reclassification) decision.

6.2 Transparency

ASMI welcomes the commitment to greater transparency in MSEAC proceedings and, for the most part, supports the moves to publish decisions, etc, of both the Committee and the decision maker. However, **ASMI needs to reserve its final position on disclosure arrangements until further clarification around the exact time frames for various processes has been provided. We would welcome further discussions on these matters;** indeed, we regard such discussions as essential and central to true and meaningful consultation.

6.2.1 Notification of applicant

Transparency needs to be balanced with proper protection of sponsors' commercial-in-confidence information. In our view, this can best be achieved by some changes in the procedures set out in the flow charts. ASMI suggests that an applicant should be notified, in confidence, of a scheduling decision before publication in the SUSMP.

6.2.2 Guidelines for use of confidential information

ASMI accepts the principles set out at p. 36 of the SPF. We consider, however, that the policies and principles set out in the FOI legislation, together with those in the Therapeutic Goods Act, provide a scheme which can be applied to scheduling matters as well as other issues.

We understand that the Government has FOI policy and legislation under review. Subject to adequate protection for Commercial-in-Confidence information, ASMI considers that the general principles arising out of the review should apply to scheduling procedures. In particular, for the most part, we see no grounds for redacting records of MSEAC, and other bodies, to suppress details of identities of persons to whom views and/or information are attributed, including "nominated" members.

6.3 Data protection

ASMI's policy stand on data protection is set out in Attachment 2.

Essentially, it is considered that a sponsor seeking a rescheduling decision should have a competition-free window of opportunity to exploit a favourable decision. Given that the expenses incurred in preparing a case, together with the proposed cost recovery fees, may be substantial, this proposal appears reasonable.

We believe it would be possible to include in the proposed legislation provisions to this effect.

Attachment 1

SUBMISSIONS MADE BY ASMI (previously PMAA) ON SCHEDULING MATTERS

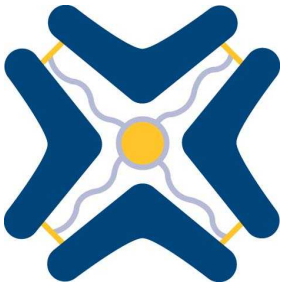
1997-present

January 1997	Submission on Restrictions on Advertising S3 Products
November 1999	Submission to the National Review of Drugs, Poisons and Controlled Substances Legislation ("Galbally Review")
April 2000	Response to Galbally Options Paper
May 2000	Further comments following meeting with Review
October 2000	Response to Draft Final Report
July 2001	Submission to Commonwealth/State Working Group on Galbally Review
April 2004	Submission to Treaties Committee of the Australian Parliament (re trans-Tasman proposal)
May 2005	Submission to House of Representatives Standing Committee on Legal and Constitutional Affairs
September 2005	Submission to TGA on Proposed Model for the Scheduling of Medicines
November 2005	Submission to the Regulation Taskforce
December 2006	ASMI Submission to ANZTPA Working Group re proposed Scheduling arrangements
July 2007	ASMI response to ANZTPA Consultation draft Policy Scheduling Framework

Attachment 2

ASMI's position in relation to data protection

ASMI Position Paper



Data Protection and Market Exclusivity for Non-prescription Complementary and Over-the-Counter Medicines

Contents

Summary

The Australian Self-Medication Industry (ASMI) is the peak national association for the non-prescription consumer healthcare products industry – comprising both over the counter (OTC) and complementary products. ASMI strives to ensure the ready availability of safe and effective self-care products to all Australians at an affordable cost, to encourage responsible use by consumers and participation in their own healthcare and to promote an increasing role for cost-effective self-medication products as part of the overall Australian health strategy.

ASMI believes that innovation through good research underpins good self-care and one of our objectives is to encourage innovation in relation to non-prescription medicines. However, innovation only occurs when the projected return on investment outweighs cost and the most favourable environment for innovation is an environment where there is the opportunity to maximise this return on investment.

The lack of data protection provisions in Australia poses a major obstacle to innovation in the non-prescription medicines industry. Most of these products are "off-patent" and there are currently no data protection provisions. Consequently, there is little or no incentive for companies to invest in research into their efficacy, new uses, new dosage or delivery forms and changed levels of access via rescheduling.

