



Medicines and Poisons Regulations

Decision Regulation Impact Statement

14 December 2015



Contents

Contents	2
Definitions used in this document	5
Executive Summary	10
Part 1: Background	13
1.1 Medicines and Poisons	13
1.2 Objectives of Medicines and Poison Legislation	15
1.3 Medicines and Poisons Act 2014	16
1.4 Current Regulations: Poisons Regulations 1965	18
Part 2: Options	20
2.1 Consultation process	20
2.2.1 Development of the Consultation RIS	20
2.2.1 Development of the Decision RIS	21
2.2.1 Background to Medicines and Poisons Stakeholders	22
2.2 Regulatory Options Considered	24
2.2.1 Status quo: Retention of the 1965 Regulations unchanged	24
2.2.2 Amend the 1965 Regulations	25
2.2.3 New Regulations: Medicines and Poisons Regulations	26
2.3 Stakeholder Recommendations	27
2.4 Preferred Option	28
Part 3: Impact Assessment	30
3.1 Introduction	30
3.2 Policy Objectives	30
3.3 Areas of Regulatory Control	31
3.4 Professional Authority	32
3.4.1 Background	32
3.4.2 Current Regulations	32
3.4.3 Current Regulatory Issues	35
3.4.4 Proposed Regulations	36
3.4.5 Impact Analysis	40
3.5 Structured Prescribing Arrangements	45
3.5.1 Background	45
3.5.2 Current Regulations and Issue Identification	46
3.5.3 Proposed Regulations	47
3.5.4 Impact Analysis	54



3.6 Electronic Prescribing	59
3.6.1 Background	59
3.6.2 Current Regulations and Issue Identification	60
3.6.3 Proposed Regulations	61
3.6.4 Impact Analysis	63
3.7 Electronic Storage and Supply Units	66
3.7.1 Background	66
3.7.2 Current Regulations and Issue Identification	67
3.7.3 Proposed Regulations	68
3.7.4 Impact Analysis	70
3.8 Licenses and Permits	71
3.8.1 Background	71
3.8.2 Current Regulations	73
3.8.3 Current Regulatory Issues	75
3.8.4 Proposed Regulations	76
3.8.5 Impact Analysis	81
3.9 Poison Controls: Schedule 5, 6, 7 & 10	83
3.9.1 Background	83
3.9.2 Current Regulations and Issue Identification	84
3.9.3 Proposed Regulations	85
3.9.4 Impact Analysis	86
3.10 Medicine Controls: Schedule 2, 3 & 4	88
3.10.1 Background	88
3.10.2 Current Regulations, Issue Identification and Proposed Regulation	89
3.10.3 Impact Analysis	93
3.11 Drugs of Addiction	95
3.11.1 Background	95
3.11.2 Current Regulations	95
3.11.3 Current Regulatory Issues	97
3.11.4 Proposed Regulations	99
3.11.5 Impact Analysis	102
3.12 Record of Drug Dependent Persons	104
3.12.1 Current Regulations	104
3.12.2 Current Regulatory Issues	105
3.12.3 Proposed Regulations	106
3.12.4 Impact Analysis	107
3.13 Electronic Real Time Controlled Drug Reporting	108



3.13.1 Background	108
3.13.2 Current Regulations and Issue Identification	108
3.13.3 Proposed Regulations	109
3.13.4 Impact Analysis	110
3.14 Destroying Drugs of Addiction	111
3.14.1 Background, Current Regulations and Issue Identification	111
3.14.2 Proposed Regulations and Impact Analysis	112
3.15 Storage and Transport of Schedule 8 Medicines	114
3.15.1 Background	114
3.15.2 Current Regulations	115
3.15.3 Current Regulatory Issues	116
3.15.4 Proposed Regulations	117
3.15.5 Impact Analysis	121
3.16 Shipping and Vessels	124
3.16.1 Background	124
3.16.2 Current Regulatory Issues	125
3.16.3 Proposed Regulations	126
3.16.4 Impact Analysis	127
3.17 Summary of Regulatory Recommendations	128
Part 4: Implementation	133
4.1 Implementation and Transition	133
4.2 Review and Evaluation	135
Appendices	136
Appendix 1: Stakeholders	136
Appendix 2: Discussion Paper: Poisons Regulations 1965	136
Appendix 3: Discussion Paper: Schedule 8 Opioid Regulations	136
Appendix 4: Discussion Paper: Poisons Schedules	136



Definitions used in this document

The following table outlines terms commonly used in this document -

Word / Abbreviation	Meaning
<i>the Act</i>	the <i>Medicines and Poisons Act 2014</i> .
<i>adopted code</i>	a code that is adopted by regulation.
<i>administer</i>	in relation to a medicine, means to apply, insert, inject or ingest (or cause this to occur), onto or into a person/patient for a therapeutic use.
<i>authorised health professional / practitioner</i>	an animal or human health practitioner who has an authority under medicines and poisons legislation to perform healthcare activities that use a medicine.
<i>CEO</i>	the Chief Executive Officer of the Department.
<i>code</i>	a code, standard, rule, specification or other document.
<i>delegate</i>	a person with authority, delegated from the CEO, to make a decision on behalf of the CEO.
<i>Department</i>	the Department of Health, Western Australia.
<i>direction</i>	regular and frequent instruction, observation or supervision, but does not necessarily imply continuous personal supervision.
<i>dispense</i>	supply of a medicine in accordance with a prescription duly issued by an authorised prescriber.
<i>distributor</i>	a person who imports, sells or otherwise supplies a poison.
<i>dosage unit</i>	an individual dose of a poison and includes a tablet, capsule, ampoule, vial, sachet or other like quantity and form.
<i>drugs of addiction / drugs of dependence</i>	Schedule 8, Schedule 9 and Reportable Schedule 4 medicines.



Word / Abbreviation	Meaning
<i>Electronic Recording and Reporting of Controlled Drugs (ERRCD) system</i>	Electronic Recording and Reporting of Controlled Drugs (ERRCD) system that involves, but is not limited to: <ul style="list-style-type: none">• the development of a nationally consistent electronic system for the recording and reporting of controlled drugs including the collection of information relating to the prescription and dispensing of controlled drugs;• the storage of that information in a database, accessible to State/Territory health Departments in real-time; and• the provision of real-time '<i>electronic decision support tool</i>' for prescribers and distributors of controlled drugs, where prescribers and pharmacists will have access, via the internet, to a secure database of prescription histories of patients.
<i>Electronic Storage and Supply Unit (ESSU)</i>	a machine or device used or capable of being used for the purpose of supplying goods without the personal manipulation or attention at the time of supply of the supplier or an employee or agent of the supplier. Is referred to as a vending machine in the Act.
<i>health professional</i>	a person who is — <ul style="list-style-type: none">(a) a registered health practitioner; or(b) a veterinary surgeon; or(c) in a class of persons prescribed by the Regulations for the purposes of this definition.
<i>licence</i>	a licence granted by the CEO under the Act.
<i>licensee</i>	the holder of a licence.
<i>manufacture</i>	includes the processes of packing and repacking, refining manipulating and mixing any medicine or poison.
<i>manufacturer</i>	a person who manufactures, produces, or packs a medicine or poison.
<i>medical practitioner</i>	a person whose name is contained in the register of kept by the Medical Board of Australia under the <i>Health Practitioner Regulation National Law (WA)</i> .
<i>medicine</i>	a substance that is a Schedule 2, 3, 4 or 8 poison.
<i>obtain</i>	in relation to a poison, means to purchase, procure or acquire.
<i>permit</i>	a permit issued by the CEO under the Act that grants the right to obtain medicines or poisons to use for industrial, educational or research purposes, or to provide health services.
<i>permit holder</i>	the holder of a permit.
<i>personal supervision</i>	close and continuous control requiring the actual presence of the person exercising the supervision.



Word / Abbreviation	Meaning
<i>pharmacist</i>	a person registered under the Health Practitioner Regulation National Law (WA) in the pharmacy profession.
<i>pharmacy</i>	a registered pharmacy as defined in the <i>Pharmacy Act 2010</i> section 3(1).
<i>poison</i>	<p>a substance that is a Schedule 2, 3, 4, 5, 6, 7, 8, 9 or 10 poison listed in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), as outlined in the table below.</p> <p>within this document, “poison” is also taken to mean any substance in the SUSMP that is not classed as a medicine.</p>
<i>possess</i>	in relation to a medicine or poison, means to have physical possession or exert control over that substance.
<i>prescribe</i>	in relation to a medicine, means to issue a prescription.
<i>prescriber</i>	in relation to a Schedule 4 or 8 medicine, means a health professional who has authority to prescribe the medicine.
<i>prescription</i>	<p>in relation to a Schedule 4 or 8 medicine, means a document (whether written or electronic) that —</p> <p>(a) sets out particulars of the medicine, or a substance that contains the medicine, that is, for therapeutic purposes, to be —</p> <p>(i) used by, or administered to, a person named in the document; or</p> <p>(ii) administered to an animal described in the document; and</p> <p>(b) is issued for the purpose of enabling the poison to be supplied for that purpose; and</p> <p>(c) complies with any requirements prescribed by the regulations.</p>
<i>professional authority</i>	<p>(a) an authorisation under section 25 of the Act to administer, possess, prescribe, supply or use a medicine; or</p> <p>(b) an authorisation under section 26 of the Act to manufacture a medicine or use or possess a Schedule 7 poison.</p>
<i>registered health practitioner</i>	a health practitioner who is registered under the <i>Health Practitioner Regulation National Law (WA)</i> to practice as a health professional.
<i>1965 Regulations</i>	refers to the <i>Poisons Regulations 1965</i> .
<i>supply</i>	in relation to a poison, means to sell, provide or supply the poison, or a substance that contains the poison, to another person, but does not include administering a poison or substance directly to another person or to an animal.



Poison Schedule

The Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP, Poisons Standard)¹ defines the scheduling standard of poisons based on the level of control required. Thus scheduling classification from 1-10 is outlined below.

Schedule 1 — [Blank]
Schedule 2 — Pharmacy medicines Substances: the safe use of which may require advice from a pharmacist and which should be available from a pharmacy or, where a pharmacy service is not available, from a licenced person.
Schedule 3 — Pharmacist only medicines Substances: the safe use of which requires professional advice but which should be available to the public from a pharmacist without a prescription.
Schedule 4 — Prescription only medicines, or prescription animal remedy Substances: the use or supply of which should be by or on the order of persons permitted under the Act to prescribe and should be available from a pharmacist on prescription.
Schedule 5 — Caution Substances: with a low potential for causing harm, the extent of which can be reduced through the use of appropriate packaging with simple warnings and safety directions on the label.
Schedule 6 — Poison Substances: with a moderate potential for causing harm, the extent of which can be reduced through the use of distinctive packaging with strong warnings and safety directions on the label.
Schedule 7 — Dangerous poison Substances: with a high potential for causing harm at low exposure and which require special precautions during manufacture, handling or use. These poisons should be available only to specialised or authorised users who have the skills necessary to handle them safely. Special regulations restricting their availability, possession, storage or use may apply.
Schedule 8 — Controlled drug Substances: which should be available for use but require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence.

¹ Commonwealth of Australia. Standard for the Uniform Scheduling of Drugs and Poisons. 2015.
<https://www.comlaw.gov.au/Details/F2015L00844>

**Schedule 9 — Prohibited substance**

Substances: which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of the CEO.

Schedule 10 – Strictly controlled substance

Substances: which require strict control of the supply and use of the substance to protect the health, safety and welfare of the public.



Executive Summary

Purpose of the Decision Regulatory Impact Statement document

The purpose of this paper, the Decision Regulatory Impact Statement (Decision RIS) is to:

- Provide background information on the development of subsidiary legislation to replace the *Poisons Regulations 1965*;
- Outline current issues with existing regulations and identify changes to regulations which will address these issues;
- Examine the impacts of the changes in regulations which have been identified via stakeholder consultation; and
- Discuss implementation plans for these changes.

Background:

The assent of the *Medicines and Poisons 2014 Act* (the Act) was tabled in the Western Australian (WA) Parliament on 2 July 2014. The Act replaces the aged *Poisons Act 1964* in regulating medicines and poisons in WA. The *Poisons Act 1964* is supported by the *Poisons Regulation 1965* (1965 Regulations). It is proposed that new subsidiary legislation be developed to support the Act and supersede the 1965 Regulations.

The Act contains an updated legal framework for the efficient and effective management of medicines and poisons. Regulations set out the detailed controls to protect the public from harms associated with medicines and poisons. A number of the existing regulations contained in the 1965 Regulations will be retained or amended to reflect different aspects of the Act. A number of new regulations are also required for the functioning of the Act.

Development of the new regulations must be conducted under the overarching framework for controls and known impacts as determined by the Act. Regulations need to address the regulatory gaps evident due to the inclusion of new powers in the Act.

It must be noted that development of the Act itself included broad stakeholder consultation and a comprehensive assessment of likely impact. Further targeted consultation has been undertaken for the formulation of regulations, particularly in areas of required reform including: corporate licences, professional authority, and enhanced controls for drugs of addiction.

Objectives:

The objective of the Act and associated regulations are to protect public health and safety, through regulation of medicines and poisons. This requires achievement of reforms relating to areas of regulatory failure in:

- National consistency;
- Excessive regulatory burden;
- Improved control over supply of drugs of addiction; and
- Access by new categories of qualified health practitioners.

The legislation aims to control those substances nationally assessed as harmful and therefore requiring protection of the public from unrestricted access.



Options Identified:

This Decision RIS identifies three options in relation to medicines and poisons regulation.

Option 1: Status quo – Retention of the current 1965 Regulations

This option suggests that the existing Regulations already provide suitable control and should be adhered to with no further alteration.

Option 2: Amend the 1965 Regulations

This option suggests that the development of exemptions and alterations is required to support the Act in areas that need new controls, as per the current approach.

Option 3: Develop a new regulatory framework, *Medicines and Poisons Regulations*.

This option suggests that the 1965 Regulations require replacement with a new regulatory framework, the *Medicines and Poisons Regulations*, to better support the new Act.

Extensive consultation has shown the third option is considered the most effective and efficient. This option is expected to best support the Act to achieve a reduction in regulatory burden, national consistency, and greatest clarity with regard to the controls over Scheduled medicines and poisons required to ensure public safety.

Guide to this document

This Decision RIS is divided into four parts and three appendices, as outlined below.

Part 1– Background

This part provides important background information. It explains what a poison is and why there is a need for medicines and poisons legislation. It provides an overview of the Act and 1965 Regulations. Part 1 explains what occurred in the lead up to this Decision RIS, including development of the Act. It also describes, in broad terms, the regulatory issues that need to be addressed regarding medicines and poisons in WA. This part explains the objectives of effective medicines and poisons regulation in general. The part also identifies the broad policy aims which have been developed during review of the 1965 Regulations. It identifies the regulatory control areas that require reform.

Part 2 – Options

This part introduces the three individual options that could be used to address the problems with the 1965 Regulations that have been identified. It highlights the preferred option, which has been tested and confirmed through comprehensive stakeholder consultation. This part describes the consultation that occurred in production of this Decision RIS.

Part 3 – Impact Analysis

Part 3 outlines the background regarding specific regulatory areas and details the known issues in each regulatory area. Additional detail on proposed regulatory changes and the justification for considering changes in specific areas has been provided. This includes an assessment of the changes proposed in each of the following regulatory areas:



- Professional Authority (3.4);
- Structured Prescribing Arrangements (3.5);
- Electronic Prescribing (3.6);
- Electronic Storage and Supply Units (3.7);
- Licencing and Permits (3.8);
- Controls by Poison Schedule (3.9);
- Controls by Medicine Schedule (3.10);
- Drugs of Addiction (3.11);
- Drugs of Dependence Records (3.12);
- Electronic Real Time Controlled Drug Reporting (3.13);
- Destroying Drugs of Addiction (3.14);
- Storage and Transport of Drugs of Addiction (3.15); and
- Ships and Vessels (3.16).

The document examines the impact of the proposed changes in each of these areas, as identified through stakeholder consultation. Sections 3.4 and 3.5 generated the most commentary on potential regulatory impact and appeared to be of greatest individual interest to stakeholders from publication of the Consultation RIS.

Part 4 – Implementation

The final part of this document describes the intended implementation and transition processes to be undertaken for the proposed regulations. It also makes recommendations regarding the future review and evaluation processes of regulations.

Appendices

Appendices have been included to provide additional or supplementary documentation that support the regulatory changes proposed. The appendices contain copies of discussion papers and other items used during consultation, which were issued or gathered as part of the impact assessment process. During the consultation phases to determine impact, stakeholders were particularly advised to review the document: *Poisons Regulations 1965 – Discussion Paper* in Appendix 2. This was the foundation for formulating the proposed changes outlined in Part 2 of the published Consultation RIS.



Part 1: Background

1.1 Medicines and Poisons

Poisons are inherently dangerous. A poison is a chemical or substance that can harm someone if used in the wrong way, by the wrong person, or in the wrong amount². A person is defined in this document as any member of the public who can access a medicine or poison. A medicine is a poison that a person can consume or apply, which also has a therapeutic or medicinal benefit.

Medicines and poisons have a wide variety of positive, valuable or desirable effects. They have established benefits, but can also cause harm. The risk of incorrect use of poisons may lead to human injury, illness, dependence or death. The potential for incorrect use is significant across the entire community and is well illustrated by the fact that each year in WA:

- There are almost 16,000 poisonings reported to the WA Poisons Information Centre³;
- Between 10,000 and 15,000 patients are admitted to hospital due to medicine misuse⁴;
- A large proportion of the population use pharmaceuticals for a purpose other than medically intended - 4.7% in 2013⁵;

The misuse of drugs is a common and growing problem. The societal costs of illicit drug use in Australia were \$8.2 billion in 2004 / 2005. In 2008 / 2009 Australian Governments spent almost \$200 million in drug related harm prevention activities alone, including for pharmaceutical drug misuse⁶.

Medicines and poisons are ubiquitous and can be found in every business and every household. As a result, medicines and poisons regulation affects everyone. Examples of poisons according to their toxicity are outlined in the Table 1.

² Western Australian Department of Health. 2015. Health http://healthywa.wa.gov.au/Healthy-WA/Articles/J_M/Medicines-and-poisons

³ Sir Charles Gardner Hospital. WA Poisons Information Centre Annual Report 2012. http://www.scgh.health.wa.gov.au/OurServices/WAPIC/pdf/WAPIC_AnnualReport.pdf

⁴ Safety and Quality Council: Second National report on Patient Safety, Improving medication Safety. Canberra: Australian Council for Safety and Quality in Health Care.

⁵ Australian Institute for Health and Welfare. National Drugs Strategy Household Survey 2013. <http://www.aihw.gov.au/alcohol-and-other-drugs/ndshs-2013/ch6/>

⁶ Australian Institute for Health and Welfare. Drugs in Australia 2010: Tobacco, alcohol and other drugs. <http://www.aihw.gov.au/WorkArea/DownloadAsset.aspx?id=10737420455>



Table 1: Medicines and poisons categories

Schedule	Poison category	Examples of common poisons
2	Pharmacy Medicine	cough and cold medicine, nasal sprays, aspirin, paracetamol, ibuprofen, antihistamines
3	Pharmacist only Medicine	asthma inhalers, cold and flu medication containing pseudoephedrine
4	Prescription Medicine	antibiotics, prescription pain killers e.g. tramadol, adrenaline, antipsychotic drugs
5	Poisons requiring caution in handling and storage	bleach, garden pesticides
6	Poisons with moderate to high toxicity	Acids, Oven Cleaners, Drain Cleaner
7	Dangerous Poisons	Cyanide
8	Controlled Drugs	Morphine, Methadone, Stimulants
9	Prohibited Drugs	Heroin
10	Strictly Controlled Substances	Amygdalin

Due to the prevalence and diversity of medicines and poisons the potential risk of harm from improper use is high. To minimise this risk, the use, manufacture, prescription and availability of substances, defined as poisons, is covered by WA legislation. The legislation seeks to make sure that all medicines and poisons used in WA for medical, household, industrial and agricultural purposes are carefully controlled. To ensure that medicines and poisons provide the most benefit to the community, and cause the least harm, this legislation controls aspects of their manufacture (including packaging and labelling) and supply to consumers.



1.2 Objectives of Medicines and Poison Legislation

Medicines and poisons legislation outlines the controls related to who can use a poison, how they can use it and whom they can supply it to. When used correctly, medicines and poisons offer great benefits to the community.

Effective medicines and poisons regulation must ensure:

- Promotion and protection of public health by ensuring that medicines are of the required quality, safety and efficacy;
- Medicines are appropriately manufactured, stored, distributed, supplied and dispensed;
- Illegal manufacturing and trade are prevented, detected and adequately sanctioned;
- Health professionals and patients have the necessary information to enable them to use medicines rationally; and
- Access to medicines is not hindered by unjustified regulatory workload.

To support these objectives, the legislation should provide controls which are proportional to the risk, ensuring as much public harm as possible is diverted, while still providing the access as required to adequately meet public needs to use these substances. With these considerations in mind, the legislation must address the need to control those substances that have been universally assessed as harmful and therefore deserving of protection from unrestrained public access.

Legislation must clearly articulate the required controls in a manner which is easy to understand and easy to enforce. The Department of Health (the Department) is cognisant of the need for this legislation to be written in a language that is easily understood by stakeholders, health practitioners and members of the public.

It must also achieve national consistency with other legislation wherever possible.



1.3 Medicines and Poisons Act 2014

The Act was passed by the Western Australian Parliament on 2 July 2014⁷. The Act replaces the aging *Poisons Act 1964*, which was supported by the 1965 Regulations. It is intended that new subsidiary legislation be developed to support the Act and supersede the 1965 Regulations.

The Act contains an updated legal framework for the efficient and effective management of medicines and poisons. It provides a method for classifying poisons according to risk to public health and for the development of rules required for their safe management.

The risk involved and the related need to regulate for a specific control for a medicine or poison is dependent on: the person who is using the poison; the toxicity of the poison; how much poison there is; and how much of the poison is available to others to access.

The Act controls medicines and poisons accessibility by determining levels of access and stipulating how a person may access a poison, based on this level of risk.

For example:

- For the public to access medicines they must obtain a prescription from an authorised professional, e.g. a medical practitioner; or
- For an individual to access a poison, the Department must issue a licence to obtain a poison.

An individual can then access a medicine or poison from an authorised person, who can be described as a custodian (holder or supplier) of that medicine or poison. The custodian, in the examples described above would be the medical practitioner or licensee, both of whom can be granted permission to be custodians under the Act. A custodian needs to be a person with the appropriate knowledge and skills to manage the risk posed by that medicine or poison. They must be a person who can take appropriate precautions when selling and supplying that medicine or poison, or otherwise authorising a member of the public to access that medicine or poison. Appropriate custodians are defined in the Act via:

- Professional authority – which can outline when and what medicine a health professional can provide, and when this authority can be revoked; and
- Licence / permit holders – which can outline when and what medicine or poison a person can supply, and when this authority can be revoked.

The Act provides a high level framework to outline who is a suitable custodian. This framework includes provisions to apply conditions that custodians must adhere to in terms of labels, packaging, storage, supply and record keeping. The Act aims to ensure the use of medicines or poisons only occurs via that custodian, and is safe and acceptable. In addition, the Act gives powers to track, control and limit the supply of medicines and poisons by these custodians, as necessary.

⁷ Medicines and Poisons Act 2014.

https://www.slp.wa.gov.au/legislation/statutes.nsf/main_mrtitle_13172_homepage.html



Regulations are necessary to set out the finer detailed controls to protect the public from harm associated with medicines and poisons. Regulations have the role of clearly defining who can have professional authority and who requires a licence or permit. Whilst the Act gives the power to issue an authority, the detail of this authority is provided in regulations.

For example:

- The Act states a health professional can be authorised to administer, possess, prescribe, supply or use medicines; or
- Regulations will list certain authorised professions and their respective restrictions,
 - e.g. a registered veterinary surgeon can prescribe for therapeutic use in animals.

In the *Poisons Act 1964*, the professional authority to purchase, have and use medicines was historically recognised for explicitly named professions, such as medical practitioners and pharmacists. The Act does not specifically name classes of practitioners in this way and new regulations are therefore necessary to authorise these persons.

In addition to the *Poisons Act 1964*, the 1965 Regulations provide an authority to use medicines for other professions regulated via national health practitioner regulatory boards and the Australian Health Practitioner Regulation Agency (AHPRA). New regulations must then provide clarity for these health practitioners on their authority to handle medicines.

There is also a growing need for the delivery of healthcare involving medicines by practitioners that are not of these established groups. The new legislation provides the possibility for this to occur.

For example:

- A framework for Structured Prescribing Arrangements for professions not clearly authorised via a national board / AHPRA
 - e.g. Aboriginal health workers.

The regulations must also provide a mechanism for individuals, organisations and for the Department to create Structured Prescribing Arrangements.



1.4 Current Regulations: Poisons Regulations 1965

The 1965 Regulations currently regulate the sale and supply of medicines and poisons in WA. They set out detailed controls to protect the public from harm associated with medicines and poisons.

The 1965 Regulations are 197 pages long and contain over 175 individual clauses, which have been regularly updated to accommodate medication and poisons issues over time.

Controls outlined in the 1965 Regulations include restrictions on supplying or using a poison, storage and disposal, packaging and labelling, record keeping and reporting, and advertising. They vary according to the risk posed by a particular medicine or poison.

