Explanatory Memoranda

Medicines, Poisons and Therapeutic Goods Bill 2013

For the purposes of the Explanatory Memoranda only, the term "handle" may be used for ease of description in describing a person undertaking the administering, or possessing, or prescribing or supplying or using or a combination any of these acts in relation to medicines or poisons.

Part 1 Preliminaries

Cl 1 **Short Title -** Self explanatory

Cl 2 **Commencement -** Self explanatory

Cl 3 **Terms used**

adopted code defines a set of rules or guidelines adopted by regulation that are derived from an authoritative source;

Agvet Code of Western Australia means a code included in the *Agricultural and Veterinary Chemicals (Western Australia) Act 1995* for the "*handling*" of pesticides and veterinary medicines in Western Australia;

authorised health professional means a health professional who has authority to administer, possess, prescribe, supply or use a medicine. This may include a veterinarian, treating an animal.

CEO means the chief executive officer of the department administering this Act;

compliance notice means a written notice issued to a person under section 70 imposing restrictions on them supplying of Schedule 5 and 6 poisons;

corporate officer is used within the text in reference to a body corporate and has the same meaning as section 9 of the *Corporations Act 2001*;

Department means the department administering this Act;

drugs of addiction record means a record retained by the chief executive officer on the supply and prescribing of drugs of addiction to drug dependent persons and over supplied persons;

health professional is a person who is registered as a health practitioner under the *Health Practitioner Regulation National Law (Western Australia*) 2010 (medical practitioner, dentists, nurses, pharmacists) plus veterinarians.
Provision is also made for the inclusion of selected classes of health professionals defined by regulation.

Investigator defines persons (public servants, environmental health officers, police officers) who perform investigations under this Act;

licence means a licence granted to either manufacture or supply a poison;

licensee means a person holding a licence to manufacture or supply a poison;

manufacture means the production of a poison including the cultivation of a plant, the making a preparation and testing, packing and labelling of the substance;

medicine defines the subset of substances within poisons that are used as medicines;

needle and syringe programme means the carrying on of the activities of:
supplying sterile hypodermic syringes or needles or spoons; or
facilitating the safe disposal of used hypodermic syringes or needles or
advising, counselling or disseminating information for the purpose of preventing the spread of blood borne infectious diseases;

permit means an authority to use a poison in accordance with the regulations;

permit holder means a person holding a permit to use a poison within the regulations;

pharmacist is a person registered as a pharmacist under the *Health Practitioner Regulation National Law (Western Australia*) 2010;

pharmacy means a premises registered as a pharmacy under the *Pharmacy Act* 2010;

poisons means a substance that has been classified according to its impact on public health and or safety into a particular schedule – Schedules 2, 3, 4, 5, 6, 7, 8 or 9;

prescribe means the issuing of a prescription;

prescriber is an authorised health professional who has authority to prescribe by the issuing of a prescription a Schedule 4 or 8 poison;

prescription means the setting out of the specific particulars (either written or electronic) of a Schedule 4 or 8 medicine to be used or administered to a person or animal for therapeutic purposes. It is issued for the purpose of enabling the supply of the particular Schedule 4 or 8 from a pharmacist or other authorised health professional**;**

professional authority means a formal authorisation:
to administer, possess, prescribe, supply or use a (Schedule 2, 3, 4 or 8) medicine or
to manufacture a medicine or
to use or possess a Schedule 7 poison;

register is a system of recording by the CEO of licences, permits and notices granted and the names of the health professionals whose professional authority is restricted in some way;

registered health practitioner means a health practitioner who is registered to practice a specific health profession under the Health Practitioner Regulation National Law;

Schedule 2 poison this sub clause is self explanatory;

Schedule 3 poison this sub clause is self explanatory;

Schedule 4 poison this sub clause is self explanatory;

Schedule 5 poison this sub clause is self explanatory;

Schedule 6 poison This sub clause is self explanatory;

Schedule 7 poison this sub clause is self explanatory;

Schedule 7 notice means an authority to restrict the supply, use or possession of a Schedule 7 poison. The restriction may be imposed on an individual or a class of individuals;

Schedule 8 poison this sub clause is self explanatory;

Schedule 9 poison this sub clause is self explanatory.

strictly controlled substance means substances that require strict controls to protect the health, safety and welfare of the public. Some substances may be exempt, for example industrial hemp

substances this sub clause is self explanatory;

supply means to facilitate the transfer of a poison or poisonous substance from one person to another (or animal) but does not include the act of administering the substance to a person or animal.
The definition of supply includes when one agrees to supply, makes available, advertises or has in ones possession with intent to supply.

Therapeutic Goods Law (WA) means the sections of the Commonwealth *Therapeutic Goods Act* 1989 adopted as law within Western Australia;

veterinary surgeon this sub clause is self explanatory.

Cl 4 **Poisons** This provision sets out the various categories of poisons that form part of a national standard of uniform medicines and poisons (SUSMP) into which substances are classified.

(1) Provides for the Governor to make regulations for the classification of substances into nine distinct schedules, dependent upon their risk to public health. The classifying of substances is dependent upon their risk to public health;

Schedule – 1 left deliberately blank.

Schedule 2 – Pharmacy medicines are a category of medicines that may require advice from a pharmacist but may be supplied by a person who holds a licence.

Schedule 3 – **Pharmacist only medicines** provides for the category of medicines that are only sold in pharmacies. Such medicines may be supplied without a prescription.

Schedule 4 – Prescription only medicines, or Prescription Animal Remedy are a category of medicines that must be prescribed by a health professional and supplied by a pharmacist.

Schedule 5 – Caution provides for the category of poisons with low potential for causing harm such as pesticides, household cleaning products and some veterinary medicines.

Schedule 6 – Poison provides for poisons with a moderate potential for causing harm. They are likely to be more toxic than those in Schedule 5.

Schedule 7 – Dangerous Poison provides for substances that have a high potential for causing harm to humans and/or animals and therefore require special precautions in their handling.

Schedule 8 – Controlled Drug are a category of medicine that in their handling requires strict controls to reduce abuse, misuse and physical or psychological dependence.

Schedule 9 – Prohibited Substances are a category of substances that the manufacture, possession, sale or use of is prohibited, except in limited circumstances with the approval of the CEO

(2) Provides for the Minister to identify a substance by regulation in any way.

(3) Provides for the Minister to adopt a particular code. It also provides for the Minister to classify a substance by reference to any way, purpose or quantity a substance is used or presented.

(4) Defines the factors that are used to describe a substance when including the substance in a schedule.

(5) This provides for the exemption of industrial hemp from being classified as a poison.

Cl 5 **Strictly controlled substances –** This clause provides for the classification of substances that require strict controls to protect the health, safety and welfare of the public. These substances may be scheduled under the SUSMP but require additional controls to protect the health, safety or welfare of the public.

(1) Provides for the Governor to make regulations for strictly controlled substance.

(2) Provides for exemption of industrial hemp from the category of strictly controlled substances.

(3) Limits the powers of the Minister to only recommend substances that she or he is satisfied are a serious risk to health and safety.

(4) Allows for the Minister to remove substances from the category of strictly controlled substance if he or she is satisfied that such a control is no longer necessary to protect the health, safety and welfare of the public.

(5) Provides a transition period for a substance that was previously in a poison schedule to transition from a poison to the new category of "strictly controlled substance".

(6) Defines the term ***control day*** to be the day on which the provision comes into operation.

(7) Requires the CEO to take all reasonable steps to notify licensees, permit holders or authorised health professionals of a substance's change of status from a poison to a strictly controlled substance under this section.

Cl 6 **Term used: manufacture –** This provision defines the various activities of manufacturing.

(1) Defines the activities that constitute the manufacture of a poison. As well as producing the poison or bringing it to its final state, manufacturing can also include such activities as cultivating the plant, making a preparation that includes the poison, and testing, packaging, labelling and storing.

(2) Describes the activities a person may undertake that are considered to be manufacturing and includes agreeing to manufacture, advertising to manufacture or having all the necessary equipment or materials to manufacture.

(3) Provides for the quantity of the poison; the purpose for which is was manufactured. It is immaterial if the person is acting as an employee or agent in determining whether a person is "manufacturing".

Cl 7 **Term used: prescription and related terms –** This provision describes the mechanisms whereby a health professional authorises the supply of a Schedule 4 or Schedule 8 medicine to a person or an animal for a therapeutic purpose.

(1) ***prescribe*** means the issuing of a prescription.

prescriber means a health professional who is authorised to prescribe a Schedule 4 or Schedule 8 medicine.

prescription means a document (written or electronic) issued for the purpose of enabling the supply of a Schedule 4 or Schedule 8 medicine for therapeutic purposes.
A prescription sets out the details of the medicine such as the name of the medicine, the dosage and quantity plus the name of the person or animal being treated.

(2) Provides for a supplier (e.g. a pharmacist) to issue a form authorising a supply in accordance with the prescription beyond the initial supply, where the prescriber has authorised multiple supplies of the medicine.

(3) Defines the circumstances whereby supply is considered to be ***in accordance with a prescription***.
These circumstances are that the supplier has the prescription, that the person to whom they supply is the person named on the prescription or the owner of the animal named on the prescription or a person who represents the individual or the owner of the animal and the quantity supplied is no more than that stated on the prescription.

(4) Allows for the supply of any brand of a Schedule 4 or Schedule 8 medicine where the prescription does not specify a specific brand, rather a generic name is used.

(5) Provides for the substitution of a brand of a Schedule 4 or Schedule 8 medicine other than that named in the prescription under certain circumstances. These circumstances are where the person is a patient in a public hospital or, in the private sector, only where the prescription makes reference to brand substitution NOT being allowed.

Cl 8 **Term used: supply –** This provision defines the activities and actions that constitute the transfer of medicines and poison from one person to another.

(1) Provides that administering a poison directly to another person or animal is not defined as supply.

(2) Defines the activities that constitute supply of a poison. These activities are broader than the physical act of supplying and include amongst other things agreeing to supply, advertising and displaying with a view to supplying.

(3) Articulates that the supply of a poison is considered to have occurred regardless of the quantity supplied, the purpose, whether an exchange of money occurs, the location of the supply or the method of supply.

Cl 9 **Supply and possession of poisons by pharmacy business** This provision ensures that it is known which pharmacist at a pharmacy business is responsible for the possession and supply of poisons at that pharmacy.

(1) Defines a pharmacy business by reference to the *Pharmacy Act* 2010 under which pharmacies are licensed.

(2) Provides for the pharmacist, with overall responsibility at a pharmacy business, as defined by the *Pharmacy Act* 2010, to also be responsible for the supply and possession of poisons by that pharmacy business.

Cl 10 **Relationship with *Misuse of Drugs Act* 1981 -** This provides for the provisions in this Act to prevail when there is an inconsistency with the *Misuse of Drugs Act* 1981

Cl 11 **Act applies to the State -** Self explanatory

Part 2 – Offences

This part codifies the various offences for the mishandling of poisons and other substances controlled by the Act.

Cl 12 Terms used

appropriate licence is one which is issued either under this Act or under an equivalent regulatory framework.

appropriate permit is one which is issued either under this Act or under an equivalent regulatory framework.