The proposed legislative provisions are intended to correct the recognised 'market failure' and provide a more conducive environment for investment in regulatory data to support applications for marketing approval for innovative products and substances as well as modification of conditions of market approval for existing products. This can be achieved by providing for a specified and limited period of market exclusivity to give innovators an opportunity – and incentive – to recoup the costs involved in generating data, before a competitor is permitted to rely on those data for the approval of a generic alternative.

The proposed provisions are not intended to be anti-competitive or compromise the public benefits derived from the availability of lower priced generic versions.

The proposed reforms also relate to the international competitiveness of the Australian non-prescription medicines industry as an exporter into growing markets, and the maintenance of strong competition in the local marketplace.

The purpose of this position paper is to gain support for the inclusion of revised and new legislative provisions which will result in an improved system for the management of data protection.

Introduction

The Australian Self-Medication Industry (ASMI) strives to ensure the ready availability of safe and effective non-prescription medicines to all Australians at an affordable cost, to encourage responsible use by consumers and participation in their own healthcare and to promote an increasing role for cost-effective self-care as part of the overall Australian health strategy.

Innovation through good research underpins good self-care and one of the policy objectives of ASMI is to encourage product innovation in order to remain globally competitive and to attract investment to provide new and innovative non-prescription medicines for Australians.

However, innovation only occurs when the projected return on investment outweighs cost. Thus, the most favourable environment for innovation is an environment where there is the opportunity to maximise this return on investment.

In recent years it has become increasingly evident that the mechanisms of data protection currently in place under the *Therapeutic Goods Act 1989* require refinements to meet both the needs of data owners and those seeking access to protected data. Achieving a legislative framework for a fair and equitable data protection scheme for the non-prescription medicines industry has been on of the strategic objectives of ASMI since 2000.

Purpose of the Position Paper

The purpose of this position paper is to increase awareness of the background, status and practical application of current legislative provisions in the *Therapeutic Goods Act 1989* and to gain support for the inclusion of revised and new legislative provisions in the *Trans-Tasman Joint Agency Bill and Rules* which will result in an improved system for the management of data protection.

The proposed legislative provisions are intended to correct the recognised ‘market failure’ and provide a more conducive environment for investment in data to support the introduction of new products, new product uses, improved formulations, new dosage and delivery systems, increased level of access via scheduling (“switch”) and innovative production procedures in the market place.

Importantly, the aims of the proposed regulatory reforms also relate to the sustainability and international competitiveness of the Australian non-prescription medicines industry as an exporter into growing markets, and the maintenance of strong competition in the local marketplace.

What is data and how is it used?

Generally, regulatory data are the data provided by an applicant so that the regulatory authority can undertake the required statutory tasks associated with providing marketing approval for products and substances.

What is data protection?

Definition: *a period of non-reliance and non-disclosure that a regulatory authority must provide in relation to data it considers and/or relies on in the context of assessing applications for products and substances for marketing approval. In general, for data to be eligible for data protection:*

- *it will be of a type specified by the regulator,*
- *it must be relevant to an application,*
- *it must be relevant to the regulator's decision.*

Data protection is a well-established mechanism in the chemical and pharmaceutical regulatory regimes of most developed countries, including Australia. It is especially relevant for off-patent products as well as products that are difficult to patent. Its general aim is to provide to a person (usually a registrant, approval holder or other data owner), who has invested in data in support of:

- an approval (or continued approval) of a substance, or variation of an approval, or variation of the conditions of an approval of a substance;
- an approval (or continued approval) of a product, or variation of a registration, or variation of the conditions of a registration of a product;

a specified period of time during which they may gain an appropriate return for that investment by either:

- having the right to prevent reliance on or reference to their information by the regulator in the making of subsequent approvals or registrations which benefit another applicant, registrant or approval holder; and/or
- having the right to negotiate the terms, including appropriate levels of compensation, under which the regulatory authority may use their information to benefit others for the purpose of subsequent approvals or registrations.