Where a pressing public need has existed, the controls outlined in these regulations have been modified or enhanced via regulatory amendments and exemptions. Exemption processes have allowed added flexibility to address health workforce or consumer medicines access issues. However, they have added a significant regulatory burden on the Department and have decreased the usability and clarity of the document for health practitioners.

For example:

- Exempting use or supply of a named medicine from provisions of the Act in specified situations
 - e.g. registered nurses in remote area nursing posts providing medicines as part of a standing order approved by the CEO.

The 1965 Regulations were written almost 50 years ago and other national frameworks and/or regulatory requirements have superseded some areas previously controlled by this legislation. This is particularly relevant in areas such as licencing and professional authorities where new regulatory authorities, such as the Therapeutic Goods Administration (TGA) or national health practitioner boards through AHPRA, now provide comprehensive national regulatory frameworks. The regulations need to be complementary to, rather than duplicative of, these other national frameworks.

Development of the Act included broad stakeholder consultation and impact assessment. It must be noted that during this consultation, much of the feedback provided by stakeholders related to issues with the 1965 Regulations. Review of the 1965 Regulations showed significant continued cohesion with the Act, but also some regulatory gaps, in which the 1965 Regulations do not adequately support the Act. In many instances, regulations from the 1965 Regulations can be directly adopted into the new regulations.

The 1965 Regulations need to be updated to meet changes to business, workforce and chemicals use, and to meet regulatory drift. A number of the existing provisions in the 1965 Regulations can be readily retained. In some areas, for example provisions on Electronic Storage and Supply Units recently introduced, the regulations could well be directly adopted into new legislation.



In other areas, the controls were out-dated due to changes to current practice, new technologies (e.g. electronic prescriptions), increased uses for different types of medicines and/or other newer pieces of legislation. Sections of the 1965 Regulations are to be amended to reflect different aspects of the Act and new regulations introduced where required for the functioning of new frameworks. Alternative regulatory bodies are considered to provide adequate protective controls in some instances, such that extra regulation in these areas is no longer deemed necessary.

Introduction of new regulatory clauses to align with the Act has considered national consistency, recognition of new roles of health professionals, amendments to control over drugs of addiction, and emerging health practice trends and issues. In addition, new regulations will assist the Department in its work in day to day application of the legislation by providing improved clarity around areas of known regulatory failure.



Part 2: Options

2.1 Consultation process

2.2.1 Development of the Consultation RIS

For consultation over new regulations, the impact assessment process required a review and update of the medicines and poisons stakeholders contacted for the Act. A comprehensive updated stakeholder engagement list is outlined in Appendix 1.

Leveraging from the momentum achieved during consultation for the Act, consultation on the regulations commenced as the Act was presented to Parliament. To develop new regulations a structured process has been applied to existing and newly identified stakeholders. This included compilation of discussion papers, initial surveys, questionnaires and targeted interviews. Regular updates on progress were made available to internal and external stakeholders via briefings and updates on the Department website.

Development of the Consultation RIS and associated recommendations was achieved using wide consultation including:

- Initial survey - August 2013;
- Distribution of Poisons Regulations Discussion Paper (see Appendix 2);
- Targeted interviews with peak representative bodies between August 2013 to July 2015 - such as the Australia Medical Association, Royal Australian College of General Practitioners (RACGP), hospital groups, nursing and Pharmacy bodies; and
- A series of face-to-face general stakeholder forums held from August 2013 to April 2014.

This consultation process informed the development of the options outlined in Section 2.2 and led to the proposed preferred regulatory options outlined in the Impact Analysis sections (Part 3) of this document.

A comprehensive stakeholder assessment process was completed according to requisite Regulatory Impact Assessment process and guided by the *Public health consultation: A guide for developers*⁸. The aim of this consultation process was to facilitate appropriate stakeholder engagement, to encourage contribution to discussions and to influence the preferred options in relation to new Regulations. Stakeholders have had significant opportunity to influence the preferred options via a range of methods. This document is the culmination of this extensive consultation process, which generated detailed views about the proposed changes and informed identification of the preferred changes.

Initially the *Poisons Regulations Discussion Paper* was developed to consider options in regulatory modification and was widely publicly circulated for comment. The discussion paper was sent out with a directed survey and the results collated. Stakeholders were encouraged to request individual interviews.

⁸ WA Department of Health. Public health consultation: A guide for developers. 2006.
http://www.public.health.wa.gov.au/cproot/1503/2/Public_Health_Consultation_Guide.pdf



Targeted stakeholder interviews were then conducted based on these requests. Group forums were also held on particular topics of regulatory failure including, Schedule 8 opiate prescribing, rural and remote health access to medicines, public health access to medicines, aspects of veterinary practice and stimulant regulatory scheme controls.

A Consultation RIS was prepared and distributed one approved. This document considered options to improve consistency of medicines and poisons regulations to support the Act. Organisations and individuals with an interest in the regulations were invited to review options proposed and provide feedback through the consultation tool.

2.2.1 Development of the Decision RIS

After publication of the Consultation RIS the Department used an online consultation tool for managing, publicising and collating the consultation activity. The approved Consultation RIS document was placed on the department website http://ww2.health.wa.gov.au/Articles/A_E/Development-of-the-Medicines-and-Poisons-Regulations. The Consultation RIS documents and the associated directed online survey remain available for viewing at: <https://consultation.health.wa.gov.au/>

Stakeholders identified in all previous consultation phases were emailed a direct link to the document and the survey to provide submissions for further feedback. The survey was open for submissions from 14/09/2015 to 6/10/2015. Software purchased to support public health consultation processes was then utilised to collate stakeholder comments and provide the Department with qualitative feedback regarding these responses.

Stakeholders were questioned about the proposed regulations and the impacts of the preferred options. The proposed regulations and the impacts were further refined based on this feedback. Feedback was received from 50 organisations and stakeholders, and was able to specifically target areas of interest and impact.

The feedback from stakeholders was generally complimentary about the extent of consultation and the scope of issues addressed in the Consultation RIS. For example, one stakeholder wrote:

- *“Congratulations on the extent to which you have sought consultation and worked to ensure the best design and implementation of these regulations”⁹.*

From the Consultation RIS, further gaps and additional issues were identified in individual regulatory areas. Areas which provoked most discussion included Professional Authority and Structured Prescribing Arrangements. This may reflect the high visibility of these issues amongst health practitioners and a real desire for regulatory reform, due to changing health consumer demands and health workforce practices.

There were a number of common themes identified from this consultation, including:

- Acceptance of the need for adjustment of regulations for national consistency;
- Need for clarity regarding some definitions used in the document;
- Recognition of the amount of consultation that has been previously undertaken;
- Synergies with other regulatory bodies;

⁹ CRIS Submission 31



- Desire of stakeholders for education regarding new regulations; and
- Stakeholders requesting opportunity to participate in future consultations.

Not all comments related directly to the intent or substance of regulations. Many submissions expressed a general desire for improvements in understanding the legislation and aspects of its normal administration by the Department.

This Decision RIS has incorporated feedback from all phases of this consultation and presents the resulting preferred options for the new regulations. Preferred options and impacts have been refined to provide a basis for legislative drafting.

The completed and approved *Decision Regulation Impact Statement - Medicines and Poisons Regulations*, will be published on the Department website and available for viewing by members of the public. Once approved, a link to this document will be also emailed to listed stakeholders and survey respondents.

2.2.1 Background to Medicines and Poisons Stakeholders

The Pharmaceutical Services Branch (PSB) within the Department was responsible for consulting over the development of new subsidiary legislation and asking stakeholders for their views about proposed new regulations. Stakeholders have had good opportunity to influence decisions and actions, via a range of methods.

Prior to commencing work on regulations, a comprehensive consultation process was undertaken in the development of the Act. This occurred between 2003 and 2013 and included:

- Release of public consultation/discussion papers;
- Targeted stakeholder consultation meetings and group forums;
- Release of public exposure drafts;
- Production of a Decision Regulatory Impact Statement.

Approximately 50 key stakeholder organisations were individually consulted through this process including Government, medical, nursing and midwifery, pharmacy, dental, allied health and consumer organisations.

Through its daily activities, the PSB and the Department are well informed of stakeholder views through:

- Responding to external regulatory developments;
- Liaison and consultation with other States and Territories regarding their legislation;
- Operational interaction with health practitioners, and license and permit holders;
- Operation of audit and compliance programs,
- Regulatory actions and prosecutions;
- Complaint letters, and responses to ministerial or internet queries;
- Provision of general public advice;



- Queries to the poisons information email facility and telephone line; and
- The Schedule 8 Prescriber Information Service telephone line.

There are also formal links with PSB across WA Health including:

- Chief Pharmacists;
- Medical Directors;
- Nursing Directors;
- Environmental Health Directorate;
- Communicable Disease Control Directorate; and
- Public Health Division.

The Department facilitates a number of statutory committees which have provided opportunities for formal discussion regarding regulatory controls, including:

- Community Program for Opioid Pharmacotherapy Management Committee;
- Stimulants Assessment Panel;
- Pesticides Advisory Committee; and
- Poisons Advisory Committee.

The Department also has frequent interaction with other Government bodies through committees and other means, including:

- National health practitioner boards and AHPRA;
- Department of Agriculture and Food WA;
- WA Police; and
- The Mental Health Commission (formally Drug and Alcohol Office).



2.2 Regulatory Options Considered

The consultations and stakeholder feedback focused on the architecture of the Regulations and key issues in each regulatory area.

Based on this consultation the following options were considered:

1. Status quo: retention of the 1965 Regulations unchanged;
2. Amend the 1965 Regulations; or
3. New Regulations: *Medicines and Poisons Regulations*.

2.2.1 Status quo: Retention of the 1965 Regulations Unchanged

Status quo would mean no change to existing legislation. Stakeholders universally identified that the existing legislation has deficiencies and was exhibiting significant failure. The current legislation does not achieve the identified objectives of the Act, particularly in relation to harmonisation with other jurisdictions, support for ongoing changes to the health workforce, reduction in regulatory burden, improving transparency of controls and providing support for initiatives to reduce diversion and misuse of pharmaceutical drugs.

Advantages:

- Short term, this is the least costly option, but very is likely to result in increasing costs in the long term.

Disadvantages:

- Does not deliver national consistency, such as with recommendations of the *Galbally Review*¹⁰, or achieve monitoring of cross border commerce of medicines and poisons; and
- Does not redress stakeholder dissatisfaction with deficiencies and regulatory failure including:
 - Expanded health workforce participation in providing healthcare;
 - Reduction in regulatory burden of dual licencing;
 - Improved transparency of controls in use; and
 - Improvement in increasing diversion and misuse of pharmaceutical drugs.

Retention of current legislation would not create any immediate costs, however there are known costs to consumers and industry at present in dealing with legislative failure. These costs would expect to increase over time.

¹⁰ Council of Australian Governments. National Competition Review of Drugs, Poisons and Controlled Substances Legislation. 2000. <https://www.tga.gov.au/review-drugs-poisons-and-controlled-substances-legislation-galbally-review>



2.2.2 Amend the 1965 Regulations

This option assumes continuation of the existing arrangements whereby controls outlined in the regulations are modified via a process of amendment and exemption. Controls outlined in the 1965 Regulations include restrictions on supplying or using a poison, storage and disposal, packaging and labelling, record keeping and reporting and advertising. They vary according to the risk posed by a particular medicine or poison. Where pressing public need exists, controls imposed by these regulations have been modified via regulatory exemption. For example, exempting use or supply of a named medicine from provisions of the 1965 Regulations in specified situations, such as registered nurses in remote area nursing posts providing medicines as part of a standing order approved by the CEO. The exemption process allows amendment, however it places significant increased regulatory burden on the Department. This option restricts development to the areas outlined in existing regulations and does not allow for introduction of new areas. In addition, continuing amendments to the 1965 Regulations are slow, costly and inefficient.

Advantages:

- Is consistent with current work processes; and
- Stakeholders are familiar with the current 1965 Regulations.

Disadvantages:

- Does not address stakeholder concerns regarding the difficulties of understanding the current legislation;
- Adds additional regulations required by the Act will take increased time; and
- Does require increased time to achieve primary objectives of:
 - National consistency;
 - Expanded realm of health workforce participation;
 - Reduction in regulatory burden;
 - Improved transparency of controls; and
 - Reduced diversion and misuse of pharmaceutical drugs.

There have been multiple regulatory failures identified during consultation and the amendments proposed by stakeholders to resolve these failures are significant in number. Achieving the primary objectives through multiple minor alterations presents difficulty due to the advanced age of the 1965 Regulations and the numerous amendments that have already been made over time. The Department supports drafting of new regulations using contemporary legal language. Stakeholders expressed a universal preference for significant legislative amendment in this area and there was clear expectation of new, modern legislation, as has already occurred in most other Australian jurisdictions.



2.2.3 New Regulations: Medicines and Poisons Regulations

An expectation of new regulations was evident even as early as during reviews conducted with stakeholders from 2001 with respect to a new Act. Stakeholder consultations have indicated the 1965 Regulations are difficult to interpret and a new approach to regulatory reforms is the preferred option.

Advantages:

- Aligns with the current Act; and
- Will achieve primary objectives of;
 - National consistency;
 - Expanded realm of health workforce participation;
 - Reduction in regulatory burden;
 - Improved transparency of controls;
 - Reduced diversion and misuse of pharmaceutical drugs; and
 - Alleviation of stakeholder concerns and dissatisfaction.

Disadvantages:

- There are minor costs to Government (the Department) during development and implementation phases; and
- There are costs for stakeholders to become familiar with new requirements and modify practice to comply with new regulations.

New subsidiary legislation would achieve the stated objectives. The proposed new Regulations can address these objectives and be constructed in response to stakeholder requirements to balance costs and benefits to consumers, industry and Government.

The new Medicines and Poisons Regulations are intended to continue to provide a framework for control of medicines and poisons in WA under the fundamental principle of the protection of public health and safety. Operational detail is not provided in the Act; the intention being to retreat from the prescriptive nature of past legislation to a more flexible modern approach. When the Act was drafted it was intended that it would be supported by comprehensive subsidiary legislation to ensure adequate compliance and appropriate regulation.



2.3 Stakeholder Recommendations

In considering the regulations, all stakeholders have indicated the need for transparent, simplified, nationally consistent legislative reforms. Key recommendations include:

- Improved clarity and flexibility regarding medicine authority for health professionals;
- Reduced red tape for licences and permits;
- Improved controls over supply of drugs of dependence;
- Fairness and transparency for those taking drugs of dependence;
- Improved national consistency for poisons through better alignment with the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP); and
- Regulatory support for adoption of new technologies.

Stakeholders highlighted strong support for these objectives, with an emphasis on the need for improving alignment of existing regulations with national legislation and reducing regulatory burden where possible. Regulatory failures, impact on consumers and business, and preferred options for reform were also strongly identified themes in the consultation process.

Stakeholders were universally supportive of Option 3: New Regulations: Medicines and Poisons Regulations. This was evident through statements such as:

- *“We...support the modernisation of Medicines and Poisons regulation in Western Australia to ensure it is fit for purpose through new Medicines and Poisons Regulations 2015 (option 3)”.*¹¹

¹¹ CRIS submission 50



2.4 Preferred Option

Section 2.2 outlined potential options for Medicines and Poisons Regulations to support the Act. Consultation supported the drafting of entirely new Regulations.

The preferred option is Option 3:

- **New Regulations: Medicines and Poisons Regulations.**

All Australian jurisdictions and all other major developed nations have similar legislative controls over a range of medicines and poisons. Current poisons laws have existed for many years and are well established as the default norm. They mirror regulatory schemes found in other advanced countries. In WA, the current approach has been in place since 1964. As such, there is limited contemporary evidence on the likely impact of an increase or potential decrease in regulation of medicines and poisons. For example, there are no known scientific trials of the effect on public harm in Australia from complete removal of poisons controls.

The need for continued controls is evident in the number of poisonings seen annually in Australia. State Governments maintain publicly funded Poisons Information Centres manned 24 hours a day by highly trained health professionals. These are connected to public hospital toxicology units. The number of calls taken by these centres each year suggests that exposure to poisons and poisoning is still a frequent event in our society. This rate is relatively constant, suggesting a residual risk associated with access to these substances, even with the existing controls in place.

WA has existing legislation that provides these controls, however it is ageing, does not meet all stated objectives, and there is regulatory failure identified by those primarily affected by this legislation. The option of maintaining the status quo does not address the known regulatory failures. Maintaining existing legislative control for medicines and poisons in WA through Option 1 or Option 2 is not consistent with other national and international standards.

Regulation in this area is not new and as such, emphasis has been placed on discussing the problems in existing regulatory areas and the potential impact of modifications necessary to support the operation of the Act. Part 3 of this document proposes the details of new regulations to address all stated objectives and rectify areas of regulatory failure. These regulatory changes are supported via stakeholder-derived evidence in key regulatory areas. It must be emphasised that in most instances these changes are enhancements of the existing regulations. The new regulations will need to adopt elements of existing regulatory controls. They will however, provide better protection for individuals, be written in more user friendly and understandable contemporary legal language, and be streamlined through formal recognition of similar controls in other similar pieces of legislation.



The proposed regulatory changes can be summarised as achieving three main legislative objectives:

1. Modernisation of existing regulation, e.g. electronic prescribing or use of Electronic Storage and Supply Units (ESSU);
2. Alignment of existing regulations with other national pieces of legislation, e.g. professional authorities for medicines and poisons controls; and
3. Reduction of red tape or regulatory burden created by existing regulation, e.g. licencing and drugs of dependence changes.

These changes will continue to ensure the most effective prevention of harm to patients and consumers from risks associated from medicines and poisons.



Part 3: Impact Assessment

3.1 Introduction

This part identifies the broad policy objectives, which have been developed through consideration of consultations undertaken by the Department, as outlined in Part 2. This part also identifies the regulatory areas that require amendment, outlines the background to known issues with the existing 1965 Regulations and details the preferred regulatory changes. Additional details on the justification for these changes are provided in specific areas, with reference to stakeholder identified impacts, as obtained during consultation.

Development of the proposed regulations was guided by discussion papers (see Appendices 2 and 3) and preliminary consultation. These discussion papers were circulated widely to key stakeholders to obtain feedback on impacts. They were also used to identify the preferred options in each of the key regulatory areas and generate the Consultation RIS.

Proposed regulations have been further refined, based on the stakeholder feedback received from the circulation of the Consultation RIS.

3.2 Policy Objectives

The following broad policy objectives were considered in the development of the preferred regulatory options:

- Improved consumer health outcomes in relation to medication and poison provision via safe access to medications and poisons;
- Providing a flexible and responsive framework that is applicable across all settings and clearly lays out minimum standards to meet public health requirements;
- Ensuring national consistency in medicines and poisons regulation;
- Reducing regulatory burden particularly in regards to mandatory reporting and licencing reciprocity;
- Responding to public health and emergency health demands requiring medicines and poisons access (e.g. vaccinations) through Structured Prescribing Arrangements; and
- Responding to current health practice and trends including expanded job roles.



3.3 Areas of Regulatory Control

Development of the new regulations will be conducted under the overarching framework of legislation determined by the Act. The proposed regulations will address the regulatory gaps evident due to the introduction of the 2014 Act, which includes new provisions. The drafting of the regulations will address:

1. Continuing existing regulatory controls from the 1965 Regulations which are working well;
2. Introducing new controls as identified by stakeholders; and
3. Considering alternative regulatory schemes, where required.

The options to address regulatory issues and the impact of proposed regulatory changes have been examined in the key regulatory areas outlined below:

- Professional Authority (3.4);
- Structured Prescribing Arrangements (3.5);
- Electronic Prescribing (3.6);
- Electronic Storage and Supply Units (3.7);
- Licencing and Permits (3.8);
- Control by Poison Schedule (3.9);
- Control by Medicine Schedule (3.10);
- Drugs of Addiction (3.11);
- Drugs of Dependence Records (3.12);
- Electronic Real Time Controlled Drug Reporting (3.13);
- Destroying Drugs of Addiction (3.14);
- Storage and Transport of Drugs of Addiction (3.15); and
- Ships and Vessels (3.16).

Under each of these regulatory areas, the purpose of regulatory control and an explanation of the impact of the proposed changes is given. The proposed changes are clearly articulated for each area and summarised in text boxes. In each regulatory area, an impact assessment has been undertaken on the potential costs / benefits and the likely advantages and disadvantages of the proposed regulations.

Areas in which regulatory failures were not identified are intended to be transferred into new Regulations without significant alteration to their intention or operation. They are not discussed further in this document.



3.4 Professional Authority

3.4.1 Background

Medicines are intended to treat ill health, to cure disease, alleviate symptoms, prevent disease progression, or to palliate. However, all medicines have adverse effects and there is significant potential for harm from incorrect use. Limiting the supply of medicines via health practitioners ensures that only those persons who have the correct skills and qualifications to perform this safely are permitted to supply or authorise supply of medicines to the public. Patients will then be adequately assessed and correctly diagnosed, and then supplied with the most appropriate and effective medicine in the most ideal form and dose. Patients will be educated and instructed in correct use. Any unwanted effects will be reviewed, so that any potential harm is identified and rapidly treated.

Health practitioners need access to medicines to administer them to patients, use them for diagnostic or treatment purposes, or to supply to individual patients for their later personal use. To reduce unwanted harm, those persons without the correct skills to safely supply to patients should be excluded from doing so.

The use of medicines should be restricted to legitimate medical uses. Controlling public access to medicines also limits the potential for misuse and abuse, diversion into non-medical or recreational use, theft and illicit sale, deliberate misadventure and other public harm.

The objective of the Regulations should then be to adequately determine:

- Which health practitioners are the safe and correct persons to use medicines;
- Allowable uses for each group;
- Limits if any, to be placed on these users, when appropriate; and
- Which uses are not acceptable.

This professional authority can be taken away, limited or modified if there are grounds for such action, where public safety is at risk. This must be a standard provision for any authority conferred, regardless of health professional grouping.

3.4.2 Current Regulations

WA uses the national SUSMP scheduling classification system for poisons. The level of State regulatory control for the various poisons is influenced both by the Schedule of medicine and any commensurate risks associated with its use¹².

One measure of control is to regulate professional authority; to ensure that only professionals with appropriate skills, knowledge and training are authorised to handle poisons.

¹² Standard for the Uniform Scheduling of Medicines and Poisons No.8. <http://www.comlaw.gov.au/Details/F2015L00128>



The regulation of this professional authority is authorised in the Act:

- Under Section 25 to administer, possess, prescribe, supply or use a medicine; and
- Under Section 26 to manufacture a medicine, or use or possess a Schedule 7 poison.

Under the *Health Practitioner Regulation National Law (WA)* (National Law)¹³ the respective health practitioner National Boards, supported by the Australian Health Practitioner Regulation Agency (AHPRA), are responsible for the implementation of the National Registration and Accreditation Scheme (NRAS) across Australia. AHPRA works with the 14 National Health Practitioner Boards in implementing the NRAS objectives, which include helping to “keep the public safe by ensuring that only health practitioners who are suitably trained and qualified to practise in a competent and ethical manner are registered”¹⁴.

The National Boards set the standards that practitioners must meet in order to register. Once registered, practitioners must continue to meet the standards, including in continuing professional development, and renew their registration yearly with the National Board. At a State level, the 1965 Regulations point to these registration mechanisms to authorise certain health professionals, when registered under NRAS, to prescribe, supply, administer, possess, dispense and use various medicines and poisons.

The 1965 Regulations authorise health professionals to handle scheduled medicines in a particular way. The specific authority is detailed in a number of sections and under a number of individual regulations according to various criteria including: “type of use”; “schedule of medicine”; and “professional endorsements”.

For example:

- Part 2A - details endorsed health practitioners’, e.g. endorsed optometrists, midwives and podiatrists;
- Part 5 - Regulation 40 and Regulation 42 lists those persons authorised to possess Schedule 4 and Schedule 8 poisons respectively; and
- Part 5 - Regulation 36 lists those person authorised to dispense Schedule 4 poisons.

An individual practitioner must therefore interpret the current 1965 Regulations to determine any statutory obligations and how a particular health profession may handle a medicine. This has resulted in confusion, with practitioners and the public being unclear on how medicines may be handled by certain health professionals.

The Act allows the authorisation of a health professional to administer, possess, prescribe, supply and use a medicine, in the lawful practice of their profession, if they are within a class prescribed by regulations.

In contrast, the *Poisons Act 1964* explicitly names authorised classes of health practitioners. The specific authorities conferred this way are outlined in Table 1. During construction of the Act the impact assessment process found that the naming of specific practitioner

¹³ Note - All States and Territories, including WA have enacted the National Law, including WA in the form of the *Health Practitioner Regulation National Law (WA) Act 2010*

¹⁴ Australian Health Practitioner Regulation Agency . About AHPRA. 2014. <http://www.ahpra.gov.au/About-AHPRA.aspx>



classes led to lack of flexibility and stifled health workforce innovation. Because practitioner authorities are no longer named, new regulations to complement the Act and confer these authorities are now necessary.