Cl 13 Offences relating to manufacture and supply of Schedule 2 and Schedule 3 poisons – This provision relates to offences associated the mishandling of medicines that do not require a prescription but may require advice from a pharmacist or supplied under licence.

(1) Describes the circumstances under which a Schedule 2 or 3 medicine can be manufactured or supplied.

(2) Provides for a situation whereby a person may supply for therapeutic purposes a Schedule 2 or 3 medicine to a patient in the absence of an appropriate licence or professional authority.

(3) Provides for the circumstance where a person may supply a Schedule 2 or 3 medicine to an agent for administration or supply to a patient for therapeutic purposes in the absence of an appropriate licence or professional authority.

(4) Places a duty on the holder of an appropriate licence or a professional authority not to supply a Schedule 2 or Schedule 3 medicine if they reasonably suspect the recipient might use it in a way that will pose a serious risk to a person or the public.

Cl 14 Offences relating to manufacture, supply prescribing and possession of Schedule 4 and Schedule 8 poisons – This provision relates to offences associated with medicines that are subject to strict controls in their manufacture, supply, prescribing and possession.

(1) Describes the circumstances under which a Schedule 4 or Schedule 8 medicine can be manufactured or supplied. The regulations will include the conditions under which each prescribed group can manufacture or supply such a medicine.

(2) Describes the special circumstances which must be in place when supply is made to a patient or their agent.

(3) Requires that only an authorised health professional can prescribes a Schedule 4 or Schedule 8 medicine. It also requires that in writing a prescription the authorised health professional is aware of and complies with requirements specified in the regulations.

(4) Prescribes the circumstances under which possession of a Schedule 4 or Schedule 8 medicine is lawful.

(5) This provision allows a "*carer*" to have lawful possession (Clause 4(e) above) of a Schedule 4 or Schedule 8 medicine. The carer may be in a paid or unpaid capacity, providing or assisting either full-time or part-time in the care of the patient.

Cl 15 **Offences relating to manufacture and supply of Schedule 5 and Schedule 6 poisons –** This provision relates to offences associated with the manufacture or supply of substances that have the potential to cause harm to the public or animals if misused.

(1) Describes the circumstances under which a Schedule 5 or Schedule 6 poison can be manufactured or supplied.

(2) Places a duty on a supplier of a Schedule 5 or Schedule 6 poison not to supply the particular poison if they reasonably suspect or ought reasonably the recipient intends to use it in a way that may pose a serious threat to the health, safety or welfare of a person or the public.

Cl 16 **Offences relating to manufacture, supply, use and possession of Schedule 7 poisons** – This provision relates to offences associated with the handling of substances that have high potential to cause serious harm to the public or animals if misused.

(1) Describes the circumstances under which a Schedule 7 poison may be manufactured or supplied.

(2) Describes the circumstances under which a Schedule 7 poison may be possessed or used. This subclause includes provision for possession and use by licensed pesticide management technicians, officers of certain government departments as well as those covered by any Schedule 7 notice such as primary producers.

(3) Places a duty on a supplier of a Schedule 7 poison not to supply the particular poison if they reasonably suspect or ought reasonably suspect the recipient intends to use it in a way that may pose a serious risk to the health, safety or welfare of a person or the public.

Cl 17 **Offences relating to manufacture, supply, use and possession of Schedule 9 poisons** – This provision relates to offences associated with handling of these prohibited substances. These prohibited substances may be used only under strict supervision, in rare circumstances for medical or scientific research or for analytical, teaching or training purposes.

It also provides a defence if the Schedule 9 substance is in or on a syringe or thing in accordance with a needle and syringe programme.

Cl 18 **Offences relating to supply and use of strictly controlled substances –** This provision relates to offences associated with the supply and use of particular substances that require stricter controls in their handling to protect the health, safety and welfare of the public

(1) Prevents the supply of a strictly controlled substance unless the supplier has been authorised by the CEO or the supplier is authorised under regulation.

(2) Prevents the use of a strictly controlled substance unless the person has been authorised by the CEO or is part of a class of individuals authorised under regulation.

(3) Provides a defence for an authorised supplier where a substance's classification changes from a poison to a strictly controlled substance and the accused did not know and could not have known of the substance's change of status.

(4) Provides a defence for an authorised user where a substance's classification changes from a poison to a strictly controlled substance and the accused did not know and could not have known of the substance's change of status.

(5) Provides a defence for a person using a lawfully prescribed Schedule 4 or 8 medicine which is subsequently reclassified as a strictly controlled substance, to continue using the substance in accordance with the prescription.

(6) Provides a defence for a person who uses a Schedule 5, 6 or 7 poison which is reclassified at a later date as a strictly controlled substance and the accused person did not know and could not have known of the substance's change of status.

Cl 19 **Use of a poison obtained under a permit –** This provision relates to offences for the misuse of a poison other than in accordance with the purpose and manner specified in the permit and in accordance with the any regulation. This provision places an onus on the permit holder to *use* a poison in the way defined by the permit.

Cl 20 **Unlawfully obtaining by wholesale** – This provision relates to an offence associated with obtaining a poison from a wholesaler unless certain conditions are met.

(1) Provides the circumstances when a person may obtain or attempt to obtain a wholesale supply from a licence holder, permit holder or an authorised health professional.
Sub clause 1 exempts the supply of Schedule 5 or 6 poisons from the provision.

(2) Extends the provisions of this offence to whether the poison was obtained or attempted to be obtained beyond the jurisdiction of this state.

Cl 21 **Fraudulent behaviour to obtain supply of poison** – This provision relates to offences associated with the use or attempted use of fraudulent means to obtain a poison.

(1) Creates an offence for the fraudulent altering of a prescription or to have in one's possession a prescription the person suspects or ought reasonably suspect has been altered.

(2) Provides a defence for a pharmacist who is given what s/he suspects is a fraudulently altered prescription.
Sub clause (b) places an onus on the pharmacist to forward the alleged fraudulent prescription to the CEO.

(3) Creates an offence for a person who uses or attempts to use fraudulent means to convince a health professional or licensee to prescribe or supply a poison.

(4) This sub clause defines the term ***fraudulent means.***

Cl 22 **Storage, handling, transport and disposal of poisons** – This provision creates an offence in relation to the storage, handling, transport and disposal of poisons.

(1) Provides that a person who is involved in the storage, handling, transport and disposal of poisons must comply with the regulations.

(2) Allows for regulations to prescribe the manner in which poisons may be stored, handled, transported or disposed.

Cl 23 **Record keeping and reporting** – This provision creates a penalty for not recording the manufacture, supply, use, prescribing or possession in a prescribed manner.

(1) Requires the licensee, permit holder or authorised health professional to keep records in a prescribed manner and to forward copies of this information to the CEO as prescribed.

(2) Creates a penalty for the entry in a record or the use of information from a record if the person knows the information is false or misleading in a material particular.

Cl 24 **Vending machines –** This provision relates to an offence associated with the remote supply of certain poisons in controlled amounts in prescribed location without the direct intervention of the licensee, permit holder or authorised health professional.

(1) Defines the terms used in this provision including:
responsible person to mean the person having the management or control of premises where a vending machine is located; and
vending machine means a machine or device that dispenses the controlled amounts of the poisons

(2) Places a duty on the responsible person within premises where a vending machine is located to only supply the poison in accordance with the regulations.

(3) This sub clause places an additional burden on a person who holds a licence or a professional authority and who has a vending machine located on their premises to similarly comply with the duty to only supply the poison in accordance with the regulations prescribed at sub clause 5.

(4) Places a duty on person to only place or authorise the placement of a vending machine within a premises in accordance with the regulations.

(5) This sub clause sets the parameters of the regulations which may prescribe the circumstances in which poisons may be supplied or the premises where the vending machine may be located.

Part 3 – Authorisation of health professionals

This part sets out the circumstances and conditions whereby a health professional may administer, possess, prescribe, supply or use a medicine.

Part 3 Division 1 – Authorisation of health professionals

This division sets out the authorities whereby a health professional may administer, possess, prescribe, supply or use a medicine.

It also allows for a pharmacist to manufacture a medicine.

Cl 25 **Authorisation of health professionals to administer, possess, prescribe, supply or use a medicine** – This provision provides the parameters under which a health professional may be authorised to administer, possess, prescribe, supply or use a medicine.
This authorisation would apply to a person who is registered under the Health Practitioners National Law (WA); veterinarians and selected classes of health practitioners that are defined by regulation.

(1) This sub clause defines the parameters associated with a health professional administering, possessing, prescribing, supplying or using a medicine. These include that he or she must operate:

- within the lawful practice of a (health) profession, and
- within a prescribed class of health professionals, and
- the specific medicine is prescribed as one that a health professional from that prescribed class may administer, possess, prescribe, supply or use; and
- the administration, possession, prescription, supply or use of the medicine is in accordance with regulations.

(2) This sub clause provides for regulations to prescribe the circumstances, manner and conditions which may be placed upon a health professional from a prescribed class of health professionals in administering, possessing, prescribing, supplying or using a medicine.

Cl 26 **Authorisation of pharmacists to manufacture medicines or use or possess Schedule 7 poisons** – This provision allows for a pharmacist to extemporaneously prepare medicines and to possess a Schedule 7 poison. Such medicines are not commercially available.

(a) This sub provision provides a pharmacist, acting in the lawful practice of his or her profession to manufacture a medicine extemporaneously and supply the prepared medicine to an individual. This could be under prescription from a medical practitioner or on the pharmacists diagnosis.

(b) This sub provision provides a pharmacist, acting in the lawful practice of his or her profession to use or possess a Schedule 7 poison that is an ingredient in a therapeutic good for the purpose of extemporaneously preparing the therapeutic good.

Cl 27 **Authorisation of employees and agents –** This provision authorises an employee or agent to act on behalf of the health professional employer or as an agent on behalf of a principal health professional but only to the extent of the health professional's authority.

(1) This provision authorises for an employee or agent acting within the scope of their authority and the professional authority of the health professional to act on behalf of the health professional *except that of prescribing a medicine.*

(2) Provides for the actions of an employee or agent of a health professional to be taken to have been carried out by the authorising health professional.

Part 3 Division 2 – Conditions, suspensions and cancellations

This division sets out the powers of the CEO of the relevant Department to restrict and monitor the handling of scheduled medicines by authorised health professionals. This power only relates to the health professional authority to administer, manufacture, possess, prescribe, supply or use a poison.

Cl 28 **Grounds for taking action** – The clause sets out the circumstances when the CEO may take action in relation to an authorised health professional.

(1) Defines the grounds for taking action against an authorised health professional or their employee or agent; including contravention of the stated Acts which control activities in relation to poisons or behaviours or conduct in relation to the handling of poisons.

(2) This sub section provides a defence for the authorised health professional if he or she can substantiate that they had no knowledge of the conduct of the employee or agent or had taken all reasonable measures to prevent the employee or agent from engaging in the conduct.

(3) This sub provision allows an authorised health professional to self report inappropriate behaviour or conduct in the handling of a poison and seek that action be taken.

