



## Draft *Medicines, Poisons and Therapeutic Goods Bill 2011* Discussion Paper

### Purpose

This Discussion Paper outlines the framework used to develop the draft *Medicines, Poisons and Therapeutic Goods Bill 2011* (draft Bill) and has been prepared to generate debate and discussion on the draft Bill.

The draft Bill has been prepared for stakeholder comment and does not necessarily represent the Government's settled position. It provides an opportunity for key stakeholders to provide comment and feedback on the issues raised in the Discussion Paper and a number of initial questions have been listed at the end of each section to help prompt reader's responses. The comments and input received during the consultation will guide the final drafting of the draft *Medicines, Poisons and Therapeutic Goods Bill 2011*.

### Introduction

The development of a new *Medicines, Poisons and Therapeutic Goods Act* is a major health initiative identified as a key target area in the 'Territory 2030 Strategic Plan'. It is consistent with the 2009 – 2012 Department of Health and Families Corporate Plan to develop and implement effective legislation and policy in the area of substance use and abuse.

The draft Bill aims to provide a modernised flexible legislative framework for monitoring and regulating activities related to the manufacturing, sale and use of medicines and poisons in the Northern Territory. The draft Bill will replace the current *Poisons and Dangerous Drugs Act (PaDDA)*, *Poisons and Dangerous Drugs Regulations* and the *Therapeutic Goods and Cosmetics Act*, providing a proactive approach to current and emerging challenges in this area.

### Background

Many aspects of the current *Poisons and Dangerous Drugs Act* and *Regulations* are outdated. The current Act was based on a South Australian Act following self-government for the NT in 1978 and does not support current business practices, the technologically changing health environment which is impacting on health practitioners' professional practice or the national *Health Practitioner Regulation National Law* which commenced on July 1, 2010 setting up the National Registration and Accreditation Scheme (NRAS) for health professions.

On 28 June 2005, the Council of Australian Governments (COAG) agreed to implement the amended recommendations of the National Competition Policy Review of Drugs, Poisons and Controlled Substances Legislation that was conducted by Rhonda Galbally. In 2006, the NT Government made a decision to upgrade the current legislation including implementation of the outstanding Galbally recommendations. Cabinet approved the drafting of new legislation on July 28 2009.

This draft Bill is the result of a review of the current Act and Regulations in response to consultation with the public and key stakeholders following the release of a Discussion Paper: *Proposed Upgrade of Northern Territory Legislation Controlling Medicines and Poisons* in late 2007. Ongoing targeted consultation since then has informed further development of the proposed new medicines and poisons legislation.

The draft Bill includes many provisions that have been in place under *PaDDA*, the outstanding Galbally recommendations that require implementation and the gaps identified from the consultation process.

### The Framework of the Bill

The following provides an outline of the proposed framework for the draft *Medicines, Poisons and Therapeutic Goods Bill 2010*. The overall format of the draft Bill firstly creates offences under the Act then looks at those who would be exempt because of being authorised under the Act or may be licensed under the Act to perform specified activities. It concludes by addressing administrative matters.

### Objectives

The current *Poisons and Dangerous Drugs Act* does not contain a statement of objectives. The draft Bill includes objectives that replicate those recommended by Galbally and were agreed to by COAG. The objectives state the public health values and outcomes that the legislation aims to achieve; reflect the strategic intent and provide the scope of the legislation.

**Issue for comment: Are there other objectives which should be included?**

### Interpretation

The draft Bill includes definitions of key terms and important concepts used throughout the Bill.

Defining concepts such as “regulated substance”; “medicine and poisons standard” and “health practitioner” and related terms are essential to the operation of the legislation and underpin the proposed Bill in its entirety.

“**Regulated substance**” means a Scheduled substance or an Appendix C substance.

“**Scheduled substance**” means a substance or preparation to which the Schedule of medicine and poisons standard.

“**Health practitioner**” means a person who is registered under the Health Practitioner Regulation National Law to practice a health profession (other than as a student).

The ‘Schedule for the Uniform Scheduling of Medicines and Poisons’ (SUSMP) is a Commonwealth legislative instrument that is commonly referred to as the ‘medicine and poisons standard’. It is defined in section 52A of the Commonwealth *Therapeutic Goods Act (TGA)*. The draft Bill adopts the SUSMP which includes the Schedules, a number of appendices and a range of miscellaneous matters relating to advertising; sale and



supply of scheduled substances; prohibitions on sale, prescribing and possession; storage and dispensed medicines.