Table 1: Poisons Act 1964 - Authorities

Class	Authority					Conditions
Pharmacist	Manu- facture	Possess	Use	Sell / Supply		At a pharmacy in the course of retail business
Medical practitioner		Possess	Use	Supply	Prescribe	In the lawful practice of that profession
Veterinary surgeon		Possess	Use	Supply	Prescribe for animal use only	In the lawful practice of that profession
Dentist		Possess	Use	Supply	Prescribe for 7 days	In the lawful practice of that profession
Nurse practitioner		Possess	Use	Supply	Prescribe	In the lawful practice of that profession
Endorsed health practitioner		Possess	Use	Supply	Prescribe	In the lawful practice of that profession, pursuant to Regulations

In 2010 Section 23 of the *Poisons Act 1964* was amended to provide for authorisation of other classes of registered health practitioners if endorsed under the National Law. These endorsed practitioners are then further detailed in the 1965 Regulations, where the actual authority and any additional limitations are set out. Other classes of endorsed practitioner currently recognised by the 1965 Regulations under Section 23 are described in Table 2.

Table 2: Poisons Regulations 1965 - Endorsed Professionals

Class	Authority Limitations
Endorsed podiatrist	Drug class, form, use and duration as set out in the Medicines List issued by the relevant National Board.
Endorsed midwives	Drug class, form, use and duration as set out in the formulary issued by the relevant National Board; Administration only of Schedule 8 drugs (no prescribing).
Endorsed optometrist	Topical eye use only.

An endorsed health practitioner, may possess, use, sell or supply, prescribe scheduled medicines according to these authorities. Use by endorsed practitioners (that is administration to a patient) is not taken to be supply under the 1965 Regulations.

The 1965 Regulations also define supply, stating that administration to a patient by a medical practitioner; nurse practitioner or dentist is not deemed to be supply.

Similarly in the 1965 Regulations, administration by a registered nurse is not supply when acting under the direction of an authorised prescriber.



3.4.3 Current Regulatory Issues

These authorities, as outlined in the 1965 Regulations, were conceived at a time when health practitioner roles were more discretely separated. They also pre-date the National Registration and Accreditation Scheme. Stakeholders have advised that the way these authorities are structured is too restrictive, prevents innovation and hampers health workforce reform with respect to medicines.

It is also noted that the regulations do not seamlessly articulate with the National Law. During consultation, National Boards and AHPRA supported changes to establish better connection of Poisons Legislation with National Law, particularly in relation to practitioners with a scheduled medicine endorsement. Any authority conferred in the regulation should align with any limitations on a practitioner class imposed by the relevant National Board.

The Act does not explicitly specify authorised classes of health professionals as outlined in the previous *Poisons Act 1964*. At the time of drafting the Act it was identified that development of modified regulation would be required to address issues regarding the changes in workforce.

This includes an opportunity to recognise some emerging registered health practitioners. Some practitioner groups are already well established and increasingly handle medicines as their professional scope of competence evolves. These groups include paramedics and Aboriginal health practitioners.

Some health practitioner groups are already registered professionals, but are also not recognised as having any authority to handle medicines by the current regulations. In these cases, they commonly work with authorised professionals and are required to handle medicines in both direct and non-direct delivery of care to patients. At present they have no specific personal authority under the existing legislation to do so. An authorised practitioner may not delegate an authority effectively in these cases and must personally supervise any other health worker as an employee. Stakeholders provided a number of examples, such as enrolled nurses, approved veterinary nurses, and other registered dental professionals.

Stakeholders also identified established and emerging roles for health workers not registered under National Law, but well integrated in the health system, such as anaesthetic technicians.

Current issues regarding professional authority can be summarised as:

- **Lack of alignment with national registration standards outlined by National Boards and AHPRA;**
- **Certain professions are not named and therefore it is difficult to identify restrictions;**
- **Current regulations are out dated in terms of current practice; and**
- **Current authority system does not allow changes to response in professional scope and therefore is inflexible to changing workforce needs.**



3.4.4 Proposed Regulations

Regulations must define which health practitioner groups need access to medicines and what criteria might include or exclude a person as part of a particular practitioner group. The regulations must also clearly stipulate that any actions must be in accordance with accepted, safe professional practice, and within the scope or valid employment of an individual. The regulations need to outline any conditions or limitations for any specific authority or practitioner group and define what legitimate practice may be for this group.

Consultation with National Boards and AHPRA has supported changes to establish more seamless articulation with National Law, particularly in relation to practitioners with a scheduled medicine endorsement. The regulations do not replace other authorisations required for legitimate practice for defined professional groups.

Professional authority specifically describes, as defined in regulations, a person's level of authorisation in relation to medicine access and distribution. Stakeholders indicated that the terms proposed are appropriate to describe practitioner access requirements.

However, there were minor discrepancies noted between some individual interpretations of medication access in relation to these terms. Consultation has highlighted the need to clearly define the terms used for professional authorisation in the regulations. Definitions that describe the intended extent of an authority in relation to medicines, along with practical examples, are outlined in Table 3.

Table 3: Definitions of Professional Authorisations

Term	Explanation	Example
Obtain	<p>Provides the authority for a person in the lawful practice of their business to procure or purchase a medicine from a wholesale supplier or authorised person.</p> <p>Practitioners who may only work under the direction of another registered health practitioner would not need authority to obtain medicines.</p>	<p>A dentist may obtain a medicine for use at his or her dental practice.</p> <p>Any medicines for use at that practice, including by another practitioner working directly to that dentist, would be obtained under the authorisation of that dentist.</p>
Possess	<p>To have in their physical possession, or stored under their control, a medicine required in relation to their employment / professional practice.</p> <p>This means that the person is lawfully able to have, hold and handle the medicine to provide health care, in their legitimate work setting.</p> <p>This may include selecting, manipulating or readying a medicine for use by another professional.</p> <p>This authority only extends to that practitioners regular place of work.</p>	<p>A paramedic may have control of a medicine in an ambulance for transport to another place and subsequent use on a patient.</p> <p>A veterinary nurse may be required to select and reconstitute an injection for administration by a veterinary surgeon to an animal.</p> <p>This authority does not extend beyond legitimate employment as a health care worker. For example, storing medicines at the paramedic's home residence would not be permitted.</p>



Term	Explanation	Example
Administer	To supply a medicine for immediate use, through applying, inserting, injecting, causing to ingest or otherwise assisting a patient to consume that medicine, for a therapeutic purpose.	<p>A nurse working at a hospital will administer a medication dose to a patient according to a medical practitioner's written order on the medication chart.</p> <p>An Aboriginal health worker may administer a vaccine by injection to a patient in accordance with a Structured Prescribing Arrangement, when for a public health purpose.</p>
Supply	<p>To sell, give or provide a medicine to patient or person on behalf of the patient, such as a parent or carer.</p> <p>Supply can be authorised under the direction of a Structured Prescribing Arrangement.</p>	<p>An endorsed optometrist may supply a patient with a bottle of eye drops intended for administration by the patient at home.</p> <p>A remote area nurse may supply a limited quantity of a medicine, intended for administration by the patient at home, in accordance with a Structured Prescribing Arrangement, when for acute treatment.</p>
Prescribe	<p>To write or issue a prescription for a medicine. The prescription instructs and authorises an authorised person to dispense a medicine to a patient.</p> <p>Prescribing is only permitted within the designated scope of practice and lawful employment of that professional. Prescribing cannot be delegated.</p>	<p>A medical practitioner may issue a prescription to instruct a pharmacist to dispense a specific medicine and quantity of that medicine to a patient.</p> <p>A nurse practitioner may issue a prescription to instruct a pharmacist to dispense a medicine and quantity of that medicine to a patient.</p>
Dispense	<p>A specialised form of supply.</p> <p>To give or provide a medicine via retail sale to a patient or person on behalf of the patient, such as a parent or carer, in accordance with the instructions contained in a valid prescription.</p>	<p>A pharmacist working in a community pharmacy will supply a packaged and labelled medicine to a person in accordance with the instructions of a valid prescription.</p> <p>Currently only a pharmacist may dispense.</p>
Compound	<p>A specialised form of manufacture of a medicine, conducted by a health practitioner.</p> <p>A practice in which an authorised health professional combines, mixes, or alters ingredients of a product to create a medication tailored to the needs of an individual patient.</p> <p>A compounded medicine can only be supplied or dispensed in accordance with any other required authority.</p> <p>Manufacturing of registered therapeutic goods which are also Scheduled medicines is a specialised activity and not within the normal practice of a health professional. This may require access to obtain, possess and supply via an appropriate license.</p>	<p>A pharmacist may modify the form of an existing medicine, or combine two or more different medicines, and dispense these in accordance with a valid prescription. For example:</p> <ul style="list-style-type: none"> • Crushing tablets and adding additional ingredients to create capsules; or • Using a substance as a raw active ingredient and through addition of various excipients creating a skin cream at varied levels of concentration according to prescription requirements. <p>A registered veterinary surgeon may compound a medicine for an animal, and supply or administer this medicine. Unlike a registered pharmacist, a registered veterinary surgeon has their own authority to authorise administer or supply medicines.</p>



Expanding on the number of professions outlined in the 1965 Regulations, it is intended that the new regulations clearly define the health care workers which are allowed to obtain, possess, administer, supply, prescribe, dispense and compound (manufacture) medicines. These groups and their proposed level of authority are outlined in Table 4.

Table 4: Health Care Professional Specific Authority

Practitioner	Obtain	Possess	Administer	Supply	Prescribe	Dispense	Compound
Pharmacist	√	√	√ *	√ *		√	√
Pharmacy technician		√					
Medical practitioner	√	√	√	√	√		
Veterinary surgeon	√	√	√	√	√		√
Approved veterinary Nurse		√	√ #				
Dentist	√	√	√	√	√		
Dental therapist Dental hygienist Oral health therapist		√	√ # *				
Nurse practitioner	√	√	√	√	√		
Registered nurse		√	√ # *	√ *			
Enrolled nurse		√	√ # *	√ *			
Endorsed midwife	√	√	√	√	√		
Registered midwife		√	√ # *	√ *			
Paramedic		√	√ # *				
Ambulance officer		√					
Endorsed optometrist	√	√	√	√	√		
optometrist	√	√	√	√ *			
Endorsed podiatrist	√	√	√	√ *	√		
Podiatrist	√	√	√	√			
Aboriginal health practitioner		√	√ # *	√ *			
Aboriginal health worker		√	√ *	√ *			
Chinese medicine practitioner		√	√	√			
Anaesthetic technician		√	√ #				

Explanatory Notes:

√ indicates that this profession has an authority for this action

indicates that a valid instruction / direction from an authorised practitioner is required to action this authority

* indicates that a Structured Prescribing Arrangement specifying a particular authority is also required to action this authority



All authorities outlined in Table 4 are intended to be limited to practitioners to use of medicines as required in the therapeutic treatment of patients under their care. It is also restricted to the course of their business or employment, in the lawful practice of health care and according to the accepted or usual scope of their specific profession.

Any authority conferred in the regulations, particularly with respect to endorsed practitioners, should be in alignment with limitations imposed by the relevant National Board.

For example:

- An endorsed optometrist administering a medicine will need to meet guidelines relating to this endorsement. This can include adhering to use of only those medicines approved by the respective National Board as in scope, such as in a published list. Should there not be a published list, they would still be limited to administration of those drugs required to treat conditions determined by the Board as within scope of this endorsement.

The authority conferred must also consider limitations around practitioner competence or scope of practice.

For example:

- A nurse practitioner may administer, supply or prescribe but this only extends to medicines within the accepted competency and scope of the individual.

Where not regulated by the National Law the authority must be specific and limited to the employment or accepted boundaries of the professional group.

For example:

- An anaesthetic technician must be a person working in a hospital and may only handle medicines as part of their employment under direction or personal supervision of an anaesthetist.

Under the 1965 Regulations, nurse practitioners must work within a designated area of practice and must have clinical protocols approved within this area of practice. Identification in the regulations, as a professional group and recognition of their appropriate level of professional authority is required.

Any confirmed authority is limited to a health professional's area of practice and does not extend beyond this to areas unconnected with the lawful practice of that profession.

For example:

- A dentist can only prescribe for the purpose of dental treatment at their dental practice;
- A veterinary surgeon can only prescribe for the purpose of animal treatment; and
- A veterinary surgeon may need to keep medicines at their usual place of veterinary practice and also transport these to the site of treatment of large animals, where the animal is normally kept.

Authority does not extend to the use of medicine for purposes other than the therapeutic treatment of a patient.



For example:

- The prescribing or supply of medicines for another person to sell for illicit use; or
- The administration for recreational purposes would not be part of lawful practice.

These proposed authorities should not prevent any permitted activity that is already allowable under the 1965 Regulations. That is to say, any medicine that can already be supplied, administered or prescribed by a specific practitioner group needs to still be available to those practitioners to treat patients under any new regulations.

For example:

- A podiatrist who does not hold an endorsement, does not have a specific authority, but can obtain and administer a limited range of scheduled medicines under mechanisms available in the 1965 Regulations. The authorities conferred in Table 4 are intended to continue this access, but not necessarily extend it.
- If a podiatrist wishes access to a wider range of medicines or to prescribe, then they would need to complete any required endorsement process through the respective National Board.

Proposed regulatory changes for Professional Authority can be summarised as:

- **Defining individual professions that need access to medicines and what includes or excludes a person as part of that practitioner group;**
- **Outlining conditions or limitations for any specific authority or group and define what legitimate practice may be for this group; and**
- **Defining appropriate levels of authority in terms of a profession's ability to obtain, possess, administer, supply, prescribe, dispense, and compound medicines and poisons.**

3.4.5 Impact Analysis

The objectives of regulations in relation to professional authorities are to ensure those persons with a legitimate need to access medicines, and who are appropriately qualified and competent to use or supply to the public, have the legal authority to do so.

The recognition of both registered and non-registered health practitioners has the potential to extend and improve access to medications to meet consumer and workforce need. Stakeholders broadly supported the need for more health practitioner groups to be properly recognised and to be able to legally handle medicines within an appropriate scope, when needed for delivery of health care. Comments in relation to the preferred options for professional authorities proposed in the Consultation RIS included:

- *"This is an important move forward to recognise there are other health professionals required to access and prepare S8 and S4 medications"¹⁵;*

¹⁵ CRIS submission 11



- *"I think it is certainly time to replace the old regulations and the new proposed regulations will fit current practices and authorities"*¹⁶;
- *"This represents a positive improvement in the regulations"*¹⁷; and
- *"The roles of health care professionals are continuing to evolve. There is clear need for health delivery to become more efficient to manage the health care needs of the aging population"*¹⁸

Consultation highlighted the collective industry experience with changes to professional scope, such as nurse practitioners over the last decade. Stakeholders indicated that the:

- *"...expanded list of health care practitioners and their specific authority represents a positive step forward, especially where a specific scope of prescription links well with specific clinical expertise, e.g. optometrists and podiatrists"*¹⁹.

Throughout consultation it was repeatedly argued that broader access to medicines would provide a positive benefit for consumers and more efficient delivery of health care. Appropriate levels of professional authority in the regulations, is likely to create flexibility and reduce regulatory burden. Expansion of the defined professional roles with medicines may reduce costs to consumers in some areas where a task may be undertaken by a different health practitioner group. It is expected to improve consumer access, timeliness of care or convenience. Stakeholders advised in respect of the Consultation RIS that:

- *"The principle of consumer access to appropriate health care should be a key consideration in reviewing the impact of the changes... may reduce costs in some areas...improve consumer access, timeliness of care"*²⁰.

Stakeholders supported the assessment that care with medicines should be provided by a suitably qualified and regulated workforce, but that this could potentially be cheaper and readily available workers:

- *"...authority to access Schedule 8 medicines to administer these in hospitals would be a significant efficiency gain for WA health"*²¹.

Limited evidence was provided to quantify this size of this impact. It is however noted that expanded medicines authorities are commonplace in other comparable overseas health systems and are managed safely, to the benefit of health consumers and health providers. For this reason these arguments are considered well accepted.

The preferred option to link professional authority to health practitioner registration complements the existing processes undertaken by National Boards and AHPRA. Stakeholder comments provided in response to the Consultation RIS suggested that this articulation was important and would benefit health practitioners:

- *"It is sensible to link national registration endorsement with prescribing as this will aid public transparency and the development of endorsement pathways"*²²; and

¹⁶ CRIS submission 20

¹⁷ CRIS submission 25

¹⁸ CRIS submission 25

¹⁹ CRIS submission 25

²⁰ CRIS submission 27

²¹ CRIS submission 6

²² CRIS submission 25



- *“National alignment of legislation is important as lack of alignment can create issues with professionals and with patients who may find they move interstate and have a different standard of care”²³.*

During consultation, stakeholders advised that many practitioners were uncertain or confused about their actual authority with respect to medicines. Stakeholders also advised that the existing authorities are barriers to consumer access to medicines, where it may actually be safe and desirable. Specific regulations outlining these authorities are expected to reduce confusion amongst health professionals. The preferred option of well-defined authorities was supported:

- *“The issues... have been addressed particularly a focus on reducing the confusion on the roles of each professional group”²⁴.*

Providing increased clarity regarding professional authority is unlikely to provide any additional cost to consumers. There will be reduced cost to the Department regulating these health professionals and to industry in complying, through using clear definitions.

Stakeholders did comment on those professions included in the preferred option. Reflecting on the Consultation RIS, stakeholders queried:

- *“It is not clear how this list might be amended as the health workforce continues to evolve”²⁵,*
- *“...should comment on process of inclusions of further professions”²⁶;*
- *“Future pharmacist prescribing practices will need to be addressed”²⁷; and*
- *“...unclear if the proposed regulations have the flexibility to respond to changing professional scope”¹⁹.*

It is acknowledged that regulations in this area may require amendment as other professions emerge or existing ones evolve. For example, an area of concern raised was that physiotherapists are not listed in the preferred option. Whilst it is recognised that there appears to be a strong desire by physiotherapists for prescribing to become available to this profession, it is not yet a routine part of current practice. Any regulations can only endorse current practices.

The preferred option for registered health practitioners was developed based on those professions known to already handle medicines as an integral part of their routine employment, or already granted authority or specific exemptions by the 1965 Regulations. With improved articulation with the National Law, it is expected that when a National Board determines a change in scope that requires a medicines authority in Poisons Legislation for effect, that this would be added through amendment to regulations. A standard process for amendment is necessary, as is normally required for such changes. It is also expected that evidence of consumer benefit and public safety would be necessary to support such changes whenever proposed. In support of the preferred option, one stakeholder suggested that:

²³ CRIS submission 25

²⁴ CRIS submission 21

²⁵ CRIS submission 25

²⁶ CRIS submission 30

²⁷ CRIS submission 23



- *“This seems to establish a clear and flexible model to accommodate future change”.²⁸*

In response to the Consultation RIS it was noted by stakeholders that where an authority is not conveyed by a National Board, it might be undertaken on a research or limited basis using a Department issued Structured Prescribing Arrangement (see Section 3.5). This would allow the controlled accumulation of any evidence required prior to entering the profession more broadly.

The preferred option for unregistered health practitioners is based on extensive consultation that identified urgent need for access by certain employed health workers in order to address serious and significant failings of health care delivery in practice. These authorities might also be amended based on robust evidence of need. The preferred option limits these practitioners to very specific situations of administration as controlled by a Structured Prescribing Arrangement (see section 3.5).

One purpose of defining of these groups and their authorities is to provide a basis for those practitioner groups who may be eligible to participate in these arrangements. In relation to the use of Structured Prescribing Arrangements it was stated:

- *“It is noted that Registered Nurses, Enrolled Nurses, Aboriginal Health Practitioners and Aboriginal Health workers require a Structured Prescribing Arrangement... this is essential for public health practice and the professional authority is supported.”²⁹*

Other stakeholders pointed out that registered health practitioners were a very clearly and specifically identifiable group. This may not be the case for unregistered health care workers. Some stakeholders expressed concern about unregistered health workers and medicines authorities, although the specific disadvantages or risk of this access were not further explained:

- *“...why these individuals with specific authority are not AHPRA registered...may not be understood by users of the health care system”³⁰.*

The preferred option acknowledges the need to clearly define unregistered health care workers in each group. For example, an Aboriginal health care worker would be considered a person engaged by a health organisation (public or private hospital, local government agency, public health unit, or aboriginal health provider) for the purposes of delivering health care to Aboriginal clients of that organisation. Any authority is limited to scope of employment and to care of those clients. In contrast to some other registered practitioners there is no professional autonomy to decide to administer or supply medicines.

In response to the Consultation RIS stakeholders raised the ideas of “advanced skills” professionals as being a subset of those groups defined. No specific evidence of impact was supplied to support this. However, it is noted that the preferred option relates to scope defined for a profession as derived from the National Law. Where an activity requires added qualifications or an endorsement is necessary to perform an activity safely, then this is inherent in the preferred option.

²⁸ CRIS submission 50

²⁹ CRIS submission 26

³⁰ CRIS submission 25



If an individual practitioner has individually acquired advanced skills which relate to medicines, but the existing authority is insufficient, then this may represent a change of scope that requires more complex regulatory consideration by the registering authority. It is anticipated that the development of “advanced skills” and access to medicines in narrow fields of expertise could be managed within the framework of Structured Prescribing Authorities for the professions listed.

The regulations must continue to prevent unqualified persons from obtaining access to medications, thereby protecting the general public from unsafe exposure to potential poisons. Responding to the Consultation RIS, stakeholders emphasised the need for regulations to provide clarity around boundaries of professional practice and scope of employment with respect to accessing medicines.

- *“Address current prescribing rights for nurse practitioners and the current lack of definition around scope of practice for dentists in greater detail”³¹;*
- *“Better protection for the public, so that patients can be sure that the professionals offering services have the necessary background knowledge and training”³²;*
- *“Administration of medications by under educated and/or inexperienced people will lead to regulatory and liability issues”³³; and*
- *“There is potential for unintended consequences and impact on availability of health measures”³⁴.*

Significant concern was raised by some stakeholders regarding the scope of practice related to cosmetic treatments specifically related to nurse practitioners and dentists. Any regulations related to professional authority must be in alignment with lawful scope of professional practice. If health professionals deviate from the scope of their lawful practice there are suitable measures across both registration, and medicines and poisons regulatory schemes, to address these issues.

Lawful practice of a profession is an issue commonly cited by stakeholders. If there is any doubt, then the actions must be personally justifiable by the individual as being part of the accepted or reasonable practice of that profession, and that individual competence and safety can be demonstrated. There are extensive resources available for practitioners on scope of practice for each registered profession provided as guidance under National Law.

³¹ CRIS submission 33

³² CRIS submission 33

³³ CRIS submission 19

³⁴ CRIS submission 21



3.5 Structured Prescribing Arrangements

3.5.1 Background

Prescribing by health professionals other than doctors is an established practice both within Australia and the international health systems. In WA, dentists, nurse practitioners, and other allied health professionals currently hold varying authorisations undertake prescribing of medicines. Prescribing in this setting includes having the authority to decide to personally administer or supply a medicine directly to a patient, to instruct / direct another practitioner to administer a medicine to a patient, or to instruct a pharmacist to dispense medicines to a patient (i.e. issuing a prescription). The Act controls this practice.

For the WA population the maldistribution of health workforce and shortage of health consumer access to prescribers of medications required is well documented. Evidence suggests that there are population pockets in regional and remote WA that are unable to access medicines in a timely manner. The vast majority of the WA landscape is considered to be regional or remote (nearly 2.5 million square kilometres), and approximately half a million people reside there³⁵.

This inability to easily access medicines when required can be attributed to a combination of factors including isolation, a paucity of staff with prescribing and / or supply rights and “specific health needs for certain subgroups often associated with harsh environments”³⁶. There is continued debate over how best to address these issues of geographic isolation and problems with access to, and shortages of, providers and services. It is widely accepted that the challenges cannot be overcome in isolation and “requires coordination across government, higher education, regulatory bodies, employers, industry, the professions, the private and the not-for-profit sector”³⁷.

Health Workforce Australia describes a model where prescribing (more accurately administration or supply) can occur via a “Structured Prescribing Arrangement” where a health worker with limited authorisation to administer or supply medicines by legislation, works to a form of “prescribing” under a guideline, protocol or standing order⁹. Structured Prescribing Arrangements provide a framework for the safe and effective governance of health care professionals who would be unable to administer or supply required medicines without the direct supervision or guidance of an authorised prescriber.

The practice of administration and supply by health professionals has progressed even in the absence of sufficient regulation documented in the 1965 Regulations. This has resulted in inconsistent approaches in the development of Structured Prescribing Arrangements outside legislation.

³⁵ WA Country Health Service. Annual Report - 2012-13.

https://www.health.wa.gov.au/publications/annual_reports_2013_WACHS.pdf

³⁶ House of Representatives, Standing Committee on Regional Australia, 2013.

http://www.aph.gov.au/Parliamentary_Business/Committees/House_of_representatives/Committees?url=ra/fifodido/report/chapter6.htm

³⁷ Health Workforce Australia. National Rural and Remote Health Workforce Innovation and Reform Strategy 2013.

http://www.hwa.gov.au/sites/uploads/HWA13WIR013_Rural-and-Remote-Workforce-Innovation-and-Reform-Strategy_v4-1.pdf



A Structured Prescribing Arrangement is where limited administration or supply might be undertaken by an authorised practitioner for a number of patients, in specified circumstances when under written direction (or “prescription”) of an autonomous prescriber or other authority.

