Australian Government

Department of Health and Ageing

Submission to the

Senate Community Affairs Legislation Committee

for the Inquiry into

Therapeutic Goods Amendment

(2009 Measures No. 2) Bill 2009

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1. Introduction

On 25 June 2009, the Therapeutic Goods Amendment (2009 Measures No. 2) Bill 2009 was referred by the Senate to the Community Affairs Legislation Committee for inquiry and report by 7 August 2009.

On 26 June 2009, Mr Elton Humphrey, the Secretary to the Community Affairs Legislation Committee invited the Secretary of the Department of the Health and Ageing, Ms Jane Halton PSM, to provide written submission to the Committee.

The following submission is provided by the Department in response to this request. It separately addresses each schedule of the Therapeutic Goods Amendment (2009 Measures No. 2) Bill 2009.

2. Schedule 1 – Scheduling of substances

2.1 Current scheduling arrangements

Scheduling of medicines and poisons is a national cooperative process involving the Commonwealth and the states and territories. Its primary purpose is to protect public health and safety by placing appropriate levels of control on public access to and availability of medicines and poisons, which includes agricultural, veterinary and domestic chemicals.

The Commonwealth's powers are limited by the Constitution. In most cases, the regulatory controls to limit access to products are the responsibility of the states and territories. However, the Commonwealth provides the framework to promote uniformity of scheduling of medicines and poisons throughout Australia. This framework is set out in the *Therapeutic Goods Act 1989* (the Act).

Presently Part 6-3 of the Act provides for the scheduling of both medicines and poisons to be undertaken by a single committee, the National Drugs and Poisons Schedule Committee (NDPSC). Decisions of the Committee are incorporated in a legislative instrument known as the *Standard for the Uniform Scheduling of Drugs and Poisons*, referred to in the Act as the 'Poisons Standard', which lists substances by schedule ranging from Schedule 1 to 9. A description of each schedule is included in Attachment 1.

Scheduling decisions recorded in the Poisons Standard are implemented by the states and territories in their respective legislation (in most states and territories this occurs by reference). Most states and territories regulate the access to medicines and chemicals under the same piece of legislation. The implementation of scheduling decisions by states and territories is detailed in Attachment 2.

The National Coordinating Committee on Therapeutic Goods (NCCTG), a subcommittee of the Australian Health Ministers' Advisory Council (AHMAC), is the national policy setting body for scheduling and provides the over-arching policy direction for scheduling arrangements.

The current system has achieved a comparatively high level of consistency and uniformity of scheduling across Australia but the efficiency and timeliness of the existing process has been criticised by industry.

2.2 Recommendations for reform

Despite the serviceability of the current scheduling arrangements a number of reviews over the years have identified ways in which they can be improved. These reviews include those undertaken by John Bissett[1] (1992), KPMG[2] (1994), the Industry Commission[3] (1996), Brian Wall[4] (1996), Rhonda Galbally[5] (2001) and more recently the Productivity Commission[6] (2008).

These reviews noted problems with efficiency and timeliness arising from a committee-based decision-making process and called for the Commonwealth regulatory authorities to assume full responsibility for scheduling of medicines and poisons.

The Industry Commission review of the Pharmaceutical Industry supported the alignment of scheduling and registration processes for therapeutic goods, a key component of the proposed new scheduling framework to be implemented with this Bill. This review also recommended that the Commonwealth, through the Therapeutic Goods Administration (TGA), should take responsibility for medicines scheduling. The Industry Commission Report led to Brian Wall recommending that the NDPSC be constituted as a statutory committee. This occurred when amendments to the Act were proclaimed in April 1999.

Areas for improvement were also identified in the National Competition Review of Drugs, Poisons and Controlled Substances Legislation undertaken by Rhonda Galbally (the Galbally Review). The final report of the Galbally Review and the AHMAC Working Party response to the review recommendations (finalised in 2003) were endorsed by the Council of Australian Governments' (COAG) in June 2005.

A number of Galbally Review recommendations related to the administrative arrangements for scheduling. A key recommendation was that the NDPSC be disbanded and replaced by two separate more specialised committees to make decisions on the levels of control which should apply to human medicines (the Medicines Scheduling Committee) and agricultural, veterinary and domestic chemicals (the Poisons (Chemicals) Scheduling Committee). The review recommended amendments to the Act to put in place the separate committee arrangements while maintaining one Poisons Standard. This recognised the close relationship between medicines and chemicals, as some substances may be used in both medicinal and chemical products (eg. antibiotics, steroids, essential oils).