**Issue for comment: *Are the proposed definitions of the key terms and concepts used in the draft Bill appropriate? Are there other definitions that should be included?***

### **Dealing with regulated substances**

The draft Bill applies the Criminal Code and introduces the notion of dealing with regulated substances. The first part of this section of the draft Bill sets out the offences when dealing with regulated substances by manufacturers, wholesalers and retailers. The next section relates to offences for the possession, supply and use of Schedule 3, 4, 7, 8 and 9 substances. Schedule 4 and 8 substances are divided into restricted and unrestricted categories.

**Issue for comment: *Are there other offences that should be included when dealing with regulated substances?***

### **Authorisations for possession, supply and use**

Who is authorised to possess, supply and use Schedule 3, 4 and 8 substances is dealt with in the draft Bill. The first groups covered are health practitioners in the course of practicing their health profession. They are also authorised to supply and administer S4 and unrestricted S8 substances, however the supply and administration of a restricted S4 must be in accordance with the conditions stated in the declaration of the substance being a restricted S4.

One section deals with authorising pharmacists. The 5<sup>th</sup> Community Pharmacy Agreement which commenced on July 1 2010 and is in force until June 30 2015 between the Pharmacy Guild and the Commonwealth contains a commitment by the Guild and the Federal Government to work together with State and Territory Governments to establish processes which will allow pharmacists to supply a single standard pack of continuous therapy medicine to a patient under specific circumstances in the absence of a current prescription. This program, known as Medication Continuance, with the objective being to facilitate patient adherence to chronic treatment medicines and to prevent treatment interruption due to the inability to obtain a timely prescription renewal requires appropriate legislation to support it.

The draft Bill includes a new provision to underpin this agreement allowing pharmacists to supply specified unrestricted Schedule 4 substances without a prescription.

Pharmacists are enabled to supply Scheduled substances in emergency circumstances under current legislation. Identified gaps have been addressed in the draft Bill. A pharmacist may supply to a person for administering to another person. This is intended to cover people who are in residential care or require a carer at home. A pharmacist may supply without consultation with an authorised prescriber under certain conditions such as:



- person provides evidence that they are being treated with a therapeutic substance for a chronic condition
- person provides evidence of their identity
- person provides information about their treating prescriber

The number of days of emergency supply has been increased to 7 in line with other jurisdictions and the National Strategy for Quality Use of Medicine. Modern communication systems are recognised by defining electronic communication to include telephone, fax and email.

Section 29 of *PaDDA* has approved specific health practitioners to supply and administer Scheduled substances. The draft Bill has separated those who were under this section into individual sections and includes a new group – ambulance officers.

*PaDDA* has defined ‘supply’ to include ‘sell’ and ‘exchange’. The draft Bill defines ‘supply’ and ‘sell’ as separate functions. Health professionals and Aboriginal health workers may administer and sell an S3 substance in the course of practicing their profession; however they are required to provide appropriate information to the recipient. The intent is to ensure that professional advice is provided to people who do not have access to a pharmacy due to their remoteness or people who purchase S3 substances for first aid kits but may not be the person who will be using the substances is provided with appropriate information.

Under the *Health Practitioner Regulation National Law s94* Endorsement for scheduled medicines, a health profession national board may endorse a health practitioner, or specific group of health practitioners e.g. eligible midwives to be qualified to perform functions that their basic registration does not approve. The draft Bill allows for these additional endorsements to be recognised in accordance to any conditions or restrictions prescribed by regulation.

The draft Bill incorporates a legislative framework that adopts a risk management approach in responding to public health risks. By adopting this approach, it will allow for flexible and timely responses to current and emerging public health risks. A provision for possessing, supplying and administering a Schedule 3, 4 or 8 substances in a declared emergency situation relating to public health e.g. influenza pandemic is included in the draft Bill. This will allow the Chief Health Officer (CHO) by *Gazettal* notice to authorise people other than health professionals to perform these functions.

**Issue for comment: Are there any other authorisations that should be included?**

### Prescriptions

Nurse practitioners will be able to prescribe. This will bring the NT into line with other Australian jurisdictions. They will have the same restrictions on them as medical practitioners. Eligible midwives will be able to prescribe unrestricted Schedule 4 and unrestricted 8 substances; however, they will be required to use only substances approved by the Nursing and Midwifery Board of Australia (NMBA). These two groups of health practitioners were given access to prescribe medicines under the Pharmaceutical Benefits Scheme (PBS) from 1 November 2010. Eligible midwives must have in place a shared arrangement with a medical practitioner to access PBS. A list of the specific Scheduled



substances they may use is available from the Medicare website. Nurse practitioners may use the same PBS Scheduled substances as medical practitioners. Restrictions on specific Scheduled substances will be placed on nurse practitioners by the NMBA.