Access to a Structured Prescribing Arrangement will not authorise an individual to write a prescription, however it can allow that person to supply or administer a medicine. This does not provide prescribing autonomy, but does mean that where the conditions of an arrangement are met, the practitioner need not refer to individual instruction from an authorised prescriber for each individual patient or circumstance. These types of arrangements are commonly termed standing orders and used to extend public access to medicines through health practitioners who are not otherwise authorised prescribers.

The fundamental prerequisites for prescribing are undertaking accredited / approved education or training to ensure competence and then obtaining recognition from the respective health practitioner National Board. The practitioner must then practice within any authority conferred by State legislation. This legislation requires that practitioners work within their lawful practice, and professional scope and competence.

In Section 3.4 the preferred options for professional authorities were outlined. Autonomous practice to supply, prescribe or administer would be conferred by an authority which links to competence determined through registration under National Law. Section 3.4 noted that not all health workers are registered under National Law. In addition, consultation provided numerous examples of where the broad categories of registration under the National Law did not link to a potential authority considered potentially necessary under Poisons Legislation. The use of Structured Prescribing Arrangements provide a flexible and responsive framework to confer extended, although still limited authority, in the cases not covered by the National Law.

3.5.2 Current Regulations and Issue Identification

The 1965 Regulations only accommodates the autonomous (or traditional) prescribing model, whereby an individual sees a medical practitioner or other authorised practitioner and receives a prescription, which provides instruction for supply of a medicine by a pharmacist

Due to the need to improve access to particular medicines, whilst still managing associated risks, specific exemption clauses have been added over time to the 1965 Regulations. This helps extend the reach of prescribers through use of registered nurses or other practitioners. It partly addresses some of these known consumer access issues. Historically, a range of special authorisations have been made under the 1965.

Where pressing public need has existed, certain practitioners without a professional authority have been afforded access via regulations that exempt administration or supply of a named medicine from provisions of the Act in specified situations.



Current exemptions include:

- Registered nurses in remote area nursing posts providing medicines as part of a standing order approved by the CEO;
- Registered nurses at regional or rural health services providing starter packs on the oral order of a medical practitioner;
- Registered nurses providing medicines for the treatment of Chlamydia in line with a Code, in the course of their employment by the Department of Health or a hospital;
- Registered nurses providing medicines for psychiatric emergencies on the oral order of a medical practitioner;
- Registered nurses administering H1N1 vaccine in their employment by the Department of Health or a hospital;
- Registered nurses administering other vaccines in accordance with a Code, in the course of their employment by the Department of Health, a hospital, Aboriginal medical service, corrections facility or local government; and
- Pharmacists administering influenza vaccines in accordance with a Code.

Regulations permit various levels of authority to administer or supply medications, under a range of protocols, codes or direct order arrangements. These exemption clauses, although effective, have significant limitations in flexibility. From a regulatory / governing perspective these are cumbersome and not readily responsive to need. To ease the regulatory burden the new regulations will provide a framework to incorporate different allowable types of Structured Prescribing Arrangements. This will provide clarity for prescribers and more effective governance for regulatory control.

Current issues relating to Structured Prescribing Arrangements can be summarised as:

- **No current framework to establish Structured Prescribing Arrangements; and**
- **Regulation currently achieved via various exemption processes, which are inconsistent, slow and difficult.**

3.5.3 Proposed Regulations

Extensive consultation has conclusively indicated that most practitioner groups consider a framework for Structured Prescribing Arrangements essential.

In a Structured Prescribing Arrangement a health practitioner or other authorised person is able to “prescribe” once to authorise repeated actions in situations that are the same. This means that they can authorise another person to administer or supply, without the requirement for individual patient authorisations (prescriptions or other direction) each time. This administration or supply is dictated by the limits and conditions outlined in the written arrangement. The process is outlined in Figure 1.



Figure 1: Prescribing under a Structured Prescribing Arrangement:



Although termed “prescribing” by national documents on health workforce, this actually refers to either administration of a medicine to a person or supply of a medicine to a person to self-administer. These arrangements are already commonly utilised in WA or elsewhere.

For example:

- A nurse at a rural nursing post provides a patient with a urinary tract infection with a course of antibiotics; or
- An Aboriginal health care worker at a remote nursing post injecting a vaccine.

It must be emphasised that this type of framework is intended to complement and improve the usual medicines use activities that already occur and are part of autonomous practices. That is, the use of Structured Prescribing Arrangements is not intended to be used by a medical practitioner to delegate all prescribing. Structured Prescribing Arrangements generally are not considered to be indicated if the usual autonomous prescribing and dispensing practitioner mechanisms are readily available to consumers, as these should be considered the gold standard of care with medicines.

Structured Prescribing Arrangements are not required where an autonomous prescriber undertakes administration or supply within their scope of practice and personal authority. Autonomous prescribers currently include medical practitioners, registered veterinary surgeon, nurse practitioners, dentists, and endorsed practitioners who may provide a prescription directly to the health consumer. These arrangements are also not required for a registered health practitioner administering medicines under the normal supervision and individual direction of another authorised prescriber, such as a registered nurse administering medicines in a hospital as instructed by a medication chart. They are not required by a pharmacist dispensing on a prescription.

To provide this framework, regulations are to be developed to support Structured Prescribing Arrangements in the instances below.

1. Emergencies and resolution of an acute health care issues.

This would involve pre-existing written orders to initiate administration of a medication to commence acute treatment.

For example:

- A patient presents at a remote nursing post and is assessed as having a urinary tract infection; a registered nurse (such as employed by the Department) can supply a short course of antibiotics according to a written order. This leads to more timely treatment and prevents delays that could lead to health care complications.



2. Public health needs.

This would involve pre-existing written orders to administer medicines necessary to deliver public health programs to eradicate or prevent disease.

For example:

- Aboriginal health care workers with appropriate training assist in the delivery of public health programs by administering vaccines or administration and supply of treatments for sexually transmittable diseases according to a written order. This leads to wider community protection and prevention of spread of communicable diseases in potentially underserved communities.

Regulations will provide the framework to support Structured Prescribing Arrangements for these situations when constructed by the authorised persons / bodies below:

1. Departmental:

These are Structured Prescribing Arrangements issued by the Department of Health, under the authority of the CEO, for a class of person, for named or classes of medicines, and for a range of treatment conditions.

For example:

- Aboriginal Health Worker approved to administer vaccinations in underserved areas of ongoing public health need; or
- In the event of a H1N1 pandemic, registered nurses at health centres could be approved to provide flu vaccinations for a short time to meet overwhelming public health need.

2. Health Organisation:

These are Structured Prescribing Arrangements for health professionals (authorised to administer or supply medicines for public health and acute treatment) employed by a health organisation (hospitals or health services) within an appropriate clinical governance structure.

For example:

- A health organisation, such as a hospital, through their appointed Drugs and Therapeutic Committee issues orders for registered nurses working in the Emergency Department to administer first doses of antibiotics to persons with febrile neutropenia to start treatment more quickly; or
- A Government contracted community-nursing program through an appropriate drug advisory (clinical governance) group writes directions for registered nurses to administer single doses of analgesia for the more timely treatment of pain.

3. Medical Practitioner:

These are Structured Prescribing Arrangements issued by individual medical practitioners to an employee who is a recognised health professional (authorised to administer or supply medicines for public health and acute treatment).



For example:

- A medical practitioner documents an arrangement with a practice nurse employed at that medical practice to be able to provide named childhood immunisations to any patient of the practice that meets established criteria, such as the standard childhood vaccination schedule.

A condition of issue of a Structured Prescribing Arrangement by the Department, health organisation or a medical practitioner must be that the authorised health professional has suitable and sufficient competence to undertake the activity authorised in the arrangement.

The examples given in this section all apply to a practitioner with an authority to administer or supply as outlined in Section 3.4. The proposed professional authorities in Section 3.4 indicate those professions which could be included in a Structured Prescribing Arrangement issued by a health organisation or medical practitioner. The parameters around the administration or supply by these professionals will need to be outlined as written conditions within any specific Structured Prescribing Arrangement that is issued under the framework of the Regulations.

Structured Prescribing Arrangements issued by the Department need to be able to apply to a class of persons and across the entire health sector. In addition, the Department would need to be able to potentially issue an authority to other health professional groups not included in Section 3.4. This should only occur where there is a clearly demonstrated need and measurable health benefit to patients. There would need to be considerable detail as part of any arrangement to outline any necessary training or mandatory safety requirements to be followed.

During consultation many stakeholders made reference to suitable training for these arrangements. Every Structured Prescribing Arrangement must ensure relevant training and competencies, including requirements about mandatory education. For a health organisation this would be assessed by the employer. For a medical practitioner this would be assessed through their individual review of that employee.

Structured Prescribing Arrangements issued by the Department, which would apply across a class of persons, need to stipulate additional qualifications or codes of practice which need to be met. Further qualifications may well be required for authorised health professionals or other persons, such as the advanced practitioner status noted in Section 3.4.

To maintain safe use of medicines under these conditions Structured Prescribing Arrangements need to meet a minimum standard to ensure that all aspects are clearly described. This includes: who can administer or supply, what medicines, to which patients, and under what conditions. These minimum parameters will outline what is authorised and what is not. Regulations are necessary to ensure that no party issues incomplete, inconsistent, unsafe or undesirable arrangements.



The minimum requirements for a Structured Prescribing Arrangement that need to be codified into regulations for this purpose include:

- Being outlined in a formal document signed by the authorised prescriber / body;
- An original copy of the document is kept and can be produced as necessary;
- Copies of the document are freely available for persons using the Structured Prescribing Arrangement to refer to, so as to safely administer or supply as directed;
- An arrangement is uniquely identifiable, such as by use of a number or appropriate code;
- The document identifies the person issuing it and the authority it is issued under;
- An arrangement only applies to a specified registered health practitioner or a class of health worker outlined in Section 3.4 and/or class or group of persons whose qualifications, employment or competencies can be defined;
- Clearly states which persons it applies to and what actions it authorises;
- That in the case of a health organisation or medical practitioner there is a defined relationship between the person(s) authorised under the Structured Prescribing Arrangement and the authorised person issuing it. That is, that there is a direct employer – employee relationship between these persons, such that an individual arrangement only applies within that employment setting;
- The written agreement meets conditions and rules outlined by regulations for minimum content or information;
- The agreement has a finite life and must be reviewed and reissued at minimum intervals of two years;
- In the case of a health organisation, that any arrangement is first approved by an appropriate clinical governance body constituted by the organisation for the purpose of reviewing the safety of such protocols and approving their use within the organisation. For example, a Drugs and Therapeutics Committee or similar; and
- That all administration or supply actions that occur under the authority of an arrangement are permanently recorded in the patient clinical notes, along with all other usual administration or supply details as required by regulations.

For example:

- A registered nurse may administer an influenza vaccine in accordance with a Structured Prescribing Arrangement issued by a medical practitioner.



In this example, the following would be necessary:

- The registered nurse must be employed by that medical practitioner or within the same health provider organisation. The arrangement may not extend beyond any terms of that employment. The arrangement is only applicable to patients under the care of that medical practitioner; and
- The arrangement must be in writing. The original document must be retained at the medical practitioner's usual place of practice. Any registered nurse authorised and using the Arrangement must be able to access a copy. The medical practitioner must be able to produce this document on demand; and
- The arrangement covers a period of up to two years, after which a review by the authorising medical practitioner must take place. If intended to continue, a new arrangement must be written. Documents must be retained for two years after expiration.

It is necessary that regulations outline the minimum content or information to support and guide the issue of a written Structured Prescribing Agreement. The arrangement for this example must contain the following minimum particulars for safe application:

- The name and address of the authorising medical practitioner; and
- Date of the arrangement; and
- Date of expiry (not more than 24 months); and
- A unique identification number (specific to the document); and
- Names and sites of practice of the registered nurse(s); and
- Medication brand, route, form and any other information required to fully identify that medicine ; and
- Patient criteria for inclusion, such as diagnosis and age; and
- Patient criteria for exclusion, such as comorbidities, allergies, age, interacting medicines; and
- Any conditions or limitations agreed by the parties as appropriate; and
- Medical practitioner's signature.

The same details are necessary in every Structured Prescribing Arrangement issued regardless of practitioner and patient groups, and conditions and medicines involved.

If a Structured Prescribing Arrangement is provided by the Department for a class of practitioner, or a group of medicines, it is likely to require additional information. This might include being supported by a Code of practice or an equivalent standard. The requirement for any relevant education for these practitioners then needs to be clearly outlined and publicly accessible. It may also need to point to adherence to clinical guidelines or outline any specific clinical practices required for the safe use of medicine including equipment, setting, method of administration, etc.

The formalisation of Structured Prescribing Arrangements in regulations also allows for improved regulatory governance. The Department will need to take a role in ensuring compliance with the framework for Structured Prescribing Arrangements. This is expected



to be offset by the major benefits to the consumers and the efficiencies within the health workforce. The Department needs to be able to enforce these regulations and to address any unsafe Structured Prescribing Arrangements. This may include directing that an arrangement not be issued or exclude a specific person from using an arrangement when they are not suitable. This is important to respond to misuse, misconduct, inappropriate application or any other behaviour resulting from these arrangements which causes harm, or places the public at risk.

In summary, introduction of regulations regarding Structured Prescribing Arrangements:

- Bring together already established initiatives that allow administration or supply to health consumers who are not able to access usual prescribing practices;
- Increase compliance with the Act by providing a single regulatory framework so health professionals can clearly see their role and responsibilities;
- Provide health consumers with improved availability and safe access to prescription medicines (particularly in times of public health need);
- Optimise use of health professional skills and time, thereby reducing inefficient use of health resources;
- Provide more flexibility, allowing extension into health workforce reform;
- Ensure responsible and safe access to prescription medicines by making limited “prescribers” adhere to controls on patient safety and professional accountability; and
- Provide regulations to allow the investigation of potential issues to safeguard and protect the public.

Proposed regulatory changes, for Structured Prescribing Arrangements, can be summarised as:

- **Providing a single regulatory framework so health professionals can clearly see their role and responsibilities;**
- **Allowing for the issue of written arrangements to allow administration or supply of medicines for public health and acute care needs;**
- **Supporting development of Structured Prescribing Arrangements from:**
 - **The Department;**
 - **For a health organisation;**
 - **For individual medical practitioners;**
- **Providing clear regulatory guidelines regarding minimum requirements of a Structured Prescribing Arrangements; and**
- **Ensuring safe application and use of Structured Prescribing Arrangements by medical other health practitioners.**



3.5.4 Impact Analysis

Comments received as a result of the Consultation RIS reconfirmed the existing industry advice that a framework for these arrangements is urgently required. Comments included:

- *“...the intent of the regulations is what is needed...”³⁸;*
- *“I totally endorse these benefits”³⁹; and*
- *“The introduction of SPAs for Registered and Enrolled Nurses and Aboriginal Health Workers and Practitioners...is strongly supported”⁴⁰.*

Development of new regulations in this area will provide several advantages and likely cost benefits to the community. Workforce shortages in health care, particularly in rural and remote areas are well documented⁴¹. Stakeholders did not further quantify the expected cost benefits that would be provided by these changes, but did endorse that the expected consumer and provider benefits were indeed likely to be achieved:

- *“We believe that such arrangements are important as they allow access to necessary medical treatments where the availability of medical services is limited or where there is an urgent need”⁴²; and*
- *“Structured Prescribing Arrangements will be a fantastic framework for the rural and remote nurses of...to work within”⁴³.*

The minimum requirement, content and information for Structured Prescribing Arrangements outlined in the preferred option were generally supported:

- *“The minimum requirements of the SPAs are reasonable and achievable and are fully supported”⁴⁴.*

Structured Prescribing Arrangements can therefore allow more people to be reached for treatment with medicines for serious and/or widespread conditions. This has significant benefit for public health programs, specifically sexual health and immunisation.

The public health benefit case is clearly demonstrated in international literature. Structured Prescribing Arrangements of this nature can have the benefit of increasing vaccination uptake for groups at risk. This has been demonstrated by use of registered nurses in WA for public health vaccine administration programs. In the United States, a review of 22 studies from 1997-2008 assessing the impact of standing orders found immunisation increased by a median of 28 points⁴⁵. This is also supported in the Australian context with success of pharmacist immunisation programs carried out in QLD⁴⁶.

³⁸ CRIS submission 12

³⁹ CRIS submission 12

⁴⁰ CRIS submission 26

⁴¹ Rural Health Workforce Australia. Annual Report 2014. http://www.rhwa.org.au/client_images/1740096.pdf

⁴² CRIS submission 33

⁴³ CRIS submission 31

⁴⁴ CRIS submission 26

⁴⁵ The Community Guide. Increasing Appropriate Vaccination: Standing Orders. 2009. <http://www.thecommunityguide.org/vaccines/RRstandingorders.html>

⁴⁶ Lau ETL, Campbell C, Glass B, Drivandi A, Nissen L. Australia's first Pharmacist Immunisation Pilot - who did pharmacists inject? In *Australasian Pharmaceutical Science Association*, 5-7 Dec 2014, Brisbane. (Unpublished). <http://eprints.qut.edu.au/79553/>



Stakeholders also strongly endorsed this view, with multiple examples of potential applications that encompassed different immunisation schedules, treatment of different sexually transmitted infections and post exposure prophylaxis (e.g. contacts of meningococcal disease).

The framework, as proposed, would not be limited to remote settings, but may be expected to have greatest benefit in these areas. In response to the Consultation RIS one stakeholder argued that the potential benefits extended beyond these remote settings:

- *“Issues are focussed on rurality / remoteness as a barrier to adequate care...I do not believe this is the only scenario where structured prescribing arrangements should be considered”⁴⁷.*

Stakeholders voiced other potential wider industry benefits from use of these arrangements:

- *“It is likely that new models of care (where health practitioners expand their scope) will develop through this sort of arrangement. This is likely to be at the leading edge of the health workforce evolution”⁴⁸.*

Structured Prescribing Arrangements could assist achieve reform in areas of workforce shortage and make more effective use of health professionals such paramedics and Aboriginal health practitioners. The preferred option can provide accountability and structure by dictating the quality and type of supervision necessary for some medicines activities and stipulate minimum requirements for Structured Prescribing Arrangements. They could be used to professionally support practitioners when handling a medicine.

For example:

- The health practitioner could ring the supervising medical practitioner for medical advice. They can seek regular review of activities, which have taken place under the Structured Prescribing Arrangement as part of their employment. The supervising medical practitioner can receive regular reports of medicines used.

During consultation it was clear that while stakeholders endorsed the proposed framework, they believed there needs to be clear limitations coded into legislation as to how far any arrangements might reach. The basis for these comments was concern that unsafe activities might be performed by persons without adequate competence with medicines.

The view was put forward that access for public health or acute care should not be extended any further, as this risk would not outweigh any perceived access benefits:

- *“We believe that SPA should be limited to these kind of situations and not allowed for treatments and procedures which are not medically-imperative”⁴⁹; and*
- *“If such restrictions are not included in the framework...could set a precedent ...unnecessarily putting patient safety at risk”⁵⁰.*

Medical groups indicated that Structured Prescribing Arrangements are important to allow access to necessary medical treatments where service availability is limited or there is public need. They also indicated belief that Structured Prescribing Arrangements are not appropriate for all situations. The examples given included cosmetic procedures, such as

⁴⁷ CRIS submission 25

⁴⁸ CRIS submission 26

⁴⁹ CRIS submission 33

⁵⁰ CRIS submission 33



administration of botulinum toxin. The preferred option, as proposed, would not consider this situation either public health or acutely necessary care.

The framework will allow the Structured Prescribing Arrangements to occur, but not dictate every likely use suitable for their application. It was pointed out that there may need to provide clear guidance to assist industry decision making about what is, and what is not, suitable for structured prescribing arrangements. One stakeholder indicated that there must be “*monitoring of misuse of arrangements*”. It may well be the case that a Structured

Prescribing Arrangement is issued outside the framework. There might also be good medical reasons to consider a specific arrangement unsafe, such as evidence of a person being hurt as a result. In these cases, there must be a mechanism and established grounds for the CEO to act. The CEO must be able to effectively withdraw Structured Prescribing Arrangements where regulatory conditions are not met, or there is a justifiable concern over public safety.

Implementation of Structured Prescribing Arrangements need to be made with due consideration of benefits and safety. Whilst the new regulations will provide the framework for these arrangements, the decision by a health organisation or medical practitioner to implement a specific arrangement needs to be made according to individual needs and requirements. Where the organisation has a particular service need, an arrangement may necessitate internal training, assessment and credentialing. Where a medical practitioner works one on one with a practice nurse who has appropriate skills, the medical practitioner will need to make a decision regarding clinical competence to complete the relevant tasks.

Opinion was provided that decisions to issue an arrangement should be consumer based and made on sound health principles. These arrangements should not compromise care or be made purely based on commercial interest. As one stakeholder eloquently argued:

- *“The decision to offer a service that includes...prescribing will be made based on health service need (not professional interest), where there is the opportunity to:*
 - *improve the quality of the service;*
 - *improve access to services;*
 - *decrease the number of steps in a patient journey;*
 - *improve the efficiency and efficacy of the service; and*
 - *fill identified gaps*⁵¹.

The preferred option includes requirements that a health organisation eligible to issue an arrangement must involve appropriate internal governance bodies. Health organisations should be expected to complete a process whereby an arrangement is assessed for suitability and safety by a multi-disciplinary health group, such as a Clinical Governance Committee, Drug and Therapeutics Committee, or other equivalent body.

⁵¹ CRIS submission 27



Consultation highlighted that there is agreement that sound clinical governance and oversight is necessary when making organisational decisions over issuing such arrangements:

- *“Suggest making it clear who has governance of SPAs”⁵²; and*
- *“Clear expectation of the internal clinical and corporate governance structure required within organisations to deliver care via structured prescribing arrangements”⁵³.*

In Section 3.5.2 the current exemptions in the 1965 Regulations allowing a number of similar programs to operate were listed. There was strong concern from stakeholders that these programs should continue. For example, it was queried as to whether the exemption to allow pharmacists to administer influenza vaccination would now necessitate individual agreements with medical practitioners. Stakeholders argued that existing programs were entrenched, provided tangible benefits and should not be made less efficient as a result of new regulation.

The preferred option provides for the issue of an arrangement by the Department, under the authority of the CEO. These arrangements can apply to a class of person and across health settings. There is a then positive mechanism in the proposed regulations for the CEO, through the Department, to issue the equivalent arrangements of the programs already existing within the 1965 Regulations exemptions. It is considered necessary that these existing programs are indeed issued as Structured Prescribing Arrangements.

This type of Department Structured Prescribing Arrangement could apply to registered and unregistered health practitioners. Any arrangement that is intended to apply to health workers that are not authorised as outlined in Section 3.4 or registered under National Law could only be issued by the Department. Given that this type of arrangement may apply across a broad group of workers practising anywhere in WA, then the stakeholder concerns about appropriate qualifications and public safety are of particular importance. The CEO should only issue such an arrangement where there is need and where there is certainty of health benefits and of public safety. This needs due consideration and a mechanism for rigorous and appropriate assessment.

Although the preferred option allows flexibility for local and regional arrangements, stakeholders did comment that they felt that where certain arrangements could apply across a class of health worker or persons, these were best issued by the Department:

- *It is good to see that the Department can issue these structured prescribing arrangements”⁵⁴; and*
- *“Given the potential for individual variation ... it would be preferable to have these issued by the Chief Health Officer... so that they can be implemented state wide”⁵⁵.*

Stakeholders did comment on necessary competency required for these arrangements:

- *“I agree that there needs to be some accredited education/training”⁵⁶.*

⁵² CRIS submission 24

⁵³ CRIS submission 31

⁵⁴ CRIS submission 12

⁵⁵ CRIS submission 12

⁵⁶ CRIS submission 12



On stakeholder further outlined how they envisaged such arrangements would actually work in practice to connect to any education and training needed for competence:

- *“Once the training has been done...could issue a certificate...of completion which would inform that employer...and then the employer would ensure on the job supervision...able to supply the medications prescribed under protocols”⁵⁷.*

It was also raised by stakeholders that an agreement issued by the Department via the CEO could have utility in the event of a declared emergency or public health epidemic. The proposed regulations would allow for the application of a Structured Prescribing Arrangement specifically tailored to an event to provide rapid or widespread care. This might occur when there was overwhelming public need, but insufficient available authorised practitioners to meet this need. Examples in when this could be enacted might include such situations as:

- Emergency provision of medication by police in event of a biohazard; or
- Provision of vaccinations by a health worker during an epidemic.