For this reason the Galbally Review acknowledged that the new arrangements would need to provide for coordination and consistency between the two committees and that this could be achieved with a single secretariat located with the TGA. The Galbally Review also recommended that the costs of operating the scheduling committees should be fully recovered.

The scheduling-related Galbally Review recommendations were advanced further by the Australian Health Ministers' Conference (AHMC) in the development of joint scheduling

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[1] John Bissett Associates International 1992; *Review of Certain Arrangements at Commonwealth Level for the National Registration of Agricultural and Veterinary Chemicals and the Poisons Scheduling of Therapeutic Goods.*
[2] KPMG 1994; *Report of the Review of the Operation of the National Drugs and Poisons Schedule Committee.*
[3] Industry Commission 1996; *The Pharmaceutical Industry*, Report No 51.
[4] Brian Wall 1996; *Review of the Poisons Scheduling Process in Australia.*
[5] Rhonda Galbally 2001; *National Competition Review of Drugs Poisons & Controlled Substance Legislation*.
[6] Productivity Commission 2008; *Chemicals and Plastics Regulation.*

arrangements as part of the development of arrangements to underpin the proposed (but now suspended) Australia New Zealand Therapeutic Products Authority (ANZTPA). The most significant change from the Galbally Review recommendation provided for the Secretary of the Department of Health and Ageing (DoHA), rather than the committees, to be the scheduling decision-maker.

The Productivity Commission (PC) Report supported the agreed AHMC reforms to the scheduling arrangement, including the separation of the NDPSC into two advisory committees, making the Secretary of DoHA the scheduling decision-maker, and states and territories adopting scheduling decisions by reference. The PC recommended that the AHMC should proceed as soon as feasible with implementing its proposed reforms. COAG in November 2008 agreed to the proposed interim COAG response to the recommendations of the PC Report which supported reform to the national decision-making mechanism for the scheduling of poisons, noting that it had significant implications for the scheduling of medicines.

2.3. Implementation of agreed reforms

2.3.1 Consultation

Extensive consultation was undertaken in the development of the Galbally Review recommendations, and industry was generally supportive of the separate scheduling arrangements at that time. The AHMAC Working Party response to the Galbally Review took into account comments from the Primary Industries Ministerial Council (PIMC) as some of the Review recommendations related to agricultural and veterinary chemicals.

The proposal to separate the scheduling committees, along with other scheduling-related Galbally Review recommendations, was to be implemented through a new scheduling model as part of the proposed ANZTPA. This model was consulted upon widely in 2005 and approved by the AHMC in 2006. Further consultation on the proposed ANZTPA medicine scheduling arrangements occurred in October 2006 with the release of a draft rule containing the medicines scheduling provisions, and in June 2007 a draft *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP) and Scheduling Policy Framework (SPF) were also released for consultation. However, consultation on these subordinate documents was not completed at that time due to the suspension of further work on ANZTPA on 16 July 2007.

Following this suspension, AHMAC noted at its meeting on 4 October 2007 the Australian Government's decision to proceed with the implementation of the new medicines scheduling model and confirmed NCCTG's role as the policy setting body to progress the review recommendations in an Australian context.

A detailed timeline (since 1996) of the reviews and extensive consultation related to the proposed scheduling changes is contained in Attachment 3.

2.3.2 Refinements to scheduling models

Acting under AHMAC's directive to finalise the detailed scheduling arrangements, the NCCTG established a working group to refine the medicines and poisons scheduling models for operational effectiveness and prepare a draft SPF and draft SUSMP for consultation.

The NCCTG endorsed the implementation of separate committee arrangements for the scheduling of medicines and chemicals, the Secretary of DoHA being the decision-maker and the establishment of expert advisory committees. Members also agreed that a single overarching SPF, a single Poisons Standard and a single secretariat supporting both committees should be implemented to maintain cohesiveness and consistency of the Poisons Standard. These fundamental characteristics were identified as the minimum requirements to satisfy the regulatory requirements of the states and territories.

The SPF will replace the current NDPSC Guidelines and will be underpinned by the Act and associated regulations as at present. The draft SUSMP will replace the current SUSDP and has been refined to implement several Galbally Review recommendations including the removal of controls on advertising, labelling and packaging where these can be included in Commonwealth registration schemes.

Consultation comments on the earlier drafts of the documents have been taken into account in the development of the latest drafts, which were consulted upon recently from 17 April to 29 May 2009.

