THE LEGISLATIVE ASSEMBLY FOR
THE AUSTRALIAN CAPITAL TERRITORY

MEDICINES, POISONS AND THERAPEUTIC GOODS BILL 2007

EXPLANATORY STATEMENT

Circulated by the authority of
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Medicines, Poisons and Therapeutic Goods Bill 2007

This explanatory statement relates to the Bill as introduced into the Legislative Assembly.

Overview

The Medicines, Poisons and Therapeutic Goods Bill 2007 consolidates four Acts and their regulations regarding ACT law on medicines, poisons and prohibited substances. The Bill repeals and replaces the *Poisons and Drugs Act 1978*, the *Poisons Act 1933,* the *Public Health (Prohibited Drugs) Act 1957* and significantly amends the *Drugs of Dependence Act 1989* to effect reforms required by the National Competition Policy Review of Drugs, Poisons and Controlled Substances legislation (Galbally Review) and to provide for a more unified and workable scheme. The Bill adopts the Standard for the Uniform Scheduling of Drugs and Poisons (the SUSDP), developed by the National Drugs and Poisons Schedule Committee established under the *Therapeutic Goods Act 1989* (Cwlth).

Therapeutic goods have been included in this Bill as the Galbally Review recommended (at recommendation 23) that each jurisdiction adopt the Commonwealth *Therapeutic Goods Act 1989* by reference. The *Therapeutic Goods Act 1989* regulates a range of activities and transactions relating to therapeutic goods but only those carried out by corporations and as part of interstate trade. This arises out of Constitutional limits on the legislative power of the Commonwealth. The purpose of recommendation 23 is to ensure that *all* activities and transactions relating to therapeutic goods can be regulated by the Therapeutic Goods Administration (TGA). This will be done without resource cost to the Territory as the TGA will expand its operations to pick up the additional matters included in this Bill. Chapter 10 of the Bill applies the Therapeutic Goods Act.

The objective of the Bill, set out in Chapter 2 and as recommended by the Galbally Review, is to promote and protect public health and safety by minimising medicinal misadventure with and diversion of regulated substances, accidental or deliberate poisonings and the manufacture of regulated substances that are subject to abuse. The Bill also has the purpose of ensuring that consumers of prescription and non-prescription medicines have adequate information to allow them to use medicines safely and effectively. The Bill establishes an authorization and licensing framework for medicines and poisons, as well as grounds and powers for disciplinary action to be taken against authorised and licences persons. The Bill also controls the way in which medicines and poisons are dealt with through a range of offences, imposing a range of potential penalties, including the imposition of terms of imprisonment where appropriate. Enforcement of the offences will be achieved through a comprehensive range of inspection and seizure powers, including the capacity to take and analyse samples.

As part of the development of the Bill, an exposure draft of the Bill and regulation was released in December 2006 and February 2007 respectively. Both were made available on the Legislation Register and forwarded to interested stakeholders. Comments were received from a number of interested bodies and considered in the further drafting of the Bill and regulation. The Bill and regulation have been developed to maintain, as much as possible, the status quo for health professionals in performing their duties. For example, the offences in the Bill are an amalgamation of offences in the Poisons Act, Poisons and Drugs Act, Drugs of Dependence Act and the Public Health (Prohibited Drugs) Act, regulations made under those Acts. These offences have been recast to comply with the *Criminal Code 2002* and, in some instances, clarified as to their effect and application.

The Regulation
To support the Bill and provide flexibility, the Medicines, Poisons and Therapeutic Goods Regulation provides the detail for the regulatory framework established by the Bill. The regulation will ensure that health professionals will still be able to prescribe, administer and dispense medicines as they can lawfully do at present. The regulation also contains the more substantive detail, specific requirements, or conditions for a range of activities and obligations contained within the Bill. Some provisions of the regulation prescribe additional information required for licences or authorisations, whereas other provisions impose statutory licence conditions, while other provisions of the regulation specify requirements for activities such as labelling or packaging.

The regulation is currently being finalised but it will be provided to the Legislative Assembly as soon as it is completed and before debate on the Bill.

Strict liability
This Bill contains strict liability offences. Strict liability is usually employed where it is necessary to ensure the integrity of a regulatory scheme, such as those relating to public health and safety, the environment and the protection of the revenue. The control of medicines and poisons requires offences that are generally at the lower end of the range of criminal conduct. Where necessary a higher, fault element, offence is included to address serious or more complex matters. The bulk of the offences are contained in chapters 4 and 5.

Professionals who deal with medicines, poisons and therapeutic goods can reasonably be expected to be aware of their duties and obligations. As such, strict liability offences are more readily justified when a defendant can reasonably be expected, because of his or her professional involvement, to be aware of the requirements of the law. A defendant's frame of mind for some regulatory offences is irrelevant, unless some knowledge or intention ought to be required to commit a particular offence. Penalties for strict liability do not exceed more than 50 penalty units or include imprisonment. The mistake of fact defence expressly applies to strict liability as do other defences in part 2.3 of the *Criminal Code 2002*.

Clauses
Given the size of this Bill, the clauses are explained generally through an overview of the chapter. Individual clauses are explained in detail, where appropriate.

Chapter 1 Preliminary
This chapter contains the preliminary and formal provisions. Clause 1 declares the name of the Bill to be the Medicines, Poisons and Therapeutic Goods Act 2007. Clause 2 provides for the commencement of the Act. It is proposed to commence the Act on a day fixed by the Minister by written notice. This enables the Minister to choose an appropriate commencement date that will provide sufficient notice to the community and give adequate time to prepare for the new arrangements. Clauses 3 and 4 provide for the dictionary and the notes to the Act. Clause 5 provides that the *Criminal Code 2002* and the *Legislation Act 2001* applies to offences in the Act.

Chapter 2 Operation of Act
Clause 6 Objects
This clause specifies the objects of the Bill. The object of the Bill is to promote and protect public health and safety by minimising medicinal misadventure with and diversion of regulated substances, accidental or deliberate poisonings and the manufacture of regulated substances that are subject to abuse.

The Bill also has the purpose of ensuring that consumers of prescription and non-prescription medicine have adequate information to allow them to use medicines safely and effectively. In regulating the Chief Health Officer may choose to take disciplinary action, such as referring a matter to a health professionals board, rather than pursue a prosecution for a breach.

Clause 7 Appropriate prescription and supply of medicines

This clause provides for the quality use of medicines principles under the national medicines policy that a health professional should consider when prescribing or supplying a medicine to a patient. A person who is authorised to prescribe, sell or supply a medicine, other than by wholesale, must ensure that the prescription, sale or supply of the medicine is for a quantity and purpose that accords with the recognised therapeutic standard of what is appropriate in the circumstances.