Cl 29 **CEO may impose conditions, suspend or cancel authority** – This clause sets out the parameters for the CEO to restrict the handling of scheduled medicines by the authorised health professional.

(1) Provides for the CEO, after concluding there are grounds for taking action, to notify the health professional of the intended action. The action may be to impose a condition on the person's professional authority, suspend the person's professional authority to handle a poison for a specified period or cancel the person's professional authority to handle a poison.

(2) Self explanatory

(3) Provides for a condition to be placed on the professional authority of a health professional to prohibit their handing of a particular poison or class of poisons.

(4) Requires that the CEO give written notice to the health professional that he/she proposes to take action and the grounds for that action.
Sub para (b) requires the CEO to give the health professional a reasonable opportunity to respond to his/her intent to place a condition on the health professional's practice.

(5) Provides for the CEO to override Clause 4 and take immediate action to impose a condition, suspend or cancel a person's professional authority in order to protect the health, safety and welfare of the public.

(6) Describes the responsibilities of the CEO to the health professional if he/she takes the immediate action provided for in Clause 5.

(7) Provides the CEO with the power to amend or revoke a condition, suspension or cancellation on a professional authority by way of a written notice issued to the health professional.

(8) Provides the power to amend or revoke the restriction on the CEO's own initiative or on the request of the authorised health professional.

Cl 30 **Effect of conditions, suspension or cancellation** – This provision articulates that any restriction placed on the health professional by the CEO is limited to the specific granted to them under either sections 25 or 26.

Cl 31 **CEO may notify regulatory authority if action taken under this Division** – This clause provides the CEO with the authority to inform the health professional's registration authority of any restriction he or she has placed on the health professional's handling of poisons and the reason for placing that restriction.

Cl 32 **Publishing notice of action taken under this Division** – This provision allows the CEO to publish a notice in the Government Gazette or the CEO's website indicating that he/she has taken action against an authorised health professional under Division 2.

Cl 33 **Review of decisions by State Administrative Tribunal** – This provision provides for the health professional to apply to the State Administrative Tribunal for a review of any decision by the CEO to restrict the health professional's handling of poisons and also defines what decisions are reviewable.

Part 4 – Licences, permits and notices

This part outlines the parameters for the issuing, amending, restricting, reviewing, and recording of licences, permits and notices for the handling of poisons.

Licences, permits and notices are primarily used to provide authority to non-health professionals in their handling of poisons.

Part 4 Division 1 – Licences and permits

This division outlines the parameters for the issuing, amending, restricting, reviewing, and recording of licences and permits.

Cl 34 **Licences** – This clause provide a person, partnership or body corporate with the authority to manufacture or supply a poison. The licence to manufacture or supply can be poison specific or activity specific.

(1) Provides the authority for the licensee to manufacture or supply a poison in accordance with the issued licence.

(2) Provides for the development of regulations for the different types of licence. These may allow the licensee to manufacture and supply by retail or wholesale.

(3) Requires for the licence to stipulate the poison to which the license applies and the activities that may be carried out under the licence.

(4) Provides for an employee or agent acting within the scope of their authority to act on behalf of the licensee to the extent of the authorisation of the licence.

(5) Provides for the actions of an employee or agent to be interpreted as having been carried out by the licensee.

Cl 35 **Licence for Schedule 9 poisons** – This clause provides for the granting of a restricted licence to manufacture or supply a Schedule 9 poison for educational, experimental or research purposes. Additional purposes to those cited may be prescribed by regulation.
Sub-clause (b) prevents the supply by retail of a Schedule 9 poison.

Cl 36 **Permits** – This clause sets out the parameters for the issuing of a permit to a person, partnership or a body corporate in order for them to use a poison.

(1) Provides the authority for the permit holder to use a poison in accordance with the issued permit.

(2) Provides for the development of regulations for the different types of permit.

(3) Requires for the permit to stipulate the poison to which the permit applies, the purpose for which the poison may be used and the manner in which it will be used by the permit holder.

(4) Provides for an employee or agent acting within the scope of their authority to act on behalf of the permit holder to the extent of the authorisation of the permit.

(5) Provides for the actions of an employee or agent to be interpreted as having been carried out by the permit holder.

Cl 37 **Permits for Schedule 9 Poisons** This clause provides for the authorisation of a permit to use a Schedule 9 poison for educational, experimental or research purposes or for a purpose prescribed by regulation.

Part 4 Division 2 – Licensing and permit procedure

This division outlines the protocols to be carried out by both parties in applying, granting, renewing and varying a licence or permit, including any applicable type of fee.

Cl 38 **Application for licence or permit or renewal of licence or permit** – This clause sets out the parameters for an application or renewal of a licence of permit.

(1) Provides for a person to apply to the CEO for a licence or permit or the renewal of a licence or permit.

(2) Provides authority for the CEO to set the format of applications for licences and permits.
Sub-clause (b) provides for the charging of a prescribed application fee and a separate licence or permit fee.

(3) Places an onus on the CEO to refund the licence or permit fee only if a licence or permit is not granted or renewed.

Cl 39 **Further information –** This clause provides for the CEO to insist on additional information from the applicant in order to process an application. This may include time limits or the production of a statutory declaration. Sub clause (3) allows for the CEO to refuse the application if the information is not forthcoming.

Cl 40 **Timing of application for renewal of licence or permit** – This provision articulates the duties of the renewing licensee or permit holder and the CEO in processing a renewal.

(1) Self explanatory
(2) Requires that the applicant applies for renewal not less than 28 days before their licence or permit is due to expire.

(3) Provides for an exemption from the 28 day pre licence expiry date requirement if the CEO is satisfied that there is sufficient time to process the renewal prior to the expiry date.

(4) Provides for the continuation of the licence or permit where a valid renewal application has been lodged unless the CEO has taken deliberative action to suspend or cancel the licence or permit.

Cl 41 **Grant or renewal of licence or permit to individual** – This provision sets out the conditions an individual needs to fulfil to be considered for the granting or renewal of a licence or permit.

(1) ***relevant activity***. in the case of a licence such authorised activities may be the manufacture, sale by wholesale, sale by retail, or sale through a broker of a poison. *Relevant activity* in relation to a permit is authorised use that may vary and include such activities as laboratory testing, gold extraction, or medical treatment of employees.

sufficient is defined to include not only compliance with the legislation but also an understanding of the impact on the health, safety and welfare of a person or the public.

(2) Stipulates the requirements an applicant must fulfil to the satisfaction of the CEO before the granting or renewal of a licence or permit.

These requirements include among others: the personal attributes of being a fit and proper person, having sufficient knowledge of each poisons, the duties and obligations of a licensee or permit holder, and the business attributes of sufficient material, human and financial resources as well as those relating to the premises where the activities will be carried out.

Additional requirements may be prescribed by regulation.

(3) Places an onus on the CEO not to grant or renew a licence or permit unless he/she is satisfied that the applicant fulfils the requirements.

Cl 42 **Grant or renewal of licence or permit to partnership** – This clause sets out the conditions a partnership needs to fulfil to be considered for the granting or renewal of a licence of permit.

(1) Stipulates the requirements a member of a partnership must fulfil before the granting or renewal of a licence or permit and in addition provides for other requirements to be prescribed by the regulations.

These requirements include the personal attributes of being fit and proper persons, plus having sufficient knowledge of each poison, and the duties and obligations of a licensee or permit holder and or sufficient human and financial resources.

(2) Places an onus on the CEO not to grant or renew a licence or permit unless he/she is satisfied that the applicant fulfils the requirements.

Cl 43 **Grant or renewal of licence or permit to body corporate** – This provision sets out the conditions a body corporate needs to fulfil to be considered for the granting or renewal of a licence or permit.

(1) Stipulates the requirements the body corporate and each corporate officer must fulfil before the granting or renewal of a licence or permit and in addition provides for other requirements to be prescribed by the regulations.

These requirements include the personal attributes of being fit and proper persons, plus having sufficient knowledge of each poison, and the duties and obligations of a licensee or permit holder and or sufficient human and financial resources.

(2) Places an onus on the CEO not to grant or renew a licence or permit unless he/she is satisfied that the applicant fulfils the requirements.

Cl 44 **Notice of decision** – Places an onus on the CEO to inform the applicant in writing of his or her decision and if the licence or permit is refused of the applicant's right of review.

Cl 45 **Form of licence or permit –** Self explanatory

Cl 46 **Duration of licence or permit –** Provides for licences and permits to be valid for a maximum of 12 months unless suspended or cancelled earlier.

Cl 47 **Licence or permit not transferable –** Self explanatory

Cl 48 **Application to vary licence or permit** – This provision sets out the procedures for the licensee or permit holder to request a variation of the licence or permit during the period for which it is valid.

(1) Provides for a licensee to vary their licence in relation to the poisons covered by the licence or the activities authorised by the licence.

(2) Provides for the permit holder to vary their permit in relation to the poisons covered by the permit or the purpose for or manner in which the poisons are used.

(3) Provides authority for the CEO to set the format of applications for variations to licences and permit and the imposition of a prescribed fee.

(4) Provides for the CEO to insist on additional information from the applicant to process an application for variation. Allows the CEO to refuse the application for variation if the information is not forthcoming.

Cl 49 **Variation of licence or permit** - This provision links the variation of a licence or permit to the criteria required by the CEO for the (original) granting of the licence or permit

(1) Stipulates the requirements an applicant (individual or body corporate) must fulfil before a variation to a licence or permit is granted and in addition provides for other requirements to be prescribed by the regulations.

(2) Places an onus on the CEO not to vary a licence or permit unless he/she is satisfied that the applicant fulfils the requirements.

Part 4 Division 3 – Conditions on licences or permits

Provides for the CEO to impose additional requirements on licences and permits. The conditions may be attached to individual licences or permits or to types of licences or permits.

Cl 50 **Regulations may prescribe conditions** – This provision allows for the creation of regulations prescribing conditions which are attached to particular types of licence or permit. In addition this provision allows for the CEO to exempt a particular licence or permit from the conditions that generally apply to that type of authority.

Cl 51 **CEO may impose conditions** – This provision allows for the CEO to impose conditions on licences and permits and articulates the procedures in relation to these conditions. The conditions may include directions on storage, disposal, record keeping and competencies of the person actually handling the substance.

(1) Provides authority for the CEO to impose any condition he or she thinks fit.

(2) Provides authority for the CEO to impose, amend or revoke a condition at any time, by issuing a written notice.

(3) Provides for the CEO to exercise his or her power independently or at the request of the licence or permit holder.

(4) Self explanatory

(5) Self explanatory

(6) Restricts the imposition of a condition until the licensee or permit holder has had reasonable opportunity to challenge the CEO's imposition or amending of conditions and take any action necessary to comply with the conditions.

Cl 52 **Application to vary conditions –** This provision allows for an application to be made to vary the conditions associated with a licence of permit.

(1) Defines the phrase ***application to vary conditions***.

(2) Provides authority for the CEO to set the format of applications for variations to the conditions in addition to allowing for the charging of a fee.

(3) Provides for the CEO to insist on additional information from the applicant to process an application for variation and allows the CEO to refuse the application for variation if the information is not forthcoming.