It is envisaged that the proposed scheduling arrangements will bring about significant changes, including:

- that scheduling decisions are made by the Secretary of the Department of Health and Ageing, or delegate, rather than the NDPSC;
- scheduling of a new substance in medicines, agricultural or veterinary chemicals will be undertaken as part of the registration process for the product (not separately as currently occurs);
- two new scheduling advisory committees will be established with specific expertise – one for medicines and one for chemicals – will replace the NDPSC;
- applications to schedule a new substance need not be referred to the advisory committees, (under the current arrangements, all scheduling applications are considered by the NDPSC);
- public consultation will only be routinely undertaken on applications to reschedule an existing substance;
- that only applications for rescheduling an existing medicine or chemical, or a contentious new medicine or chemical will be considered by the advisory committees (under the current arrangements, all scheduling applications are considered by the NDPSC);
- the costs of scheduling will be fully recovered from industry.

A table highlighting the differences between the current and proposed scheduling model is contained in Attachment 4.

2.3.3 Legislative change to underpin separate scheduling arrangements

The legal framework for these long anticipated reforms to scheduling arrangements as set out in Schedule 1 of the Bill is consistent with recommendations from the Galbally Review, the AHMC agreed model and the PC Report recommendation which has been accepted by COAG. The amendments in the Bill also reflect extensive consultation with industry and other interested parties.

The legal basis for separate arrangements for the scheduling of medicines and chemicals will lie in three sets of documents: the Act – which sets out a high level framework, the Regulations – which provide details of committee arrangements, and the Scheduling Policy Framework notified by the NCCTG. The current arrangements are based on a similar division between the Act, the Regulations, and the NDPSC guidelines.

Schedule 1 of the Bill provides for:

- the establishment of separate advisory committees – the Advisory Committee on Medicines Scheduling and the Advisory Committee Chemicals Scheduling and their functions;
- medicines (including biologicals and other therapeutic goods) and chemicals to be assessed and scheduled by the Secretary on the advice of relevant expert committees, where required (with the intent that this power, as with most other powers of the Secretary, would then be delegated to the appropriate operational areas of the Department);
- scheduling decisions will still be included in the 'Poisons Standard' as a single legislative instrument as required by the states and territories, for implementation through their respective legislation; and
- an application fee.

Subject to passage through Parliament, Schedule 1 of the Bill will commence on 1 July 2010. A fixed date provides certainty to the pharmaceutical and chemical industries and other interested parties about the new separate arrangements for the scheduling of medicines and chemicals. It also provides ample time for the TGA to finalise amendments to the Therapeutic Goods Regulations 1990, the SPF and the SUSMP and to institute new administrative arrangements required by these changes.

2.4. Comments from industry group

An industry group, the Advocate for the Consumer, Cosmetic, Hygiene and Specialty Products Industry (ACCORD), has called for greater change in scheduling arrangements. It has asked that the poisons scheduling committee be established under another Act with an expectation of a clear separation between chemicals and medicines scheduling at all levels (from policy to the standard). There have also been calls for the Commonwealth to take over the implementation and enforcement of scheduling decisions from the states and territories. Such a move would have significant resource implications for the Commonwealth.

Scheduling is a substance-based (individual chemicals) regulatory process with equivalent requirements being applied to all products containing the substance as specified in the Poisons Standard (SUSMP). However, there is some industry support for product based scheduling (to provide and support greater intellectual property and data protection rights and a further period of market exclusivity). This approach would be unacceptable to the states and territories and would introduce serious enforcement difficulties to the broader scheduling regulatory environment including those provisions administered through the Act.

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

appropriate reference in their respective legislation). ACCORD has been advised of this a number of times in meetings with the TGA and in related correspondence.

3. Schedule 2 – Medical Devices

3.1 Regulation of Medical Devices as therapeutic goods

Medical Devices are regulated as a distinct group of therapeutic goods under Chapter 4 of the Act. This chapter regulates the importation, manufacturing, supply and export of medical devices in Australia. Medical devices include such things as heart pacemakers, artificial joints, medical gloves and surgical instruments.

To be included in the Australian Register of Therapeutic Goods (the ARTG, also known as 'the Register'), a medical device must satisfy all of the application and certification requirements set out in the Act. These requirements include certifications by the applicant that the kind of medical device complies with the essential principles, that it is intended for a specified purpose (as ascertained under subsection 41BD(2)), and that an appropriate conformity assessment procedure has been applied.

3.1.1 Inappropriate purposes for devices

At present the Act provides that a kind of medical device that satisfies all of the application and certification requirements under the Act is to be included in the Register. Therefore, even if a device is intended for a purpose that would be a risk to public health, the TGA is currently not able, under the Act, to prevent it being approved and made available if it meets the necessary requirements relating to its safety in use and fitness for purpose.

This issue has recently arisen in relation to devices for home-testing by consumers for serious illnesses and conditions. The amendments to the Act proposed under Schedule 2 of the bill are intended to address these concerns.