Clause 8 Obligations under other territory laws

This clause provides that the obligations and duties arising under this Bill operate in addition to duties that people may have under other enactments, for example, *Dangerous Substances Act 2004* and the *Health Professionals Act 2004*. The obligation must be complied with unless this Act or the other law provides otherwise. People who deal with medicines, poisons and therapeutic goods will therefore need to ensure that they are familiar with all relevant legislation and the duties imposed on them under those laws.

Clause 9 Inconsistency between Act and medicines and poisons standard

One of the purposes of this Act is to give effect to the *Standard for the Uniform Scheduling of Drugs and Poisons* (SUSDP). The SUSDP is known as the medicines and poisons standard in the Bill. This clause provides that the Act prevails if there is an inconsistency between the Act and the medicines and poisons standard. The medicines and poisons standard is incorporated by reference at clause 15.

Chapter 3 Important Concepts

This chapter defines the substances to which the Act applies. The current Acts use a number of concepts – poisons, poisonous substances, drugs of dependence, prohibited drugs, prohibited substance, restricted substance, biological preparations - to describe the medicines and poisons regulated by the SUSDP. In this chapter, the terms used by the SUSDP are grouped under one term, *regulated substance*.

Clause 10 Meaning of *regulated substance* provides that a regulated substance means a medicine, poison, prohibited substance or appendix C substance. These terms are further defined in accordance with the classifications for the schedules used in the SUSDP at Clause 11 Medicine-related definitions, Clause 12 Poison-related definitions and Clause 13 Meaning of *appendix C substance* and *prohibited substance*. These classifications are explained in the notes to the above clauses.

Clause 14 Meaning of *regulated therapeutic good*

This clause provides a definition for regulated therapeutic good, which is a term defined under the *Therapeutic Goods Act 1989* (Cwlth). A regulated therapeutic good may be a therapeutic good; a medical device; or a therapeutic device. A regulated therapeutic good can also be anything else, except for a regulated substance, that is prescribed in the Regulation.

Clause 15 Meaning of *medicines and poisons standard*

This clause provides for the incorporation by reference (see Chapter 10, *Legislation Act 2001*) of the poisons standard, known as the *Standard for the Uniform Scheduling of Drugs and Poisons* as in force from time to time and subject to any modification by regulation made under this Act.

Subsection (2) provides that the modification of a standard takes effect on the date notified unless the date of effect is modified by a regulation made under this Act.

Clause 16 Interpretation provisions in medicines and poisons standard - application to Act

This clause provides that a term defined in the medicines and poisons standard has the same meaning in the Act. The exception to this provision is the definition of poison. The standard uses this term for any substance or preparation, including medicines, included in the schedules, however this Bill defines poison at clause 12 to be a poison as listed in schedules 5, 6 and 7 of the SUSDP.

Subclause (2) provides that the interpretation provisions of the standard apply in the interpretation of this Act, including that a substance in a schedule or appendix includes, subject to stated exceptions, every salt, active principle or derivative of the substance.

Clause 17 When medicines and poisons standard *applies* to substances

This clause gives effect to an exclusion or restriction included with a scheduled substance. A substance may have an exclusion or restriction. The substances may also be in more than one schedule, or in an appendix to the medicines and poisons standard, which affects the availability and use of the substance. The SUSDP advises that schedule entries can be expressed in either positive or negative terms. Care should be taken to distinguish between the two forms of expression.

Clause 18 Inspection of medicines and poisons standard

This clause requires the Chief Health Officer (CHO) to have a copy of the medicines and poisons standard available for inspection by the public at reasonable times during business hours at an office administered by the CHO. The standard is currently only available in hard-copy form.

Clause 19 Meaning of *deals* with a regulated substance

This clause explains the concept of *deal.* This concept is central to the operation of the Bill. The Bill establishes the regulatory scheme for the licensing, authorisation and notification of activities in relation to medicines and poisons. Therapeutic goods are not captured by the definition of 'regulated substance'.

The concept of *deals* is broadly defined so that it covers most, if not all, of the activities through which a medicine or poison is dealt with. This includes an extended meaning of possession in subclause (2).

Clause 20 When *authorised* to deal with a regulated substances

This clause outlines when a person is *authorised* to deal with regulated substances. A person is authorised to deal with a regulated substance where that person has a licence or permit under a Commonwealth Act (eg, Therapeutic Goods Act), this Act or another Territory law that authorises the dealing. The clause also provides for persons that may or must deal with the medicine or poison and provides for supply by wholesale where that person is authorised under a corresponding law, does not have a place of business in the ACT, complies with conditions and restrictions imposed by the corresponding jurisdiction and has not been prohibited by the Chief Health Officer from supplying the substance by wholesale.

Subclause (3) restricts the authorisation in subclause (2) where it is an administration-related dealing with a dangerous poison, prohibited substance or appendix C substance for human use only if is a dealing authorised by a licence for the purposes of research.

This provision is included to allow ACT based research institutes to conduct experiments, including clinical trials, where that research is approved by a human research ethics committee, established in accordance with the National Health and Medical Research Council.

Clause 21 Meaning of *deals* with a regulated therapeutic good

This clause explains the concept of *deal* for the purpose of regulated therapeutic good. Deal is restricted in this clause to supply of the good. Supply is defined at clause 24 and includes sell, dispense, etc, but does not include administer.

Clause 22 When *authorised* to deal with a regulated therapeutic good

This clause provides that a person is authorised to deal with a regulated therapeutic good if the person has a licence or permit under a Commonwealth Act, this Act or another Territory law that authorises the dealing. The clause also provides for persons that may or must deal with the good and provides for supply by wholesale where that person is authorised under a corresponding law, does not have a place of business in the ACT, complies with conditions and restrictions imposed by the corresponding jurisdiction and has not been prohibited by the Chief Health Officer from supplying the good by wholesale.

Clause 23 Meaning of *supply authority*

This clause defines a supply authority to include a written prescription, a written requisition, a purchase order, a standing order or a document that purports to be any of the previous documents. Supply authority is a concept used in the Bill to authorise the giving and receiving of regulated substances to people and entities.

Clause 24 Meaning of *possess*, *sell* and *supply*

This clause provides extended meanings for possess, sell and supply.

> *Possess* - in addition to the usual meaning of "being in possession", the definition covers receiving or obtaining possession, having control over the disposition of a thing (even if it is not in the person's custody) and possessing a thing jointly with someone else.
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> *Sell* – this is an important definition in the Bill because of the extensive use of the term "sell" (or sale etc) throughout the Bill. In addition to the usual meaning of sell, the term also covers offer or expose for sale; dispose of by any method for value.
>
> *Supply* – this is a broader term than 'sale', though it includes sell, and, includes offer or expose for sale, dispense, supply under a requisition of standing order; dispose of by any method for free (other than by discarding), but does not include administer.

Chapter 4 Offences relating to regulated substances

This chapter creates offences relating to regulated substances. These offences bring together offences in the Drugs of Dependence Act, Poisons Act, Poisons and Drugs Act, Public Health (Prohibited Drugs) Act.

