A S M I

BETTER HEALTH THROUGH RESPONSIBLE SELF-MEDICATION

Submission to

the

House of Representatives Standing Committee on Legal and Constitutional Affairs

regarding the

Harmonisation of Legal Systems Relating to Trade and Commerce

by the

Australian Self-Medication Industry

May 2005

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Executive Summary

- The regulatory environment for therapeutic goods in Australia is partly a Commonwealth and partly a State responsibility.

- The Therapeutic Goods Act provides a statutory scheme but it extends to natural persons and intra-State corporations only to the extent of State "mirror" legislation.

- The legislation of the States does not always provide a perfectly uniform regulatory scheme.

- The States also retain control of so-called "poisons" legislation and this means subtle but commercially inefficient State-by-State differences.

- The Australian Self-Medication Industry (ASMI) wishes to see a completely uniform regulatory scheme in force in all parts of Australia and New Zealand.

- The proposed Trans Tasman Joint Agency to regulate therapeutic products provides an opportunity to "cover the field" by legislation based on these placita of s.51 of the Constitution

  - (i) Trade and commerce with other countries, and among the States;

  - (xx) Foreign corporations, and trading or financial corporations formed within the limits of the Commonwealth; and

  - (xxix) External affairs.

- **ASMI is concerned that the Australian Government is not disposed to take this step, although no well-argued case for not doing so has been made public.** Thus the present overlaps and inefficiencies will continue.

This submission

This submission is made by Australian Self-Medication Industry (ASMI), the industry association which represents the interests of all non-prescription medicine (including complementary medicines) manufacturers in Australia. The non-prescription sector makes a sizeable contribution to economic activity in Australia and many of our members are active in finding and growing export markets.

ASMI welcomes this Committee's enquiry, as we are concerned that there should be a consistent, complete and truly uniform regulatory environment (as between the States) governing the manufacture and supply of therapeutic goods in Australia. Also, however, there should be uniformity with New Zealand. Many of our member companies base their Australasian operations in Australia and service the New Zealand market from here. Some New Zealand companies do the same in the other direction.

Our submission therefore focuses on the last two of the Committee's issues of interest:

- Standards of products; and
- Legal obstacles to greater federal/state and Australia/New Zealand co-operation.

The regulatory environment for therapeutic goods

Complex and multi-layered arrangements

As will appear below, one of the consequences of Australia's federal system of government is that the powers and responsibilities of the States and the Australian Government overlap. In the end, the High Court may adjudicate but before that Court comes to a view, there is considerable scope for bureaucratic and political game-playing as jurisdictions claim and counter-claim responsibilities.

Business is the loser. Nothing inhibits economic activity and growth like regulatory uncertainty. In the regulation of therapeutic goods, the differences in the rules as between States and as between the Commonwealth and the States are often small and subtle, almost non-existent.

Scheduling of non-prescription analgesic products containing codeine

The Schedule 2 entry for **codeine** in the New South Wales *Poisons List* differs from that recommended in the Commonwealth *Standard for the Uniform Scheduling of Drugs and Poisons* (SUSDP) in two ways.

1. The SUSDP Schedule 2 (Pharmacy Medicine) entry imposes a pack size restriction of 25 dosage units for products containing codeine when compounded with a single non-opiate analgesic substance, whether in the form of tablets, capsules of individually wrapped powders. Packs containing more than 25 dosage units are included in Schedule 3 (Pharmacist Only Medicine).

   In New South Wales, there is no Schedule 2 pack size restriction for these products.

2. Within specified parameters, the New South Wales Schedule 2 *Poisons List* entry allows combinations of codeine with one or more other therapeutically active substances other than a non-opiate analgesic substance.

   The SUSDP S2 codeine entry, while specifying the same limits, does not exclude a non-opiate analgesic from combinations with one or more other therapeutically active substances.

Businesses competing in the marketplace can only wonder why such small distinctions and contradictions in the rules have come about. Why is selling the same medicine in Perth or Brisbane subject to small differences? Why are "the same" laws drafted differently, according to different "drafting conventions", in one State compared with another? Why are the (apparently) same rules administered or interpreted differently in the various States?