Part 4 Division 4 – Change of management or death of licensee or permit holder

This division sets out the procedures for approval or refusal of a change in the corporate officers within a body corporate and in the circumstances of the death of an individual licensee or permit holder. This division also includes an offence where approval for a change in the body corporate was not sought prior to that change taking place.

Cl 53 **Term used: change of management –** Defines the term for the purposes of this division to include, with respect to a body corporate, the replacement of a person who was or is a corporate officer.

Cl 54 **Unauthorised change of management –** This clause sets out the circumstances a body corporate must follow to ensure they do not have an unauthorised change of management. An unauthorised change of management may lead to the laying of offence charges.

(1) Creates the offence provision if there is a change of management in a body corporate that has not been given prior approval by the CEO via the usual application processes.

(2) Creates a defence for a licensee or permit holder that is a body corporate who did not know or could not reasonably be expected to have known of the change of management provided they follow the alternate process for approval of the change as described in Clauses 56 and 57, as soon as practicable. The defence also extends to the circumstance where the alternate application has been made under Clause 56 and the CEO is yet to complete consideration of the application.

Cl 55 **Application for approval of proposed change of management –** This provision sets out the parameters for making an application including the power to set an applicable fee.

(1) Self explanatory

(2) Prescribes the manner, form, details, date and possible fee required for making an application.

(3) Provides for an exemption from the 28 day pre change of management application requirement, if the CEO is satisfied that there is sufficient time to process the application prior to the change.

(4) Provides for the CEO to require the production of additional information from the applicant to process an application for variation and allows the CEO to refuse the application for variation if the information is not forthcoming.

Cl 56 **Grant or refusal of approval of proposed change of management** – This provision sets out the procedure the CEO must follow in granting or refusing the approval of a proposed change of management.

(1) Stipulates the requirements the proposed member of the body corporate must fulfil before the change is approved. These requirements include the personal attributes of being fit and proper persons, plus having sufficient knowledge of each poison, and the duties and obligations of a licensee or permit holder.

(2) Mandates that approval cannot be given for a change of management unless the CEO is satisfied that the proposed member of the body corporate fulfils all the requirements.

(3) Places an onus on the CEO to make a decision on the application or seek further information for a proposed change of management within the specified time. If a timely decision is not made, approval is automatic.

(4) Allows the CEO after seeking further information in order to make his or her decision, to extend the timeframe.

Cl 57 **Application for approval after change of management occurs –** This clause describes the manner, form, information and time period required for an application for a change of management within a body corporate where the change has already occurred. The provision also allows for the prescribing of a fee (if any) and an extension of time if further information is required by the CEO.

Cl 58 **Grant or refusal of approval of change of management** – This clause sets out the circumstances that must be in existence, to the CEO's satisfaction before he or she grants an application for a change of management made after the change has occurred.

Cl 59 **Death of individual licensee or permit holder** – This provision defines the processes that must be followed in the event of the death of an individual licensee or permit holder.

(1) Defines the terms ***executor*** and ***permission*** for this provision.

(2) Provides for the individual's executor to apply to the CEO for permission to act in the place of the licensee or permit holder for the purpose of winding up the estate.

(3) Self explanatory

(4) Places an onus on the CEO to either grant permission for a specified period or refuse to grant permission.

(5) Provides the CEO with the power to impose any conditions on the licence or permit held by the executor.

(6) Provides the CEO with the flexibility to extend or revoke the permission on the executor or the conditions on the licence or permit.

(7) Provides clarity over the exact dates that the executor is considered to be the licensee or permit holder.

Part 4 Division 5 – Amendment, suspension and cancellation

This division sets out the actions the CEO may take in amending, suspending or cancelling a licence or permit and the power to issue a notice of the action taken.

Cl 60 **Grounds for taking action** – This provision sets out the circumstances when the CEO can take action in relation to amending, suspending or cancelling a licence or permit.

(1) Defines the ***grounds for taking action*** against a licensee or permit holder or their employee or agent. These may include contravention of the various Acts which control activities in relation to poisons or various inappropriate behaviours or conduct in relation to the handling of poisons.

(2) This sub section provides a defence for the licensee or permit holder if he or she can substantiate that they had no knowledge of the conduct of the employee or agent or had taken all reasonable measures to prevent the employee or agent from engaging in the conduct.

(3) Provides additional grounds for the CEO to take action where incorrect or misleading information was given; where the CEO is no longer satisfied that the licensee or permit holder fulfils all the stipulated requirements including such things as being of good character, knowledge of the poison(s) and sufficient material, human and financial resources; or where the classification of the poison covered by the licence or permit has changed. There is also provision for the CEO to take action where the licensee or permit holder makes a request for such an action.

Cl 61 **CEO may amend, suspend or cancel licence or permit** – This clause sets out the parameters and protocols for the CEO to amend, suspend or cancel a licence or permit.

(1) Requires that the CEO give a written notice to the licensee or permit holder to amend, suspend or cancel their licence or permit, if he or she has formed the view that there are grounds for taking action.

(2) Describes the requirements for a notice that amends, suspends or cancels a licence or permit.

(3) Requires that the CEO gives written notice to the licensee or permit holder that he/she proposes to take action and the grounds for that action in addition to giving the licensee or permit holder a reasonable opportunity to respond.

(4) Provides for the CEO to take immediate action if required to protect the health, safety and welfare of the public.

(5) Describes the responsibilities of the CEO to the health professional if he/she takes immediate action.

(6) Self explanatory

Cl 62 **Publishing notice of action taken under this Division** – This provision gives the CEO the discretionary power to publish in the *Gazette* a notice of his or her action against a particular licensee or permit holder.

Part 4 Division 6 – Review of licensing and permit decisions

This division provides for specific decisions made by the CEO in relation to licences or permits to be reviewable by the State Administrative Tribunal.

Cl 63 **Review of decisions** – Defines the term ***person affected*** as being either the applicant or the licensee or permit holder and lists the specific decisions that are ***reviewable decisions*** .This clause also provides for a person with a right to seek a review by the State Administrative Tribunal.

Part 4 Division 7 – General provisions

This division defines a number of general provisions and creates three offences for non compliance associated with licences, permits or notices.

Cl 64 **False or misleading information** – This clause creates an offence for knowingly giving false or misleading information in relation to an application.

Cl 65 **Amendment to correct error** – This clause gives the CEO the power to correct errors and then give written notice of the amendment to the licensee or permit holder.

Cl 66 **Licence or permit to be produced if amended** – This clause provides that in the circumstance that a licence or permit is varied or amended to correct an error or has a condition added, removed or changed the licence or permit must be returned to the CEO and a replacement document issued.

Cl 67 **Replacement licence or permit** – Self explanatory

Cl 68 **Certified copy of licence or permit** – Self explanatory

Cl 69 **Production of licence or permit for inspection** – This provision creates an offence for a licensee or permit holder who fails to produce their licence or permit when asked to do so by an investigator.

Cl 70 **Return of licence or permit** – This clause creates an offence if the individual does not return a cancelled or suspended licence or permit as well as a duty on the CEO to return any suspended licence or permit at the completion of the suspension.

(1) Creates an offence for the non-return to the CEO of a cancelled or suspended licence or permit within 7 days.

(2) Creates a duty for the CEO to return a suspended licence or permit as soon as practicable after the suspension is lifted.

Part 4 Division 8 – Notices

This division provides for an additional mechanism for restricting the supply, use or possession of particular classifications of poisons – the Notice. The purpose for such notices is the safe guarding of public health.

Cl 71 **Compliance notices** – This provision allows for the CEO to issue a written notice to a person to restrict their supply of a Schedule 5 or 6 poison.

Cl 72 **Schedule 7 notices** – This provision enables the control of the supply, use or possession of Schedule 7 poisons (primarily pesticides).

(1) A Schedule 7 notice can apply to an individual or to a class of persons. If the notice applies to a class of persons it must be published in the *Gazette*. The restrictions associated with a Schedule 7 notice are to safeguard public health.

(2) Self explanatory

Cl 73 **Review of decisions** – This clause provides for an individual to whom a Schedule 5, Schedule 6 or Schedule 7 notice applies to seek a review of the decision from the State Administrative Tribunal.

Part 5 – Register of licences, permits, notices and restricted professional authorities

This part outlines the authority for the creation of and format for the maintenance of a record by the CEO of the licences, permits, and notices issued plus the restrictions a health professional may have associated with their authority to handle medicines.

Cl 74 **Terms used –** This clause links the terms used in this part to definitions used elsewhere and defines ***restricted health professional*** as a health professional whose authority to handle scheduled medicines is restricted. "Health professional" for the purposes of this Bill includes registered health practitioners, veterinarians and other classes of persons prescribed by regulation. Authority to handle scheduled medicines is normally linked to their registration as a health practitioner or veterinary surgeon.

Cl 75 **CEO to maintain register** – This clause requires the CEO to keep an accurate record of the information prescribed by the regulations in relation to licences, permits, notices and restricted health professionals.

Cl 76 **Inspection of register** – This clause places responsibilities on the CEO in relation to accessing the register.

(1) Provides authority for authorised health professionals, licensees and permit holder to access the register during normal office hours. To holders of appropriate licences or permits and authorised health professionals.

(2) Provides that the information may be available on an internet website.

(3) Requires the CEO to provide a copy or certified copy of all or any part of the register to the holder of an appropriate licence or permit or an authorised health professional on payment of a fee.

Part 6 – Application of Commonwealth therapeutic goods laws to Western Australia

This part ensures that natural persons trading therapeutic goods exclusively within this jurisdiction are subject to the same regulatory framework as corporations – inclusion on the Australian Register of Therapeutic Goods (ARTG). Only therapeutic goods deemed to be safe, efficacious and of high quality can be included on the ARTG.

Part 6 Division 1 – Preliminary

Cl 77 **Terms used –** This clause defines the terms used for this Part.

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Part 6 Division 2 – Application of Therapeutic Goods Law in this jurisdiction

This division defines the interaction between the Commonwealth *Therapeutic Goods Act* 1989 and particular Western Australian legislation that will constitute the Therapeutic Goods Law (WA) for the purpose of the *Medicines, Poisons and Therapeutic Goods Act* (WA) in order to regulate individuals who trade therapeutic goods solely within Western Australia.

Cl 78 **Application of Therapeutic Goods Law**

(1) Creates a new term, the **Therapeutic Goods Law (Commonwealth)** text which encompasses the Commonwealth *Therapeutic Goods Act* 1989 as well as any regulations, orders and manufacturing principles made under that Act.

(2) Provides for the Therapeutic Goods Law (Commonwealth) text to apply as law in this jurisdiction within the *Medicines, Poisons and Therapeutic Goods Act* and be referred to as the *Therapeutic Goods Law (WA*).

(3) Provides for a limiting context to the application of the Therapeutic Goods Law

(4) Provides for the modification of the Therapeutic Goods Law (Commonwealth) text through state-based regulation.

Cl 79 **Exclusion of legislation of this jurisdiction** –This provision excludes the Therapeutic Goods Law (WA) from the requirement to comply with the listed Western Australian Acts.