Clause 25 Meaning of *declared substance – pt. 4.1*

This clause provides that some regulated substances are declared substances. A declared substance is a medicine, a dangerous poison, a prohibited substance, an appendix C substance or any other regulated substance prescribed by regulation. Low harm and moderate harm poisons are excluded from the offences in this part.

Division 4.1.2 Declared substances - supply

This division creates offences of supply of declared substances in various circumstances – supply; supply on invalid supply authority; failure to cancel, etc, an invalid supply authority; failure to provide information to the chief health officer of supply of certain declared substances.

Clause 27 is a strict liability offence. The offence concerns a person who is authorised to supply a declared substance on a supply authority (eg, a pharmacist or a wholesaler) and the person supplies the substance in circumstances where the supply authority is illegible; changed or marked cancelled, etc.

Clause 31 is an offence about failing to give information to the Chief Health Officer regarding the supply of certain declared substances. Strict liability has been applied to an element of the offence. This does not make all of the offence strict liability. The application of strict liability to (1)(b) and (2)(b) is included here to disapply the default fault element provision of the Criminal Code, section 22. The prosecution is still required to prove that the Chief Health Officer was not given the information required.

Division 4.1.3 Regulated substances – other dealings

This division create offences relating to other dealings of regulated substances. These other dealings include manufacture, discarding, obtaining, possessing, administration, issuing purchase orders, requisitions, prescriptions and standing orders, and reporting the loss of theft of certain medicines.

Clause 35 Obtaining certain declared substances

This clause provides for two offences. The first is a fault element offence for more serious instances where a person obtains a declared substance that they are not authorised to obtain. An example of not being authorised is not having a prescription for a controlled medicine from a health professional. Subclause (2) creates a lower order offence for when a person obtains a prescription only substance when they are not authorised to obtain the prescription only substance. This is a strict liability offence that is justified to apply outside of the professional example stated in the overview. Members of the public are aware that a prescription only substance must be obtained on prescription. The misuse of prescription only medicines can cause harm to the individual and affect the integrity of the public health and safety if it were possible to obtain the substance without appropriate authorisation.

Clause 37 Administering certain declared substances

This clause creates an offence of administering a declared substance to someone else without authorisation and to administer a declared substance to themselves, also without authorisation. The clause expressly excludes pharmacy medicine or pharmacist only medicine (ie, over the counter medication). This clause is directed at preventing the misuse of declared substances. It should be noted that the clause does not prevent a person from administering, for example, insulin to themselves as this is a substance obtained on prescription or supply authority (an authorisation). Authorisations are provided for in the regulation.

Clause 38(2) is a strict liability offence. The offence applies to a person who is authorised to issue a purchase order for a declared substance and issues the purchase order in contravention of the requirements prescribed by regulation. Strict liability is appropriate as the person is in a professional position and ought to be expected to know the requirements that apply in issuing a purchase order.

Clause 43 Medicines for animals not to be prescribed, etc for human use

This clause creates an offence of prescribing, supplying or administering medicines for animals to humans. There are substantial risks associated with medicines for animals being diverted to human use, including adverse health effects.

Division 4.1.4 Dealings – other offences

This division provides for contravening authorisation conditions for regulated substances and pretending to be authorised to deal with regulated substances.

Clause 44(2) is a strict liability offence. It is a lower order offence to the recklessness offence at clause 44(1) for contravention of a condition imposed on an authorisation.

Part 4.2 Records for regulated substances – offences

This part provides offences for keeping of records for regulated substances. The keeping of records, including ensuring that records are kept, are accessible, and signed, are important to a regulatory scheme. Given their unique regulatory function, a number of the offences in this part are strict liability (clauses 46, 47, 49(2), 50(2), 51, 52, 56).

Part 4.3 Regulated substances – other offences

This part provides offences for packaging and labelling, storage, containers, representations and advertisements, vending machines and paints.

Clauses 59 and 60 create two offences each in relation to packaging and labelling – one is a higher level offence, and the other is a lower order offence which is strict liability. Strict liability is appropriate as the person is in a professional position and ought to be expected to know the requirements that apply in packaging and labelling supplied regulated substances.

Clause 64 False statements to obtain certain regulated substances etc

This clause provides offences for providing false statements to obtain certain regulated substances and supply authorities. These offences are included for those circumstances that a person is attempting to obtain a controlled medicine, a dangerous substance, a prohibited substance, or appendix C substance (*reportable substance,* see clause 39) for an illegitimate reason.

Subclause (1) creates an offence of making a false or misleading statement for the purpose of obtaining a substance from an authorised person. Subclause (2) provides for an offence of making a false or misleading statement for the purpose of obtaining a prescription or purchase order. Subclause (4) is a strict liability offence for falsely stating a name or residential address to a person authorised to dispense a reportable substance or their agent.

Clause 65 Falsely representing that substance is regulated

This clause provides for an offence of falsely representing a substance is a regulated substance. While in most instances the purported regulated substance may be harmless, there is potential for harm if a person were to represent, for example, a poison to be a controlled medicine or an inactive substance to be presented as a medicine with certain therapeutic properties. This false representation could then lead to medical complications which may not be able to be addressed quickly when a person presents to hospital or to a health professional.

Clause 66 Advertising controlled medicines and prohibited substances

This clause creates an offence of publishing an advertisement that promotes or encourages the use of a controlled medicine or prohibited substance. A second offence is provided for a person who advertises that they are willing or authorised to supply a controlled medicine or prohibited substance. An exception is provided for an advertisement in an industry publication, eg, a publication primarily for dentists, doctors, pharmacists or veterinary surgeons. The Regulation will also provide exceptions for pharmacist advertising to the community and some other forms of advertising. However, the publication of advertisements of this nature will be required to be in accordance with the Galbally Review. The advertising of controlled medicines is restricted to ensure their use is not inappropriately encouraged. It should be noted that the supply of prohibited substances is illegal.

Clause 68 Vending machines – use for supply of regulated substances

This clause continues the ban on using vending machines to supply certain substances, though it now applies to regulated substances. Under the current provision in the Poisons Act, section 15, it applies to a poison or a poisonous substance, two terms with quite broad application. Furthermore, there was previously a prohibition on vending machines contained in the now repealed *Pharmacy Act 1931*. When the Pharmacy Act was repealed by the Health Professionals legislation the prohibition on vending machines was not preserved as it was anticipated that this Bill would regulate vending machines.

Clause 69 Vending machines – use for supply of unscheduled medicines

This clause eases the restrictions contained in the current ban, to permit the vending of unscheduled medicines that is supplied in a manufacturer's pack containing no more than 2 adult doses of the medicine. The vending machine must, however, be presented and located in a way that makes unsupervised access by children unlikely.

Clauses 70, 71, 72 and 73 create offences regarding the manufacture, supply and use of paints in certain circumstances.