⁵⁷ CRIS submission 12

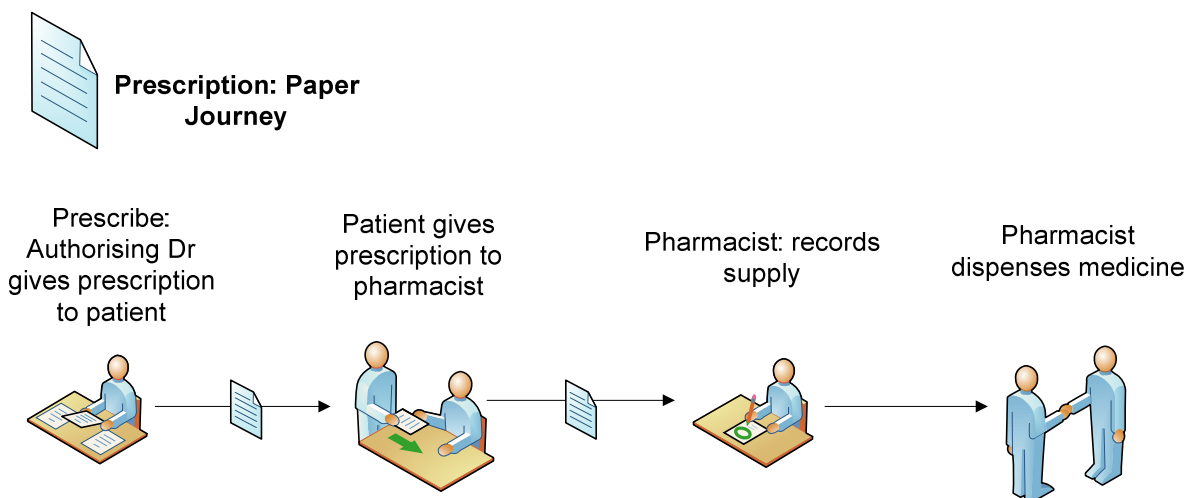


3.6 Electronic Prescribing

3.6.1 Background

A prescription medicine is any medicine that needs written authorisation by a doctor or other authorised prescriber before a pharmacist can dispense it. Prescriptions contain information about the dose and type of medicine the prescriber has advised an individual to take. The usual process for a prescription is that the patient goes to the doctor who provides a paper based prescription. The person takes this piece of paper to the pharmacy and the piece of paper tells the pharmacy exactly what to dispense. This process is illustrated in Figure 2. The authorising person is the doctor and the record of supply is held at the pharmacy.

Figure 2: Usual paper process for paper based authorisation of supply



The minimum information required to instruct the pharmacist or patient on the safe supply and use of a medicine is already well established from historical practices and highly consistent across all States and Territories. This needs to remain as outlined in existing regulations.

More recently, the concept of electronic prescriptions as a way of transferring prescription information has become both technically feasible and accepted as important for progress of modern health care. An electronic prescription would be one that is only ever contained in an electronic form. That is, that the prescription never exists on a piece of paper. If there is a piece of paper, it would simply be a key to access the prescription, rather than the official or legal prescription itself.

A prescription that is properly stored securely in electronic form could prevent issues of prescription forgery or altering of prescriptions. The electronic communication of these instructions has the potential to reduce the risk of dispensing error. It can also make the transmission of information faster, cheaper and more efficient. There would also be potentially greater security to prevent the unauthorised supply of medicines.



Benefits would be evident for health professionals such as the medical practitioner and pharmacist who will not need to deal with hard copy documents, which require manual handling, tracking and archiving. Consumers will benefit as their prescription will always be readily accessible from any pharmacy they present to. It cannot be lost, misplaced or forgotten. From a regulatory point of view there is a lower risk of manipulation or alteration of the prescription.

3.6.2 Current Regulations and Issue Identification

In 2008 the 1965 Regulations were amended to allow use of electronic prescriptions. They state that approved systems must be secure and only allow an authorised person to prescribe or dispense a medicine or poison. Industry standards for passwords must be achieved. Information in the system must be protected and private, and unable to be erased. System access must be controlled and the system must have a human administrator.

This implies a single electronic system being used, however the likely future will involve a network of systems and users. This view is then possibly out-dated and does not readily support expected business practices or full potential of electronic prescribing.

The 1965 Regulations do not specify a need for an electronic signature, or state what this must be. Rather, they require that access codes are used and the code must establish the identity of the prescriber or dispenser. An approved system must record each person that is provided with an access code. These codes must be changed regularly. It is an offence to access the system unless authorised, to reveal an access code to another person, or allow unauthorised access.

Each entry (or transaction) in the system is required to be uniquely numbered, include a time and date, and have the access code of the person attached. Appropriate back up measures must be in place, administrator records are retained for the required period and the system must be able to generate copies of all records on demand.

The overall principles captured by these regulations, regarding supply and recording of medicines, are generally consistent with expected future requirements, however they do need to be modernised to reflect current technology capabilities.

Details for prescriptions are not outlined in the Act. The Act does allow for additional requirements, stating that a prescription (regardless of hand written or electronic) must comply with any requirements set out in regulation.

Current issues regarding Electronic Prescribing can be summarised as:

- **Existing regulations are potentially out-dated and do not support the expected business practice or future potential of electronic prescribing; and**
- **Need to safeguard and protect electronic prescriptions from misuse or abuse of data (e.g. forgeries).**



3.6.3 Proposed Regulations

It is important that regulations support the ongoing development and use of electronic prescribing. This includes guidance on acceptable electronic system requirements and use of digital signatures. For the safe supply of a medicine, an electronic system would need to communicate the same information elements as contained in a paper-based prescription. Because the Act requires that all supplies of a medicine must comply with minimum requirements, regulations must detail what these specific prescription requirements are.

For prescriptions issued electronically an approved system should:

- Only allow a prescription to be produce by an authorised prescribed;
- Contain at least the minimum information necessary to instruct supply;
- Be the permanent record of instruction to supply, for a determined period of time;
- Not be able to be deleted or altered;
- Allow the dispenser to permanently mark that a supply has been made and keep records of this mark;
- Prevent the repeat of this supply unless authorised;
- Not allow external tampering or alteration, copying or dissemination to multiple dispensers; and
- Be able to reproduce records on demand to allow administration of the Act.

The information in any system is sensitive as it contains private personal health information. For this reason systems must also meet minimum privacy and security standards. It is important the systems in use meet the requirements above. Any system that is not suitable must be able to be excluded from use. It is also important to discourage poor practices in organisations that could allow access by unauthorised persons, fraudulent behaviour in issuing prescriptions or compromise of the integrity of the information contained.

This need is supported by the National E Health Transition Authority (NEHTA) who has published minimum technical standards for these systems and published guidance for prescription exchanges⁵⁸. It is expected that these electronic systems will be far more robust in preventing single isolated forgeries. On the other hand they may present a new and prime target for organised systemic attack (e.g. hacking) instead.

Victorian Poisons Legislation has recently developed criteria for approval of e-prescriptions⁵⁹, which was been supported as generally appropriate during preliminary consultation. Consultation has indicated that these systems will be used nationally and therefore there national consistency in regulation is of prime importance. At the time of this RIS, NEHTA is in consultation with jurisdictions to define proposed national requirements for electronic prescriptions. The Department is cognisant of this ongoing work and supports robust regulations to define minimum requirements for electronic prescribing systems.

⁵⁸ National E Health Transition Authority. Electronic Transfer of Prescriptions. Technical Specifications Document NEHTA 1381:2013

⁵⁹ Victorian Department of Health, Drugs and Poisons Regulation, Criteria for e-prescriptions. 2014.
<http://www.health.vic.gov.au/dpcs/approve.htm>



The software issuing electronic prescriptions will need to define the relevant roles of users, assign access rights accordingly and only allow those persons who are authorised under the legislation to generate electronic prescriptions for medicines.

The digital signature, or equivalent, of an authorised prescriber must be included in the electronic prescription content. The generation of the digital signature for an electronic prescription needs to follow the following criteria:

- The prescriber must possess a credential (private key) that asserts the identity of the prescriber;
- The prescribing software must display the prescription and obtain a final approval from the prescriber prior to generating a prescription for electronic distribution; and
- The prescribing software must re-authenticate the prescriber's credentials at the point at which an electronic prescription for any medication, including drugs of dependence (which includes all Schedule 8 poisons and some Schedule 4 poisons), is generated.

Electronic prescriptions generated by prescription software will put the script information in an electronic format that is aligned with national medications messaging standards or related Australian Technical Specifications. The standards must include secure messaging (such as encryption) and application level acknowledgement, indicating positive or negative receipt of this information.

During consultation, NEHTA proposed that *“Healthcare organisations that operate electronic prescribing systems be responsible for identifying the prescribers that use those systems and for providing assurance to pharmacists of the origin of the electronic prescriptions that they generate”*⁶⁰.

They suggested that the electronic transfer of a prescription (e-prescribing) must use national standards for clinical information, terminology and medications in both prescribing and dispensing organisations. Furthermore, they stated that the exchange of electronic prescription detail should include the following capabilities:

- Indirect communication path between the prescriber and the dispenser(s) in which the individual (or their agent) can select the dispenser(s) at any time after the prescription is created;
- A single point of control for each prescription that allows the prescriber to electronically cancel an electronic prescription. From the time of cancellation, the dispenser(s) system will inactivate the dispensing of any prescription items that have not been actioned;
- Management of security of the electronic prescription records that are distributed, including taking reasonable measures to apply current and future principles to:
 - Prevent disclosure of information in the prescription record to unauthorised parties;
 - Ensure that the view of the prescription in both the prescribing and dispensing systems is consistent;
 - Protect against fraudulent electronic prescriptions;

⁶⁰ CRIS submission 13



- Included particulars of any prescription issued in the clinical or medication record of that person or animal; and
- Preserve the clinical or medication record of the person or animal for which the prescription was issued for at least two years from the date of generation of the prescription and produce this when required.

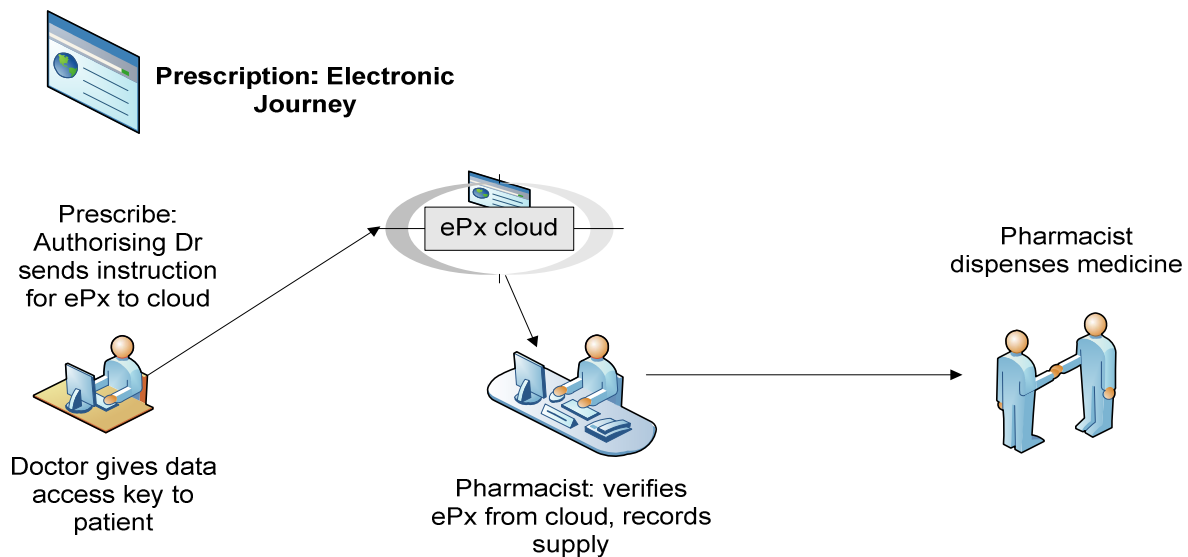
Proposed regulatory changes, for Electronic Prescriptions can be summarised as:

- **Regulations to outline details regarding how the electronic systems can be used including: what information needs to be supplied, how it is supplied and when it is supplied; and**
- **Electronic prescriptions must meet existing details regarding prescription information requirements.**

3.6.4 Impact Analysis

Electronic script exchanges are already in use^{61,62}. The process of “electronic prescribing” is illustrated in figure 3.

Figure 3: Illustrates the electronic prescription journey



In this model, a prescription is generated on prescribing software by a prescriber on an electronic device at their place of practice. The details of the prescription are transmitted to a “cloud” and stored in a secure electronic environment (script exchange), which may be provided by commercial interests. The patient is provided with a printed paper prescription that includes a printed bar code. The bar code acts as a document access key.

⁶¹ <http://medisecure.com.au/>

⁶² <http://www.erp.com.au/>



When presented at the pharmacy the prescription is scanned by the dispensing software that uses the bar code to link to the prescription exchange, and confirm the details of the printed prescription. In this arrangement the computer printed prescription is still the official prescription and the electronic process merely validates the information, speeding data transfer and minimising input errors.

It is envisaged that eventually the electronically stored details in the script exchange would be the official prescription and no paper document may be involved at all. A document access key might be provided to the patient, but this may be issued on a piece of paper, electronically or even some other way.

This model has significant potential to improve the validation of a prescription by a pharmacist. The Department is already aware of examples where use of the printed prescription bar code has been used to identify skilful forgeries and prevent unauthorised supply.

There are a significant number of forgeries reported to the Department of Health each year and a variety of fraudulent methods used. Information extracted from the Department of Health WA Pharmacy Case Management system for 2014, reports over 152 incidents, which includes 32 known forgeries resulting from altered prescriptions⁶³.

These forgeries range from simple modification of handwritten details to sophisticated reproduction techniques of computer generated documents and medical practitioners' signatures. This latter type can be indistinguishable from legitimate prescriptions. The use of secure electronic prescribing could potentially decrease the number of reported forgeries and unauthorised access to medicines.

Responses to the Consultation RIS provided limited comment and did not identify additional impacts. Overall the need to support electronic prescribing and the possible benefits were supported.

- *".....congratulates the Department of Health for proposing to update the regulations to support the future implementation of full electronic prescribing"⁶⁴; and*
- *"Implemented nationally, e-prescribing has the potential to contributing to a safer, higher quality and more efficient health system for all Australians"⁶⁵.*

The need to ensure that these systems are private and secure, through regulation of these practices was reinforced:

- *"Any electronic database system for prescriptions must have strong protections built in to maintain patient confidentiality"⁶⁶.*

It was also highlighted that as prescribing, medicines funding, practitioners and patients are mobile within Australia that similar regulation in each jurisdiction is imperative:

- *"It is vital that jurisdictions ensure their relevant legislative instruments, including approval mechanisms, are nationally consistent"⁶⁷.*

⁶³ WA Department of Health. Pharmacy Case Management Extract: 01.01.2014 to 31.12.2014. Unpublished data.

⁶⁴ CRIS submission 13

⁶⁵ CRIS submission 13

⁶⁶ CRIS submission 13

⁶⁷ CRIS submission 13



NEHTA has proposed national requirements which they intend to be a draft of model provisions that each jurisdiction could insert into their current regulatory framework. NEHTA state these are “intended to give prescribers, dispensers, patients and the relevant authorities assurance that e-prescriptions are secure, protect against fraudulent activity, and only allow authorised persons to generate prescriptions for all medications”. As in the preferred option, the NEHTA requirements are largely based on Victoria’s criteria for e-prescriptions.

It was recommended by one stakeholder that the CEO in WA retains their current role as the approval authority for e-prescription systems, to be consistent with poisons and medicines regulations across the country. This would allow application of NEHTA standards, technical specifications or other protections as required to ensure the secure operation of these systems and is consistent with the preferred option.



3.7 Electronic Storage and Supply Units

3.7.1 Background

The *Poisons Act 1964* does not allow the supply of medicines and poisons via an automatic machine. The prior limitations of technology mean that historically Electronic Storage and Supply Units (ESSU) could not have been made to meet requirements of all the controls inherent in that Act and the 1965 Regulations. As such the protections necessary for public safety when selling or supplying medicines and poisons would have not been achievable. The prohibition on automated machines was intended to prevent the supply of medicines or poisons to potentially unauthorised persons in an unrestricted or untraceable manner.

Since this time newer technologies have emerged that are now sophisticated enough to limit access to persons that are identified and validated according to their respective authority. They can also keep comprehensive records of items supplied. In particular, these machines have been developed for use in medical settings and have been in use overseas for some years. They are available for purchase and increasingly entering use in Australian healthcare settings elsewhere.

There is a significant body of published evidence on the nature, capabilities and benefits of such machines. The machines include technologies like “robots” in hospital pharmacies, dose administration aid packing machines, anaesthetic trolleys, and automated “dispensing” medicines on hospital wards. This technology is expensive, but based on the efficiencies returned are often employed in health services, hospitals and large-scale pharmacy supply chains. As capabilities and potential uses increase and as cost decreases, their application will become more widespread, extending into smaller health businesses where medicines are frequently supplied. There are frequent requests for installation of these devices in pharmacies and nursing homes, veterinary surgeries and wholesale business practices.

Professional organisations support use of these technologies but not without regard for quality, minimum safeguards and patient protections.⁶⁸ The expense and complexity means most will be purchased and run by organisations rather than individual health practitioners. They will be accessed by many health practitioners (potentially hundreds in a hospital). The upkeep, functioning, maintenance and responsibility must rest with appropriate and responsible individuals.

On the basis of improved accountability, these machines could well be considered suitable for storage of Schedule 8 medicines. In fact, the machines offer even greater potential efficiency benefits for practitioners, when used to assist with the additional recording and storage requirements for Schedule 8 medicines. However, these medicines are a common target for theft, can enter the illicit market and fetch high prices if illegally sold. The machines can build in protections for these substances, but generally do not replicate the existing storage conditions required of large and heavy drug safes. It is therefore important that when used for Schedule 8 drugs, these machines should not compromise security or provide any less public protection.

⁶⁸ Society of Hospital Pharmacists of Australia. Position Statement - Automated medication systems. 2003.
http://www.shpa.org.au/lib/pdf/positionstatement/amds_ps_aug03.pdf



Minimum regulatory protections are necessary for these machines. Many machines will meet informal industry product expectations for keeping inventory secure and tracking supply, necessary for business purposes. As such they will also generally provide reasonable security measures. Large health organisations normally have quality procedures and systems of independent review⁶⁹ for medicines management that may also assist. There is also guidance for practitioners regarding patient safety when using these machines⁷⁰.

However, the Department is not aware of any legislation or enforceable industry standard to prevent inferior machines being employed and allowing unauthorised public access to medicines. The machines themselves vary greatly, with constant improvements occurring. It is difficult to be prescriptive regarding necessary security features, but principles around the minimum security functions are possible to devise.

To date, the Department has not received requests to utilise the machines for domestic poisons. These are generally low cost items, are frequently bulky or in liquid form and not considered suited for automated supply. It is not proposed that supply via these technologies be considered for Schedule 5 or Schedule 6 poisons. Schedule 7 poisons are highly dangerous and both their supply and use is heavily restricted. Due to their inherent toxicity these poisons should not be considered suitable for supply from an ESSU.

3.7.2 Current Regulations and Issue Identification

The *Poisons Act 1964* expressly forbids the use of an automated supply machine or ESSU for the supply of a poison. At the time of conceiving this legislation, the available technology would not have allowed a machine to identify and distinguish between persons accessing the machine and receiving supplies. Supply of poisons could then not be tracked and there be assurance that supply is only made to appropriate persons.

For example:

- A child might access a machine in a public place and receive multiple and dangerous supplies of medicine.

Lack of human intervention would prevent any expert assessment of intended use. There would not be any certainty that the use was for a therapeutic, legitimate or correct purpose. Use of machines would have allowed uncontrolled and potentially unsafe access by the public to both medicines and poisons.

The Act provides a definition of a vending machine (considered synonymous with an automated supply machine, or ESSU) capable of supply without attention or personal manipulation of the supplier. It allows for the use of these machines when complying with regulations.

⁶⁹ Australian Commission on Quality and Safety in Health Care. Safety and Quality Improvement Guide Standard 4 Medication Safety. 2012. http://www.safetyandquality.gov.au/wp-content/uploads/2012/10/Standard4_Oct_2012_WEB.pdf

⁷⁰ Institute for Safe Medicines Practices. Guidance for Interdisciplinary Safe Use of Automated Medicines Cabinets. 2008. http://www.ismp.org/Tools/guidelines/ADC_Guidelines_Final.pdf



Current issues relating to Electronic Storage and Supply Units can be summarised as:

- **Regulation is required in this area to ensure benefits realisation of automation and future proofing.**

3.7.3 Proposed Regulations

In 2015 the 1965 Regulations were amended to provide for use of ESSU, when approved and under strict conditions for security. It is the preferred option that these regulations continue, so that the machines can be used, but only when meeting minimum standards.

Stakeholders have supported the use of such machines. The use of these devices meets the primary intent of the legislation to ensure there is public access to essential medicines when necessary to meet medical needs.

Allowing use of these machines where principles of safe supply are met would therefore achieve aims of the legislation. Regulations to control and limit use of the machines can ensure public risk is still managed and is the preferred option. Based on the types of machines in use elsewhere in the market place it is proposed that any device must:

- Only be employed when a health practitioner provides professional oversight immediately prior to supply to an authorised patient, unless otherwise approved by the CEO;
- Only be placed and used on the site or place of lawful business of an individual health practitioner, or for an organisation, the authorised place of use on a poisons licence or permit;
- Meet recognised standards to ensure secure storage and prevent tampering or theft;
- Store the medicines in such a way as to prevent public access;
- Remain under the supervision and control of the authorised person or in the case of an organisation a suitable responsible person;
- Be able to distinguish between persons accessing the machine and only allow access by an authorised person;
- Keep a record of each occasion of supply, including the person making the supply, date and time, medicine and quantity, and produce these records on demand for purpose of compliance with the Act; and
- Meet any conditions deemed necessary for storage and supply of Schedule 8 medicines to ensure security consistent with the risk posed.

One stakeholder highlighted that the Consultation RIS made specific mention of the potential for misuse and potential for harm that access to poisons via “vending” machines poses. They suggested that regulation should be specific to control for this risk.



In particular, it was suggested there must be continued practitioner oversight of any ESSU:

- *“To ensure the “principles that underpin the National Strategy for Quality Use of Medicines framework are not compromised”⁷¹; and*
- *“The need for professional oversight of a pharmacist as an essential step in the provision of a scheduled medication, where at all possible”⁷².*

The recent changes to the 1965 Regulations stipulate that ESSU still require the oversight of an authorised person. It is the preferred option that this requirement remains.

Consultation did provide comment over sale of therapeutic devices that are not medicines through such machines. One stakeholder reported that:

- *“Although they are neither poisons nor medicines, needles and syringes are available via vending machines at a number of sites in WA”⁷³.*

Scheduled medicines are classed as therapeutic goods and are also regulated in this way by relevant Commonwealth law. The Act does not govern therapeutic goods that are not also Scheduled medicines.

The 1965 Regulations do provide for the approval of needle and syringe programs. The objectives of these program is to reduce harms from sharing injecting equipment, reduce transmission of blood borne viruses (such as hepatitis), and ensure the safe disposal of used injecting equipment⁷⁴. An approved program will distribute clean needles and syringes, and provide means for safe disposal of this injecting equipment once used. Needle and syringe programs are cost effective and may be the only contact that some people who inject drugs have with the health system.

Under the 1965 Regulations, both needle and syringe programs, and their operators must be approved. It is the preferred option that the current regulatory approach continues. Access to sterile needles and syringes is still a high priority for harm prevention. The supply of these therapeutic goods would still need to be permitted as part of an approved needle and syringe program. The proposed regulations regarding automated machines would not prevent the supply of needles and syringes. Where automated machines are currently in operation in an approved needle and syringe program approval, this could continue under the preferred option.

Proposed regulatory changes, for Electronic Storage and Supply Units, can be summarised as:

- **Allowing the use of Electronic Storage and Supply Units to allow realisation of benefit of technological automation in the supply of medicines; and**
- **Providing a clear regulatory framework to ensure that minimum requirements are met for security of medicines, accountability of health practitioners and patient safety when these machines are used for supply.**

⁷¹ CRIS submission 39

⁷² CRIS submission 39

⁷³ CRIS submission 26

⁷⁴ http://ww2.health.wa.gov.au/Corporate/Articles/U_Z/Why-needle-and-syringe-programs-NSP-are-necessary



3.7.4 Impact Analysis

Automated supply machines are justified on the basis of business efficiency, improved patient safety and accountability in health care⁷⁵. ESSU can reduce stockholdings, reduce wastage and loss (such as to expired stock), and theft. They are well demonstrated to increase patient safety by reducing medicine selection errors.

For example:

- A machine can match a product barcode to a prescription or dispensing entry to ensure that only the type, strength and quantity of the item ordered are correctly supplied.

They can improve security and governance over medicines when programmed to only provide a product to a person recognised and confirmed as having an appropriate authority.

For example:

- In a hospital an ESSU could exclude general staff, but recognise and record individual nurses accessing medicines.

The machines can be programmed to ensure that no supply can be made without a record. They can be constructed so that unauthorised access by an otherwise authorised person (i.e. theft and diversion) might be readily detected and prevented. It has been previously recommended that public hospitals should employ such machines to improve issues of accountability with medicines⁷⁶.

The inability to utilise these machines will prevent realisation of the benefits described. Denying access of health practitioners to these machines hampers technological, business efficiency and workplace improvements in the Western Australian health system. A strong driver for their use is the demonstrated improvement in patient safety through prevention of medication errors and resulting adverse events.