On the face of it, you would think that the Australian demographic is so homogenous that the medicine-taking public is unlikely to display different characteristics, depending on their State of origin. The same extends to New Zealand. Yet the only justification for differing rules and standards would have to rest on the contrary view.

There has been some progress towards "harmonisation" of standards, but for business, only complete harmonisation will suffice. Either the rules are the same, or industry has to operate on a national scale but cope with different standards, labelling, marketing protocols and so on, within the limits of each State. All this costs money and time and it is inevitable that the consumer pays.

In the next two sections, we shall show how two separate regulatory processes operate in Australia in relation to therapeutic goods. One is based on Commonwealth law — the Therapeutic Goods Act. But another is based on the States' legislation regarding "poisons", which is held to extend to medicines.

Further complicating the issues of Commonwealth-State divisions of powers and responsibilities, are the matters arising from the Australian and New Zealand Governments' decision to set up a joint agency to regulate therapeutic products. Apart from a Discussion Paper issued in June 2002[1] and the text of a Treaty between Australia and NZ,[2] very little is

[1] *A Proposal for a Trans Tasman Agency to Regulate Therapeutic Products*, Discussion Paper, June 2002.

known about how the new agency will work. Nothing more than a "legislative framework" has been made public and it contains insufficient detail for industry to get on with planning for its expected entry into force on 1 July 2006. Industry fears, however, that the States' idiosyncratic administrative arrangements, possibly as well as some from New Zealand, may have been retained so that we shall continue to have to take account of nine jurisdictions' approaches to the regulation of therapeutic goods.

The Therapeutic Goods Act

Therapeutic goods are regulated at the Commonwealth level under the *Therapeutic Goods Act 1989* (C'wth). The Act contains an apparently complete statutory scheme which regulates the manufacture, registration (after evaluation), listing, sale and advertising of therapeutic goods. Therapeutic goods are defined in s.3 of the Act to include all products which make a therapeutic claim — see box.

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[2] *Agreement between the Government of Australia and the Government of New Zealand for the establishment of a joint scheme for the regulation of therapeutic products*, 10 December 2003.

The Treaties Committee considered the Agreement and reported on it in Report 62, tabled on 30 March 2004. The issue of concern to ASMI is touched on at paras 2.50-2.52 of the report (p.18).

Therapeutic Goods Act 1989 — s.3 Interpretation

(1) In this Act, unless the contrary intention appears: ...

therapeutic goods means goods:

(a) that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be:

(i) for therapeutic use; or

(ii) for use as an ingredient or component in the manufacture of therapeutic goods; or

(iii) for use as a container or part of a container for goods of the kind referred to in subparagraph (i) or (ii); or

(b) included in a class of goods the sole or principal use of which is, or ordinarily is, a therapeutic use or a use of a kind referred to in subparagraph (a)(ii) or (iii);

and includes medical devices and goods declared to be therapeutic goods under an order in force under section 7, but does not include:

(c) goods declared not to be therapeutic goods under an order in force under section 7; or

(d) goods in respect of which such an order is in force, being an order that declares the goods not to be therapeutic goods when used, advertised, or presented for supply in the way specified in the order where the goods are used, advertised, or presented for supply in that way; or

(e) goods (other than goods declared to be therapeutic goods under an order in force under section 7) for which there is a prescribed standard in the Australia New Zealand Food Standards Code as defined in subsection 3(1) of the *Australia New Zealand Food Authority Act 1991*; or

(f) goods which, in Australia or New Zealand, have a tradition of use as foods for humans in the form in which they are presented. ...

therapeutic use means use in or in connection with:

(a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons or animals; or

(b) influencing, inhibiting or modifying a physiological process in persons or animals; or

(c) testing the susceptibility of persons or animals to a disease or ailment; or

(d) influencing, controlling or preventing conception in persons; or

(e) testing for pregnancy in persons; or

(f) the replacement or modification of parts of the anatomy in persons or animals.

Ever since the Act first came into force, however, successive Commonwealth Governments have apparently taken the view that the statutory scheme in the Act does not extend to corporations trading only within the limits of a State, nor to sole traders. Section 6 therefore defines the extent of the Act in these terms:

"6 Operation of Act

(1) This Act applies to:

(a) things done by corporations; and

(b) things done by natural persons or corporations in so far as those things are done:

(i) in the course of, or in preparation for, trade or commerce between Australia and a place outside Australia, among the States, between a State and a Territory or between 2 Territories; or

(ii) under a law of the Commonwealth relating to the provision of pharmaceutical or repatriation benefits; or

(iii) in relation to the Commonwealth or in relation to an authority of the Commonwealth.