Data protection provides for a defined and limited period during which the regulatory authority must not refer to the data of one party to grant registration or approvals for another party without the agreement of the owner, or where specified, unless agreed or arbitrated terms of access have been reached.

In essence, data protection recognises the significant investment necessary to generate and provide data to meet regulatory requirements. It encourages maintenance, product development, innovation and access to substances and products by providing for a defined period of exclusive data protection, or, third-party access through a scheme of compensated cross-referencing.

Patents and data protection

Patents and data protection are two different forms of intellectual property protection and there is no connection between the purposes they seek to achieve. Whilst data protection for an original registration of a new substance and its associated product(s) will operate concurrently with a patent, it would be a rare situation where the data protection period of the initial data package did not expire prior to the expiry of the patent. Additionally, the vast majority of non-prescription products are not covered by a patent.

Data protection is an incentive for innovation in relation to off-patent products, whereas patent protection is usually, but not exclusively, reserved for new substances, which are generally introduced into the marketplace as prescription medicines.

Australia's obligations

Australia joined the World Trade Organisation on 1 January 1995 and as such is obligated to abide by various trade agreements, including *Trade-Related Aspects of Intellectual Property Rights (TRIPS).* Australia is a signatory to the TRIPS agreement and has been required to comply with it since 1 January 2000.

This agreement recognises that intellectual property protection encourages inventors because they can expect to earn some future benefits from their creativity. This in turn encourages innovation where development costs are extremely high but where social benefits are delivered as a result.

Most countries maintain that data protection is also an obligation under the TRIPS agreement. There seems to be consensus that this is true for new substances (New Chemical Entities) although the term is not specified. There are some countries that maintain that this obligation stands in relation to new indications for existing substances and products as well.

Failure to legislate and implement data protection required under TRIPS leaves non-compliant countries open to complaint and resolution in accordance with the World Trade Organization (WTO) dispute mechanism.

Current status internationally

The USA provides considerable encouragement for innovation in the self-care product industry. Public Law 98-417 was enacted in 1984 and requires five-year data protection for new substances once approved for sale; a copy cannot be approved for five years after the innovator. The Act also calls for a three-year data exclusivity period for other types of self-care products requiring clinical trials.

The European Union has also recognised the need for encouragement for innovation and in March 2004 the European Parliament and the Council of Ministers signed revisions to pharmaceutical legislation, which include a provision for one year of exclusivity on data used for prescription to non-prescription switches and new uses or indications.

Problem identification

There are major impediments to innovation in the non-prescription medicines industry in Australia. Most of these products are "off-patent" and there are currently no data protection provisions. Consequently, there is little or no incentive for manufacturers to commission research into: efficacy; new uses (indications), new dosage or delivery forms and compilation of data to support applications for rescheduling ("switch").

A company which invests in innovation in relation to an existing product has an enormous regulatory burden compared with that of the company which introduces the second-entry product. In addition, regulatory delays can result in the second-entry product coming to market at the same time as the product they copy, to the commercial detriment of the innovator.

It is clear that companies which are keen to invest in innovation must be given an opportunity – and the incentive – to recoup the enormous costs involved in generating data to gain regulatory approval before a competitor is permitted to rely on those data for the approval of the copy.

Without the period of market exclusivity provided by a patent, the research-based industry would not have any incentive to undertake the research leading up to the discovery of innovative drug therapy. Without data protection, the company which invests in innovation in relation to established substances and products would be placed at an unfair commercial disadvantage when compared to their competitors.

Current legislative provisions

In April 1998, the *Therapeutic Goods Act 1989* was amended to make provision for data protection for 'therapeutic goods' (medicines). The amendments provide only for protection of the data contained in applications for registration of new substances from use by the Therapeutic Goods Administration (TGA) when evaluating other therapeutic goods. The data are protected for 5 years from the date of marketing approval, i.e. entry on the Australian Register for Therapeutic Goods (ARTG).

The data protection provisions do not apply to:

- Off-patent products which are rescheduled ("switched") to lower schedules, e.g. from prescription to non-prescription schedules or within non-prescription schedules (S3 to S2 or S2 to open sale);
- New indications and/or dosage regimes for existing products;
- New delivery systems or routes of administration;
- New or modified substances, or new product combinations or formulations;

- New ingredients for “Listable” products (which include the vast majority of complementary medicines).