Podiatrists have been able to prescribe Scheduled substances in other jurisdictions. Practitioners of this profession are part of those professions who are included under the National Registration and Accreditation Scheme that commenced 1 July 2010. This group will also be recognised as being able to prescribe Scheduled substances. They are endorsed by the Podiatry Board of Australia to prescribe from a limited list of Scheduled substances. The Board has also put restrictions on being able to use certain substances e.g. co-prescribe with a medical practitioner, only provide a prescription that will allow the patient to have a set supply for a limited time or only be allowed to prescribe the substance if they have completed further education to use that substance.

Schedule 4 and 8 substances have been divided into two categories under the draft Bill – unrestricted and restricted. Prescribers are authorised under the draft Bill to prescribe these substances if they are a veterinarian or in the course of practising their health profession. Extra restrictions have been placed on prescribers who are authorised to prescribe restricted S4 or S8 substances

The draft Bill includes a provision allowing an authorised prescriber to issue a prescription to a person for the therapeutic use of their partner to treat a prescribed medical condition. This provision will underpin Patient Delivered Partner Therapy specifically for the treatment of Chlamydia. The Northern Territory has the highest rates of sexually transmitted infection (STI) in Australia. When a health care practitioner treats a person with an STI, it is important to also treat their sexual partner(s). In many cases traditional forms of finding and treating these partners is difficult, resource intensive and in the end unsuccessful. This means that partners are left untreated and the person is at risk of being re-infected and that the untreated partner may potentially infect others. This provision sets in place a system that can be utilized to address other health issues when they arise.

Under *PaDDA*, the onus for obtaining an emergency prescription from a prescriber was placed on the dispensing pharmacist. The draft Bill places the responsibility on the prescriber to provide the pharmacist with a script within 7 days of making the request.

**Issue for comment: *Do you think there is a need for any other restrictions to be placed on prescribers? What are they? Are there other prescribing issues that need to be addressed?***

### **Other requirements for regulated substances**

Packaging and label requirements by manufacturers of medicines and poisons are covered mainly under the *TGA*. The draft Bill includes the labelling of regulated substances by the person who supplies the substance to the end user i.e. the patient. Appendix L of the *SUSMP* details the requirements for dispensing labels for human and veterinary medicines. These are reflected in the draft Bill.



Vending machines were covered under the *Therapeutic Goods and Cosmetics Act*. Galbally recommendation 8 was to permit the sale of unscheduled medicines from vending machines in packs containing a maximum of 2 adult doses. The draft Bill includes provisions that address these issues.

The storage and transportation of Scheduled substances is incorporated in the risk management framework and based on the National *Code of Good Wholesaling Practice for Schedule 2, 3, 4 and 8 substances* which comes into force April 1 2011.

The draft Bill sets out the requirements for the destruction of Schedule 8 substances. And is applicable to any person who is authorised under the Act to possess, supply or use these substances.

Drinking or supplying methylated spirits to someone for drinking continues to be prohibited under the draft Bill. The provision under *PaDDA* in regards to additives to this substance was revoked by a *Gazetta* notice in 2001 but *PaDDA* had not been amended to reflect this.

The requirements for paints were included in the *PaDDA* Regulations by reference to Appendix I of the poisons standard. These requirements have been clarified in the draft Bill.

Advertising of Scheduled 8 and 9 substances is only allowed in publications meant for health professionals and veterinarians. This reflects miscellaneous regulations in relationship to advertising contained in Part 3 of the SUSMP.

**Issue for comment: Are there other requirements that you believe should be included?**

### Authorisations

The draft Bill includes a range of authorities that may be granted upon application to the Chief Health Officer following assessment as to the person's suitability to be issued with the authority. These authorisations include licenses for the manufacture, wholesale or retail of a Schedule substance and for pest management technicians. Licenses may be granted for up to 3 years. Authorisations are available Schedule 4, 7 and 8 substances; prohibited substances, research or medical kits.

The draft Bill set out the application process and the restrictions that may apply to an authorisation. The individual authorisation specifies what the holder may do with the specific substance e.g. prescribe it, administer it etc and the specific circumstances it may be used in or a specific purpose that it can be used for. The CHO is provided with the power to vary i.e. amend, impose or remove a condition on an authority.

A process has been included in the draft Bill to for the suspension or cancellation of an authority which includes the authority holder being issued with a show cause notice, when the show cause notice ceases, timeframes for the return of a cancelled authority and suspension of an authority pending formal cancellation.