Cl 80 **Interpretation of *Therapeutic Goods Law (WA)*** – This provision requires a reference to Commonwealth legislation when interpreting the specific statutory provisions and regulations of the Therapeutic Goods Law (WA).

Cl 81 **No double jeopardy for offences under *Therapeutic Goods Law (WA)* and *Therapeutic Goods Act* 1989 (Commonwealth) –**– This provision links an offence committed under the Therapeutic Goods Law (WA) and the *Therapeutic Goods Act* 1989 (Commonwealth).
In addition it ensures the individual cannot be punished under both pieces of legislation.

Part 6 Division 3 – Application of Commonwealth laws to *Therapeutic Goods Law (WA)*

This division ensures that an individual subject to the *Therapeutic Goods Law (WA)* is subject to exactly the same regulatory requirements as a corporation is under the Commonwealth Therapeutic Goods.

Cl 82 **Application of Commonwealth administrative laws in relation to *Therapeutic Goods Law (WA)* –** This clause provides for the application of Commonwealth administrative law in the context of matters that may arise in relation to the *Therapeutic Goods Law (WA).*

(1) Commonwealth administrative law is to apply in relation to the *Therapeutic Goods Law (WA*) matters and although the *Therapeutic Goods Law (WA)* is Western Australian legislation it is applied and pursued as Commonwealth law.

(2) Provides for exemptions from Commonwealth law by way of regulation

Cl 83 **Functions and powers conferred on Commonwealth officers and authorities** – This provision defines the duties, functions and powers of Commonwealth officers in relation to the *Therapeutic Goods Law (WA).*

(1) Links the Commonwealth administrative law associated with the *Therapeutic Goods Law (Commonwealth)* to the functions and powers to be performed under the *Therapeutic Goods Law (WA)*.

(2) Requires a Commonwealth officer or authority to take action consistent with Commonwealth administrative law when performing a function or exercising a power under the *Therapeutic Goods Law (WA).*

Cl 84 **Reference in Commonwealth administrative law to a provision of another law –** This provision links the application of any Commonwealth administrative law within the *Commonwealth Therapeutic Goods Law* and the *Therapeutic Goods Law (WA)* to the extent it is relevant.

Cl 85 **Construction of references to Part IVA of Commonwealth AAT Act** – This provision allows the limited number of individuals affected by the *Therapeutic Goods Law (WA)* access to the Commonwealth Administrative Appeals Tribunal .

Part 6 Division 4 – Functions and powers under applied provisions

This division defines the functions and powers of the relevant persons under the Commonwealth *Therapeutic Goods Act* 1989 that are required to give effect to the Therapeutic Goods Law (WA).

Cl 86 **Functions and powers of Commonwealth Minister –** This provision identifies the Commonwealth Minister as having the same functions and powers under the *Therapeutic Goods Law (WA)* as the *Commonwealth Therapeutic Goods Act* and its regulations, codes and manufacturing principles.

Cl 87 **Functions and powers of the Commonwealth Secretary** – This clause identifies the Commonwealth Secretary as having the same functions and powers under the *Therapeutic Goods Law (WA)* as he or she exercises in administering the relevant sections of the Commonwealth *Therapeutic Goods Act* 1989.

(1) Provides for the Secretary to perform the same functions and exercise the same powers, regulations, orders and manufacturing principles under the *Therapeutic Goods Law (WA.)*

(2) Ensures the regulatory framework surrounding the Australian Register of Therapeutic Goods and the Secretary's associated powers are applied to therapeutic goods manufactured and supplied by individuals (not corporations) within Western Australia.

Cl 88 **Functions and powers of other persons –** This provision allows for the nominating of authorised persons to carry out functions.

(1) Defines an ***authorised person*** by reference to the Commonwealth *Therapeutic Goods Act* 1989
An *authorised person* under that Act is one authorised by the Secretary or a member of the Australian Federal Police or Customs officer.

(2) Identifies the authorised persons as having the same functions and powers under the *Therapeutic Goods Law (WA)* as under the *Therapeutic Goods Law (Commonwealth)* and its associated regulations, orders and manufacturing principles.

Cl 89 **Delegation by the Commonwealth Minister or Secretary** – This clause extends the delegations of the Commonwealth Minister or Secretary made under the Commonwealth *Therapeutic Goods Law* to the *Therapeutic Goods Law (WA*).

Cl 90 **Appointments under the *Therapeutic Goods Act 1989 (Commonwealth*)** – This provision allows for any appointment under the *Therapeutic Goods Act 1989 (Commonwealth)* to similarly be taken to extend to and have effect for the purposes of the *Therapeutic Goods Law (WA*).

Part 6 Division 5 – Fees

This division provides for the imposing of fees for the performance or functions associated with this Part.

Cl 91 **Fees** – This provision allows for the levying of the same fee as charged by the Commonwealth for the granting, variation, suspension, revocation of a licence to manufacture therapeutic goods or the consideration and assessment of medical devices.

Part 6 Division 6 – Conferral of functions of Commonwealth Director of Public Prosecutions

This division provides for the prosecution of individuals who breach the *Therapeutic Goods Law* (WA) when manufacturing or selling therapeutic goods within the confines of the State.

Cl 92 **Conferral of functions on Commonwealth Director of Public Prosecutions** – This provision allows for the Commonwealth Director of Public Prosecutions to institute prosecution of individuals under the *Therapeutic Goods Act (WA)* and also conduct prosecution following a written request from the state Attorney General or state Director of Public Prosecutions.

Part 6 Division 7 – Relationship with other State laws

This division provides for the modification of the Commonwealth *Therapeutic Goods Act* as the *Therapeutic Goods Law* (WA),

Cl 93 **Relationship with other State laws** – This clause provides for the State to make regulations that may counter or modify the impact or application of the *Therapeutic Goods Law (WA)*.

Part 7 – Drugs of addiction

This Part sets up a regime for the identification and monitoring of the prescribing and use of therapeutic drugs of addiction by health professionals and patients with the intent of protecting the patient's health and welfare.

Part 7 Div 1 – Preliminary

This division defines the terms used in Part 7.

Cl 94 **Terms used** – This provision defines the substances covered and the persons affected by this Part.

client defines the person a pharmacist, veterinarian or authorised health professional can supply or prescribe a drug of addiction.
drug dependent person defines a person who has acquired an overpowering desire for the continued administration of a drug of addiction or Schedule 9 poison.
oversupplied person defines a person who obtains quantities of drugs of addiction in excess of what would be necessary for the individual's personal therapeutic use (doctor shopping).
Schedule 4 reportable poison – defines a subset of Schedule 4 medicines under regulation that have a high risk of misuse, abuse or illicit use.

Part 7 Division 2 – Self-prescription

This division places restrictions on registered health practitioners self-medicating drugs of addiction.

Cl 95 **Self-prescription** – This clause provides for the self-medication of drugs of addiction to be an offence.

Cl 96 **Defence: emergency** – This clause provides a defence for the self-medication of a drug of addiction in an emergency.

Part 7 Division 3 – Drug dependent persons

This division sets out the responsibilities of authorised health practitioners, the CEO and the individual in the identification of a drug dependent person and the subsequent inclusion of the person's name on the drug dependent record.

Cl 97 **Practitioner to inform CEO of drug dependent status of patient –** This provision requires an authorised health professional to inform the CEO, within 48 hours of forming the view, if they reasonably believe a particular patient is a drug dependent person.
A failure to comply attracts a penalty.

Cl 98 **CEO may include drug dependent person on drugs of addiction record –** This provision sets out the steps the CEO must undertake before deciding to place a person's name on the drugs of addiction record.

(1) Provides for the CEO to make a decision to record the name of a person as a drug dependent person on the drugs of addiction record.

(2) Places an onus on the CEO to inform the person that he or she intends to record the person as a drug dependent person along with the reasons for the record. The CEO must also inform the person of the consequences of this type of record. In addition, the person must be given a reasonable opportunity to show why they should not be recorded as a drug dependent person.

Cl 99 **Recording and notification of drug dependent status** – This clause prescribes the format and actions the CEO must take when recording an individual as a drug dependent person.

(1) Requires that the CEO record his or her decision on the status of a drug dependent person and the reasons for the decision. The clause further requires the CEO to inform the drug dependent person of his or her actions. The CEO must also inform the notifying health professional (if any) and the person's primary health care provider (if any).
Where the CEO considers it is in the best interests of the drug dependent person's health, he or she must inform other health practitioners who may prescribe or supply a drug of addiction to the person.

(2) Prescribes the format the CEO must follow when notifying the drug dependent person and relevant health practitioners of the circumstances and consequences of the patient being recorded as a drug dependent person.

Cl 100 **Supply or prescription of drugs of addiction to or for drug dependent persons –** This clause provides for the making of regulation and a penalty for a breach of the regulations associated with the prescribing and supply of drugs of addiction for a person recorded as a drug dependent person.

(1) Provides for regulations relating to the supply and prescribing practices of health practitioners when treating a patient whose name is on the drugs of addiction record as a drug dependent person.

(2) Provides for a penalty for health practitioners who supply or prescribe contrary to the regulations.

Part 7 Division 4 – Oversupplied persons

This division sets out the responsibilities of authorised health professionals, the CEO and the individual in the identification of an over supplied person and the subsequent inclusion of the person's name on the drug dependent record.

Cl 101 Practitioner to inform CEO of oversupplied status of client – This provision requires an authorised health professional to inform the CEO, within 48 hours of forming the view, if they reasonably believe their patient is an oversupplied person.
Penalties apply for non compliance.

Cl 102 CEO may include oversupplied person on drugs of addiction record – This provision sets out the parameters the CEO must consider before the inclusion of the name of an oversupplied person to the drug addiction record.

(1) Provides for the CEO to make a decision to record the name of a person as an oversupplied person.

(2) Provides a specific discretionary provision where the CEO is satisfied there is a reasonable explanation for the quantity of drugs of addiction obtained by or prescribed for the person.

(3) Places an onus on the CEO to inform a person that he or she intends to record the person as an oversupplied person along with the reasons for the record. The CEO must also inform the person of the consequences of this type of record. In addition, the person must be given a reasonable opportunity to show why they should not be recorded as an oversupplied person.

Cl 103 Recording and notification of oversupplied status – This clause prescribes the format and actions the CEO must take when recording an individual as an oversupplied person.

(1) Requires that the CEO record his or her decision on the status of an oversupplied person on the drugs of addiction record and the reasons for the decision. The clause further requires the CEO to inform the oversupplied person of his or her actions. The CEO must also inform the notifying health practitioner (if any) and the person's primary health care provider (if any).

Where the CEO considers it is in the best interests of the oversupplied person's health, he or she may inform any other person who may prescribe a drug of addiction to that person.

(2) Prescribes the format for the CEO when notifying the oversupplied person and other relevant persons of the circumstances and consequences of the patient being recorded as an oversupplied person.

Cl 104 **Supply or prescription of drugs of addiction to or for oversupplied persons** – This clause provides for the making of regulation and a penalty for a breach of the regulations associated with the prescribing and supply of drugs of addiction for a person recorded as an oversupplied person.