Deficiencies in current legislative provisions

Rescheduling ("switch")

Under the current scheduling system it is the substance, not the product, which is re-scheduled. A sponsor submits an application to the National Drugs and Poisons Schedule Committee (NDPSC) for a substance in a particular product to be rescheduled. If successful, the scheduling decision is gazetted, and becomes effective after a specified timeframe. All products containing the same substance of the same strength(s) (and where relevant, dosage and indications) are automatically rescheduled as well, based on the data submitted to support the original switch application.

There are no legislative provisions which require the regulatory authority to provide protection for supporting data when evaluating an application for rescheduling ("switch") to increase appropriate access by consumers to products. Not only is there an absence of data protection, but the rationale and indication(s) are made public through gazettal, which means the information can be used for the approval of an application(s) for second-entry product(s).

The fact that scheduling decisions are substance- and not product-based, together with the current timeframe for a gazettal notice to become effective, allow all sponsors with similar products to benefit from the scheduling decision. That is, all sponsors have the opportunity to launch their rescheduled products at the same time as the original applicant, without any intellectual property investment other than a re-labelling application to the regulatory authority.

Obviously, the investment in the switch application by the innovator is markedly greater than that of the second-entry substitute; however both products can enter the market at approximately the same time.

New indications and/or dosage regimes for established substances and products

Most innovations for well-established substances and products result from research into new uses (indications) for such products. For example, the growth of products containing St. John's Wort came about as a result of many clinical trials by one innovator for a new use as a minor antidepressant.

The benefits of research advances in relation to older products are equally, if not more important as discoveries of new substances which have the same effect as existing substances. Ironically, a new breakthrough for an existing substance will not generally receive the same market protection that a new substance within an existing therapeutic class may receive.

At present, if another product with the same substance is entered on the Australian Register for Therapeutic Goods (ARTG) the required information provided by the sponsor is not "protected information" under the Act. This means that other sponsors can adopt the new indication which resulted from research and development by the innovator.

These factors provide a major disincentive for companies to undertake the necessary research and development to generate sufficient data to introduce new indications for existing substances.

New delivery systems and routes of administration

This category refers to applications where sponsors have had to provide a justification for a 'variation' to the usual registration pathway. Once this has occurred, other sponsors' products are automatically evaluated in the same way, without any recognition of the intellectual effort required by the initial sponsor.

New or modified substances for "Listable" Medicines

This category would include data generated through research undertaken by an innovator that would result in a Compositional Guideline being developed by the regulatory authority. Compositional Guidelines are identity and physico-chemical specifications for new complementary substances that are not characterised within a recognised pharmacopoeial monograph. An example of this would be where a substance is combined with a proprietary excipient to produce an innovation in drug delivery.

Currently, Compositional Guidelines do not have legislative standing and are published by the TGA for comment prior to finalisation. This gives competitors the opportunity to broaden the proposed Compositional Guideline to include the same of similarly named substances which do not meet the original narrow specifications, resulting in a serious detriment to the company which developed a well defined compound.

New indications for "Listable" Medicines

For "Listable" medicines, which include the vast majority of complementary medicines, one of the conditions of market entry is that a sponsor holds data (evidence) which substantiates the indication(s) for which the product is listed on the ARTG. The data are not peer reviewed and are not required to be in the public domain. In theory it means that the indication(s) cannot be copied. However, there is seldom a challenge made if a second product is listed with the same indication(s) to establish whether the sponsor of the second product holds the required substantiating data.

The TGA document, *"Guidelines for Levels and Kinds of Evidence to Support Indications and Claims for Non-Registrable Medicines, including Complementary Medicines, and other Listable Medicines"* (The Guidelines), specifies three types of claims and indications for Complementary Medicines. These are:

- High level - treats/cures/prevents or manages a disease/disorder;
- Medium level - health enhancement, risk reduction/aids in the management or relief of the symptoms of a disease/disorder; and
- General level - health maintenance, supplementation and relief of symptoms.