⁷⁵ Australian Commission for Safety and Quality in Health Care. Evidence Briefings on Interventions to Improve Medicines Safety. Vol 1 Issue 2 July 2013. <http://www.safetyandquality.gov.au/wp-content/uploads/2013/12/Evidence-briefings-on-interventions-to-improve-medication-safety-Automated-dispensing-systems-PDF-832KB.pdf>

⁷⁶ Office of the Auditor General. Western Australian Auditor General's Report: Pharmaceuticals Purchase and Management of Pharmaceuticals in Public Hospitals. 2012. [http://www.parliament.wa.gov.au/publications/tabledpapers.nsf/displaypaper/3814893a80778ac5be8fa6c248257a1c001a6c15/\\$file/4893.pdf](http://www.parliament.wa.gov.au/publications/tabledpapers.nsf/displaypaper/3814893a80778ac5be8fa6c248257a1c001a6c15/$file/4893.pdf)



3.8 Licenses and Permits

3.8.1 Background

The Department is responsible for issuing licences, permits and other authorisations to supply medicine or poisons, in accordance with poisons legislation. A licence allows supply onwards; to sell or give a medicine or poison to someone for their own purpose or use. A licence may be granted to manufacture, distribute, sell or supply a medicine or poison by wholesale, or to sell or supply a medicine or poison by retail.

For example:

- A Pharmacist's (poisons) licence currently allows a pharmacist to dispense a medication to patient at a pharmacy on the order of a valid prescription.

A permit allows a person to use a poison. A permit may be granted to purchase poisons for industrial, educational or research purposes or to provide health services.

For example:

- A school purchases bromine to use as part of experiments in science classes.

If an individual makes or manufacturers a medication or poison, which they intend to sell or supply, then they require a wholesale licence. Wholesaling can be defined as the sale of goods or merchandise to retailers; to industrial, commercial, institutional, or other professional business users; or to other wholesalers and related subordinated services. These would include cases where the person the wholesaler supplies is not the end user, the medicine or poison is intended to be supplied onwards, or the quantities supplied are large and not intended for individual use.

Examples of wholesalers include:

- Businesses who manufacture farm chemicals;
- Businesses who sell poisons to the mining industry; or
- Pharmaceutical manufacturers.

Retailing, in the context of a licence, can be defined as the sale of medications and poisons in small quantities directly to consumers who will be using the substance, such as the supply of an individual prescription item to a patient on a prescription, as normally occurs at a pharmacy.

A licence allows the holder to sell or supply, by retail or wholesale, those poisons specified on the licence conditions.

The types of poisons licences available under the 1965 Regulations are:

1. Wholesale/Manufacturer's licence

This authorises the holder to procure, manufacture and supply by wholesale dealing specified poisons at or from specified premises;



2. Pharmacist's licence

This is restricted to pharmacies registered in WA, which are registered under the *Pharmacy Act 2010*;

3. Schedule 2 Retail licence

This allows for the holder to procure and sell by retail poisons included in Schedule 2. These licences are made available to appropriate retail businesses located in regional areas at distances greater than 25km from the nearest community pharmacy; and

4. Schedule 7 Retail licence

This allows the holder to sell by retail to authorised persons; chemicals, agricultural pesticides and herbicides, included in Schedule 7.

A permit allows the holder to purchase those poisons listed in the permit for a specified use but not for resale. Poisons Permits are required by businesses, companies and Government Departments for poisons included in Schedules 2, 3, 4, 7 and 8.

Permits may be for a single substance, such as hydrofluoric acid in Schedule 7 for brick cleaning, or they may be for a range of poisons, such as for a public hospital pharmacy. Table 5 outlines who needs a poison licence or permit.

Table 5: Current requirements for poisons licences and permits

Poisons Schedule	Licence required to sell by retail	Licence required to sell by wholesale	Permit required to use by business or Government
2	Yes	Yes	Yes
3	Yes	Yes	Yes
4	Yes	Yes	Yes
5	No	No	No
6	No	Yes	No
7	Yes	Yes	Yes
8	Yes	Yes	Yes
9	Prohibited	Prohibited	Prohibited



The Department has a number of permit types available, which allows for the purchase of poisons and medicines according to the individual requirements of the user.

For example:

- University researcher has a permit to access poisons for use in specific research;
- An occupational health company has a permit to purchase medicines for treatment of employees at remote mine sites;
- A stainless steel fabricator has a permit for purchase of poisons used for cleaning during the fabrication process; or
- Residential care facility has a permit to allow an imprest (store) of medicines for urgent treatment of residents when instructed by a medical practitioner.

3.8.2 Current Regulations

The Act provides for the granting of licences and permits to allow persons to manufacture, supply or use a medicine or poison. It also outlines who may be an eligible person to be issued with a licence, sets out how a person must apply for a licence, and how the Department must manage any requests received to issue a licence. The Department cannot grant a licence unless minimum criteria are met. In addition, the person applying must be deemed to have sufficient knowledge and capability to safely handle those medicines or poisons.

The Act allows for conditions to be placed on any licence or permit issued as required, where deemed necessary for public safety. These conditions may restrict access to any type of medicine or poison, the allowable quantity or permissible actions. Conditions might also relate to any other control such as records, reporting, storage or meeting a particular quality standard. The Act allows for Regulations to be made in relation to licence and permit conditions.

Rules regarding the issue of licences and permits ensure there are appropriate controls over access to medicines and poisons. Regulations support the administrative rules that govern how the Department issues licence and permits. Stakeholder consultation identified key areas of reform needed to ensure licence and permit holders had appropriate and efficient access to medicines and poisons as required. The framework for many of these reform areas are provided in the Act.

The Act has made provision for the following key changes:

- Issue of licences to supply and permits to use for a 12 month period from date of issue;
- Removal of requirement for Schedule 6 wholesale licences;
- Removal of requirement for pharmacist licences;
- Recognition of licences issued by other authorities, such as the TGA;
- Provision for corporate licences with multiple sites;



- Provision of a permit system for access to Schedule 9 substances; and
- Incorporation of a non-refundable application fee and fees for amendments to existing licence and permits.

It is essential that proposed regulations support the key changes in the Act and the reforms it seeks to achieve. Regulations need to stipulate the types of licences and permits that should be available, any further eligibility criteria that may be necessary, and the applicable fees or charges for their issue. Regulations need to also stipulate any general conditions of medicines and poisons control that need to be applied across an entire type of licence or permit.

The types of licences and permits outlined in the existing 1965 Regulations are listed in Table 6.

Table 6: Existing types of licences and permits

Licence / Permit	Authorises
Wholesale/Manufacturing	Purchase, manufacture or supply of poisons from a specified premises, in accordance with conditions outlined in regulations.
Pharmacist	Sale or supply poisons from the pharmacy cited on the licence.
Retail	Sale of Schedule 2 poisons from the premises cited on the licence.
	Sale of Schedule 7 poisons from the premises cited on the licence.
Pharmaceutical sample	Supply of Schedule 2, 3 or 4 poisons to medical practitioners, nurse practitioners, veterinary surgeons, dentists, pharmacists or authorised health practitioners under certain conditions.
Industrial	Purchase of industrial poisons listed on the permit. Currently includes veterinary practices.
Educational, advisory, research	Purchase for educational, advisory or research purposes as specified on the permit.
Health service	Purchase of poisons by private hospitals, day surgeries, doctors' surgeries, ambulance services, and companies providing medical support to industry/mining.
Departmental and hospital	Purchase and use of poisons specified on the permit by State or Commonwealth Departments, or public hospitals.
Stock feed manufacturer	Permit to obtain antibiotics to add to stock feed.

While the types of licences are clearly articulated, the 1965 Regulations do not adequately support the new licencing control requirements outlined in the Act. In developing the Act, stakeholder consultation indicated the existing licencing and permit approach needed reform.



3.8.3 Current Regulatory Issues

Industry feedback has indicated that rolling expiry dates are more financially acceptable to business. This will facilitate the timely processing of renewals and avoid the current annual licencing congestion that is seen with a fixed annual expiry date. Rolling expiry dates will spread the workload associated with the renewals process, throughout the year, rather than maintaining a peak period in June each year. There is an expected improvement of service delivery for licence and permit holders from this reform. Some savings are also expected.

For example:

- A manufacturer applies for a licence in March and pays the full fee. Currently this licence is then valid until end June (3 months). In future this licence would be immediately valid for 12 months and expire in March the following year.

Modifying regulations allows the Department to support the new provisions outlined in the Act. This includes adjusting the different licence and permit types that are available and setting fees accordingly, so as to reflect current industry practices. Comparison of licence requirements across jurisdictions has indicated that WA is the only state that requires a licence to wholesale Schedule 6 poisons. Stakeholder feedback suggested that the current licence and permit types do not exactly fit with how certain businesses handle medicines or poisons or how they label their own business activities. Businesses therefore have difficulty identifying which licence or permit fits their requirements. There is business confusion, particularly related to the naming of licence and permit types, and the intended reason for requiring a licence or permit.

For example:

- A health services permit covers a wide range of activities involving use of medicines, such as medical practices, residential care facilities, veterinary surgery, and ambulance services.

Businesses have also over time changed their patterns of use in delivering health care and methods of supply and distribution to other businesses.

For example:

- The changing environment created by Internet sales means that some people who sell poisons do not actually physically store poisons or interact with business purchasers in person.

In relation to poisons controls, stakeholders identified inconsistencies between jurisdictions in relation to Schedule 7 licences and permits. They also cited duplication of licensing under different regulatory regimes, which were believed to increase costs but not add additional protective benefit to the public.

Stakeholders identified the need for alternative types of licences to allow for electronic commerce. The Regulations provide an opportunity to review the current licence and permit types.



Current issues regarding Licences and Permits includes:

- **Inflexible regulation;**
- **Duplication in licence requirements due to lack of reciprocity rules;**
- **National inconsistency with Schedule 7 permit requirements; and**
- **Gaps in meeting demands for certain types of trading.**

3.8.4 Proposed Regulations

The Department recognises that there are other regulatory agencies that may assess a person or organisation to handle a poison. Those poisons may be included in different regulatory schemes, for other purposes. It is recognised that in relation to poisons, a licence or permit holder, may also need to comply with a range of other regulatory instruments or requirements. These other scheme might already provide adequate assessment and oversight to ensure public safety.

For example:

- A mining company may also have a dangerous goods licence at a specific site that allows use or transport of a poison.

The Act has provisions to allow recognition of licences and permits issued by regulatory authorities other than the Department. In these cases an additional licence or permit would not be needed. Regulations need to outline any conditions regarding this recognition, such as the licence being current, being governed by appropriate licencing standards and which authorities might be recognised for this purpose. This would reduce the need for a business to obtain multiple licences to perform effectively similar activities with a medicine or poison.

If a person is an authorised professional they do not need a permit to authorise the purchase, use or supply of a medicine for the practice of their profession. This is outlined in Section 3.4. However, it is a common business model for health practitioners for practice in in partnerships, in professional groups at one location, or corporately owned practices. In these cases medicines are purchased and stored on behalf of the practice as a whole. The use of the medicines may be by any professional working at that practice. Where the medicines are being purchased and used on behalf of a business, rather than as an individual practitioner, a permit is required.

For example:

- A medical practitioner does not need a permit to purchase medicines, but where the medicines are purchased by the practice, and used by all medical practitioners at the practice, a permit for poisons is needed.



The Regulations will have a role in identifying which standards or licencing authorities could be recognisable for reciprocity for both medicines and poisons. Licencing standards and licencing authorities could be defined as:

- Licencing Standards -

Standards that identify the requirements to obtain a licence. This implies the standards are fit for purpose; and

- Licencing Authority -

The regulatory authority that determines the licencing standards or issues licences. This implies the authority is a reputable source.

In identifying appropriate standards and authorities for acceptability of an existing licence it is expected that:

- Licences are current (in date);
- Licences comply with existing State legislation and are consistent with the Act;
- Licensees are monitored to ensure compliance with licence requirements established by that authority; and
- The authority or regulator has mechanisms to enforce compliance.

For example:

- A mine site storing poisons has a Dangerous Goods Site Licence issued by the Department of Mines and Petroleum for cyanide. As they are licenced by another licencing authority the site should not require a permit from the Department; or
- A person has a Therapeutic Goods Administration licence to manufacture, and should not require a wholesale licence from Department; or
- A veterinary practice registered under the veterinary surgeons act, which employs multiple veterinary surgeons, would not require an additional permit from the Department. Any non-registered premises would still require a permit from the Department.

Similarly, the removal of pharmacy licences is consistent with this approach. The *Pharmacy Act 2010* already regulates pharmacy premises in WA. The Pharmacy Registration Board of WA assesses and registers pharmacies according to regulatory criteria outlined in the *Pharmacy Act*. Many of these standards relate to the suitability of the premises for the storage and supply of medicines, the primary function of a pharmacy. Because the Register is made publicly available, consumers have ready access to information about the pharmacies that have met these minimum standards. The Register also identifies the pharmacist with overall responsibility.

The Department will currently issue a Pharmacist's licence to the pharmacist nominated as the responsible pharmacist on this Register. The supply of the medicines themselves at a pharmacy is governed by poisons legislation, irrespective of the issue of a licence. In 2015/2016 the cost of a poisons licence for a pharmacy for 12 months was \$126. As at October 2015 the Department had record of 607 active pharmacy licences. This represents a cost of over \$ 70,000 annually to industry and to the Department in managing this function.



Removing this duplicative activity could save an estimated \$ 60,000 to \$ 80,000 each year in this industry alone. Similar savings of various magnitudes would also be seen in other industries where this duplication can be removed.

Consultation identified other potential opportunities for recognition of other regulatory licences associated with the industrial use of poisons. These types of uses are often subject to relevant industry codes of practice that also support appropriate storage and handling of poisons.

For example:

- Recognition of Schedule 7 permit requirements for recognised industrial uses, at clearly identifiable industrial locations.

Stakeholders indicated difficulty in determining when a wholesale licence might be necessary, as opposed to a retail licence. Wholesalers are subject to the *Australian Code of Good Wholesaling Practice for medicines in Schedule 2, 3, 4 & 8*. This Code is concerned with ensuring that quality is maintained during wholesaling activities and sets out appropriate standards to be applied in the handling, storage and distribution of medicines. It also outlines specific storage facility requirements.

Examples of activities requiring wholesale licences include:

- Buying groups purchasing medicines or poisons in larger amounts for redistribution to the end retail supplier; or
- Selling medicines to a medical treatment business, where the medicines are not for a known named patient, but intended to be supplied at a later point to a patient as determined by the medical treatment business.

Wholesaling poses additional public risks. This includes matters of stock handling, for example the need to meet stringent temperature control requirements. This is due to amount of time in storage, the large quantities stored and because the wholesaler is not the final user. It also includes stock control issues such as the ability to deal with product recalls for dangerous faults. There are a number of serious medicine product recalls each year at wholesale level. A retailer, if operating as a wholesaler, may not adequately action recalls, potentially leaving faulty goods in circulation that could result in harm to consumers.

In practice, wholesalers can refer to this wholesaling Code to provide practical assistance on such matters. It is proposed that the wholesalers continue to apply the TGA *Code of Good Wholesaling for Medicines in Schedules 2, 3, 4, and 8*. Consultation has not readily identified other codes or guidelines used by suppliers applicable to other situations.

At present, there is no licence or permit requirements for the retail sale of Schedule 5 or Schedule 6 poisons. Under the 1965 Regulations a wholesale licence is still required for Schedule 6 poisons. This is not required for Schedule 5 poisons and not required in other States and Territories. Controls over packaging, labelling, storage and disposal (see Section 3.9) apply equally to retailing and wholesaling for Schedule 5 and 6 poisons and should be considered adequate in both circumstances. A wholesale licence for Schedule 6 poisons provides little added benefit and should be removed as a requirement. This is consistent with other States and Territories, reduces some cost for business, and does not increase public risk.



Schedule 7 licences and permits cover chemicals normally used widely in mining, heavy industry primary production or farming. Examples of Schedule 7 poisons include hydrofluoric acid, cyanide, mercury, agricultural pesticides and fox baits. The productivity commission recommended that where a poison was adequately covered under workplace substances regulations, and there is demonstrated compliance with those regulations, that State and Territory Governments should exempt those users from poisons controls⁷⁷.

The Department's experience is that in general, larger commercial organisations in this sector are likely to have multiple levels of employee protection for safe handling of toxic substances. This includes Occupational Safety and Health legislation compliance and dangerous goods licences. In this way, there are other regulatory regimes which can provide adequate protection in specific sectors, for example large-scale mining operations.

These alternative protections do not appear as robust for smaller-scale uses or for individuals working as sole traders, outside an organisational structure. In these areas there is likely to be continued and potentially uncontrolled risk with poisons if permits are not applied. For example, Schedule 7 poisons stored at a place of residence by a business owner / operator amongst other domestic dwellings could be a public risk and therefore still requires regulation via permits. These issues are to be addressed in new Regulations.

For example:

- A large mining corporation, where use is clearly for industrial purposes, does not require a permit for mercury use; or
- A sole trader or individual gold prospector who wants to store mercury requires a permit.

As currently required in the 1965 Regulations, any person selling a Schedule 7 by wholesale or retail should continue to need to be licenced. This is consistent with requirements across the rest of Australia and provides clear protections for highly dangerous substances like arsenic, mercury cyanide, hydrofluoric acid, and chlorine gas. Sellers must have access to appropriate storage facilities and skills to properly assess that the person they are selling to is an authorised user who will safely and responsibly use those poisons.

Interaction with stakeholders identified the need for a facility to accommodate indent style trading practices with medicines or poisons. This would be a new and specific type of licence, which could assist reduce regulatory burden as an additional and more appropriate category of wholesale licence to accommodate brokers and traders. An indent licence requires assessment of whether the licensee has knowledge to be able to access the authority or eligibility of the purchaser. They do not need to have knowledge of the substances themselves in terms of storage and physical handling, as they do not deal with the physical product. Accordingly there is no need for the Department to assess the physical premises for this type of licence.

⁷⁷ <http://www.pc.gov.au/inquiries/completed/chemicals-plastics/report/chemicals-plastics-regulation.pdf>



For example:

- A broker sells Schedule 7 farm chemicals by taking orders and passing these to a wholesale supplier who delivers the poisons. They operate the business from a home office. The Department requires the broker to have systems in place to ensure clients are bona fide primary producers. There are no requirements for the broker to have facility for storage of dangerous poisons.

This type of licence still necessitates regulation, but would attract a lower fee, because less assessment is required. Similar systems are in place in Victoria and have shown to assist contain business costs for these traders. Use of indent licencing is likely to be a more common phenomenon with the increase of electronic commerce. The introduction of indent licences will provide safer electronic commerce relating to supply of poisons and clarity regarding accountability of the parties involved.

The new Act allows for the issue of permits to use Schedule 9 poisons (prohibited drugs). These permits are restricted by the Act to research, experimental or educational purposes. Regulations need outline specific criteria for issuing Schedule 9 permits, which must at least include:

- Allowable use of Schedule 9 substances;
- Any qualifications or necessary experience of the permit holder to handle prohibited items safely; and
- Any additional storage or security conditions.

Due to the inherent danger of Schedule 9 poisons and the fact that they are otherwise prohibited, the granting of such a permit is a decision that must be carefully considered. It should be weighed against possible risks and each decision made consistently based on established criteria. Any permit granted then needs to meet strict assessment criteria.

Schedule 9 permits must identify a person to take overall responsibility for Schedule 9 poison and the permitted site of use. In contrast to any other type of permit, a Schedule 9 permit must specifically list individuals or employees, who have legitimate need for access based on their job and the intended use of the substances at that site. Regulations need to identify any allowable uses that might exist including bona fide academic research, analysis, treatment of exotic animals and training of drug detector dogs.

The Act provides for the regulations to set fees for issuing and amending licences and permits. Fees and charges should be based on a cost recovery model. Permits and licence fees might then differ based on the complexity of the issue or amendment of an individual licence or permit type. These fees must include other activities associated with the operation of the Act relating to these license or permits, for example compliance monitoring.



Proposed regulatory changes, for Licences and Permits, can be summarised as:

- **Persons possessing a recognised licence or permit issued by a recognised regulatory authority other than the Department would not require an additional licence:**
- **Removal of Schedule 7 permit requirements for recognised industrial uses at clearly identifiable industrial locations;**
- **Removal of:**
 - **Schedule 6 Wholesale licences; and**
 - **Pharmacist's Licence;**
- **Introduction of:**
 - **Indent licences; and**
 - **Permits for Schedule 9s;**
- **Establishment of a revised, cost-recovery based schedule of fees; and**
- **Licences and Permits to be provided with expiry/renewal dates based on initial date of issue.**

3.8.5 Impact Analysis

Changes in the area of licences and permits aims to provide improve cost efficiencies for businesses and improve capacity for the Department to monitor regulatory compliance. Clarity in the type and scope of licences and permits will improve stakeholder compliance with licence provisions.

Any licence or permit that is no longer required is an immediate cost reduction to business. Stakeholders indicated that overlaps in current licencing requirements impose unnecessary costs and administrative burdens to businesses. For example, one stakeholder argued that the regulations should not require a licence or permit for the use or application of a medicine or poison which was not deemed to be onward supply. This was stated to be extra expense and administrative burden, without tangible value. The specific example offered was assisting a patient to take a medicine where that medicine has been lawfully prescribed and dispensed under the Act:

For example:

- A school holding a medicine already supplied by a pharmacy for use by that child during school time.

This would add cost and complexity and is not a requirement of the preferred option. The Act provides protections for the carer of a person to be in possession of a prescription medicine: for the purposes of supplying or administering the posing to the patient in accordance with the instructions of the prescriber.



Recognition of specific and licences or permits issued by other authorities as suitable for the needs of the Act will also reduce costs to business. Preliminary consultation identified that the expense and effort to obtain a poisons licence was a noticeable burden for Schedule 7 permits. The exact expense was not quantified, but the Department estimates a sizable number for the current permits will be purely industrial in nature. There will be cost efficiencies created for Government by decreasing duplication of licencing tasks.

This view was supported by one stakeholder when responding to the Consultation RIS, who endorsed the view of the Productivity Commission:

- *“This overlap between domestic poisons controls and those on workplace substances could impose unnecessary costs on firms that have to meet additional requirements, with little benefit to public health (or occupational health and safety) outcomes”⁷⁸; and*
- *“Therefore, we consider that the S7 (licence) obligation should not be applied to any industrial purposes”⁷⁹.*

Furthermore, it was noted by another stakeholder that a registered veterinary surgeon may have a requirement to handle or use S7 poisons, which are important for certain registered livestock preparations. These persons would already be registered with a regulatory authority as indicated above, and the uses of these substances in line with any notice issued under the Act. This would be consistent with those uses already recognised as industrial purposes by primary producers. The preferred option would not require further licensing as is required at present.

One stakeholder noted that:

- *“The addition of Schedule 9 substances to the permit system will allow better oversight for compliance officers in large varied institutions such as universities”⁷⁹.*

It was noted by one stakeholder that for some organisations which currently hold multiple poisons licences or permits (issued to individual persons), that there can be frequent turnover of staff, which necessitates continual amendments. Annual licences, fees for amendments and the need to maintain changes may then be challenging. The specific costs of this were not detailed. The ability to access a corporate licences or permits would be of benefit in such a situation.

Indent licences will provide similar cost benefits to businesses, as the licensee will pay for a type of licence suited to their activities and costed accordingly. This contrasts the current need to obtain an expensive wholesale licence that relates to physical premises

Public consultation over the proposed options in the Consultation RIS reconfirmed the need for reform and improved efficiency for business. There was general industry endorsement for the preferred options of recognition of existing licenses. No further material issues of cost impact were raised for licenses and permits.

⁷⁸ CRIS submission 29

⁷⁹ CRIS submission 44



3.9 Poison Controls: Schedule 5, 6, 7 & 10

3.9.1 Background

National consistency is vital to ensure that a poison is instantly recognisable and treated with due care in all situations. This is important for domestic purposes in households that purchase a poison, as well as for businesses with industrial or manufacturing uses of poisons. Poisons are sold and supplied right across Australia. The majority of large-scale medicine and poison manufacturing is considered to originate outside WA. There is significant trade in these items flowing into WA from other States and Territories. These items are also made within WA and sold interstate. Consistency across jurisdictions is then important to make sure that a poison made or transported from any State or Territory in Australia provides the same protection to consumers from spills, ingestion by a child, or other harm, regardless of where it ultimately ends up.

In 2012 the former National Coordinating Committee on Therapeutic Goods (NCCTG) undertook a national consultation process to review consistency in relation to poisons controls⁸⁰. This process considered current controls across Australia, including those present in poisons legislation in WA. The document *Strategies to implement a national approach to poisons chemical controls Decision Regulation Impact Statement* provided recommendations for adoption of a national standard on poisons controls. This review proposed that uniformity could be achieved in regulation through each State and Territory adopting the same controls, with the same standardised wording. This would provide industry with improved business certainty, reduced variation and therefore lower business costs in compliance. It would also ensure that the public is afforded equal protection from poisons anywhere in Australia, regardless of origin. A summary of the impacts on WA regulations of the recommendations from this committee are contained in the discussion paper in Appendix 4.

Preliminary consultation over the 1965 Regulations provided limited additional commentary related to consistency or regulatory failure matters for poisons as raised by the NCCTG. Comment was still sought from industry groups, specific to poisons controls. The national consultation process was stated by stakeholders to have been comprehensive and provided good opportunity for engagement and comment by all states, including WA. Overall the recommendations of NCCTG review document were endorsed. No significant WA related differences were identified with respect to the controls deemed most acceptable. Stakeholders did comment on different requirements for licencing and permits between jurisdictions. These licensing matters are further detailed in Section 3.8.