(1) Provides for regulations relating to the supply and prescribing practices of health practitioners when treating a patient whose name is on the drugs of addiction record as an oversupplied person.

(2) Provides for a penalty for health practitioners who supply or prescribe contrary to the regulations.

Part 7 Division 5 – Drugs of addiction record

This division provides the framework for the format and operation of the drugs of addiction record. The drugs of addiction record holds specific information on drug dependent persons, over supplied persons and the health professionals associated with treating these patients.

Cl 105 **Drugs of addiction record –** The clause describes the information that the CEO may record on the drugs of addiction record and the manner and form of that record.

(1) Compels the CEO to keep a record of the supply and prescription of drugs of addiction and persons who have been determined by him or her to be drug dependent or oversupplied.

(2) Requires that the record include the names of drug dependent and oversupplied persons and the reasons for the inclusion of their names. The record must include other information if prescribed by regulation.

(3) Provides for the record to hold additional information, by way of regulation, that the CEO may see fit to collect to aid in the treatment of the individual or to protect the health, safety and welfare of the public.

(4) Provides a regulation making power for the exemption of certain information from the record.

(5) Self explanatory

Cl 106 **Purposes for which drugs of addiction record is kept** – The provision sets out the purposes for the collection and retention of information on the drugs of addiction record.

Cl 107 **Amending information in drugs of addiction record** – This clause provides a right for a person to seek amendment to the information held about them on the drugs of addiction record.

(1) Identifies the type of amendments that may be sought.

(2) Provides for the CEO to amend the record under defined circumstances.

Cl 108 CEO may authorise disclosure of information – This clause allows for the disclosure by the CEO of information from the drugs of addiction record under limited circumstances.

(1) Authorises the CEO to disclose information about a patient to an authorised health professional treating that patient. An authorised health professional is one who may prescribe or supply a drug of addiction.

(2) Authorised the disclosure of de-identified information for management, research and evaluation purposes.

(3) Requires the CEO to provide a copy or certified copy of information about a patient to a person who supplied a drug to the patient (for evidentiary purposes) or to an authorised health professional proposing to supply or prescribe a drug of addiction to a patient.

Part 7 Division 6 – Review of decisions by State Administrative Tribunal

This division provides for decisions made by the CEO to include the names of persons on the drugs of addiction record to be reviewed by the State Administrative Tribunal.

Cl 109 Review of decision to include person in drugs of addiction record – This clause defines a ***reviewable decision*** as the inclusion of a person's name by the CEO as a drug dependent person or an oversupplied person and gives that person the right to request review through the State Administrative Tribunal.

Part 8 – Investigation and Enforcement

This part of the Bill provides the powers, parameters and penalties for the investigation and enforcement of compliance with the replacement Act.

Part 8 Division 1 – Preliminary

Cl 110 **Terms used –** Defines the terms of ***place***, ***vehicle*** and ***entry warrant*** relevant to this part.
Each term is self explanatory.

Cl 111 **This Part's relationship to other laws –** This clause ensures there is no diminution in the powers conferred on individuals between the replacement Act, the *Health Practitioner Regulation National Law (Western Australia*) or the *Misuse of Drugs Act* 1981.

Part 8 Division 2 – Investigators

This Division describes how investigators are appointed, how they are identified and the limitations on their power.

Cl 112 **Designation of investigators** – This clause sets out the process to be undertaken by the CEO for the appointment, tenure and powers of investigators.

(1) Provides the CEO with a power to, in writing, appoint specified types of persons to be investigators.

(2) Self explanatory

(3) Self explanatory

(4) Allows the CEO to limit or place conditions on the actions of the investigator.

Cl 113 **CEO has functions of investigator** – Self explanatory

Cl 114 **Police have functions of investigator –** This provision allows for police officers to have investigational powers for the purpose of this Act, which are in addition to their powers of investigation under any other law.

Cl 115 **Identity cards** – This clause provides the mechanisms for the issuing, format and use of identity cards by investigators.

(1) Mandates that the CEO issue an identity card to each investigator.

(2) Self explanatory

(3) Provides for a penalty for the non-return (within 14 days) of a person's identity card when the authority to act as an investigator ceases.

(4) Self explanatory

Cl 116 **Production and display of identity card** – This clause requires the investigator to produce their identity card at the commencement of an investigation or at the first reasonable opportunity.

Cl 117 **Limitation on powers of investigators** – This clause describes the mechanisms by which the powers of investigators may be limited.

Part 8 Division 3 – Investigations

This division outlines what an investigator can and cannot do in the course of conducting an investigation.

Cl 118 **Investigations: purpose and procedure –** This clause outlines the purposes for which an investigation may be carried out and provides the power to make regulations in relation to the procedures that must be followed by investigators when carrying out his or her functions under the Act.

Cl 119 **Entry powers** – This provision sets the parameters for entry to places by investigators.

(1) Restricts the investigator to entering a place, at a reasonable time, where he or she has reasonable cause to believe there are relevant records or where there has been a contravention of the Act. An investigator may also enter a place where an authorised health professional, licensee or permit holder carries on a business.

(2) Prevents the investigator from entering a restricted place unless the occupier of the premises consents or the investigator has an entry warrant.

(3) Defines the term ***restricted place*** which includes a residence or a health care space where a patient is being treated.

Cl 120 **Powers after entry for investigation** – This provision codifies what an investigator can do once they have entered the place.

(1) Codifies the actions an investigator may undertake once entry has been gained to a place, including directing the actions of persons at the place.

(2) Prevents the investigator from seizing patient records or patient data without consent.

(3) Excludes prescription and records of supply or administration of a medicine to a patient from the definition of a patient record.

(4) Requires the investigator to issue a receipt for seized items.

Cl 121 **Obtaining information and documents** – This provision sets out how the investigator obtains information and documents.

(1) Allows an investigator, in relation to the investigation only; to direct a person to give information, answer questions or produce a record within their custody or control. The sub clause also allows the investigator to examine and make copies of a record that has been produced.

(2) Requires the investigator to communicate in writing the time frame and methods of presentation of the required information or answers.

(3) Requires the investigator to communicate the time frame and methods of presentation of the requested records.

Cl 122 **Use of force and assistance** – This provision describes the circumstances under which force and assistance can be used by an investigator.

(1) Provides for the investigator to use assistance and force to the extent that is reasonably necessary.

(2) Tempers the use of reasonable force where it is likely to cause significant damage to property, requiring the investigator, in such circumstances to seek the authorisation from the CEO.

(3) Provides for the investigator to request a police officer or other person to assist them in exercising their powers under this Act.

(4) Provides equivalent powers, responsibilities and protection from liability for a person assisting the investigator.

(5) Self explanatory

Cl 123 **Obstruction** – This clause provides for a penalty for a person who hinders or obstructs a person authorised to exercise a power conferred by this Act. It also provides a defence for the person where the investigator did not identify themselves and the person did not know they were an investigator.

Cl 124 **Directions generally** – This clause provides for a penalty for a person for failing to comply with a direction from an investigator. The direction may be given orally or in writing.

Cl 125 **Investigator may supply, obtain and possess poison** – This clause provides for an investigator to supply, obtain or possess a poison or a strictly controlled substance, but only in the course of conducting an investigation.

Part 8 Division 4 – Entry warrants

This division sets out the parameters for the issuing, effect and execution of entry warrants.

Cl 126 **Warrant to enter place** – This clause describes how an application for an entry warrant is to be made.

(1) Provides the power for an investigator to make application for an entry warrant to a justice of the peace.

(2) Allows for an entry warrant to be sought even if one is not required for authorisation of entry to that place.

(3) Requires the application for an entry warrant by the investigator to comply with the requirements of section 13 of the *Criminal Investigation Act* 2006.

(4) Requires that the particularities, grounds, purpose and any other information prescribed by regulation must be included on the application for an entry warrant.

Cl 127 **Issue of entry warrant** – This provision sets out the parameters for the justice of the peace when granting an entry warrant.

Cl 128 **Effect of entry warrant** – This provision describes the effect of an entry warrant.

Cl 129 **Execution of an entry warrant** – This clause provides for any investigator to execute the entry warrant once acquired. In addition, it requires the investigator to produce the entry warrant upon a reasonable request of a person apparently in charge of the place.

Part 8 Division 5 – Seized things and forfeitures

This division provides for the seizing or forfeiture of materials by the court

Cl 130 **Forfeiture on conviction –** This clause provides for the forfeiture and seizure of property and enforces that forfeiture when a person has been convicted of an offence under this Act.

(1) Provides for the court upon the conviction of a person to order the forfeiture of any thing that was the subject of, used in or otherwise involved, in the commission of an offence.

(2) Provides for the order to be made whether or not the things was seized in the course of the investigation or has or has not been returned to the owner.

(3) Empowers the court to enforce the forfeiture.

Cl 131 **Disposal of seized and forfeited property –** This clause provides for the relevant Department to hold and ultimately dispose of seized and/or forfeited property.

Part 8 Division 6 – Penalties and other orders

This division provides for the setting of penalties for a range of offences. This division also allows for the court to order costs for analysis and notification of the CEO in the event of a conviction of a licensee, permit holder or authorised health professional.

Cl 132 **General Penalties** – This clause provides for three levels of penalty for offences committed under this Act.

(1) Prescribes a penalty of up to $45 000 and three years imprisonment or alternatively a fine for offences relating to a drug of addiction, Schedule 9 poison or a strictly controlled substance.

(2) Prescribes a penalty of up to $30 000 for offences relating to such activities as the manufacture of Schedules 2 or 3 medicines, unlawfully obtaining poison by wholesale, or supplying or prescribing a drug of addiction to a person whose name appears on the drugs of addiction record.

(3) Prescribes a penalty of up to $15 000 for offences relating to such activities as the failure by a body corporate to inform the CEO of a change of management, the failure of a person to produce a licence or permit when requested by an investigator, a failure to inform the CEO of a belief that an individual is a drug dependent person or the misuse of information obtained when exercising a function under this Act.

Cl 133 **Order as to costs of analysis –** This clause enables for the court to make a specific order of costs for analysis of a poison regardless of the outcomes of the proceedings.

Cl 134 **Court to notify CEO of conviction of licensee, permit holder or authorised health professional** – This provision imposes on the court the requirement that the CEO be notified of the findings and penalty imposed upon a licensee, permit holder or authorised health professional.

Part 8 Division 7 – Liability of certain persons

This division sets out the liabilities for corporate officers, principals and employers to be held liable for the actions of their body corporate, their agent, or employees respectively.

Cl 135 **Liability of corporate officers for acts of body corporate –** This clause provides for the liability associated with the offence to extend to every corporate officer within a body corporate if there is an allegation of an offence.

(1) Provides for every person who was a corporate officer within the body corporate at the time to be charged with the offence.

(2) Extends the liability of a corporate officer if the charge is proven against the body corporate to have also committed the offence.

(3) Provides a defence for a corporate officer if he or she can prove the offence was committed without their knowledge, authority or consent and the officer undertook all measures to prevent the commission of the offence.

Cl 136 **Liability of of members of partnership for acts of other members of partnership –** This clause provides for the liability associated with the offence to extend to every member of a partnership if there is an allegation of an offence.