An innovator who has generated data to support a new "general" or "medium" level claim/indication for a complementary medicine, either through new research or through compilation of a bibliographic submission, would currently "List" the new indication(s) as part of an application for marketing entry. However, until the compliance with The Guidelines is ensured, competitors can copy such indication(s) for any "Listable" product.

An innovator may attempt market exclusivity for its pioneering product by submitting an application for marketing approval through the "Registration" pathway (as opposed to the "Listing" pathway). In the case of a "high level claim", market exclusivity could be achieved through the measures proposed earlier in this paper for "Registered" products. However, if the new indication is a "general or "medium" level claim, "Registration" of the product by the originator would not prevent competitors from "Listing" comparable claims for their competitor product.

Desired outcomes

The self-medication industry would like to achieve a defined and limited period of effective market exclusivity, i.e. a period of time with exclusive rights for non-prescription medicines. This may vary, depending on the effort for innovation required in a particular circumstance.

This could be achieved through adequate data protection - a period of non-reliance and non-disclosure the regulatory authority must apply to data used in the assessment of applications for new substances and products, or variations of market entry conditions for existing substances and products.

The following areas have been identified where market exclusivity is justified:

- Rescheduling ("switch") of a substance and associated product
- New indications, including new patient populations and significant label changes
- New or modified substances
- New delivery systems, routes of administration and dosage regimes.

Proposed reforms

Legislative provisions for "Registrable" products and substances

The current section 25A of the *Therapeutic Goods Act 1989* contains limited data protection provisions. It is proposed that this section be used as the basis for drafting data protection provisions in the new *Trans-Tasman Joint Agency Bill and Rules*, with the following amendments:

- Clarify that the existing section 25A applies to new substances ; and,
- Introduce an additional section to make provision for data protection in relation to substances other than new substances.

The current section 25A of the *Therapeutic Goods Act 1989* provides data protection only for new substances. An amendment to the title is proposed to clarify that it only relates to new substances.

The proposed new section should mirror the protection for data on new substances by providing protection for data submitted for the "Registration" of:

- new indication(s),
- new route of administration,
- new or modified excipient(s),
- new combination(s) of two or more "Registrable" products,
- rescheduling of "Registrable" products,

for specified periods of time.

The specified periods of data protection should be determined by and reflect the nature (type) and complexity of data as well as the nature and scope (magnitude) of the investment by the innovator. Examples of the types of data and the period of protection include:

- Pivotal pre-clinical AND clinical safety and efficacy studies – 5 years
- Non-pivotal pre-clinical OR clinical studies – 3 years
- Bibliographic, market, safety and analytical data – 2 years

Provisions for "Listable" Medicines

To create in an innovative environment for complementary medicines in Australia, an essential first step is to ensure compliance with "The *Guidelines for Levels and Kinds of Evidence to Support Indications and Claims for Non-Registrable Medicines, including Complementary Medicines, and other Listable Medicines"* (The Guidelines). This will make claims specific to products, and ensure that the consumer is not misled. By ensuring that product claims are meaningful and substantiated, innovators, consumers and the public health system will benefit significantly.

There are two areas where market exclusivity for complementary medicines could be justified:

- New indications, including new patient populations and significant label changes

- New or modified substances.

Possible avenues that may produce the desired outcome(s) include:

- Amending section 25A of the Therapeutic Goods Act1989;
- Different effective gazettal date for sponsors not submitting new data.
- A control mechanism incorporated in the Electronic Lodgement Facility (ELF).

New Indications for existing "Listable" Medicines – "General" to "Medium" level claims and indications

The inability of the "registration" pathway to provide market exclusivity for "general" and "medium" level indication(s) could be addressed by implementing these types of indications as "Coded Indications" on the Electronic Lodgement Facility (ELF 3), with control mechanisms similar to the conditional rules in the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) or through a policy determination by the Complementary Medicines Evaluation Committee (CMEC). This would enforce a specified period of restriction on the use of such indications by competitors.