⁸⁰ National Coordinating Committee on Therapeutic Goods. *Strategies to implement a national approach to poisonous chemical controls: Consultation Regulation Impact Statement*. 2012.
<http://www.health.qld.gov.au/ph/documents/ehu/ris-consult-paper.pdf>



3.9.2 Current Regulations and Issue Identification

Existing WA regulations regarding poisons include requirements over sale, purchase, storage, packaging, labelling, advertising, record keeping, disposal and hawking. Current packaging regulations include such matters as durability and breakage resistance of packaging, and child resistant protections. Current labelling regulations include statements of contents and concentration, standard text for warnings and safety, and size and location of any warnings. Regulations currently require poisons to be stored to preclude contamination of food and drug and prevent access by children, with increasing restrictions according to higher scheduling classification and increased toxicity. There has been no suggestion by stakeholders during preliminary consultation or as a result of the Consultation RIS that the specific controls outlined in existing regulations are ineffective, unnecessary or inadequate.

Under the *Poisons Act 1964*, Schedule 7 poisons may only be supplied by a person licenced to do so, in accordance with any notice or regulations and only to a person permitted to use them. Similar provisions exist in the new Act. The 1965 Regulations require an authorised supplier to keep a register for Schedule 7 poisons that records the date of sale, the name and address of purchaser, name and quantity of poison sold, address the poison is delivered to, intended place of use (if different to delivery address), and signature of the purchaser. The register may be kept in writing or electronically and must be available for inspection, as required in compliance with regulations.

Substances in Appendix C of the SUSMP are those that are of such risk to the public that they should be prohibited. They may however have possible uses in research settings. These substances are recognised in the Act as “strictly controlled substances”. In the most recent edition of the SUSMP, substances in Appendix C have been placed in the newly created Schedule 10.

Substances in Appendix C were previously considered individually and listed as prohibited substances under the 1965 Regulations based on WA requirements in relation to these poisons. The process for inclusion in Appendix C did not previously mirror that used for the Schedules for the SUSMP. This made Appendix C listed substances unsuitable for automatic adoption into the 1965 Regulations. Inclusion in Schedule 10 now means that there is a robust process for poisons to be evaluated and listed, which is consistent across all medicines and poisons Schedules. The adoption of Schedule 10 into the SUMSP ensures that appropriate consultation and impact assessment occurs in classification of these prohibited substances. The adoption of Schedule 10 by WA into new regulations would achieve national consistency, reduction variation and decrease costs and regulatory burden for WA.

Current issues related to Schedule 5, 6, 7 & 10 Poisons are:

- **Lack of national consistency, which creates cost and confusion for industry, especially national companies; and**
- **Licensing requirements for some poisons Schedules are out-dated (see licencing section).**



3.9.3 Proposed Regulations

Table 7 summarizes the preferred regulatory controls as outlined in the *Strategies to implement a national approach to poisons chemical controls Decision Regulation Impact Statement*⁸¹ and the proposed regulations for WA.

Table 7: Preferred Regulatory Poison Controls Schedule 5, 6, 7 & 10

Control	Schedule	Preferred national option	Proposed WA regulations
Storage	5	No explicit controls over retail storage	No explicit controls over retail storage
	6	Outcome based control to limit retail storage.	Adoption of outcome based control to limit retail storage
	7	Outcome based control, with “deemed to satisfy provisions” to limit retail storage	Adoption of outcome based control with provisions to limit retail storage
Disposal	5, 6, 7	Outcome based control to prevent public harm from unsafe disposal	Maintain existing regulatory control
Labelling	5, 6, 7	Labelling provisions of the SUSMP as is	Maintain adoption of SUSMP labelling provisions
Packaging	5, 6, 7	Packaging provisions of the SUSMP as is	Maintain adoption of SUSMP packaging provisions
Record Keeping	7	Adopt a prescriptive control for keeping of records for supply of Schedule 7 poisons	Maintain existing regulatory controls, and include requirement for record keeping storage for 5 years
Advertising	7	Remove controls	No controls required
Hawking	5, 6, 7	Adopt a prescriptive control	Maintain existing regulatory controls
SUSMP Appendix C	10	Adopt a prescriptive control by removing prohibited substances from Appendix and including in a new schedule	Adoption of Schedule 10
SUSMP Appendix I: Uniform Paint Standard		Implement provisions of the SUSMP Schedule as written	Maintain existing regulatory control consistent with national standard
SUSMP Appendix J: conditions for availability		Adopt a prescriptive standard once appendix J has been subject to review and update	Maintain existing regulatory control consistent with national standard

The Regulations need to outline specific criteria for Schedule 10 poisons as strictly controlled or prohibited substances. This must include:

- Allowable uses of the Schedule 10, if any;

⁸¹ National Coordinating Committee on Therapeutic Goods. Strategies to implement a national approach to poisonous chemical controls: Consultation Regulation Impact Statement. 2012.
<http://www.health.qld.gov.au/ph/documents/ehu/ris-consult-paper.pdf>



- Records of use; and
- Storage conditions.

Proposed regulatory changes, for Poison Controls: Schedule 5, 6, 7 & 10 are summarised as:

- **Adoption of national controls to ensure national consistency for storage, disposal, record keeping, labelling, packaging advertising and hawking;**
- **Changes to reduce unnecessary red tape for Schedule 6 and Schedule 7 licensing (see also Section 3.8); and**
- **Adoption of SUSMP Schedule 10 and provision of regulatory controls for restricted use of these strictly controlled substances.**

3.9.4 Impact Analysis

The need for continued poisons controls is evident in the number of poisonings seen annually in Australia. The number of calls taken by poison information centres each year suggests that exposure to poisons, poisoning and related consumer harm is still a frequent event in our society. The rate is relatively constant suggesting a residual risk associated with access to these substances.

Regulatory reform in this area primarily aims to achieve national consistency by action of standards outlined in the SUSMP. This has the benefits of:

- Consistent and best practices in storage and other controls nationally;
- Decreased confusion for stakeholders operating between jurisdictions, which is relevant given the national business interests of most poisons stakeholders;
- Uniform consumer experience across States and Territories; and
- Reduced red tape from having to accommodate differing regulations, for example: the retail storage of products can be uniform for organisation regardless of jurisdiction.

For industry, variations in packaging by State or Territory are more difficult to comply with. Meeting several different standards adds costs to production and is therefore a financial penalty to manufacturers and/or suppliers. National consistency of regulatory requirements is the most cost effective for all States and Territories, including WA. Adopting SUSMP standards for labelling and packaging, storage and other controls without modification will align WA regulation with that in place in other jurisdictions. Assessment of the 1965 Regulations requirements against the national standard suggests that there is either a reduction in regulation, adoption of a more flexible outcome based regulatory approach, or maintenance of existing controls. The impact for business is therefore reduced costs,



possibly improved efficiency or negligible change, respectively. Alignment with national standards is supported by stakeholders who have frequently stated during consultation that inconsistency between jurisdictions adds complexity and cost to industry:

- *“The current regulatory framework for poisonous chemical regulation does not deliver consistent national controls. The inconsistent laws add complexity and cost to industry. To address the current impediments with the Poisons legislation and to ensure a sustainable industry, we support the proposed national approach”⁸².*

The Consultation RIS did not identify further costs or impacts that should be considered around these consistent national controls.

The nationally proposed standard for record keeping duration of five years for Schedule 7 supply records is longer than currently required by the 1965 Regulations. The time period for keeping this business information is already required for a number of other purposes, e.g. taxation records. The Consultation RIS suggested the impact would be limited and no further information on impact has been provided by stakeholders.

Development of regulations surrounding Appendix C / Schedule 10 poisons is necessary for the operation of the Act. It will assist in ensuring that rules applying to substances which are highly toxic and have no legitimate industrial use be either prohibited or otherwise strictly controlled regarding supply. The Act provides a basis for this. Regulations are then necessary to enforce the prohibition or to describe the controls required to ensure that use or supply is contained to specific, limited areas. This is fundamental to protect the health, safety and welfare of the public.

Proposed regulation in this area will improve national consistency through appropriate adoption of Appendix C / Schedule 10 substances in the SUSMP as strictly controlled substances in WA. Adoption of Schedule 10 will decrease cost to Government, as individual WA based assessment of substances is not required. Use of the robust national evaluation process for the listing of Schedule 10 substances will ensure better assessment of impacts on business operating nationally and potentially improve the quality of decisions.

The existing familiarity of businesses with the SUSMP, as opposed to state regulatory notices, means that adoption of Schedule 10 is expected to increase clarity regarding the restrictions of use of these substances, within WA and other jurisdictions. Better understanding of the status of these toxic substances is expected to improve compliance with any prohibition. Stakeholders did not provide further information on impacts or costs to business in relation to adoption of Schedule 10.

⁸² CRIS submission 29



3.10 Medicine Controls: Schedule 2, 3 & 4

3.10.1 Background

Legislative controls over Scheduled medicines are intended to minimise the incidence of:

- Accidental and deliberate poisoning;
- Medicinal misadventure; and
- Diversion for abuse or manufacture of substances of abuse.

The regulatory controls for Schedule 2 and 3 “over the counter” medications are primarily concerned with supply of medication when via retail sale at a pharmacy. An authorised practitioner may also provide these medications as part of a consultation.

For example:

- People entering a pharmacy to purchase a Schedule 3 “pharmacist only medicine” such as an inhaler containing salbutamol; or
- An optometrist might provide Schedule 2 “pharmacy medicine” eye drops as part of a consultation, but cannot offer retail sale of eye drops outside a professional consultation.

Certain information must appear on the labels of medicines, such as the product name, concentration, quantity and relevant poisoning warnings. These standards are adopted all around Australia and originate from the SUSMP. There are also requirements on how these items are packaged, for example the use of child resistant packaging. Regulations that adopt national standards regarding labelling and packaging provide consistency in terms of best practice for safety and consumer experience, as well as lowest administrative burden for medicines manufacturers and suppliers.

The purchase, use, storage and disposal of both Schedule 4 and 8 medicines are subject to jurisdictional legislative requirements. The normal mechanism for consumer access is for an authorised prescriber to write a prescription and for that prescription to be dispensed by a pharmacist. Anyone who supplies Schedule 8 medication must notify the Department that this medication is supplied. This notification is also potentially relevant for some Schedule 4 medicines that are subject to diversion and abuse. These Schedule 4 medicines may be suitable for additional reporting along the lines of that required for Schedule 8 medicines.

Anyone supplying or prescribing these medications should follow the same general principles:

1. Assessment that a genuine therapeutic need exists;
2. Taking reasonable steps to prevent abuse or diversion; and
3. Only providing medications within expertise or scope of practice.



Additional issues in related to Schedule 8 medications and those Schedule 4 medicines identified as problematic for misuse include:

- Prescribing codes for the prescription of drugs of addiction;
- Reporting requirements; and
- Identification of, and prescribing to, persons with drug dependency.

3.10.2 Current Regulations, Issue Identification and Proposed Regulation

Controls over the handling of medicines increase when moving from Schedule 2 through to 4. This is in line with the increasing inherent toxicity of the items in each Schedule as they rise, as outlined in figure 4 below. The existing regulations are guided by the SUSMP Schedules and provide rules regarding consumer access to medicines. Areas recommended for change, are illustrated in red.

Figure 4: Regulatory Controls Schedule 2, 3 and 4



3.10.2.1 Schedule 2 Medicines

No amendments were identified as necessary by stakeholders in relation to the existing Schedule 2 labelling, packaging and supply. The Department is not aware of any gross regulatory failure or argument for change to current regulation for these medicines. The regulations should support a registered health practitioner (as defined by their scope and professional authority) to supply Schedule 2 items, as part of their lawful practice.

For example:

- Schedule 2 cough and cold remedies can be purchased as part of retail supply from a pharmacy; and
- It is acceptable for other practitioners to provide or use Schedule 2 medicines as part of a consultation with a patient, if this is within their professional scope and if necessary for treatment of the patient while under their care.



3.10.2.2 Schedule 3 Medicines

Part 3 of the SUSMP recommends labelling and recording of all Schedule 3 medicines in recognition of assessment of therapeutic need. Labelling is regular practice in some States such as Queensland. In WA this is a long standing and currently required practice for a number, but not all, Schedule 3 medicines. Notably it includes strict labelling and recording requirements for pseudoephedrine. Labelling offers the same benefits as labelling of prescription medicines. This includes advantages to the user with specific instructions for use (if any), personalised supply of the medicine by labelling it for one individual, and clear identification of the supplier. Recording sale offers a supply history that can be used by both the patient and pharmacist to assess effectiveness and safety. At present, a pharmacist must personally supervise the retail sale of a Schedule 3 substance and take steps to establish that there is therapeutic need. It has been proposed by some stakeholders that WA regulations require all Schedule 3 medication should be labelled and recorded, and that this apply to pharmacist or any other person supplying a Schedule 3 medicine as part of usual professional practice.

For example:

- For practitioners providing as part of a consultation with a patient a Schedule 3 medicine, the supply should be recorded and the product labelled with a patient name.

It is anticipated that labelling of medicines would assist with making clinically appropriate decisions regarding prior supply. This offers benefit to regular customers in terms of ensuring quality use of medicines and supports the requirement of identification of therapeutic need prior to dispensing. This should apply to any person supplying a Schedule 3 medicine for patient use.

The 1965 Regulations have been amended over time to allow the supply of some Schedule 3 items for use in life saving situations, such as life threatening anaphylaxis. In these cases the supply is not to the end user, but is rather to have a medication on hand for use a later point to treat an unknown patient in the event of an emergency. The person supplying cannot assess therapeutic need in these cases. In addition, the person keeping or supplying the item later could be contravening poisons legislation. "Good Samaritan" type exemptions have made allowance for these cases. The medicines are still potentially toxic and can be misused, but this is balanced by the potential to save a life in an emergency.

At present, there is facility for the emergency treatment of persons with specific Schedule 3 medicines for anaphylaxis and acute asthma at places like schools or child care centres. Consultation suggests that this is effective and essential to continue. It was identified that other circumstances of need might exist and should be accounted for. The preferred model to deal with this potential extension is to provide flexible protections to allow onward supply and use when need exists, it is performed with due care and in good faith, for emergency situations only.



3.10.2.3 Schedule 4 Medicines

For Schedule 4 medicines, some long term regulatory failures have been identified by stakeholders. Consultation did recommend changes in terms of record keeping, storage reporting and supply, however the following regulatory rules were confirmed as needing to continue to apply:

- Safe storage of prescription medicines, including explicit instruction on ensuring the public does not have unauthorised access;
- Ensuring distinction between animal and human treatment;
 - e.g. labelling animal treatment clearly, so it is clear a medicine is not suitable or intended for human consumption; and
- Provisions for emergency supply when a lack of continuity of treatment would cause harm.

It has been frequently identified that more detailed provisions are necessary to guide the appropriate authorisation of administration of a medicine to a patient in a hospital setting. Administration of medicines in a hospital may be via an order, which must contain specific information and must be signed by an authorised prescriber. Regulations currently support the verbal approval of administration, so that a medication can be administered under the direction of an authorised prescriber. In addition, health institutions are requesting other flexible ways to generate, communicate and record instructions by authorised prescribers to administer medicines in hospital.

Appendix D of the SUSMP makes recommendations for additional controls over Schedule 4 medicines. This is where additional serious risks have been identified, for example birth defects. Additional prescribing requirements for these medicines can include limitation of prescribing to specialist practitioners, to prevent their inappropriate use and subsequent harms. Appendix D recommendations are implemented in practice in WA through individual regulations in the 1965 Regulations for each substance. In order to clarify prescribing restrictions, the 1965 Regulations outline the authorised providers:

For example:

- Thalidomide may only be prescribed by a specialist physician or dermatologist and must be labelled with warning causes birth defects.

Whilst there may be a residual need to restrict medications in this way, it is considered that there are often other mechanisms and regulatory systems in place that mean these restrictions are not always required. Such mechanisms normally include:

- Improved access to drug information by health practitioners and consumer awareness through electronic sources, enhanced product warning requirements, and labelling and packaging innovations;
- Restrictions through funding schemes such as authority rules of the Pharmaceutical Benefits Scheme (PBS) that restrict subsidised funding to prescriptions written by certain specialists only; or
- Risk Management Programs mandated by the TGA, such as for thalidomide or mifepristone that require registration of both prescriber and dispenser.



3.10.2.4 Schedule 4 Reportable Medicines

Some Schedule 4 medicines have a potential for misuse and or dependency, but the risk is accessed as lower than a Schedule 8 medicine. The Act allows for some Schedule 4 medicines to be named as “Schedule 4 Reportable”. Being named as reportable allows the Department to keep a record of supply and prescription of these medications.

For example:

- It has been suggested that classes of medications such as benzodiazepines are of such risk that they should be tracked and monitored by the Department.

Medicines identified as being necessary to classify as Schedule 4 Reportable included commonly used oral benzodiazepines, “z drugs” (zopliDEM and zopiclone), prescription only codeine products and other medicines identified from time to time as being misused.

In responses arising from the Consultation RIS stakeholders did identify benzodiazepine and codeine containing drugs as appropriate for Schedule 4 reportable criteria. There was support for making the supply history of these medications available to practitioners to assist with prescribing decisions.

The Consultation RIS did note that a medicine named as a Schedule 4 Reportable medicine would then be considered a drug of addiction under Part 6 of the Act. This means that the following provisions of the Act apply including:

1. Treatment as a drug of addiction by the Act;
2. Mandatory notification of dependence or oversupply;
3. Keeping of a record of prescribing and supply, such as in an electronic recording system for medical practitioner use; and
4. Subsequent restrictions on prescribing for notified dependent or oversupplied persons.

For a medicine named as Schedule 4 Reportable, some other controls that apply to Schedule 8 medicines would not apply. For example the storage, packaging and labelling for a Schedule 4 Reportable item would remain as per usual for a Schedule 4 medicine.



Issues and proposed regulatory changes, for Medicine Controls: Schedule 2, 3 & 4, can be summarised as:

- **Clarifying allowable circumstances of supply of Schedule 2 and 3 items by health practitioners;**
- **Ensuring individualised and safe supply of Schedule 3 medicines by all health practitioners;**
- **Providing for supply Schedule 3 items in specific situations where there is emergency need;**
- **Rationalising prescribing restrictions for specialised Schedule 4 items; and**
- **Inclusion of named Schedule 4 medicines at moderate to high risk of abuse or misuse as Schedule 4 Reportable items.**

3.10.3 Impact Analysis

Stakeholders confirmed that there was continued need to Schedule 3 medicines for defined emergency uses (anaphylaxis and asthma) in schools, kindergartens and similar institutions. It was also noted that there were other potential settings with similar needs that may not be covered by existing regulations. In addition there is possible need in other emergency situations, for example use of “peer” administered naloxone to reverse heroin overdose. This confirms the need for the preferred option that facilitates this supply, with the necessary flexibility.

In response to the Consultation RIS the impact of labelling and recording of Schedule 3 supplies by health practitioners was commented upon specifically by several stakeholders. It was suggested that:

- *“The labelling of Schedule 3 medicines might impress upon the recipient that these are serious medicines and need to be treated with care”⁸³.*

It was also argued that this control may not provide any appreciable clinical treatment value. The proposed option in the Consultation RIS outlined that Schedule 3 medicines can only be supplied as a result of individual assessment of therapeutic need by a health practitioner and are therefore supplied on the basis of the individual needs of one individual. That is the medicine supplied is only intended for that one person.

It was suggested that labelling and recording of all Schedule 3 medicines may increase administrative burden. The extent or cost of this burden was not quantified by stakeholders.

A number of submissions clearly acknowledged that there were issues of overuse and misuse of Schedule 3 medicines that required some type of regulatory response. Several stakeholders proposed that real time reporting of certain “substances of concern” was necessary and that pharmacists’ required access to these records to be able to meet their professional and regulatory obligation when supplying. Stakeholders suggested that the retention and expansion of the current Appendix J of the 1965 Regulations was a suitable way to address the regulatory concerns outlined and limit administrative burden.

⁸³ CRIS submission 21



Appendix J lists a subset of Schedule 3 medicines that require labelling and / or recording. Specifically, codeine products were cited as substances that when in Schedule 3 should be subject to recording and labelling needs of Appendix J. It was strongly suggested they be included in a real time reporting database, such as already in place for pseudoephedrine.

The feedback supports the need for the ability to require labelling and / or recording in some cases. The preferred option is for the inclusion of facility in regulation to require the labelling and/or recording of items where a demonstrable clinical or other public safety need exists. This could include a subset of medicines already identified by the 1965 Regulations and those proposed in the submissions received. Any requirements should apply to retail sales and also to any supply of a Schedule 3 medicine, by an authorised health practitioner.

Stakeholders supported the inclusion of certain substances of concern as Schedule 4 Reportable medicines. One stakeholder noted that a fundamental requirement of such a system would be a system that allowed the electronic exchange of the records of supply.

As outlined in Section 3.13, this reporting is intended to provide information about the person a particular medicine was supplied to and becomes part of a record of care of that person. Access to prior supply information should assist to ensure appropriate and safe supply of medicines. Ideally, these mechanisms would be built upon existing work processes, without additional administrative burden. This is possible where it is already part of the inherent processes for collecting the information. It is expected that the information would already be collected as part of existing requirements to keep a prescription book. The information will be stored electronically by pharmacies, which do so for several purposes, including keeping a clinical record and for financial reimbursement under the Pharmaceutical Benefits Scheme. The system provided for Schedule 4 Reportable medicines, if using the same technology as for Schedule 8 medicines, would represent negligible cost to collect and transmit the information.

Stakeholders indicated support for the changes to Schedule 4 medicines with one stakeholder describing Schedule 4 Reportable medicines as:

- *“A good initiative for the medical profession and pharmacists”⁸⁴.*

These medicines are not Schedule 8 medicines and the preferred option does not impose extra storage or supply requirements on health practitioners. Therefore, the introduction of Schedule 4 Reportable has limited implications for hospitals, nursing homes or those administering these medicines.

The benefits that including these medicines under Part 6 of the Act provides in terms of increased public protections from diversion and misuse to enhance individual patient safety was acknowledged by stakeholders. Stakeholders did indicate some likely costs at the point of implementation, however confirmed these are consistent with the preferred option for reporting of Schedule 8 medicines, so are unlikely to create additional workload.

Veterinary stakeholders did note that any Schedule 4 medicine supplied for animal treatment was not intended for human consumption and therefore a registered veterinary surgeon would not derive any benefit from viewing these records. Consistent with the preferred option in Section 3.12 and 3.13, the reporting requirements of Part 6 would not apply to animal treatment.

⁸⁴ CRIS submission 38



3.11 Drugs of Addiction

3.11.1 Background

The Act defines drugs of addiction as those substances listed as Schedule 8 and 9, or a Schedule 4 reportable medicine. Substances included in Schedule 8 are used for therapeutic purposes and have been recognised in the SUSMP as having a potential for dependency. Schedule 9 substances are illicit substances without any defined medicinal value. The major controls around illicit possession or supply of these medicines are covered by the *Misuse of Drugs Act*. The Act is primarily controlling the legitimate medicinal use of Schedule 8 substances, whilst at the same time preventing dependency, diversion and misuse.

Historically, medical professionals, lawmakers and the public have had concerns about the addictive potential of Schedule 8 substances and the potential for diversion or abuse to occur. The legislation relating to regulation of Schedule 8 substances in WA was introduced over 50 years ago. Since then, drugs listed in Schedule 8 have become much more widely used in the treatment of chronic pain and are more frequently prescribed by medical practitioners in the course of treatment. New dosage forms, such as long-acting preparations, as well as new agents that are reported to be less likely to cause misuse, have been developed.

Evidence suggests prescription medicine misuse is an increasing problem across the community⁸⁵. This is a major public health concern and suggests that there is a clear need for strict regulation, whilst still allowing legitimate access to these medicines.

3.11.2 Current Regulations

The 1965 Regulations provide a range of controls intended to allow consumer access to Schedule 8 poisons for legitimate medical needs, while still protecting against diversion, misuse or abuse. These rules are very similar in most States and Territories of Australia.

They have the primary effect of limiting one patient, to one prescriber (or medical practice), at any one time. Authorisation to prescribe is only issued to one prescriber (or practice) at a time. If a patient moves to a new prescriber, then a new authorisation is required. If a new authorisation is issued, this cancels any prior authorisation. The intent is that all prescriptions for that patient are supplied by the same medical practitioner, who will be able to detect emerging dependence issues and respond to any overuse that is evident.

The 1965 Regulations state that a medical practitioner cannot provide a Schedule 8 medication for a period of longer than 60 days, or to someone with documented prior drug dependency, without obtaining permission from the Department. This is in recognition that longer-term treatment may be associated with dependence. It does allow for short-term treatment without unnecessary impact on clinical autonomy. Due to this risk of dependence permission for longer treatment may also be subject to prescribing conditions.

⁸⁵ National Pharmaceutical Drug Misuse Framework for Action (2012-2015). A Matter of Balance.
[http://www.nationaldrugstrategy.gov.au/internet/drugstrategy/Publishing.nsf/content/9C52D7D6E2C14A72CA257C3F001F009D/\\$File/National%20PDM%20Framework.pdf](http://www.nationaldrugstrategy.gov.au/internet/drugstrategy/Publishing.nsf/content/9C52D7D6E2C14A72CA257C3F001F009D/$File/National%20PDM%20Framework.pdf)



The 1965 Regulations limit patients to supply of a Schedule 8 from one pharmacy for the life of that prescription. In addition, Schedule 8 dispensing information is provided from every WA pharmacy to the Department. At present this information is collected retrospectively and is only accessible by the Department. The 1965 Regulations require every pharmacy to complete a report after the end of each month with details of all Schedule 8 drugs dispensed.