The concerns regarding the purposes for medical devices are twofold.

First, devices that are intended for self-testing at home without support or intervention by a qualified health professional pose a risk to the individual using the test, as they would not necessarily have the necessary medical and psycho-social support to fully understand the result, the medical implications of the result, or the options for treatment.

By way of example, if a person were to self-test for HIV and the test returned a positive result, the person may not been aware that there are effective treatments available and would not have access to medical and psychological support. As a result, the person may not seek appropriate medical care.

Secondly, individuals self-testing for illnesses or diseases that require notification in Australia would be unlikely to notify their test result as they may not know they are required to do so, or may not wish to do so. Notification of certain diseases and illnesses is essential to enable effective surveillance of diseases, and thereby identify national trends, guide policy development and resource allocation.

Using HIV as an example, a person who self-tests for HIV and receives a positive result may be unlikely to notify this result to public health authorities. This would prevent the effective

mapping of the spread of the disease and may hinder the ability of health authorities to investigate and implement measures to reduce the spread.

3.1.2 Examples of devices with inappropriate purposes

There have been recent enquiries and applications received by the TGA from prospective in-vitro diagnostic device sponsors seeking to include products in the Register for purposes that may pose risks to personal and public health.

Predominantly, but not exclusively, these have been from sponsors seeking to have approved self-test kits for HIV. The TGA is also aware of other home-use test kits available overseas such as for genetic marker testing to predict serious diseases such as Huntington Disease, and cancer marker testing.

Individuals enquiring with the TGA about including in the Register self-test kits for HIV are referred to the National HIV Testing Policy, released in 2006, and, as with all enquiries regarding applications for including a device in the Register, advised of the process and costs involved.

The National HIV Testing Policy does not support home-based testing for HIV in Australia and sets out the policy for pre- and post-test discussions and counselling. However, the policy does not prevent a person from pursuing an application to the TGA for inclusion in the Register of a HIV self-test device, should they wish to.

The policy was informed through a joint group of the Ministerial Advisory Committee on AIDS, Sexual Health and Hepatitis; HIV/AIDS and Sexually Transmissible Infections Subcommittee; and the Intergovernmental Committee on AIDS, Hepatitis and Related Diseases.

The National HIV Testing Policy is available on the Department of Health and Ageing's website at:
http://www.health.gov.au/internet/main/publishing.nsf/Content/F4F093E1E22A7478CA256F1900050FC7/$File/hiv-testing-policy-2006.pdf

The TGA is also aware of a self-test kit to detect prostate specific antigen (PSA). Increased levels of PSA can indicate the presence of prostate diseases such as cancer. The test would be used by a person at home as a predictor for prostate disease.

Medical professionals use PSA tests as part of a range of clinical investigations, including physical examination, to assess the risk of prostate disease. Further investigation or medical intervention can then be provided if necessary.

There is concern that, should such a PSA test be available for home use, individuals using it would not receive the necessary medical advice, care and support that is necessary to obtain a correct diagnosis and effective treatment. Individuals using the test may also be misled by the result as increased levels of PSA do not necessarily correlate with prostate cancer.

The TGA expects that there will be an increase in applications made in the near future for self-tests that satisfy the necessary application requirements but which are for an inappropriate purpose and the TGA will be unable, under the Act as it stands at present, to preclude this.

The amendments proposed in Schedule 2 aim to address this by enabling devices to be prevented from being included in the Register for inappropriate purposes.

4. Schedule 3 – Other amendments

4.1 Part 1 – Amendments commencing on day after Royal Assent

4.1.1 Consultation with the Gene Technology Regulator
Items 1, 3 and 4 of the bill

Presently, sections 30C to 30E of the Act enable the TGA to consult with, or seek the advice of, the Gene Technology Regulator regarding therapeutic goods that contain genetically modified products. However, the TGA has become aware that there may also be therapeutic goods that are or contain genetically modified organisms.

The current provisions in the Act, inserted in 2000 when the regulation of genetic technology in Australia was in its early stages, inadvertently do not presently enable the TGA to consult with the Gene Technology Regulator regarding therapeutic goods that are or contain such genetically modified organisms.

To address this, and reflect the significant advances in genetic technology developments over the past nine years, Schedule 3 of the bill will enable the TGA to consult with the Gene Technology Regulator regarding any therapeutic good that is or contains a genetically modified component as originally intended.

4.1.2 Inappropriate advertising of therapeutic goods
Items 2 and 5 of the bill

Presently subsection 22(5) of the Act provides that it is an offence for the sponsor of a therapeutic good (other than a medical device) to advertise the good for a purpose that is not an approved indication.