It is important to note that these provisions would not prevent other sponsors who independently generate the required data to support similar indications, to make application to the regulatory authority to use the same or similar indications. In this way anticompetitive regulatory measures are avoided.

There should also be provision for an innovator to enter into licensing agreements for the supply of finished products with other parties to permit the use of approved "general" and "medium" level indications. In such a case the product carrying the approved indication could be set up in the ELF 3 system under one of the mechanisms outlined below.

New indications for "Listable" Medicines – "High" level claims and indications

The proposed new section 25AA mentioned earlier under "Legislative provisions for Registrable products" will mirror the protection for data in relation to new substances by providing protection for information submitted for the "registration" of:

- New indication(s),
- New route of administration, or
- New or modified excipient(s),

for a specified and limited period of time.

New or Modified Substances or Excipients for "Listable" Medicines

The regulatory authority requires a considerable amount of data to support applications for new substances to be used in "Listable" Complementary Medicines. When a new substance is approved, it can automatically be used by other sponsors to launch competitor products. Whilst sponsor applications are treated as 'commercial-

in-confidence', the CMEC decisions are published before the eligibility of the substance is gazetted.

As mentioned earlier, Compositional Guidelines for new substances are published for public comment and have no legal underpinning.

The following legislative provisions could provide an incentive for innovators to seek approval for new substances for use in "Listable" products:

- Create a mechanism in the ELF system that will only allow the original sponsor, and any other sponsor(s) who may wish to enter into a licensing agreement with the originator, to use the ingredient(s) for "Listing" applications. This can be achieved by using the existing mechanisms within the ELF system:
  - Proprietary Ingredients: if the new substance is designated as a Proprietary Ingredient (PI) for a specified period (to ensure market exclusivity), it can be linked on the ELF system to a particular sponsor. The originator can then specify which sponsors are permitted access to the particular PI.
  - Code stocks: Sponsors are granted access to Code stocks through authorisation by the originator and this mechanism can also be utilised to restrict access to those products which have gained regulatory approval on the basis of protected substantiating data.

These measures would not prevent other companies to independently generate the required data to support similar applications for the approval of a new substance.

Conclusion

Data protection is a well-established mechanism to provide protection of intellectual property. It is especially relevant for "off-patent" products as well as products that are difficult to patent. Its general aim is to provide innovators who has invested in research to generate data required by regulatory authorities for marketing approval for substances and products, a specified period of time during which they may gain an appropriate return for that investment.

Without data protection, companies which invest in innovation in relation to established substances and products would be placed at an unfair commercial disadvantage when compared to their competitors.

The lack of data protection provisions poses a major obstacle to innovation in the non-prescription medicines industry in Australia. Most of these products are "off-patent" and there are currently no data protection provisions. Consequently, there is little or no incentive for companies to invest in research into their efficacy, new uses and new dosage or delivery forms.

The proposed legislative provisions are intended to correct the recognised 'market failure' and provide a more conducive environment for investment in regulatory data to support applications for marketing approval for innovative products and substances.

The proposed regulatory reforms also relate to the international competitiveness of the Australian non-prescription medicines industry as an exporter into growing markets, and the maintenance of strong competition in the local marketplace.

Bibliography

1. The New Data Protection Provisions and the Agvet Industry. Australian Pesticides and Veterinary Medicines Authority.

2. Data Protection for Agvet Chemicals - What you should know! Avcare Aug 2000

3. Intellectual Property – A vital asset for Australia. Reprinted February 2001

4. Data Protection – A policy paper to provided a new system of protection of information against unauthorised use when that information is given to the Australian Pesticides and Veterinary Medicines Authority. May 2003.

5. Encouragement of New Clinical Drug Development: The role of Data Exclusivity. International Federation of Pharmaceutical Manufacturers Association 2000.

6. Data Protection for Agvet Chemicals. Australian Consumer & Specialty Products Association (ACSPA) Briefing note. 20 August 2004.

7. Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement. Carlos María Correa, University of Buenos Aires.

8. Supporting Innovation in the Self-Care Product Sector. Nonprescription Drug Manufacturers Association of Canada (NDMAC). September 2002.

9. The need for innovation in the Canadian Self-care Industry. NDMAC