Chapter 5 Offences relating to regulated therapeutic goods

This chapter provides for offences related to regulated therapeutic goods. These offences are intended to cover those matters not dealt with by the Therapeutic Goods Act. Clause 74 creates an offence for the unauthorised supply of a regulated therapeutic good to a person. Additionally, an offence is created at (2) of supplying a good to themselves, similar to the administration offence at clause 37.

Clause 75 provides an offence for contravening authorisation conditions for regulated therapeutic goods. It is a strict liability offence. This is appropriate as a person would be aware of the conditions imposed on the authorisation. Clause 76 and 77 create offences of pretending to be authorised and falsely representing a thing to be a regulated therapeutic good respectively.

Chapter 6 Licences for regulated substances and regulated therapeutic goods

This chapter provides for the licensing of licence-holder to deal with a regulated substance or a regulated therapeutic good, and the criteria for assessing the suitability of a person to hold a licence under this Act. The regulation will prescribe licences for this Act.

Clause 78 Meaning of *licence* – ch 6

This clause provides for the meaning of licence for this chapter. A licence authorises a licence-holder to deal with a regulated substance or regulated therapeutic good. A regulation may prescribe the type of licences that may be issued under the Act. Subclause (3) provides,

however, that the chief health officer may issue a licence even though the licence is not prescribed by regulation for subsection (2). This power is included to ensure that there is no gap in the regulatory system in the event that a regulation has not provided for the licence.

Clauses 79 and 80 provide definitions for close associate (for an individual application) and influential person (for an application from a corporation).

Clause 81 sets out the criteria for determining whether a person is suitable to hold a licence. In summary, these criteria focus on matters such as:

- knowledge, training and experience in relation to the regulated substances or regulated therapeutic goods;
- the dealings to which the licence relates;
- general honesty and integrity, including close associates;
- previous disciplinary and/or compliance history; and
- anything prescribed by regulation.

Subclause (2) provides an individual is not a suitable person if they or a close associate have been found guilty of an offence or convicted in the previous five years; are an undischarged bankrupt or executed a personal insolvency agreement; was involved in the management of a corporation that became subject to a winding-up or administration or control; or any circumstance prescribed by regulation. The Chief Health Officer may, under subclause (3), decide to issue a licence to an unsuitable person if satisfied the dealings to be authorised are not inconsistent with the Act and it is otherwise in the public interest.

Clause 82 sets out the criteria for determining whether a corporation is suitable to hold a licence.

Clause 83 ensures that the Chief Health Officer can obtain information relevant to making a decision about an application for a licence, by asking applicants, licensees or other to provide relevant information. This information can include information or documents in the possession of a third party, or access to financial records. Until the person complies with the request for further information, there is no obligation to decide the application (see subclause (3)(b)).

Clause 84 provides for licence applications. The clause also provides that if a change arises affecting the application, the person must provide the information to the Chief Health Officer.

Clause 85 provides for the decision on an application. An applicant must provide all relevant information. There is no obligation to consider applications that do not include all the information required under this Act or the regulation. It is important that all relevant information is included with licence applications to ensure that licences to deal with regulated substances or regulated therapeutic goods are only issued once a full and proper assessment of the person's suitability to hold a licence and ability to comply with the Act is completed.

Clause 86 explains that licences can be granted for up to three years, or a shorter period specified by the regulations. The term must be stated on the licence. It is appropriate that the suitability of people to hold licences is reviewed regularly. This clause ensures that people who wish to deal with regulated substances or regulated therapeutic goods are required to reapply for a licence at least every three years.

Clause 87 provides that a licence is not transferable. A licence is issued on the basis of a person's suitability to deal with regulated substances or regulated therapeutic goods. It is not appropriate that a licences be traded or transferred, including when transferring a business.

Clause 88 lists the matters that must be set out in the licence, including conditions imposed on the licence by the Chief Health Officer. The conditions may be included in a separate document attached to the licence.

Clause 89 provides for statutory licence conditions included in the Act and anything prescribed by regulation.

Clause 90 provides for licence conditions imposed by the Chief Health Officer, who may include a condition to ensure that regulated substances and regulated therapeutic goods are properly dealt with under the licence. These may include supervision of dealings, security, and the keeping of records.

Clause 91 provides for the amendment of licence conditions on the Chief Health Officer's initiative. The Chief Health Officer must provide written notice of the proposal to amend the licence, allow time for comment on the proposal and consider the comments. Following this, the Chief Health must provide written notice of the amended licence condition. An amendment takes effect on the day notice is given on a day specified in the notice.

Clause 92 allows a licence-holder (licensee) to seek an amendment to a licence, such as changing one of the conditions that applies to the licence. This provision could be used, for example, if a licence-holder has subsequently gained a further qualification or completed further training in handling restricted substances and wishes to be authorised to undertake a greater range of activities.

Clause 93 requires a licensee to inform the chief executive of changes to particulars affecting suitability to hold a licence or included in an application to amend a licence. The purpose of this requirement is to ensure that the regulatory authorities are informed of changes within 7 days of the expected change that have the capacity to affect a licensee's suitability to deal with regulated substances or regulated therapeutic goods.

Clause 94 provides for the returning of licences for amendment. A licence-holder commits a strict liability offence if they fail to comply with a request to return a licence.

Clause 95 deals with the issuing of replacement licences where they have been lost, stolen or destroyed.

Clause 96 creates offences for contravening a condition imposed on a licence. A high level offence, providing for recklessly contravening an offence is provided at (1), while a lower order, strict liability offence is provided for at (2). The licence-holder would be in a position to know the conditions that apply to the licence.

Clause 97 provides a mechanism whereby a licensee can surrender a licence to the chief executive. This mechanism could be used, for example, where the licensee decides to retire or move interstate before his or her licence expires.

Disciplinary action against licence-holders is provided for in Chapter 8 of the Bill.

Chapter 7 Enforcement

This chapter sets out the enforcement provisions for the Bill. These powers are necessary to ensure that inspectors are able to monitor compliance with the legislation and are similar to powers of inspectors under the current legislation and other regulatory schemes.

Pursuant to clause 98 of the Bill an occupier of premises includes persons apparently in charge of the premises and any person believed on reasonable ground to be an occupier of the premises. Extending the meaning of occupier in this way is necessary to avoid enforcement provisions, including search and seizure powers, from being thwarted or improperly exercised because the actual occupier either could not be identified or is not present.

Clause 100 provides for the appointment of a public servant to be a medicines and poisons inspector by the Chief Health Officer. A police officer may also be an inspector for this Act (see clause 99). The Chief Health Officer must issue an identity card to a public servant appointed a medicines and poisons inspector (Clause 101). It is a strict liability offence if when an inspector ceases to be an inspector they fail to return the identity card.