**Issue for comment: *Are there other types of authorisations that you believe should be included?***

### **Authorised Officers**

The draft Bill establishes who is a poisons officer. It empowers the CHO to appoint authorised officers. Included in the draft Bill are the functions and powers of poisons officers that will ensure that the legislation is being complied with.

A provision that authorised officers must carry an identity card when exercising their powers or performing a function under the legislation and that these identity cards must be returned within 21 days following cessation of their appointment is included in the draft Bill.

### **Powers of entry, inspection and seizure**

The draft Bill provides a range of enforcement powers to authorised officers which are reflective of those powers possessed under the current legislation. It also provides authorised officers with very broad general powers to monitor compliance and investigate possible contraventions of the legislation.

**Issue for comment: *Are the functions and powers of authorised officers appropriate? Are there any other additional powers that should be included in the draft Bill?***

### **Penalties**

The draft Bill imposes a range of penalties which reflect the seriousness of offences. The penalties include both fines and terms of imprisonment. The Regulations of the *Penalty Units Act* currently set a penalty unit as \$130. The proposed penalties range from 20 penalty units (\$2,660) to 500 penalty units (\$66,500) and imprisonment terms range from 12 months to 5 years.

**Issue for comment: *Do you think the penalties in the draft Bill are reasonable and fair?***

### **Information**

The draft Bill provides for the exchange of information between health practitioners in the course of practising their profession. It also provides for the CHO to authorise other persons to receive or give information and maintain records in relationship to substance information if required by their employment.

### **Chief Health Officer**

The draft Bill provides the Chief Health Officer with a range of powers and functions including:

- delegation of specific powers and functions of the CHO



- matters relating to regulated substances – exemptions, declarations and approvals
- declarations by *Gazetta* notice

The CHO is provided with the power to make emergency authorisation for the supply, or administration, of a specified Schedule substance in an emergency related to public health even if there is no declaration of a public health emergency in force under the *Public and Environmental Health Act*.

The CHO is provided with the power to place an emergency ban on a substance that is identified as being a threat to public health such as the “Drug Bomb” that was being given to people in Tennant Creek without appropriate health assessment or information. This substance had the potential to cause severe harm to people with severe renal impairment.

**Issue for comment: Are the powers of the Chief Health Officer adequate? Are there additional powers required and what are they?**

### Enforcement

The draft Bill applies the NT *Criminal Code* in setting out provisions for the liability and conduct of representatives as per section 43AX of the Code and for the criminal liability of an executive officer of a corporate body.

### Reviews and appeals

The current Act has limited ability for a person to have a decision in relationship to their authorisation being varied or to lodge an appeal against a decision. A process for the appeal of a decision is included in the draft Bill in relationship to the following:

- Registrations
- Licenses
- Authorities

The draft Bill contains a Schedule of reviewable decisions and the affected person who may appeal a decision.

### Commonwealth *Therapeutic Goods Act*

Galbally recommendation 22 was that all jurisdictions adopt the Commonwealth Therapeutic Goods Act 1989 into their relevant legislation. The draft Bill includes provision to do this.

### Agency Registers

The draft Bill provides for the CHO to keep a register in any form, including electronic, of the following:

- Registered businesses
- Licenses
- Conditions on authorities
- Exemptions given under section 233 of the draft Bill

- *Gazetta* notices

### Code of Practice

The draft Bill includes power for the CHO to approve a Code of Practice relating to any matter that is required in relationship to the Act. A Code may apply, adopt or incorporate a matter contained in another document of legislative instrument. If the Code relates to restricted Scheduled 4 or 8 substances, the CHO must consult the Schedules Substances Clinical Advisory Committee

### Regulations

The draft Bill maintains the regulation-making powers of the Administrator.

A draft of the new Regulations is available for comment. The draft Regulations cover:

- Dealing with regulated substances
  - Supplies and prescriptions
- Packaging and labelling
- Manufacture, supply and use of paints
- Advertising
- Authorities to deal with regulated substances
- Records and notices
- Legal proceedings
- Administrative matters

The draft Bill provides for some provisions to prescribe by regulation e.g. s87 (2) (b) of the draft Bill allows for 'a prescribed condition'. Draft regulation 6 which is the regulation linked to this provision states that the 'prescribed condition' is Chlamydia.

Provisions allowing prescribing certain matters by regulation provide the framework to address issues that may arise in the future e.g. new health practitioner groups such as Physicians Assistants being covered under the legislation.

**Issue for comment: *Are there any other regulations that should be included?***

### Response and Contact Details:

Please direct any responses to the *Medicines, Poisons and Therapeutic Goods Bill 2010* discussion paper to:

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