However, it is now common for persons other than the sponsor of a therapeutic good to advertise it, and the TGA has identified a number of instances where such persons have advertised therapeutic goods for purposes for which they were not approved. For example:

- The Advertising Unit of the TGA frequently deals with on-line pharmacies that sell a large number of medicines, but are not the 'sponsor' of any of them. It is not uncommon for the Unit to identify an on-line pharmacy advertising a therapeutic good with claims that are outside the scope of the indications approved for the good. Presently, the Advertising Unit is not able to take action to prevent such inappropriate advertising as the on-line pharmacy is not the sponsor of the product.

- Recently a complaint was handled by the Advertising Unit about the advertising of a cream listed in the Register, which, among other issues, was being promoted by a distributor for uses not accepted and published on the label (known as ‘off-label’ uses). The sponsor of the cream had developed the formulation, and had a business agreement with the distributor who marketed and sold the product. The Advertising

Unit could not refer to the offence under subsection 22(5) when working to enforce compliance of the distributor's website.

The current limitation in subsection 22(5) means that persons other than sponsors can advertise therapeutic goods to consumers for potentially unsafe and ineffective purposes for which the good has not been approved.

The TGA has recently made the Register publicly available on the TGA website, enabling anyone to view the goods approved for supply in Australia and the conditions for which they are approved. As a result, any person wishing to advertise a therapeutic good is able to confirm the approved purpose for the good from the Register.

The TGA believes that it is now reasonable to extend the advertising offence provision to any person inappropriately advertising a therapeutic good. This amendment will ensure that appropriate, consistent and accurate information is provided to the public to support the safe and effective use of therapeutic goods.

4.1.3 Delegation under subsection 57(8)
Item 6

Paragraph 57(8)(b) of the Act presently enables delegation of the Secretary's power under section 19A which relates to exempting unapproved goods so they may be used as a substitute for approved goods that are not available.

Presently this provision refers to the head of a specific branch of the TGA. The bill will enable office held by the delegate to be specified in the regulations instead, to allow for changes in administrative structures within the TGA. Although the delegation would be set out in the regulations it is intended that only officers holding SES Band 1 positions or equivalent and higher would be given a delegation.

4.2 Part 2 – Amendments commencing on a day to be proclaimed

4.2.1 Advisory statements on medicine labels
Presently the Therapeutic Goods Regulations 1990 (the regulations) require certain specified medicines to be supplied with labels that comply with the requirements of the *Required Advisory Statements for Medicines Labels* (RASML).

These statements are to assist consumers in choosing the most appropriate medicine and using it safely and effectively as the medicines these statements apply to are generally those which individuals chose themselves or with the assistance of a pharmacist.

The amendments in the bill will improve the transparency of these requirements by empowering the Minister to specify them in a legislative instrument. Any medicine that the regulations list for the purposes of the legislative instrument will now be required to include the advisory statements relating to it that are set out in the instrument.

The first instrument will include those statements specified in the RASML immediately before the instrument is made, with only minor changes that would have otherwise been made to the RASML had the instrument not replaced it.

The sorts of advisory statements that labels will be required to include will depend on the medicine but would include, for example, such statements as:

- ‘Do not use on broken skin’;
- ‘Vitamins can only be of assistance if the dietary vitamin intake is inadequate’;
- ‘If symptoms persist beyond 5 days consult a doctor’.

By setting out standardised statements this will ensure that consumers receive consistent information and advice in language that is easy to understand and clear to read. Further, by including these statements in a legislative instrument, registered in the Federal Register of Legislative Instruments, this will make the setting of these statements more transparent for the pharmaceutical industry to assist in compliance with these required label statements.

Description of the Schedules

Drugs and poisons are classified according to the Schedules in which they are included. The following is a general description of the Schedules. For the legal definitions, however, it is necessary to check with the relevant State or Territory Authority.

Schedule 1. [This Schedule is intentionally blank.]

Schedule 2. **Pharmacy Medicine** – Substances, the safe use of which may require advice from a pharmacist and which should be available from a pharmacy or, where a pharmacy service is not available, from a licensed person.

Schedule 3. **Pharmacist Only Medicine** – Substances, the safe use of which requires professional advice but which should be available to the public from a pharmacist without a prescription.

Schedule 4. **Prescription Only Medicine,** or **Prescription Animal Remedy** – Substances, the use or supply of which should be by or on the order of persons permitted by State or Territory legislation to prescribe and should be available from a pharmacist on prescription.

Schedule 5. **Caution** – Substances with a low potential for causing harm, the extent of which can be reduced through the use of appropriate packaging with simple warnings and safety directions on the label.