Division 7.1.3 Powers of medicines and poisons inspectors

Clause 102 contains a power for inspectors to enter premises. It describes the circumstances in which the power to enter may be exercised. Entry may be at any reasonable time when the public is entitled to use the premises or it is open to the public, or at any time with the occupier's consent.

An inspector may also enter the premises at any time if the inspector believes on reasonable grounds the circumstances are so serious and urgent that immediate entry is required without the authority of a warrant. This third ground for entry is contemplated for the rarest of circumstances. It's use is dependent upon circumstances of such seriousness and urgency as to justify entry without a warrant. For example, situations where immediate entry is required in order to prevent or mitigate a serious threat to the life or safety of a person or persons could amount to circumstances which would justify entry without a warrant. Accordingly, the power to enter without a warrant under this provision has not been limited to police officers as it is possible that any duly authorised inspector could encounter such a situation. Were this ground for entry to be limited to only police officers it could result in a delay that could have dire consequences.

Clause 103 requires inspectors to produce their identity cards when asked to do so by the occupier of premises that they enter. An inspector who does not produce his or her identity card must leave the premises.

Clause 104 explains the way in which an inspector can obtain the consent of the occupier to enter premises. The purpose of this provision is to ensure that the person's consent is fully informed. Among other matters, the inspector must ask the occupier to sign a written acknowledgement of consent. If a written acknowledgement of consent is not produced in court in subsequent proceedings, the Court must find that the occupier of the premises did not consent to the entry.

Clause 105 sets out the general powers of inspectors on entry to premises that they have entered under this Act. These powers will enable the inspectors to examine things, make copies, take samples, open packages, operate plant or equipment, take measurements, conduct tests, make records, seize items, and to ask questions or obtain information. Inspectors may also ask another person at the premises for assistance in doing any of these things. These comprehensive powers are essential to ensure that inspectors can effectively monitor compliance with the proposed Act.

Clause 106 gives an inspector the power to seize things if the inspector is reasonably satisfied that the seizure is necessary to stop the thing from being concealed, lost or destroyed, or used to commit an offence.

An inspector may also seize things if they are satisfied that the thing puts the health or safety of people at risk or is likely to cause damage to property or the environment. It is a strict liability offence to interfere with something that has been seized by an inspector without the inspector's approval

Clause 107 provides an inspector with the power to destroy unsafe things. It applies to anything inspected or seized under the part where the inspector is satisfied on reasonable grounds that the thing puts the health or safety of people at risk or is likely to cause damage to property or the environment. The inspector may direct the occupier to dispose of the thing. It is an offence to fail to comply with a direction.

Clause 108 provides an inspector with the authority to require a person to provide their name and address if the inspector believes on reasonable grounds the person is committing or has just committee an offence against the Act. It is a strict liability offence to fail to comply with the request.

Division 7.1.4 Search warrants

This division contains provisions dealing with search warrants. These provisions are similar to search warrant provisions contained in other regulatory legislation. They explain the process for applying for a search warrant, the actions that search warrants may authorise, powers exercisable under search warrants that are to be executed, how searches are to be conducted, the movement of things to another place for examination or processing, and associated matters.

Search warrants can also be sought by a police officer under the Drugs of Dependence Act, part 11.

Clause 109 explains that inspectors can apply to a magistrate for a search warrant. Search warrants can be issued if a magistrate is satisfied that there is likely to be evidence of an offence under the legislation at premises either currently or within the next 14 days. A warrant issued by a magistrate must contain details such as when it is to be executed, the items that it applies to, the offence that it relates to, the actions that it authorises and the period for which it remains in force. Warrants may be sought by phone, fax, radio or another form of communication if urgent or special circumstances apply (clause 110). If a warrant is obtained in this manner, an inspector is required to send the sworn application and completed warrant form to the Magistrate. In executing a warrant, an inspector must announce their entry under warrant (clause 111). Announcement need not be made if there are reasonable grounds to believe that effective execution of the warrant will be frustrated or for the safety of anyone.

Clause 112 requires inspectors to give details of a search warrant to the occupier of the premises that are to be searched under the warrant and that person is generally entitled to be present during a search (clause 113). A person can be excluded if his or her presence would impede the search, or if he or she is under arrest and being present at the search might interfere with the objectives of the search.

Clauses 114, 115 and 116 provide for examination of equipment, including computers, and things, including the movement of things to another place. Clause 117 permits the securing of electronic equipment at premises while expert assistance is being sought. Copies of things seized under the warrant are to be provided to the occupier (clause 118).

Division 7.1.5 Return and forfeiture of things seized

This division contains provisions dealing with the return and forfeiture of things seized. These provisions are similar to provisions contained in other regulatory legislation.

Clause 119 provides that a receipt must be given for things seized. Clause 120 provides a right of access to documents or other things that are seized under this chapter. The right of access applies to any person who would be entitled to inspect the item if it had not been seized. The right of access is limited and does not apply to a thing seized because it poses a risk to health or safety of people or of damage to property or the environment or if possession of the thing or information would be an offence.

Clause 121 deals with the return of seized items. It sets out the circumstances in which items must be returned to the owner, or in which reasonable compensation is to be paid to the owner for the loss of the thing seized. In brief, these circumstances are:

- where, within 90 days of seizure, no infringement notice has been served on the owner and no prosecution was started within the 90 day period;
- an infringement notice was served but was then withdrawn and no prosecution is subsequently initiated against the owner;
- an infringement notice is served but disputed, and an information is not laid in the Magistrates Court within 60 days of the disputed notice or it is laid but the Magistrate Court does not find the offence proved.

The clause does not apply if the thing is seized because it poses a risk to health or safety of people or of damage to property or the environment or if possession of the thing would be an offence.

A person may seek an order from the Magistrates Court under clause 122 within 10 days to disallow the seizure. No application can be made for items that were seized because they posed a risk to the health and safety of people, property or the environment. The Court may make the order under clause 123 if the Court is satisfied that the thing is not connected to an offence, and possession of the thing is not an offence, or the Magistrates Court is satisfied that that there are exceptional circumstances to justify disallowing the seizure. If the seized item cannot be returned, or if it has suffered a loss in value since it was seized, the Magistrates Court can also order the Territory to pay reasonable compensation. The Magistrate Court may adjourn a proceeding on its own initiative or on application by the Chief Heath Officer if it appears that the seized thing is required to be produced in evidence in a pending proceeding (clause 124).

Clause 125 deals with the forfeiture of things that have been seized under this chapter. It explains that if a forfeited item has not been returned, destroyed or otherwise disposed of, and no application has been made to disallow its seizure, the item is forfeited to the Territory and it may be sold, destroyed or otherwise disposed of as directed by the Chief Health Officer. Clause 126 enables the chief executive to return something that has been forfeited under clause 125 but has not been finally disposed of. The Chief Health Officer can return the item if he or she is satisfied that the item is not connected to an offence.