(2) Without limiting the effect of this Act apart from this subsection, this Act also has the effect it would have if the reference in paragraph (1)(a) to things done by corporations were confined to things done by trading corporations for the purposes of their trading activities."[3]

Sub-s. 4(2) also states that

"(2) This Act is therefore not intended to apply to the exclusion of a law of a State, of the Australian Capital Territory or of the Northern Territory to the extent that the law is capable of operating concurrently with this Act."

Finally, s.9 allows arrangements to be made with the States for them to carry out, in effect, some functions the Act assigns to the Commonwealth's Therapeutic Goods Administration (TGA).

The Act establishes a statutory scheme for the registration, listing, advertising and sale of therapeutic goods. It lays down penalties for breaches of the Act, or failure to follow Good Manufacturing Practice (GMP) requirements. However, because of the provisions outlined above, the States are given, or assumed to possess under the Constitution, certain powers.

Only two States have passed so-called "mirror legislation" in which the Therapeutic Goods Act is replicated, partly replicated, or adopted "by reference", sometimes with small or subtle variations. The position in the majority of States is far from clear.

Thus the actions of other than sole traders or one-State corporations are uniformly regulated by the Commonwealth Act, but the former are governed in various fashions under the same or similar State laws.[4]

Especially in Queensland, sole traders are well aware of the "loophole" which they have exploited to offer products which have not been listed or registered by the TGA.

[3] See also ss. 6AAA, 6AAB, 6AAC, 6AAD, 6AAE, 6B and 6C, where various practical consequences of the supposed limitation in the reach of the corporations power are spelled out.

[4] Attachment 1 lists the State or Territory statutes that "mirror" the Therapeutic Goods Act, as at present.

Case study

Advertisement published in the Australian Journal of Pharmacy Vol. 81 March 2000. This journal is distributed nationally

NEW Available in Queensland only (QLD Sole Trader)
Ibuprofen with MINI dose and MAXI effect.

Only the S(+) Ibuprofen-enantiomer is the active component in the body. Therefore S(+) Ibuprofen is more effective than regular Ibuprofen.

Capsules with 100 mg (S+) Ibuprofen (Dexibuprofen) have approx. the effect of 200 mg regular ibuprofen, but the body has only 100 mg to metabolise and correspondingly the side-effects are less.

Available either as:

Art No 744 100 mg S(+) Ibuprofen (Dexibuprofen):

IBU Mini-Max 100 mg 50 Caps or

Art No 217 200 mg S(+) Ibuprofen (Dexibuprofen):

IBU Caps (S+) 200 mg 24 Caps

Both products: Wholesale $3.00 Retail $4.50

Buy a dozen (mixed) pay only $30.-

Content: Each capsule contains: S(+) Ibuprofen (Dexibuprofen).

Non-steroidal anti-inflammatory agent, analgesic, antipyretic.

Dosage: Adults and Children over 12 years: Initial dose two capsules taken with fluid, then if necessary one or two capsules every 4 hours if necessary. (Do not exceed 6 capsules per day. Not to be given to children under 12 years. If symptoms persist for more than three days, consult a doctor. See Ibuprofen for other warnings. As with all drugs, it is recommended that Ibuprofen (S+) should not be taken during pregnancy except under medical supervision. Do not use during the last three months of pregnancy.

Indication: Relief of pain states in which is an inflammatory component. Rheumatoid arthritis, primary dysmenorrhoea.

WARNING – This medication may be dangerous when used in large amounts or for a long time.

Other S2 and S3 products available:

Diclofenac Cream: Foltrex Top; Aciclovir Cream: Read My Lips

Ibuprofen Cream: Ibu Top crem; Minoxidil 2%: Hair Force Gel

Send your order together with a cheque to:

Qld Sole Trader t/a Deka Health & Nutrition

P.O. Box 4104 Eight Mile Plains QLD 4113

"Poisons" regulation

Before, and since, the entry into force of the Therapeutic Goods Act (C'wth), mechanisms involving federal/state co-operation have been developed relating to the method by which "poisons" are "scheduled". Scheduling governs the degree of access people can have to the substances concerned, and under what conditions. The scheduling system classifies all poisons in the *Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP)* in one of a set of schedules, rising from S2 (considered the least risky) to S9 (very dangerous indeed and banned from access).[5]

[5] There is no Schedule 1, except in Victoria – see Attachment 2.

Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP)

In addition to the Introduction, the SUSDP consists of 5 Parts:

- Part 1 Interpretation
- Part 2 Labels and Containers
- Part 3 Miscellaneous Regulations
- Part 4 The Schedules
- Part 5 Appendices

The SUSDP is 'adopted' by the States and Territories by either referencing a Part in their legislation or including the information in the legislation. None of the States or Territories adopts the entire SUSDP.

In relation to the Schedules, the States and Territories either adopt by reference or include the full list in their own legislation, e.g. Tasmania. **Victoria** adopts the schedules by reference, but has to gazette advice to this effect. **Northern Territory** gazettes adoption of, inter alia, Part 4 of the SUSDP. **Tasmania** publishes a Poisons List Amendment Order each time the SUSDP is updated.

New South Wales only lists differences to the SUSDP scheduling requirements in its Poisons List.

The *SUSDP* has been developed by the National Drugs and Poisons Scheduling Committee (NDPSC). It has included State, NZ and industry and expert members. For years, it operated entirely without any Commonwealth legislative base. In 1999, a new Part 6-3 of the Therapeutic Goods Act constituted the NDPSC and Regulations made under the Act now prescribe the way in which the Committee must operate.[6]

For the medicines industry, the issue of which Schedule your product is classified to is of vital commercial significance:

- unscheduled products can be sold anywhere and can be advertised[7];
- S2 products must be sold in a pharmacy but can be advertised;
- S3 products must be sold by a pharmacist but some only may be advertised[8]

[6]One consequence of the inclusion of the NDPSC in the Therapeutic Goods Act is that the Committee's decisions are now decisions of an administrative character for the purposes of the Administrative Decisions (Judicial Review) Act. But the *SUSDP* would appear not to be a disallowable instrument under the Legislative Instruments Act, by virtue of sub-s. 44(1) of that Act. Nor, it would seem, would the guidelines made by the National Co-ordinating Committee of Therapeutic Goods (NCCTG) under s.52E of the Act. The NCCTG has a preponderance of State officials as members. It is not established by statute but has issued guidelines relating to whether, and the conditions under which, S3 medicines may be advertised. **This is no small issue for industry.**

[7]All advertising of therapeutic goods is subject to statutory and co-regulatory process.

[8] See footnote 6, *supra*.

- S4 medicines can only be supplied on prescription and may not be advertised.

The operating regulations for the NDPSC entrench a State "veto" on all decisions of the NDPSC.[9] Industry objects to this arrangement but our concerns have been disregarded.

The decisions of the NDPSC are subject to ratification by each State and Territory.[10] There is no established uniform procedure for this process. Each State can cherry-pick what it likes or dislikes of the decisions, and/or amend or vary any decision, and/or delay its entry into force.

Because the scheduling decisions about any medicine are integral to the approval process, the mere existence of the State-based NDPSC process, and the latter uncertainties in giving effect to their decisions, add significantly to business uncertainty and hence to the costs of production and marketing.

Case study

During 1999, a particular over-the-counter substance was rescheduled from schedule 3 to schedule 2. For the companies involved in marketing the products containing the substance, this meant the development of display stands for use in pharmacies because theoretically the product should have been able to be self selected by the consumer rather than being stored in the dispensary for dispensing by the pharmacist.

The situation was not so clear-cut. Some States required that the product, while being allowed to be on display, be out of reach of the consumer. Other States allowed the product to be on display stands in the stores but there had to be a locking device on the stand so that the product couldn't be selected without at least talking to a pharmacy assistant. Other States allowed the product to be freely displayed within the pharmacy.

The companies responded by developing display stands of numerous sizes and with optional locking devices to suit all of these circumstances.

[9] Therapeutic Goods Regulations 42ZCE and 42ZCR.