Schedule 6. **Poison** – Substances with a moderate potential for causing harm, the extent of which can be reduced through the use of distinctive packaging with strong warnings and safety directions on the label.

Schedule 7. **Dangerous Poison** – Substances with a high potential for causing harm at low exposure and which require special precautions during manufacture, handling or use. These poisons should be available only to specialised or authorised users who have the skills necessary to handle them safely. Special regulations restricting their availability, possession, storage or use may apply.

Schedule 8. **Controlled Drug** – Substances which should be available for use but require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence.

Schedule 9. **Prohibited Substance** – Substances which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities.

State and Territory Implementation of the Poisons Standard

State or Territory	Legislation	Relevant Provisions referencing the Commonwealth Poisons Standard
NSW	*Poisons and Therapeutic Goods Act 1966* *Poisons and Therapeutic Goods Regulations 2008*	Subsection 8(7) provides 'An amendment of the Poisons List may be made by applying, adopting or incorporating, with or without modification, the current Poisons Standard (within the meaning of Part 5B of the Commonwealth Act) or any other published standard, as in force at a particular time or as in force from time to time.' Each schedule in the Poisons List (under the PTG Act) includes the entries from the corresponding Schedule of the Poisons Standard incorporating any local variations.
VIC	*Drugs, Poisons and Controlled Substances Act 1981.* *Drugs Poisons and Controlled Substances (Commonwealth Standard) Regulations 2001*	Section 4 of the *Drugs, Poisons and Controlled Substances Act 1981* defines 'poisons or controlled substances' as the substances as listed in the schedules to the 'Commonwealth standard'. The *Drugs, Poisons and Controlled Substances (Commonwealth Standard) Regulations 2001* define the Commonwealth standard as the current Poisons Standard within the meaning of the *Therapeutic Goods Act 1989* of the Commonwealth. Section 27A of the Act requires labelling, packaging, advertising and storage of poisons or controlled substances to be in accordance with the Commonwealth standard. Section 12 of the Act provides that the Poisons Code prepared by the Minister must contain a Poisons List which may contain a list of substances in the Commonwealth standard that are not for general sale by retail, and a list of exemptions from the Schedules to the Commonwealth standard.

State or Territory	Legislation	Relevant Provisions referencing the Commonwealth Poisons Standard
QLD	*Health (Drugs and Poisons) Regulation 1996*	'Standard' is defined as 'the Standard for the Uniform Scheduling of Drugs and Poisons published by the Commonwealth' (Appendix 9). Various provisions of the regulations apply the standard – for example, 'A person must not sell a controlled drug, restricted drug or a poison, unless the way it is packed complies with part 2 of the standard' (reg 10(1)).
WA	*Poisons Act 1964* *Poisons Regulations 1965*	For the purposes Part 1 of Appendix A of the Act, SUSDP means the "the current Poisons Standard as defined in section 52A of the *Therapeutic Goods Act 1989* of the Commonwealth." If for the purposes of this Appendix it is necessary to interpret a Schedule to the SUSDP, the definitions and interpretation provisions in the SUSDP apply to the interpretation of that Schedule.
SA	*Controlled Substances Act 1984; Controlled Substances Act (Poisons) Regulations 1996*	Uniform Poisons Standard' is defined as 'the Standard for the Uniform Scheduling of Drugs and Poisons published by the National Drugs and Poisons Schedule Committee' [reg 4(1)]. Reg 5 provides that 'the Uniform Poisons Standard, as modified by Schedule A of these regulations, is incorporated into these regulations'. Various provisions of the regulations [reg 6 (declaration of poisons), reg 8 (certain new poisons to be taken to be schedule 4 poisons), reg 9 (application of these regulations), reg 18 (packaging of poisons), reg 19 (labelling of poisons) and reg 22 (prohibition on use of certain poisons for certain purposes)], Schedule A refer to the Uniform Poisons Standard.

State or Territory	Legislation	Relevant Provisions referencing the Commonwealth Poisons Standard
TAS	*Poisons Act 1971; Poisons Regulations 2002*	'Uniform Standard' is defined as 'the Standard for the Uniform Scheduling of Drugs and Poisons published by the Commonwealth under the *Therapeutic Goods Act 1989* of the Commonwealth, as amended from time to time' (Regs, reg 3(1)) Reg 82(1) provides 'Subject to subregulation (3) and to any provision to the contrary in these regulations, Part 2, paragraph 41 in Part 3 and Appendices E, F and J in Part 5 of the Uniform Standard (in this regulation referred to as 'the applied provisions') have effect as if they were provisions of these regulations.
ACT	*Medicines, Poisons and Therapeutic Goods Act 2008*	In accordance with part 3.3, Section 15, Subsection 1 of this Act, medicines and poisons standard means the poisons standard, as in force from time to time and as modified by regulation (if any) and "….poisons standard means a document made under the *Therapeutic Goods Act 1989* (Commonwealth), section 52D (2)."
NT	*Poisons and Dangerous Drugs Act 2007, Poisons and Dangerous Drugs Regulations 2005*	Part 6 of the Act, defines the "SUSDP" as "Standard for the Uniform Scheduling of Drugs and Poisons" published by the Commonwealth. Part 3 of the Regulations defines a "Scheduled substance" as a substance referred to in Part 4 of the SUSDP.