Clause 127 explains that where the Territory incurs costs in storing and disposing of a forfeited item and a person who was the owner of that item has been convicted or found guilty of an offence in relation to that item, the Territory can recover those costs from that person.

Division 7.1.6 Medicines and poisons inspectors – other provisions

Clause 128 authorises the disposal of things obtained otherwise than under part 7.1. This power is included as from time to time the Chief Health Officer, and persons acting under his or her authority, come into possession of a regulated substance or a regulated therapeutic good. This possession may arise, for example, if abandoned regulated substances or a regulated therapeutic goods are surrendered to the Chief Health Officer, or their location has been reported to an inspector.

Clause 129 requires inspectors to take all reasonable steps to minimise inconvenience, detriment and damage when exercising powers or functions under the Act. If damage does occur, the inspector must notify the owner of the thing that was damaged.

Clause 130 enables a person to claim compensation from the Territory for loss or expenses arising from the exercise, or purported exercise of functions under this chapter. Any court of competent jurisdiction can decide applications for compensation. The section does not authorize a court to order payment of compensation where the thing seized is seized because of a recall under the Therapeutic Goods Act.

Part 7.2 Taking and analysis of samples of substances

This part provides for the taking and analysis of samples from premises inspected under this Act. Clause 131 provides that an inspector can buy a sample of a substance for analysis for the purpose of routine monitoring with the Act without complying with the requirements of the part, which provides for the occupier to be told a sample is to be analysed (clause 132), that the inspector must pay or offer to pay for the sample, either in accordance with an amount specified in the regulation or the current market value, if no amount is prescribed (clause 133).

If the sample is to be taken from a packaged substance that contains two or more smaller packages of the same substance, the inspector may take one of the smaller packages (clause 134), otherwise clause 135, procedures for dividing samples, applies. The sample must be divided into three parts, and marked and sealed accordingly. One part must be given to the occupier of the premises from where the sample is taken, one part must be retained by the inspector for analysis, and the remaining part must be retained for future comparisons with the other two parts. The procedure in clause 135 is subject to clause 136, which provides that a sample need not be divided in certain circumstances, for example, if dividing it would impede accurate analysis.

The analysis on the sample may only be undertaken by an authorised analyst or a person who is supervised by an authorised analyst (clause 137). An authorised analyst is a person appointed under the *Public Health Act 1997* and who is authorised under that Act to exercise a function under this Act. The analyst is required to give a certificate to the Chief Health Officer identifying the method of analysis and the findings of the analysis. This certificate is not an evidentiary certificate. Evidentiary certificates are provided for under section 135A, Public Health Act. This is a new section and is contained in schedule 2 of the Bill.

Chapter 8 Restrictions on dealing with regulated substances and regulated therapeutic goods

This Chapter provides for the taking of disciplinary action for authorisations for holders of authorisations and licences; disqualification by courts; and provides for the surrender of prescribed authorisations.

Part 8.1 Authorisations - disciplinary action

This part applies only to an authorisation under this Act and not a dealing authorised by a permit or licence under the Therapeutic Goods Act (clause 138). The term authorisation is used broadly, as section 22 of the Bill provides. This part uses the term authorisation holder who is or has been authorised to deal with a regulated substance or regulated therapeutic good (clause 139) for the taking of disciplinary action. The grounds for disciplinary action are provided for in clause 140 and includes such matters as provide information to the Chief Health Officer that is false or misleading in a material particular; there has been a contravention of the Act by the holder or their agent/employee, etc.

Clause 141 provides that the Chief Health Officer may take a number of disciplinary actions in relation to the breach by a current authorisation holder under clause 140. The range of disciplinary action is limited by (2) with respect to a former authorisation holder, but the Chief Health Officer may, for example, disqualify them from being authorised to deal with a regulated substance or a regulated therapeutic good for a stated period.

Clause 142 describes the process to be followed by the Chief Health Officer when he or she proposes to take disciplinary action. The Chief Health Officer must be satisfied that a ground exists, then a notice must be given to the authorisation holder. These processes are designed to ensure that a current or former authorisation holder against whom the disciplinary action is proposed is given proper notice of the proposed action and allowed to give a written response before a decision is taken. The notice must detail the disciplinary action proposed to be taken, and it may be two or more of actions mentioned in clause 141.

Clause 143 explains that when an authorisation holder is given a disciplinary notice, the Chief Health Officer can also give the authorisation holder an immediate suspension notice, the effect of which is to suspend their authorisation pending resolution of the disciplinary action. Before suspending the authorisation, the Chief Health Officer must consider the circumstances that lead to the decision to give a disciplinary notice and that they believe it would be in the public interest to suspend the authorisation while disciplinary action takes place. If a suspension notice is given, it takes effect when the notice is given. Clause 144 explains the effect of suspension.

Clause 145 is a strict liability offence for failing to return a varied, suspended and cancelled licence or approval.

Clause 146 is a procedural provision that sets out the actions that the Chief Health Officer must take when a licence is amended, suspended or cancelled following disciplinary action.

Part 8.2 Controlled medicines and prohibited substances-disqualification by courts

This part provides for a person to be disqualified by a court that a person must not, for a stated period, deal with a controlled medicine or prohibited substance (or both), where that person has been convicted or found guilty of an offence against chapter 4 of this Bill, chapter 6 of the Criminal Code or part 10 of the Drugs of Dependence Act. The court may only disqualify the person if the court is satisfied it is in the interests of the person or the public. If a direction is given, notice must be given to the person and to the Chief Health Officer. The Chief Health Officer is then obliged to give a copy of the direction to the person's employer, if any, and to the relevant health profession board if the person is a health professional. This part is intended to ensure a person convicted of a drug-related offence is restrained from dealing with controlled medicines and prohibited substances, which are serious drugs for a person to misuse.

Chapter 9 Review of decisions

This chapter provides for the review of a decision made under the Act by the Chief Health Officer. Schedule 1 provides for those decisions subject to review by the Administrative Appeals Tribunal (AAT) under the *Administrative Appeals Tribunal Act 1989*. Clause 155 requires written notice to be given to an affected person of a decision made by the Chief Health Officer.

Chapter 10 Incorporation of Commonwealth therapeutic goods laws

This chapter applies the Therapeutic Goods Act and any instruments made under the Act as a law of the Territory. As mentioned in the overview, one of the recommendations of the Galbally Review was to incorporate by reference the Therapeutic Goods Act.

The purpose of this chapter is to specifically authorise Commonwealth officers with the power to exercise powers under Territory laws. This chapter is based on equivalent provisions contained in the New South Wales *Poisons and Therapeutic Goods Act 1966.*

Clause 158 provides that the Commonwealth *Acts Interpretation Act 1901* applies in the interpretation of the applied legislation. Division 10.2.2 provides that the functions, delegations and appointments of people under the applied law are the same functions, delegations and appointments those people have under the Therapeutic Goods Act. Division 10.2.3 provides that Commonwealth administrative law applies as a law of the Territory in relation to the applied provisions. Division 10.2.4 provides that an offence against the applied provisions are to be treated as an offence against a law of the Commonwealth, including the investigation and prosecution, through to sentencing, appeals, fines, etc. Clause 168 provides that a person who exercises a function of the applied law must act as nearly as practicable as the officer or authority would act for the corresponding provision of the Commonwealth law. Division 10.2.5 provides that the Commonwealth secretary may keep fees paid to or recovered by the secretary in relation to the exercise of functions given by the applied provisions.