(1) Provides for every person who is a partner at the time to be charged with the offence.

(2) Extends the liability of committing an offence by one member to all members of a partnership.

(3) Provides a defence for a partner if he or she can prove the offence was committed without their knowledge, authority or consent and the partner undertook all measures to prevent the commission of the offence.

Cl 137 **Liability of principal for acts of agent –** This clause provides for liability to be extended to the principal if there is an allegation or finding of an offence against an agent.

(1) Provides for the liabilities of an agent being charged with an offence to also be extended to the principal being charged with the same offence.

(2) Provides for a principal to also be guilty of an offence if the agent is convicted.

(3) Extends the liability of a principal to be charged with the offence independent of whether or not the agent is charged.

(4) Continues the liability of the principal for the actions of his or her agent despite proof that the agent committed the offence.

(5) Provides a defence for the principal if he or she can prove the offence was committed without their knowledge authority or consent and the principal undertook all measures to prevent the commission of the offence.

Cl 138 **Liability of employer for acts of employee –** This clause provides for liability to be extended to the employer if there is an allegation or finding of an offence against an employee.

(1) Provides for the liabilities of an employee being charged with an offence to be extended to the employer being charged with the offence whether or not the employee acted without the employer's authority or contrary to the employer's orders or instructions.

(2) Provides for a employer to also be guilty of an offence if the employee is convicted.

(3) Extends the liability of a employer to be charged with the offence independent of whether or not the employee is charged.

(4) Continues the liability of the employer for the actions of his or her employee despite proof that the employee committed the offence.

(5) Provides a defence for the employer to a charge to prove that the offence was committed by the employee without their knowledge authority or consent and the employer undertook all measures to prevent the commission of the offence.

Part 8 Division 8 – Legal Proceedings

This division outlines the persons who can commence proceedings and the limits on prosecution.

Cl 139 **Who may commence proceedings –** This provision restricts the authority to commence proceedings to the CEO or a person authorised by him or her.

Cl 140 **Time limit for prosecutions –** This provision outlines the parameters for the commencement of prosecution.

(1) Requires that a prosecution be commenced within two years.

(2) Allows for a variation on when a prosecution must be commenced if the prosecution notice specifies the day on which evidence of the alleged offence first came to the notice of the CEO or authorised person.
It also allows for the prosecution notice to not contain particulars of the day on which the offence is alleged to have been committed.

(3) Provides for the day on which evidence first came to the attention of a person authorised to institute a prosecution, without evidence to the contrary is that which is stated on the notice.

Part 8 Division 9 – Evidentiary Matters

This division outlines the evidentiary matters available for the purpose of proceedings for an offence under this Act.

Cl 141 **Terms used –** This provision defines the terms used in this division and is self explanatory.

Cl 142 **Application of Division** – This provision sets out the parameters of this division to that of proceedings for an offence under this Act which are in addition to and do not affect the operation of the *Evidence Act* 1906.

Cl 143 **Evidence of various matters** – The clause lists a number of matters that if alleged in a prosecution notice are taken to be proven.

Cl 144 **Evidence of purpose or intent** – This clause provides for an assertion in a prosecution notice for a specific purpose, intent or knowledge to be taken as proven if the act being carried out by the person is proven.

(1) Defines that an ***act*** in this section includes the possession of a thing.

(2) Provides for an allegation in a prosecution notice for a specific purpose, intent or knowledge to be taken as proven if the act being carried out by the person is proven.

Cl 145 **Evidence in relation to documents** – This clause provides for documents that if certified by the CEO as true copies are taken to be proven as true copies at that date and may be used as evidence. The specified documents are used in the administration and monitoring of medicines and poisons.

Cl 146 **Evidence of analysis of substance** – This clause provides for the presumptions of a proven state in analysing substances.

(1) Defines the terms used in this section.

(2) Provides for a report to be proof of the matter, if the sample was taken and analysed in the prescribed manner.

(3) Provides for an assertion within a report, that the sampling was conducted in the prescribed manner, as proven.

(4) Provides for a sample taken in the prescribed manner, if proven to be representative of all of the substance sampled.

Cl 147 **Presumptions arising from labels** – This clause provides for presumptions in proceedings in the labelling of containers.

(1) Defines the terms used in this section.

(2) Provides for the descriptive label on a container, to be proven as the content of the container.

(3) Provides for it to be taken as proven if the label on a container includes certain information such as the name of persons who manufacture or supply, or a particular batch, lot or consignment.

(4) Provides for if, any part of a batch, lot or consignment, is proven to be a poison, it is proven to be representative of the entire batch, lot or consignment.

Part 9 – Regulations

This part provides for a general power to make regulations for the purpose of this Act and for the adoption of codes by regulation.

Cl 148 **General power to make regulations** – This clause provides for the Governor to make regulations prescribing all matters in order to give effect to the purposes of the Act. This section also provides for a penalty (up to $15,000) for contravention of a regulation.

Cl 149 **Regulations may adopt codes** – This clause provides for the adoption by regulation of codes developed elsewhere.

(1) Defines the terms ***adopted code***, ***code*** and ***code document*****.** *Code document* also includes either any amendment associated with that code that may be included from time to time.

(2) Self explanatory

(3) Self explanatory

(4) Requires the CEO to ensure the adopted code is available to the public for inspections and/or acquisition.

Part 10 – Miscellaneous

Cl 150 **Protection from liability for wrongdoing** – This provision outlines the protections from liability of persons acting in good faith while still binding the Crown for actions undertaken by individuals performing their assigned roles under this Act.

Cl 151 **Information officially obtained to be confidential** This provision binds those who have access to information obtained under this Act or the repealed Act to maintain the confidentiality of that information except when disclosing for prescribed purposes. A breach of this provision attracts a penalty.

Cl 152 **Review of Act** – Self explanatory

Part 11 – Repeals and transitional provisions

The clauses in this part enable the continuation and transition of legislative and regulatory regimes for the control of medicines and poisons.

Part 11 Division 1 – General

Cl 153 ***Interpretations Act* 1984 not affected** – Self explanatory

Part 11 Division 2 – Repeals

This division repeals the *Poisons Act* 1964 and the *White Phosphorus Matches Act* 1912 and the two sets of regulations that will become redundant when the replacement Act comes into existence.

Cl 154 ***Poisons Act* 1964 repealed** – Self explanatory

Cl 155 ***White Phosphorus Matches Prohibition Act* 1912 repealed** – Self explanatory

Cl 156 **Regulations repealed** – Self explanatory

Part 11 Division 3 –Saving and transitional matters

The clauses in this division facilitate the transition of the rights, responsibilities, obligations and liabilities of persons presently regulated by the repealed *Poisons Act* 1964 and the *Drugs of Addiction Notification Regulations* 1980*.*

Part 11 Division 3 Subdivision 1 – *Poisons Act* 1964

This subdivision provides the transition of the rights, responsibilities, obligations and liabilities of persons presently regulated by the repealed *Poisons Act* into the replacement Act – the *Medicines, Poisons and Therapeutic Goods Bill* 2013.

Cl 157 **Terms used** – This clause defines the terms ***commencement date*** and ***repealed Act***.

Cl 158 **Continuation of licences and permits** – This clause provides for the continuation of the authority and controls prescribed by regulation for licences and permits under the repealed Act into the replacement Act.

Cl 159 **Existing applications for licences and permits** – This clause provides for an application for a licences or permit that has not yet been determined to retain its validity under the replacement Act.

Cl 160 **Continuation of notices given to health professionals** – This clause provides for a restriction notice placed upon a health practitioner's professional authority to practice under the repealed Act to retain its authority and validity under the replacement Act.

(1) Defines the section of the repealed Act that provides for the making of regulations associated with ***a notice under the repealed Act*** given by the CEO (of the Department of Health). The notice may place conditions, restrictions or revoke completely the health professional's professional authority to handle particular medicines.

(2) Maintains the authority of the particulars, including the duration of the notice under the repealed Act into the replacement Act.

Cl 161 **Continuation of the notices in relation to Schedule 6 poisons** – This provision enables the authority associated with the conditions on a notice to sell Schedule 6 poisons by retail to be maintained into the replacement Act.

Cl 162 **Continuation of notices in relation to Schedule 7 poisons** – This clause maintains the conditions or restrictions placed on any notice issued on a Schedule 7 notice under the repealed Act into the replacement Act. Schedule 7 notices regulate the use, possession and or sale of such substances as pesticides, strychnine, cyanide and chorine gas.

Cl 163 **Minister may exempt certain therapeutic goods from requirements of *Therapeutic Goods Law (WA)*** – This clause allows for the Minister to exempt a particular therapeutic good from the requirement to comply with the *Therapeutic Goods Law (WA)* under certain circumstances.
The exemption is published in a notice in the Government Gazette.

(1) Requires the Minister to be satisfied that the therapeutic goods was being produced prior to the commencement day of the Therapeutic Goods Law (WA) and that manufacture and use of the good will not pose a risk to the health, safety and welfare of the public.

(2) Describes the requirements for the content of the notice.

Cl 164 **Transitional Regulations** – This clause provides a regulation making power to facilitate all matters that are required or necessary to transition from the repealed Act to the replacement Act.

(1) Provides for a broad power to make regulations to aid in the transition to the replacement Act.

(2) Self explanatory

(3) Self explanatory

(4) Allows for the regulations to come into effect before gazettal but not the commencement date.

(5) Self explanatory

(6) Protects the rights of the individual if the transition regulations affect the individual adversely prior to the regulations being gazetted.

Part 11 Division 3 Subdivision 2 - *Drugs of Addiction Notification Regulations* 1980

This subdivision ensures that particular information from the Drugs of Addiction Notification register is transferred to the drugs of addiction record created under the replacement Act.

Cl 165 Transfer of information from former register to drugs of addiction record – The provision details the particulars and protocols to be followed in transferring information from the drugs of addiction register to the drugs of addiction record

(1) Defines the ***commencement date*** for the repeal of the *Drugs of Addiction Notification Regulations* and the ***former register*** as the register of details collected on the Drugs of Addiction Notification register.

(2) Requires the CEO, within twelve months of the commencement date to destroy the former register and any information not transferred to the new drugs of addiction record.

(3) Provides for the CEO to transfer information from the former register to the drugs of addiction record if s/he is satisfied that the information is accurate, up-to-date and of the kind that would be collected under the replacement Act.

(4) Provides for the information transferred to the drugs of addiction record to be subject to the removal protocols to be established for the drugs of addiction record from the time the information was originally recorded in the former register.

Part 12 – Consequential amendments

Part 12 Division 1 – *Health Act* 1911 amended

The *Health Act* 1911 was the original Act used to regulate the use of poisons and medicines in Western Australia. The replacing *Poisons Act 1964* did not provide for the deletion of the particular provisions within the *Health Act* 1911 that controlled the use of poisons. These sections have not been utilised for many years or were incorporated into the *Poisons Act* 1964.

Cl 166 **Act amended** – Self explanatory

Cl 167 **Section 3 amended –** This clause provides for the deletion of a number of terms that relate to the regulation of poisons and medicines. This provision also provides for an amendment to the definition of ***meat***, by deleting the words "except in Division 3A of Part VIIA".