Key Events and Related Consultation

- Consultation was undertaken as part of the Industry Commission Report on the Pharmaceutical Industry in 1996. An Industry Committee finding was that the scheduling of drugs should be conducted separately from poisons.
- Stakeholders were consulted extensively throughout the course of the National Competition Review of Drugs, Poisons and Controlled Substances Legislation (the Galbally Review) published in 2001. The Gabally Review as part of Recommendation 7 recommended that the National Drugs and Poisons Schedule Committee be replaced by two separate committees, one responsible for the scheduling of medicines and the other for the scheduling of agricultural, veterinary and domestic chemicals. The Galbally Review stated that "Industry was generally in favour of separating medicine scheduling from poisons scheduling" (p 76 Part B).
- The Australian Health Ministers Advisory Council (AHMAC) Working Party response to the Galbally Review recommendations was unanimously endorsed by Australian Health Ministers' Conference (AHMC) in the last quarter of 2003.
- The Council of Australian Governments (COAG) in June 2005 endorsed the final report of the Galbally Review and the AHMAC Working Party response to the review recommendations. COAG agreed that a response to recommendation 7 be finalised by AHMC after consideration of further refinements to the scheduling model for medicines and poisons, and the implications of the proposed establishment of the Australia New Zealand Therapeutic Products Authority (ANZTPA).
- Stakeholder consultation on the proposed scheduling models and a draft Scheduling Policy Framework developed by the National Coordinating Committee on Therapeutic Goods (NCCTG) was undertaken in August – September 2005 following COAG endorsement of the Galbally Review response. This included a face-to face meeting with selected stakeholders in Sydney on 5 August 2005. The consultation documents and the consultation outcome can be found at http://www.tga.gov.au/consult/2005/scheduling.htm.
- Stakeholder comments received in the 2005 consultation process were taken into account by the NCCTG in the development of the final AHMC medicines scheduling model for implementation with ANZTPA.
- The final medicines scheduling model formed the basis of the scheduling related provisions of the draft Australia New Zealand Therapeutic Products Regulatory Scheme (Administration and Interpretation Rule) which was made available for stakeholder consideration in October – December 2006. The consultation documents can be found at http://www.anztpa.org/consult/consdocs2.htm. Focus group workshops on the proposed medicines scheduling provisions were held in Auckland and Sydney on 8 and 13 November 2006 respectively. Questions and answers representing key questions raised during the focus group workshops can be found at http://www.anztpa.org/meds/qascheduling.htm.
- The draft Standard for the Uniform Scheduling of Medicines and Poisons (Poisons Standard) and the draft Scheduling Policy Framework under ANZTPA developed by the NCCTG was released for public consultation in June – July 2007. The consultation documents can be found at http://www.anztpa.org/consult/dr-scheduling.htm. The Scheduling Policy Framework took into account stakeholder comments on the earlier draft released for consultation in August 2005.

- The establishment of ANZTPA was suspended on 16 July 2007 following an announcement by the then New Zealand State Services Minister, Annette King, that the New Zealand Government was not able to proceed with the legislation to establish the Authority due to insufficient numbers in Parliament.
- Extensive consultation was undertaken by the Productivity Commission in preparing its research report into *Chemicals and Plastics Regulation* which was published in July 2008. The PC report can be found at http://www.pc.gov.au/projects/study/chemicalsandplastics/docs/finalreport.
- The PC Report recommended (Recommendation 5.1) that the Australian Health Ministers' Conference should:

  - proceed as soon as feasible with implementing its proposed reforms to separate poisons and medicines scheduling processes, including that poisons scheduling decisions be made by the Secretary of the Department of Health and Ageing, upon advice from a Chemicals Scheduling Committee; and
  - undertake a review of the Australian Health Ministers' Advisory Council model for poisons two years after commencement, including:
    - an analysis of the consistency between the recommendations of the Chemicals Scheduling Committee and the decisions of the Secretary of the Department of Health and Ageing
    - an analysis of the impact of the model on national uniformity of poisons regulations.