Chapter 11 Procedural and evidentiary provisions

This chapter sets out procedural and evidentiary provisions for the Bill, including criminal liability of executive officers of corporations and other unincorporated bodies that may contravene the Bill, powers for the courts to make remedial orders, costs orders.

Clause 171 Acts and omissions of representatives of individuals

This clause deals with legal liability in respect of acts and omissions done by a person's representative, that is, someone who is employed by, or is an agent of a person. This clause explains the circumstances in which a person will be held liable for the acts or omissions of his or her representative. In brief, a person will be liable if the representative acted within the scope of the representative's actual or apparent authority. Accordingly, people who routinely use representatives to deal with regulated substances or regulated therapeutic goods should ensure that their representatives are properly trained and educated about their responsibilities under the Act, and that it is made clear to them that they have no authority whatsoever to act otherwise than in strict accordance with the legislation.

Clause 171 operates to extend the liability for conduct engaged in by a persons' representative to the person. Accordingly, conduct by a person's representative that is within their actual or apparent authority is taken to be the actions of the person. However, a person may not be held accountable if they can establish that they took all reasonable steps to prevent the conduct of their representative. In deciding whether or not a person took reasonable steps the Court must consider the level of management, control and supervision exercised over the representative. The Court must also consider actions taken by the person to ensure the representative had reasonable knowledge and an understanding of the legal obligations that were contravened. Should a person be convicted of an offence by way of the vicarious liability provisions of clause 171 they cannot be punished by imprisonment.

Clause 172 Criminal liability of corporation officers

This clause imposes criminal liability for certain offences on the executive officers of a corporation, in certain circumstances. In summary, an executive officer of a corporation will be liable for an offence by the corporation if the executive officer was reckless about whether the offence was committed, that officer had been in a position to influence the corporation's conduct, and he or she failed to take all reasonable steps to prevent the commission of the offence.

The purpose of this provision is to ensure that senior managers within corporations who deal with regulated substances or regulated therapeutic goods ensure that they do everything reasonably within their power to ensure that their corporation complies with the legislation.

Clause 173 No defence to claim deterioration of sample

This clause deals with samples that have been kept for future comparison with samples that have undergone analysis. It makes it clear that it is not a defence in a criminal proceeding under the legislation to claim that any part of the sample that has been kept for future comparison has deteriorated, perished or undergone a material change in its constitution. This provision recognises that some substances will ordinarily deteriorate over time, and given that there may be a considerable period of time elapsing between the analysis of a sample and the time that a proceeding comes before the court, the comparison sample may have deteriorated significantly in that period.

Clause 174 Remedial orders by courts for offences

This clause enables a court to make a remedial order against a person convicted or found guilty of an offence against the Act. A remedial order directs a person to take any steps the court considers necessary and appropriate to rectify a state of affairs that resulted from the guilty person's conduct. This power is additional to the power of the court to make a reparation order under the *Crimes (Sentencing) Act 2005*.

Clause 175 Court may order costs and expenses

This clause gives the court the power to make orders about any costs and expenses relating to the examination, seizure, detention, storage, analysis, destruction or other disposition of any thing that is covered by a proceeding for an offence against the Act. This power is in addition to any power that the court already has to make orders about costs in criminal proceedings.

Clause 176 Court may order forfeiture

This clause provides that the court can order the forfeiture of any thing that was used in the commission of an offence against the Act. This power is additional to any powers the court may have under the *Confiscation of Criminal Assets Act 2003.*

Clause 177 Notice of non-compliance by territory entities

This clause applies to offences that are committed by Territory entities. Under section 121 of the *Legislation Act 2001*, the Crown, in any of its capacities, is not subject to criminal proceedings. This provision is sometimes referred to as "the shield of the Crown". It is therefore necessary to include other mechanisms to deal with offences, which are infringement notice offences, committed by Territory entities. This clause allows a notice of non-compliance to be served on the chief executive of the Territory entity that has committed the offence. The chief executive is required to publish in the annual report for that entity the number of non-compliance notices that have been served under this clause. This mechanism ensures that government entities can be held accountable for their actions.

Part 11.2 Evidentiary provisions

This part provides for a number of evidentiary provisions for this Bill.

Clause 178 Evidence-authorisations under Commonwealth and State laws

This clause provides that for a prosecution for an offence against chapter 4 or 5 of the Bill, if it becomes necessary to prove a person was not authorised to deal with a regulated substance or therapeutic good, a person is not taken to have been authorised. This is subject to evidence to the contrary.

Clause 179 Presumptions

This clause provides that in a proceeding for an offence against this Act, it is presumed until the contrary is proved on the balance of probabilities, that:

- a regulated substance or regulated therapeutic good that were part of a batch, lot or consignment of the same kind or description is representative of all the substances or good in the batch, lot nor consignment;
- a sample divided in accordance with the Act for analysis, that each part was of uniform composition with every part of the sample;
- that a person is in control of the manufacture, packing or supply of a regulated substance or regulated good if the person appears from any marking or label on an article, container or package on a good or substance available for sale;
- a thing that is labelled with the name of a regulated substance or regulated therapeutic good is the substance or good.

Clause 180 Certificate evidence etc

This clause provides that in a proceeding for an offence against this Act that a document that appears to be a copy of a licence, authorisation, or approval under this Act is evidence of the issue or giving the licence, authorisation, or approval. The use of the language "appears to be a copy" is intended to capture photocopies and facsimiles of a licence, authorisation, or approval. It is also intended to capture documents that were intended to be a licence, authorisation, or approval but due to a technical deficiency are not valid or proper. The use of the language "appears to be a copy" is not intended to permit the use of forged or fake documents.

The clause also provides that a certificate that appears to signed by or on behalf of the Chief Health Officer which states the matters in (3) is evidence of the matters contained in the certificate. Matters for certification may also be prescribed by regulation. A court must accept a certificate or other document as proof of the matters stated in if there is no evidence to the contrary.

Clause 181 Admissibility of analysis of sample taken by inspector

The clause provides that an analysis of a sample taken by a medicines and poisons inspector is admissible for a proceeding for an offence against this Act. A sample, however, is only admissible if the sample was taken as required or allowed under part 7.2.