[10] Attachment 2 lists the legislation of each of the States and Territories in relation to Poisons.

Case study

Dear PMAA,

POISONS LICENCES IN QUEENSLAND

Our company has 4 representatives in Queensland. Recently we have been required to send four cheques to different places to register four individuals. This seems a complete waste of our time.

I thought you may be interested in this example of an unfortunate system. I hope you can help them centralise.

Yours sincerely,

The correspondence from Queensland Health, provided with the above letter starts: "From 1 January 2000, Queensland Health has decentralised some licensing activities."

Further on, under the heading of Drugs & Poisons Licences, it states "Where multiple licences are held for premises located within different regions, each completed application form and correct payment must be returned to the EHS office in which each premises is located. Separate cheques / money orders should accompany each set of forms to be forwarded to the relevant office."

For companies operating nationally, as most do, this simply adds complexity and cost to doing business. Most alarming is that it is a recent decision and not an artefact of days past.

Case study

In 1998, the NDPSC decided to permit advertising for a Schedule 3 substance. After telephoning each State and Territory it was not clear whether the effective date would be the same nationally.

This is difficult to manage when a national advertising campaign is at stake.

After months of keeping up with each of the States' legislation changes, the last jurisdiction advised that it would not prosecute the company for advertising even though its legislation had not changed by the effective date published in the SUSDP.

The States' poisons legislation was reviewed under the competition legislation review program. The review was conducted by Dr R. Galbally in 1999. **That was five years ago and, at the time of writing no decision has been publicly announced** by either the States or

the Commonwealth as to what action is to be taken to give effect to the recommendations of that review.[11]

ASMI has been given to understand that the Galbally recommendations are being, or will be, taken up in connection with the proposed joint Trans-Tasman agency. But nothing has been publicly announced. This issue is further considered below.

Proposed Trans-Tasman agency

ASMI has been a strong supporter of the Australian and New Zealand Governments' decision to establish a joint agency to regulate therapeutic products.[12] We repeatedly urged the Governments to take advantage of the availability of the external affairs head of power to legislate by "covering the field". That is, the idiosyncratic differences between States' "mirror" legislation and the poisons scheduling hodge podge could be straightened out in the legislation, which we understand is in preparation, to set up the new Agency.

In our submission to the Treaties Committee, ASMI said:

> "In para 28 of the National Interest Analysis, it is said that an issue raised with the States and Territories was:
>
> > "the capacity for the Agency instead of State and Territory authorities to regulate sole traders (individuals who trade in therapeutic products only within a State or Territory)."
>
> It was stated that "no significant concern" was raised by the States and territories in relation to this matter. However, in para 29, it is said:
>
> > "The main concern raised by States and Territories was the future of their role in the regulation of access to, or the availability of, scheduled drugs and poisons. They were assured that the Agreement would not be used to vary their existing roles and responsibilities in these areas. Consultation will continue with States and Territories through the exposure draft of the legislation."
>
> ASMI regards the statement at para 28 as correctly describing the Constitutional position. By virtue of the Treaty, the Parliament of the Commonwealth will be able, under the external affairs powers, to extend the operations of the successor to the Therapeutic Goods Act to sole traders. In the light of this, we view with some concern the passage in para 29, which appears to suggest that the individual States may wish to retain a discretion to fiddle with the uniform scheduling arrangements.

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[11] To illustrate the complexity and significance to industry of this matter, Attachments 3, 4 and 5, respectively, are the executive summaries of:

(3) ASMI's submission to Dr Galbally (November 1999);

(4) ASMI's submission to the TGA about the draft report (October 2000); and

(5) Submission to the Commonwealth-State Working Group (July 2001).

Copies of the full submissions can be provided if desired.

Exhibits

[12] Attachment 6 reproduces ASMI's submission to the Joint Standing Committee on Treaties, dated April 2002. See especially Attachment 2, which is the text of a Joint Australia-New Zealand Industry statement of principles which we consider should apply to the Trans-Tasman arrangements.