- The November 2008 COAG meeting agreed to the proposed interim COAG response to the recommendations of the PC Report (See http://www.coag.gov.au/coag_meeting_outcomes/2008-11-29/docs/Business_Regulation_and_Competition_Working_Group-Attachment_B.pdf)
- The Scheduling Policy Framework and Standard for the Uniform Scheduling of Medicines and Poisons (Poisons Standard) underpinning the separate arrangements for the scheduling of medicines and chemicals in an Australia-only context were released for consultation during April – May 2009. The development of these documents was informed by the earlier consultations. The consultation documents can be found at http://www.tga.gov.au/regreform/drscheduling.htm. The TGA also announced at the same time its intent to introduce amendments to the *Therapeutic Goods Act 1989* during the winter parliamentary sitting to implement the AHMC endorsed scheduling reforms.

Comparison between the current arrangements, the Galbally recommendations and the AHMC-agreed scheduling models

	Current Scheduling Model	**Galbally Model**	**AHMC Agreed Model (Australian Implementation)**
Committee	NDPSC[7] Established under the *Therapeutic Goods Act 1989*	NDPSC split into two separate decision-making committees: MSC and CSC to be established under the *Therapeutic Goods Act 1989*	NDPSC split into two separate advisory committees: ACCS and ACMS Established under a single Australian Act (*Therapeutic Goods Act 1989*)
Membership	Mix of experts and representative mix including Commonwealth, States and Territories and New Zealand	Considered options, however did not make recommendations regarding specific membership.	Expert membership with the Commonwealth, States and Territories able to each nominate a member. All other expert members to be appointed by the Minister.
Governance	AHMC/AHMAC	AHMC/AHMAC	AHMC/AHMAC
Policy Direction including Framework	NCCTG (Jurisdictional members) Guidelines for the National Drugs and Poisons Schedule Committee	NCCTG (Jurisdictional members)	NCCTG (Jurisdictional members) Scheduling Policy Framework (including scheduling criteria) for Medicines and Poisons
Decision maker	NDPSC for all scheduling decisions (Jurisdictional, expert and representational members).	MSC - medicines CSC – poisons	Decision-making power provided to the Secretary of the Department Health and Ageing (Delegated to: - Office of Health Protection for poisons; - TGA for all medicines.

[7] See Glossary below for abbreviations

	Current Scheduling Model	**Galbally Model**	**AHMC Agreed Model (Australian Implementation)**
Implementing the decision	Possible for States and Territories to implement a different decision but this is infrequent, in practice.	States and Territories adopt by reference.	States and Territories adopt by reference but may take action to implement a different decision. Variances to be reported annually by the NCCTG.
Reconsiderations	TG Act provides for internal review. Scheduling decisions (legislative in character) only reviewable by High Court under Judiciary Act	*N/A*	Internal review of draft decision by more senior delegate. As scheduling decisions are legislative in character they are only reviewable by High Court under Judiciary Act [8]
Record of decisions	SUSDP (single hard copy document).	SUSMP	SUSMP published as "Poisons Standard" on FRLI
Secretariat	Single secretariat	Single secretariat located within the TGA.	Single secretariat located within the TGA
Matters referred to committee	All scheduling applications	All scheduling applications	All rescheduling applications New substances in public interest (as defined in policy framework). Schedule 9 and Schedule 7.
Substances common to both committees		Proposed joint meetings of both committees	Advice provided by joint meeting of both committees
Public consultation	All scheduling applications	Streamline scheduling and evaluation scheduling processes without compromising public health and safety	All rescheduling applications as part of committee consideration. New substances in public interest (as defined in policy framework)
Cost recovery	Nil	Full cost recovery	Application fee to be introduced. Full cost recovery from industry

[8] Adapted following Federal Court decision in *Roche Products v National Drugs and Poisons Schedule Committee* (30 August 2007) that scheduling decisions are legislative, not administrative.

GLOSSARY

ACCS ..... Advisory Committee on Chemicals Scheduling
ACMS ..... Advisory Committee on Medicines Scheduling
AHMAC..... Australian Health Ministers Advisory Council
AHMC..... Australian Health Ministers' Conference
FRLI..... Federal Register of Legislative Instruments
NCCTG..... National Coordinating Committee on Therapeutic Goods
NDPSC..... National Drugs and Poisons Schedule Committee
SPF..... Scheduling Policy Framework
SUSDP ..... Standard for Uniform Scheduling of Drugs and Poisons
SUSMP ..... Standard for Uniform Scheduling of Medicines and Poisons
TGA ..... Therapeutic Goods Administration