Cl 168 **Section 5 amended –** This clause removes from the section dealing with a breach of contract on the sale of food and or drugs (sec 5(6)), any reference to the sale of a drug.

Cl 169 **Part VIIA heading replaced –** This provision removes from the Part VIIA heading reference to drugs, medicines, disinfectants and therapeutic substances. Reference in the heading to the regulation of ***Pesticides*** remains.

Cl 170 **Part VIIA Division 1 heading replaced –** Self explanatory

Cl 171 **Section 202 deleted –** Self explanatory

Cl 172 **Part VIIA Divisions 5, 6 and 7 deleted –** This clause removes reference to Division 5 – the division on drugs; Division 6 – the division referencing medicines and disinfectants and Division 7 – the division providing for the regulation of the manufacture of therapeutic goods.

Cl 173 **Section 246A amended** – Self explanatory

Cl 174 **Part VIIA Division 9 deleted –** This clause removes the division that provided for the making of regulations associated with the (now) deleted reference to drugs, medicines, disinfectants and therapeutic goods.

Cl 175 **Section 360 amended –** Self explanatory

Cl 176 **Section 377 amended –** This clause deletes from the provision on evidence reference to "an analyst" and deletes reference to the purchasing of any drug for evidentiary purposes.

Cl 177 **Schedule 5 amended** – Self explanatory

Part 12 Division 2 – *Health Professionals (Special Events Exemption) Act* 2000 amended

Amendments to this Act will allow for visiting health professionals, accompanying overseas delegations, under the authority of the CEO to treat their own personnel under the same rights and responsibilities when handling medicines as existed under the repealed Act.

Cl 178 Act amended – Self explanatory

Cl 179 Section 3 amended – This clause provides for the deletion of a number of terms that will no longer exist in the replacement Act. It also inserts a definition of ***medicine***.

Cl 180 Section 8 amended – This provision rephrases the manner in which a visiting health professional may handle a medicine within the confines of an equivalent registered health profession and the replacement Act.

Cl 181 Section 9 replaced – This clause deletes the provision that allows for the issuing of prescriptions and the supply of certain substances and replaces it with a provision with equivalent powers and intent that accommodates the wording in the replacement Act.

Cl 182 Section 11 amended – This provision provides for the equivalent exemptions granted under various Acts, particularly the *Misuse of Drugs Act* 1981, to enable visiting health professionals to continue to handle medicine when treating their personnel in attendance at the special event.

Part 12 Division 3 – *Misuse of Drugs Act* 1981 amended

This division amends the *Misuse of Drugs Act* 1981

Cl 183 Act amended – Self explanatory

Cl 184 Section 3 amended – This clause removes a number of definitions used in the repealed Act and replaces them with definitions applicable to the replacement Act.

Cl 185 Section 3B inserted – This additional clause provides a regulatory power for prescribing certain substances to be specified drugs.

3B This clause provides a power for the respective ministers' responsible for the replacement Act and the *Misuse of Drugs Act* 1981 to make regulations prescribing certain substances to be specified drugs. The making of such regulations is constrained by the relevant Minister being satisfied that the substance(s) have a high propensity to be misused, abused, used illicitly or diverted for manufacture into a substance with a similar outcome.

Cl 186 Section 4 amended – This clause removes the term "*prohibited plants*" mentioned at section 5 of the repealed Act.

Cl 187 Section 5B inserted – This clause provides for the authorisations to handle various substances, applicable under the replacement Act that would, except for the authorisation, be "prohibited drugs" and subject to prosecution under the *Misuse of Drugs Act* 1981.

5B. Authorisation under *Medicines, Poisons and Therapeutic Goods Act* 2013

(1) Defines three terms used in the replacement Act.

(2) Provides for the manufacture or preparation of a prohibited drug if it is manufactured under an appropriate licence or professional authority and in accordance with any applicable regulation.

(3) Provides for the sale or supply of a prohibited drug if it is supplied under an appropriate licence, permit or professional authority and in accordance with any applicable regulation.

(4) Provides for a person to manufacture, prepare, sell or supply a prohibited drug if the person has the appropriate authority and the manufacturing, preparation, sale or supply is in accordance with the appropriate licence, permit or authority.

(5) Allows for a person to possess a prohibited drug under specifically defined circumstances.

(5(a)) Allows for the possession by a person of a Scheduled 4 or 8 poisons if the person has appropriate authority as defined under section 14(4) of the replacement Act including (but not exhaustively) a professional authority, an appropriate licence or permit, the carer of a patient (or animal) whom has been prescribed the medicine or the poison is on or in a used hypodermic syringe, needle or other thing for the purpose of disposal.

(5(b)) Allows for the possession by a person of a Scheduled 9 poisons if the person has appropriate authority as defined under section 17 of the replacement Act.

(6) Provides for a person to use a prohibited drug if the person has been prescribed the drug by an authorised prescriber and the use is in accordance with the instructions of the prescriber.

(7) Provides for an "investigator" as defined under the replacement Act to supply, obtain, or possess a prohibited drug in the course of conducting an investigation.

Cl 188 **Section 5 amended** – This provision deletes reference to the repealed Act in addition to inserting a subclause (5(3)) of two defences to the commissioning of a simple offence for the manufacture, sale, supply or use of a prohibited drug or plant if the handling is authorised under the *Misuse Use of Drugs Act* 1981or the replacement Act.

Cl 189 **Sections 6 and 7 replaced** – This clause replaces the two provisions while still retaining the original intent of creating offences in relation to prohibited drugs and prohibited plants in addition to providing for a number of defences if the actions of the person are in accordance with the replacement Act.

Sections 6. Offences concerned with prohibited drugs generally

(1) Retains the offence of possession with intent to sell, supply, manufacture or prepare a prohibited drug.

(2) Self explanatory

(3) Provides a defence to the commissioning of a crime or a simple offence if the possession or delivery is authorised under the replacement Act or the possession is for the purpose of analysis under the *Misuse of Drugs Act* 1981.

(4) Provides a defence to the commissioning of a crime if the manufacture, preparation, sale or supply of a prohibited drug if the handling is authorised under the *Misuse Use of Drugs Act* 1981 or the replacement Act.

(5) Provides a defence to the commissioning of simple offence if the use of a prohibited drug if the use is authorised under the *Misuse Use of Drugs Act* or the replacement Act.

Section 7. Offences concerned with prohibited plants generally – This clause incorporates into the ***Misuse of Drugs Act*** 1981 the changes introduced by the replacement Act in relation to prohibited plants.

(1) Provides for the possession or cultivation for the intent or the selling or supplying of a prohibited plant to be a crime.

(2) Provides for the possession or cultivation for the intent or the selling or supplying of a prohibited plant to be a crime.

(3) Provides for the possession or cultivation for the intent or the selling or supplying of a prohibited plant to be a crime.

Cl 190 **Section 7B amended** – Self explanatory

Cl 191 **Section 8 deleted** – This deletion removes reference to a person forging or engaging in fraudulent behaviour in relation to a prescription within the *Misuse of Drugs Act* 1981. It is accommodated at Clause 21 of the Bill.

Cl 192 **Section 14 amended** – This provision inserts reference to the replacement Act and provides for a defence to the offences provisions for the possession of certain substances or things (category 1 items or category 2 items and

substances) to reflect the language and intent of the replacement Act.

(1) Self explanatory

(2) Replaces section 14(4) with a defence for the committing of an offence if the person can prove their possession of a category 1 item or 2 item and substance was authorised under the *Misuse Use of Drugs Act* 1981 or the replacement Act.

Cl 193 **Section 27 amended** – This provision amends section 27(1) to accommodate the wording of the replacement Act.

Cl 194 **Section 38D amended** – This clause provides for a code certified under the replacement Act to be accepted as evidence in proceedings under the *Misuses of Drugs Act* 1981.

Cl 195 **Section 41 amended** – Self explanatory

Cl 196 **Schedule I heading amended** – Self explanatory

Cl 197 **Schedule II heading amended** – Self explanatory

Cl 198 **Schedule III amended** – Self explanatory

Cl 199 **Schedule V amended** – Self explanatory

Part 12 Division 4 – Other Acts amended

Cl 200 ***Biosecurity and Agriculture Management Act* 2007 amended –** This provision deletes the term *Poisons Act* 1964 from this Act and replaces it with the term *Medicines, Poisons and Therapeutic Goods Act* 2013.

Cl 201 ***Constitutions Acts Amendment Act* 1899 amended** – The provision deletes mention of the Poisons Advisory Committee as this committee will no longer exist.

Cl 202 ***Emergency Management Act* 2005 amended** – This clause provides for an insertion (sec 76A) that enables the manufacture, supply or prescribing of medicines under the authorisation of the CEO (of the Department of Health) for the purposes of emergency management.

Cl 76A(1) defines a number of terms used in this clause with reference to the replacement Act.

Cl 76A(2) provides the power for the CEO to authorise the manufacturing, supply or prescribing of a medicine and for (any) person so authorised to manufacture, supply or prescribe a medicine.

Cl 76A(3) outlines the particulars of an authorisation made by the CEO.

Cl 76A(4) allows for the authorisation to be made in writing or orally. The verbal authority must be reinforced in writing as soon as is practicable after the giving of the oral instruction.

Cl 76A(5) provides a defence for a person or class of person acting under the oral authorisation should there be a failure by the CEO to commit his or her authorisation to writing.

Cl 76A(6) requires the authorised person or class of persons to comply with the terms and conditions of that authorisation and the directions of the CEO or State Emergency Coordinator.

Cl 76A(7) provides for this section within the *Emergency Management Act* 2005 to

override any provision within the *Medicines, Poisons and Therapeutic Goods Act* 2013 and the *Misuse of Drugs Act* 1981.

Cl 203 ***Fair Trading Act*** **2010 amended –**Self explanatory

Cl 204 ***Pharmacy Act*** **2010 amended –** This provision amends several sections to accommodate the changes included in the replacement Act.

(1) Self explanatory

(2) This subclause replaces the term ***the practice of pharmacy*** (section 3) with a definition that reflects the terminology used in the replacement Act.

(3) Self explanatory

(4) Self explanatory

(5) Provides for an additional clause (section 51A) requiring the Pharmacy Board to provide the CEO with information recorded on the register.

Cl 205 ***Police (Medical and other Expenses for Former Officers) Act*** **2008 amended -** The clause replaces references to the *Poisons Act* 1964 with the term *Medicines, Poisons and Therapeutic Goods Act* 2013.

Cl 206 ***Road Traffic Act*** **1974 amended** – This clause amends the term ***drug*** to accommodate terminology used in the replacement Act.

Cl 207 ***Tobacco Products Control Act*** **2006 amended –** This provision amends the term ***tobacco product*** to accommodate terminology used in the replacement Act.

Cl 208 **Veterinary Chemical Control and Animal Feeding Stuffs Act 1976 amended -** Self explanatory

Cl 209 ***Workers Compensations' and Injury Management Act*** **1981 amended –** This provision amends the terms ***drug of addiction*** to accommodate terminology used in the replacement Act.