Clause 182 Power of court to order further analysis

This clause provides that the court hearing a prosecution for an offence against this Act may order further analysis. An order may only be made if the court is satisfied that there is disagreement between the evidence of the analysts of the parties to the proceeding. The Chief Health Officer can be ordered by the court to send the part of the sample kept for comparison to an independent analyst. The analysis must be reported to the court. The cost of the analysis will be the expense of the Territory unless the court makes an order under clause 175, Court may order costs and expenses.

Chapter 12 Regulations about regulated substances and regulated therapeutic goods

This chapter sets out the regulation-making powers. To provide greater flexibility, the Medicines, Poisons and Therapeutic Goods Regulation expands upon the regulatory framework created by the Bill.

Clause 183 defines a regulated thing to be a regulated substance or regulated therapeutic good. The executive may make regulations for this Act and the regulation may create offences with maximum penalties of no more than 30 penalty units (clause 184).

A regulation may be made with respect to a regulated thing (clause 185); to authorisations (clause 186); the keeping of records electronically (clause 187); the medicines advisory committee (clause 188); the application of an instrument made by another instrument (clause 189); and the exemption of people, dealings and regulated things from the Act (clause 190).

Chapter 13 Miscellaneous

This chapter contains some miscellaneous provisions, concerning such matters as directions that can be made and guidelines issued by the Chief Health Officer (clauses 191 and 192); the approval of non-standard packaging and labelling by the Chief Health Officer (clause 193); the determination of fees (clause 197) and approved forms made under the Act (clause 198).

Clause 194 creates the Medicines Advisory Committee (MAC). This committee currently exists as the Drugs Advisory Committee (DAC) under the Drugs of Dependence Act. The DAC is integral to the authority process for the prescribing of drugs of dependence. The DAC is authorised to approve and to review approvals made by the Chief Health Officer. The DAC is to be remade as the MAC, with the members of the DAC to be taken to be a member of the MAC unless the person's appointment is ended under this Act (clause 551).

Clause 195 Secrecy

This clause is a standard clause requiring that any protected information about a person obtained through the exercise of regulatory functions to be protected by Government officers.

Clause 196 Protection of officials from liability

This clause is a standard clause providing officials protection from liability for performing acts done or omitted to be done honestly and without recklessness in the exercise of a function or in reasonable belief exercised under this Act. Any civil liability attaches to the Territory.

Chapter 14 Transitional

Given the complexity of reforming a number of Acts and regulations and the necessity of allowing licences and authorisations made under those Acts to continue until replaced by new licences and authorisations, transitional provisions have been included in this Bill.

Clause 501 is a power to make regulations dealing with transitional matters and makes it clear that the regulations can modify the operation of this chapter of the Bill so that it covers any matter the executive believes to have been inadequately dealt with by this chapter. The purpose of this provision is to facilitate a smooth transition to the new legislation. A clause of this nature is usually included when an enactment is being repealed and replaced. It ensures that any matters that may have been inadvertently omitted when developing the Bill or transitional provisions can be dealt with appropriately. This is necessary in order to facilitate a smooth transition from the old scheme to the new scheme.

Clause 503 provides that chapter 14 expires two years after commencement day of the Act. The purpose of this provision is to ensure that transitional provisions are not retained on the statute books for any longer than necessary.

Clause 510 provides that schedule 2 makes amendments to various legislation as a result of the Bill.

Clause 511 provides for the repeal of the Poisons Act, the Poisons and Drugs Act and Public Health (Prohibited Drugs) Act; regulations made under the Poisons Act and the Poisons and Drugs Act. A number of instruments, including approved forms, made under the Drugs of Dependence Act are also repealed. The Drugs of Dependence Act is not repealed by this Bill. The continuing effect of the Drugs of Dependence Act is explained in Schedule 2.

Part 14.3, 14.4 and 14.5 provide that licences, authorisations (including prescriptions) and approvals that were in force under the various Acts just before the proposed Act commences will be regarded as continued under this Act. The part also provides that any uncompleted applications may be continued under this Act. Clause 524 provides that if an AAT review has not been completed at the time of commencement of the Act, the proceeding may be continued as if it related to a licence under this Act.

Schedule 1 Chief Health Officer's decisions reviewable by AAT

Schedule 1 identifies decisions by the Chief Health Officer under the Act that are reviewable by the Administrative Appeals Tribunal (the AAT). The decision making power is devolved to the Chief Health Officer, a statutory position created under the *Public Health Act 1997*, in preference to the chief executive.

Schedule 2 Consequential and other amendments

A number of amendments to Acts and regulations have been made to remove references to the repealed Poisons Act, the Poisons and Drugs Act and Public Health (Prohibited Drugs) Act; and to those provisions repealed from the Drugs of Dependence Act. Redundant provisions are also omitted. The majority of the amendments adjust the terminology used in the repealed legislation to reflect the change from the old scheme to the new scheme. This includes new or revised definitions of regulated substances and regulated therapeutic goods.

The *Crimes Act 1900* is amended to incorporate offences related to anabolic steroids that are currently in the Poisons and Drugs Act.

The Drugs of Dependence Act, as amended, will continue to provide for the Simple Cannabis Offence Notice Scheme, manufacturing etc and enforcement of offences by police officers. These provisions will eventually be moved to a new Bill to be developed by the Department of Justice and Community Safety to consolidate the law relating to the search, seizure and enforcement of certain offences in the ACT. The Act will also continue to provide for part 9, Treatment. This part, which concerns treatment of drug-affected offenders, is currently part of a review of diversion programs by ACT Health.

A provision removed from the Drugs of Dependence Act is for the analysis of drugs and the appointment of the Government Analyst and Analysts. These provisions are to be inserted into the Public Health Act. As a consequence, the *Animal Diseases Act 2005*, *Environment Protection Act 1997* and *Food Act 2001* are amended to refer to an analyst appointed under the Public Health Act. To ensure analysis can be performed under the various Acts which authorise the analysis, section 15A, Pubic Health Act, is amended to authorise an appointed analyst to be an authorised analyst for the Public Health Act, the Drugs of Dependence Act, Food Act, and this Act. A new section 15AA is to be inserted to give authority to an analyst or an assistant to do anything necessary to be done within the scope of their employment to carry out an analysis. New section 135A provides for the certificate of the analysis.

The *Health Act 1993* is amended to include a restriction on pharmacies in supermarkets currently contained in the Health Professionals Regulation 2004.

The *Health Professionals (Special Events Exemptions) Act 2000* is amended to recognise the Medicines, Poisons and Therapeutic Goods Act, and the term prescription medicine, rather than the Poisons Act, the Poisons and Drugs Act and the Drugs of Dependence Act.

Provisions relating to the supply of syringes, also from the Drugs of Dependence Act, have been inserted into the Public Health Act.

Dictionary

The Dictionary contains definitions of terms used throughout the Act. Definitions within the Dictionary include *dispense*, *drug-dependant person*, *hospital*, *institution, opiod dependency treatment centre*, *prescribe*, *prescription, residential aged care facility* and *standing order*.