> Industry has been waiting for years now for the outcome of the "Galbally review" of the scheduling arrangements. That review was critical of the States' propensities to fiddle with individual scheduling decisions.
>
> ASMI has strongly supported the joint agency at least in part because we expected its regulatory activities within Australia to "cover the field". We note with some concern that "consultation will continue with States and territories through the exposure draft of the legislation". Any provision in that legislation that would extend to the States an entrenched discretion to fiddle with scheduling decisions will be of serious concern to ASMI."[13]

We view with concern the apparently uncritical endorsement by the Treaties Committee of the States' desire that "existing roles and responsibilities of States in this area" will not be varied.[14] No reasons are given to show that these existing roles and responsibilities are in the public interest.

ASMI takes a more forward-looking view. We believe it is important to streamline administrative processes for the regulation of therapeutic goods. The artificial differences between various States' approaches can be ironed out, by virtue of the external affairs power.[15] Whether the Australian Government will seize this opportunity remains to be seen when the legislation is finally introduced.

Conclusions

The present division of powers and responsibilities for the regulation of therapeutic goods is a product of history and of an unduly cautious approach by successive Australian Governments in assessing the Constitutional position. The consequences for industry have been anything but academic or trivial. There is no doubt that existing overlaps and uncertainties add to management and compliance costs to industry. Consumers end up paying more. Our efforts to grow export marketing are hampered to some extent as well.

The opportunity is now open to the Australian Government to improve and simplify the regulatory arrangements by removing "differences that have an impact on trade and commerce". What we propose will "reduce costs and duplication", as the present inquiry is seeking ways of achieving.

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[13] Footnote 11 in the submission reads:

"For example, access conditions for certain analgesics for no reason other than State political preferences. Such idiosyncratic differences are very costly and irritating to industry."

[14] Treaties Committee, Report 62, para 2.51.

[15] See placita (i), (xx) and (xxix) of s.51 of the Constitution. In our view, these provide ample heads of power for the new Agency to "cover the field".

Attachment 1

Only Victoria and New South Wales have legislation complementary to the Therapeutic Goods legislation - Therapeutic Goods (Victoria) Act 1994 and Poisons and Therapeutic Goods Act 1966 and accompanying 2002 Regulations respectively.

Western Australia introduced a Bill into Parliament in 1999/2000. Its status is unclear.

Queensland 'poisons' legislation is to be reviewed in the near future. However, it is our understanding that, *inter alia*, the review is to enable it as stand-alone legislation, rather than as currently, regulations under the Health Act. It is not clear whether this review will consider harmonising with the Therapeutic Goods legislation, or the upcoming Joint Agency legislation. ASMI has been advised that a Regulatory Impact Statement is to be commenced shortly.

As far as ASMI is aware, no other States have implemented legislation that is complementary to the Therapeutic Goods legislation.

Attachment 2

State and Territory "Poisons" Legislation

NSW

The *Poisons and Therapeutic Goods Act 1966* (NSW) establishes a Poisons List. The State Act incorporates into the List various parts of the *SUSDP*, "with the exception of entries relating to Codeine."

Victoria

Under the *Drugs, Poisons and Controlled Substances Act 1981* (Vic.), changes to *SUSDP* are automatically adopted. Advice concerning the adoption of any scheduling changes must be gazetted and specify an 'effective' date. However, the Victorian Act was amended by the *Chinese Medicine Registration Act 2000* (Vic.) to include a Schedule 1 in the "Poisons List", covering Chinese medicines.

Queensland

The *Health Act 1937* (Q'ld) apparently adopts the *SUSDP* automatically.

Western Australia

Under the *Poisons Act 1964* (WA), any new *SUSDP* is automatically adopted but amendments to the existing *SUSDP* are not incorporated automatically.

South Australia

The Controlled Substances (Poisons) Regulations 1996, made under the *Controlled Substances (Poisons) Act 1984* (SA) appear to incorporate the *SUSDP* into SA law but the Regulations can be overridden by local action.

Tasmania

Under the *Poisons Act 1971* (Tas) the Minister has made and can amend the Poisons List in ways other than required by successive issues of *SUSDP* or its amendments.

Northern Territory

The Poisons *and Dangerous Drugs Act 1983* (NT) appears to give the Minister a discretion not to amend the *SUSDP* as amended from time to time.

Australian Capital Territory

In the ACT, changes to *SUSDP* are automatically adopted under the Poisons *and Drugs Act 1978* (ACT). However the Minister can modify *SUSDP* by instrument, which is disallowable.