An example of this process is:

- For a person with a history of drug abuse, opiates may be medically indicated for treatment of pain. A doctor can apply to the Department for permission to prescribe. The Department may issue an authorisation that restricts prescribing to one doctor, or practice. The Department monitors dispensing records to ensure the prescribing continues to be linked to the authorised prescriber.

A highly specific area of existing regulation is the restrictions on the prescribing of Schedule 8 drugs. A comprehensive discussion paper was developed to support consultation in this particular area and is contained in the Appendix 2. This paper detailed the specific regulations that already apply to prescribing and dispensing. Although the 1965 Regulations apply to all Schedule 8 prescribing, the consultation to date has been predominantly concerned with prescribing of opioids, such as morphine or oxycodone.

In recent years the Department has developed a code to help the safe prescribing of Schedule 8 medicines and assist practitioners in the navigation of the Department authorisation process⁸⁶.

In addition to the Schedule 8 prescribing the 1965 Regulations outline requirements related to use of specific Schedule 8 medicines including:

- Community Program for Opioid Pharmacotherapy (CPOP); and
- Stimulant Regulatory Scheme.

These programs are controlled by similar codes of practice and new regulations must include reference to the code or policies applicable to each program area.

The Pharmaceutical Services Branch administers the regulatory controls for the Community Program for Opioid Pharmacotherapy (CPOP) in Western Australia as set out in the Regulations. Regulation in this area is guided by published policy and procedures⁸⁷.

The CPOP provides a scheme for opioid replacement treatment in primary health care settings for patients who have been identified as opioid dependent and wish to engage in treatment. Current pharmacotherapies available are methadone as a syrup or solution, and buprenorphine as Subutex®, or with naloxone as Suboxone®. Medical practitioners and pharmacies require approval to participate in the CPOP.

⁸⁶ WA Department of Health. Schedule 8 Prescribing Code. 2014.

<http://ww2.health.wa.gov.au/~media/Files/Corporate/general%20documents/medicines%20and%20poisons/Word/schedule-8-medicines-prescribing-code.ashx>

⁸⁷ Drug and Alcohol Office. Clinical Policies and Procedures for the Use of Methadone and Buprenorphine in the Treatment of Opioid Dependence. 2014.

http://www.dao.health.wa.gov.au/DesktopModules/Bring2mind/DMX/Download.aspx?Command=Core_Download&EntryId=166&PortalId=0&TabId=211



The Stimulant Regulatory Scheme commenced in August 2003 in response to the paper, *Attentional Problems in Children: diagnosis and management of Attention Deficit Hyperactivity Disorder (ADHD) and associated disorders*⁸⁸. The Stimulant Prescribing Code is referenced in the 1965 Regulations and sets the criteria for the prescribing and dispensing of stimulant medicines (dexamphetamine, lisdexamphetamine and methylphenidate) in WA.

The Code states that treatment with stimulant medicines may only be initiated by an authorised prescriber with specialist qualifications in psychiatry, paediatrics, neurology. A prescriber must obtain a Stimulant Prescriber Number from the Department. Stimulant medicines may only be prescribed for the treatment of ADHD, depression, brain damage, narcolepsy, and other conditions as approved by the CEO.

Regulations mean it is not acceptable for a practitioner to supply or dispense a Schedule 8 medicine to further a person's addiction. Medical practitioners must notify the Department if a person they treat is identified as drug dependent. The Department uses a standard format to guide practitioners when notifying of a drug dependent person.

3.11.3 Current Regulatory Issues

Regulations governing the use, sale and supply of Schedule 8 drugs are currently provided for in the 1965 Regulations. The Act provides a framework for regulating the prescribing of substances in Schedule 8, but the mechanics of the controls will continue to be retained in regulations. Regulations need to cover the rules relating to prescribing and dispensing of Schedule 8 drugs to patients and in particular, to patients who are drug dependent. The Act states that only an authorised prescriber can prescribe a Schedule 8 medication to a drug dependent or over supplied person.

The number of patients receiving Schedule 8 opioid medications is increasing⁸⁹. The number of opioid medications and formulations available is also expanding⁹⁰. More professional groups are now prescribing and some of these can prescribe opioid medicines. With an aging population, the prescription of use of opioids for palliative care and pain associated with malignancies is likely to remain an important treatment modality. There is mounting evidence that prescribed opioids are increasingly diverted into illicit use and responsible for harm from overdose and other misuse. The overall risk to the public may then be increasing.

With increasing prescribing of Schedule 8 medicines use there is an administrative burden for health practitioners in prescribing and dispensing, and for Government in administering regulations. The Act allows for the records of prescribing and dispensing to be made visible to health practitioners. It is the intention that this will be done through a secure electronic system. When the prescriber or dispenser is able to see the prior supply, they will be able

⁸⁸ Office of Mental Health. *Attentional Problems in Children*. 2002
http://ww2.health.wa.gov.au/~media/Files/Corporate/general%20documents/medicines%20and%20poisons/PDF/Attentional_problems_in_children_Mgmt%20of%20ADHD.ashx

⁸⁹ Nicholas R, Lee N, Roche A. *Pharmaceutical Drug Misuse Problems in Australia: Complex Issues, Balanced Responses* [pdf]. Adelaide (AUST): Flinders University, National Centre for Education and Training on Addiction; 2011.
http://nceta.flinders.edu.au/files/6113/2823/3742/EN448_Nicholas_2011.pdf.

⁹⁰ Harrison CM, Charles J, Henderson J, Britt H. Opioid prescribing in Australian general practice. *Med J Aust*. 2012; 196(6): 380-1. <https://www.mja.com.au/journal/2012/196/6/opioid-prescribing-australian-general-practice>



to take this information into account when making clinical decisions to prescribe or dispense.

In general, the current Departmental authorisation system is not sustainable indefinitely with the current growth rate in the use of Schedule 8 drugs. The current system is also paper based and labour intensive for prescribers who must work with it. Authorisations represent an administrative burden for prescribers that add time and cost to treatment, as well as potential delays for patients while waiting authorisation. Improved flexibility in this area could vastly reduce the time taken for the authorisation of prescribing of a Schedule 8 medicine.

Consultation has indicated an awareness of this growth and concerns regarding community practitioner management of Schedule 8 medicines. In particular, medical practitioners raised concerns about specific higher potency or more addictive medications, and the need for education programs regarding opioid harm minimisation.

Available data on the movement and use of Schedule 8 medicines shows a significant and continuing trend of annual increase⁹¹:

- In 2003 in WA, 197,354 opioid prescriptions were dispensed;
- In 2013 in WA, 598,572 opioid prescriptions were dispensed;
- This represents an increase of an additional 200% over this ten year period;

Local Departmental records indicate growth of Schedule 8 medicine prescriptions:

- Authorisations for Schedule 8 medicines are increasing 16% per year; and
- Authorisations for Schedule 8 medicines, for people with drug dependency, are increasing at 19% per year.

Stakeholders also suggested that opioid detoxification should be considered as a separate treatment form compared to long term pharmacotherapy, such as CPOP. Opioid detoxification is defined as the medically supervised, rapid withdrawal from opioids, where opioid agents may be administered to reduce symptoms and improve patient safety during this period. Detoxification might be considered to be limited to a short acute treatment, such as up to two weeks period, while they are medically supervised, such as in a hospital. Supply or administration outside this period should not be considered detoxification and should be subject to the usual rules for opioid pharmacotherapy to treat dependence.

Detoxification is currently undertaken in WA in a limited number of settings. The current regulations do not allow for detoxification in community-based settings.

⁹¹ Department of Health and Ageing Office of Chemical Safety: NDS Transaction Data 2013. Unpublished data.



Current issues regarding Drugs of Addiction:

- **Increasing illegitimate use of Schedule 8s;**
- **Increasing licit use means authorisation requirements are becoming an administrative burden to practitioners;**
- **Justification for determining that some medicines are named as Schedule 4 reportable; and**
- **Rules regarding detoxification in approved settings are undefined.**

3.11.4 Proposed Regulations

The development of new regulations provides an opportunity to review the current Schedule 8 framework. New legislation must still ensure that both patients and public are protected from risks associated with use of Schedule 8 drugs. The availability of real time reporting as outlined in Section 3.13 will assist in this area. The regulations will be amended to ensure that authorised health professionals will only be able to prescribe Schedule 8 drugs in accordance with the requirements specified in published guidelines such as a regulatory code.

It is proposed that a supportive regulatory code is published which defines the broad parameters for prescribers to work within that represent safe practice for Schedule 8 medicines. This sort of code is used extensively already within the 1965 Regulations, such as for CPOP and stimulants and would be readily adaptable for this situation. When prescribing outside the parameters of the code, this might be considered a higher risk activity and therefore require closer scrutiny by the Department. These patients would continue to require a positive authorisation.

A practitioner prescribing a Schedule 8 medicine within the code will be required to make a judgement based on the clinical assessment of the patient's condition and other information available, such as the patient's prescription history. This history would be available from the Department database of dispensed medicines as in Section 3.13. It is envisaged that this will encourage appropriate and timely treatment of all patients based on the medical practitioner's assessment. Whilst the Regulations will not refer to specific medicines, a code may provide more targeted advice on specific medicines, forms and doses.

Prescription for low risk and persons who are not dependent can be facilitated through this prescribing Code. Reporting, prescribing and dispensing, of these drugs is the same, however in low risk users, an authorisation from the Department would not be required if all aspects of the code are met.

The criteria for low risk and high risk prescribing will not be outlined in the Regulations but will be included in a Code. Within the low risk criteria practitioners could self-manage without needing prior authorisation to prescribe. This could also capture any requirements for the prescribing of Schedule 4 reportable medicines.

For high risk prescribing, such as very high doses, or to oversupplied persons, then prior authorisation would be required. It is expected that approval would continue to be contingent on medical specialist support or some other similar higher-level control.



This option focusses any regulatory burden on high risk prescribing. It assumes that the majority of risk from opioid prescribing is manageable by individual practitioners based on other available professional guidance and tools, and therefore does not routinely require approval by the Department.

Consultation indicated that the identification of high risk versus low risk could also consider dosage and types of opiate, to encourage use of lesser harm medicines and discourage those that are known to be more subject to abuse. The code might incorporate advice regarding opiates which have demonstrated a particular lower risk of dependency or abuse.

The Department already publishes a Schedule 8 Prescribing Code intended to assist prescribers in complying with the 16965 Regulations when prescribing Schedule 8 medicines. It is expected that under new regulations the supporting code setting out criteria might be modelled on this existing tool. This will allow much of the lower risk Schedule 8 prescribing to be managed without direct intervention from the Department. This code will need to be referenced in regulations and enforceable as a required standard of behaviour. The code will need to set out the criteria for prescribing, where Department interaction is required and when additional regulatory controls are to be exercised.

It is the preferred option that regulations be amended to allow the prescribing of Schedule 8 drugs for the treatment of a drug dependent person for the purpose for detoxification. This would be separate to, but may complement, the current pharmacotherapy interventions. Given the inherent issues in treating dependency with medicines that also cause dependency, and the potential public risk from misuse or diversion, regulations should be specific about who may receive the medication and who may prescribe or administer the medication.

Similar to current pharmacotherapy regulations, the legislation needs to stipulate who is authorised, such as a practitioner with appropriate qualifications or having completed an approved course. Approved prescribers might administer approved Schedule 8 drugs for opioid detoxification. Approval will involve specific rules for patient assessment including appropriate systems, policies and procedures. The Department must be notified regarding individual patient details and medication protocols, at the time of detoxification. Compliance with the authorisation and notification would potentially support detoxification in settings that are not hospitals, but are still safe. Records will need to be kept regarding administration of Schedule 8 drugs over the detoxification period, as per usual Schedule 8 requirements.

The CPOP has not exhibited any significant regulatory failure. Consultation did not identify any demand from stakeholders to dramatically alter the current program as part of the preferred option.

The existing Stimulant Regulatory Scheme is established, but still relatively new and believed to meet client needs⁹². No regulatory modification is required apart from consideration of minor flexibility issues relating to reporting requirements. The preferred option is for this scheme to continue as is.

The rules underpinning the Schedule 8 programs are outlined in Table 8.

⁹² WA Department of Health. Stimulant Prescribing Code: Clinical criteria for the prescribing of stimulant medicines in Western Australia. 2014 <http://www.public.health.wa.gov.au/cproot/3591/3/stimulant-prescribing-code-march-2014.doc>



Table 8: Rules underpinning regulatory programs for Schedule 8 Supply

Program	Who can prescribe?	Who can receive?	Who can supply?	According to what rules?
Schedule 8 Medicines	All medical practitioners or nurse practitioners*	Any patient meeting criteria of code	Any pharmacy	Published Schedule 8 Code
		"High risk" patients requiring individual authorisation	Any Pharmacy	According to conditions of authorisation criteria
CPOP	Authorised providers only	Authorised patients (on drug dependent record)	Authorised pharmacy	Published CPOP Code
Stimulants	Approved specialists and Nominated Co-prescribers	Patients meeting criteria (e.g. patients with ADHD)	Any pharmacy	Published Stimulant Prescribing Code
Schedule 4 Reportable Medicine	Any medical practitioner or nurse practitioner*	Any patient	Any pharmacy	No specific rules
		Patients with a record of oversupply or drug dependence requiring individual authorisation	Any pharmacy	Proposed code as per Schedule 8 Medicines
Detoxification	Authorised prescriber	Patients that meet criteria (i.e. drug dependent)	Authorised prescriber can administer	Published Code

*Other authorised health professional groups may also be able to prescribe/administer/supply a limited amount of Schedule 8 or Schedule 4 Reportable medicines as per Section 3.4.

These models support prescribing according to best practice and basic principles of authorisation based on risk. Depending on the program, the prescribing health practitioner will need to ask for permission and may have to meet more stringent criteria in the interest of the individual patient. For certain patient groups, prescribers must always seek authorisation, such as in very young children or those who have previously had a drug dependency issue. Consistent with the established approach with existing authorisations, prescribing in these patients will be limited to one practitioner at a time. If a patient transfers to a new treatment provider, the previous authorisation would be terminated and a new authorisation will be required.

During consultation it was noted that registered veterinary surgeons commonly prescribe or supply Schedule 8 medicines for animal treatment. It is not lawful to use an animal remedy in a human. Prescribing for humans is also outside lawful practice for a veterinary surgeon. As an animal cannot seek treatment or administer a medicine without human intervention, the risks outlined above in relation to these medicines do not readily translate to this sector. The regulations as proposed address the legitimate use in humans. It is acknowledged that illicit diversion of veterinary Schedule 8 medicines by humans is possible, however the programs outlined should not be applicable to animal treatment.



Nurse practitioners are already able to prescribe Schedule 8 medications in WA. At present a nurse practitioner must be designated and provide clinical protocols to the Department of Health. These restrictions are not likely to transition in to new Regulations. To date Schedule 8 prescribing by this group appears to be part of collaborative care, is generally continuation of that commenced by a medical practitioner, or restricted to specialised areas such as palliative care. This may not be the case in the future. Any developments will likely be addressed by discipline specific regulation.

Proposed regulations for Drugs of Addiction can be summarised as:

- **Use of enforceable published codes to reduce regulatory burden.**

3.11.5 Impact Analysis

The key objectives of the reform in this area are to develop a system that:

- Ensures appropriate, effective and timely treatment with schedule 8 drugs;
- Is open and transparent; and
- Minimises the potential of abuse and diversion of schedule 8 drugs.

All stakeholders that commented have readily acknowledged the issues regarding misuse and abuse of pharmaceutical drugs, and the potential harm of inappropriate opioid prescribing.

Ensuring legitimate access where there is medical need, while adequately protecting patients in this area will be also facilitated by the introduction of real time reporting (see Section 3.13.). A number of stakeholders acknowledged the real time monitoring of Schedule 8 supply is the most critical important step to ensure appropriate access and to support any proposed regulatory prescribing requirements for Schedule 8 medicines.

Introduction of modifications to the Schedule 8 prescribing code could reduce the current administrative burden on prescribers. This will minimise unnecessary interaction with the Department, decrease authorisation waiting times and associated inconvenience to the patient.

These proposed changes would continue to provide public protection, however this will be targeted at specific predetermined risk areas. The regulatory burden on the Department would be reduced as monitoring could be targeted towards compliance with high-risk authorisation requirements. The Department would need to identify patients or prescribing patterns of concern and manage these accordingly.

For example:

- Low risk: a patient presents with a need for prescription of oxycodone to treat cancer pain. Medical practitioner takes reasonable steps to check for prior drug dependency and therapeutic need, and prescribes according to the published code. In this case there is no need for authorisation; or



- High risk: a person with recent history of illicit substance use presents at medical practice. The medical practitioner identifies a medical need for opiate treatment and applies to the Department for authorisation to prescribe. The Department may provide authorisation, inclusive of any stated conditions (e.g. weekly dispensing of medicine).

Inclusions of rules at a code level will enable the use of clinical language, which is less legal in nature and more usable in clinical practice. This will have benefits of increased compliance and flexibility, whilst still maintaining the level of public safety required.

Limited feedback was provided in response to the Consultation RIS. Stakeholders commenting in this area did suggest that such a code had the ability to shape clinical practice towards better prescribing choices and more rational treatment with schedule 8 medicines:

- *"I believe this differential would be a strong incentive for...to choose these opiates ahead of the others"⁹³; and*
- *"The overall drive should be for opioid minimization in non-cancer care"⁹⁴.*

It was also suggested that the proposed regulations could assist with cost and complexity of the current approach:

- *"This proposal should remove a lot of low level, low risk people that currently over stretch the resources of the specialist services"⁹⁵.*

While not a specific legislative concern, stakeholders did identify the need for good practitioner education on specific drug regimens and management of low level opiate issues. The Department will be expected to have an ongoing role in providing this sort of information and clinical support when managing the other regulatory requirements for Schedule 8 medicines.

⁹³ CRIS submission 10

⁹⁴ CRIS submission 17

⁹⁵ CRIS submission 28



3.12 Record of Drug Dependent Persons

3.12.1 Current Regulations

The 1965 Regulations require a medical practitioner to obtain permission prior to prescription of a Schedule 8 medicine if a person has a dependency or if treatment is required for a period longer than 60 days. The *Drugs of Addiction Notification Regulations 1980* (the Notification Regulations) require a medical practitioner who in the course of his / her practice becomes aware of, or suspects a person of having a drug dependency, to inform the Department. A register of Notified Drug Dependent Persons (the Register) is required to be maintained by the Department.

A person may be added to the Register in two ways:

1. A medical practitioner is required to notify the Department if they become aware or suspect that an individual has a dependency to a drug; or
2. To receive treatment for drug dependence under the CPOP, clients need to sign a statement to acknowledge that they are aware their name will be included on the Register.

The Register is only intended for the purposes of guiding medical treatment with Schedule 8 medicines. If a person on the register requires treatment with a Schedule 8 medicine (like an opioid analgesic) then their medical practitioner is required to make an application to the Department before prescribing. This allows any dependency concerns to be identified and appropriate precautions to be taken by the practitioner to minimise adverse outcomes from use of that medication.

Emergency administration of Schedule 8 medicines is excluded from this requirement. For example, it is permitted to treat a patient after cardiac arrest or treatment in hospital after surgery. Information about people on the Register is only provided to prescribers who are involved in a person's treatment, when needed to make decisions about the person's care. Information from the Register is not available to employers, police or other Government agencies. The Register does not connect to any other legislation and is not employed for any other purpose.

The Notification Regulations⁹⁶ describe how a name may be removed from the Register.

The criteria are:

- The person referred to in the register has died;
- The entry was, for any reason, false or incorrect;
- After the person has been drug-free for 2 years, the Director, Alcohol and Drug Authority has advised that the person referred to in the register has ceased to use drugs; or
- There has been no contact with the Department for 5 years.

⁹⁶ Drugs of Addiction Notification Regulations 1980.
https://www.slp.wa.gov.au/legislation/statutes.nsf/main_mrtitle_1327_homepage.html



The Department periodically assesses those persons believed to have died or where there has been no contact for a period of at least 5 years. The information is validated and then the eligible persons removed from the Register. This occurs on an ongoing basis.

The Department also maintains a process for people to apply for information about their status on the register and to provide advice for those people wishing to seek removal.

3.12.2 Current Regulatory Issues

The regulations covering the Register currently sit under the *Health Act 1911*. This legislation is also being reformed, with a replacement *Public Health Bill 2015* before the WA Parliament at the time of this Decision RIS. In development of the Bill, it was considered appropriate for notification regulations to be included in the Medicines and Poisons legislation, which is the only legislation that articulates with the Register. The Act has made provision for drug dependent persons to be considered under its powers. It is therefore important that the details regarding notifications are adequately supported by the subsidiary legislation for the Act.

The Department must maintain a record of people notified as drug dependent. It is essential that such records are accurate. During development of the Act the Department was aware of some medical practitioner reluctance to notify patients whom they suspect are drug dependent, due to concerns about patients not seeking care. The present system may also act as a perceived barrier to the legitimate use of Schedule 8 medicines for a person on the Register.

The current system does not recognise the difference between people using drugs and people seeking them with the intention selling them for illegal use. There are limited provisions to deal with people who are not on the Register but are clearly obtaining excessive quantities. Drug dependence has the connotation that an individual is taking drugs. The term doctor shopper tends to be more related to people selling medication.

Under the existing system, patients can be 'notified' without their knowledge. Inaccurate information, the stigma attached to the label of a 'drug addict', and the lack of any appeal provisions when a name is added to the Register, all contributes to a lack of confidence in the use and maintenance of the record. The growing awareness of consumer rights associated with privacy of information need to be addressed in the legislative framework.

Regulations need to allow a person to apply to and have the information on record amended or removed, when this is appropriate. This would include if a person can prove that there mistaken identity or assessment, the notification was vindictive or erroneous, they are no longer dependent, or if there has been no use of drugs of addiction for over 5 years.



Current issues regarding the Record of Drug Dependent Persons include:

- **The Department and health practitioners must be able identify drug dependent people and doctor shoppers;**
- **The process for process for addition and removal to the existing Register of Drug Addicts is not transparent; and**
- **Current rules for the existing Register are perceived as a barrier to treatment.**

3.12.3 Proposed Regulations

The Act requires that drug dependent persons are reported and that prescribing restrictions are applied to this group. The reporting of a drug dependent person will remain the responsibility of the treating medical practitioner based on their professional assessment of dependency. Guidance over who is drug dependent needs to be based on input from medical practitioners. Consultation recommended that the Department endorse the Diagnostic and Statistical Manual (DSM) criteria for drug dependency to support practitioners when making reporting decisions.

The Act does allow the Department to form a view that a patient may be oversupplied based on prescription records. Pharmacists, a medical practitioner, a nurse practitioner, or the Department may all identify oversupplied doctor shopping patients. This would apply to persons attending multiple practitioners concurrently or receiving large amounts over time, that are well in excess of personal needs based on the prescribed dosage. Once identified an oversupplied person would be subject to prescribing controls, such as an authorisation system, similar to that for a drug dependent person.

The Department needs clear criteria to definitions for what constitutes possible oversupply. Currently the Department reviews information regarding the numbers of doctors seen, frequency and quantity of the access to medication. Before considering a person may be oversupplied the Department will investigate the reasons for the occurrence, which may be valid medical need such as increased supply due to scheduled holidays. It is proposed that if a person is oversupplied they will be subject to similar provisions to drug dependent persons and permission will need to be sought prior to Schedule 8 prescribing.

Two years is considered the minimum risk period during which a person's name needs to be flagged on the record for their protection. At present, a person's details may be removed from the record in instances when defined conditions are met. Stakeholder feedback indicates that regulations need to clearly stipulate what these conditions should be. Consultation suggested that if someone has legitimately been included on the record, then after 2 years, if they are drug free, it should be acceptable to be removed from this record. Claims of being drug free need to be clinically and objectively verified by a medical practitioner.

Under the Notification Regulations one pathway for removal was with the recommendation of the Drug and Alcohol Office (DAO) after a two-year period. With the current community based pharmacotherapy program many patients are not managed directly by DAO. It has also been proposed that other medical practitioners could safely determine people eligible to be taken off the record. To be considered for removal, the person should have a history of treatment with a medical practitioner over a reasonable period of time, so that the



practitioner has a good knowledge of their medical status. This should also be confirmed through other methods such as clinical examination, plus independent objective assessment like urine tests. If there are no interactions with the Department, a person will automatically be removed after 5 years, without requiring confirmation by DAO or another medical practitioner.

Proposed regulations for the Record of Drug Dependent Persons can be summarised as:

- **Providing health practitioners with guidance on what constitutes drug dependency and oversupply for the purposes of the legislation; and**
- **Providing a regulatory framework to allow the removal of persons from the Record when medically appropriate and safe to do so.**

3.12.4 Impact Analysis

It is expected that under the new Act medical practitioners may report people who would previously have been on the Register. There are currently 7961 people on the Register, which represents approximately 0.3% of the total WA population. There are an additional several hundred notifications each year. As the scope of reporting is the same under the Act, it is not anticipated that there will be significant change to the number of people reported.

It is expected that a number of people will be newly identified as over supplied, however there may be significant overlap between the two groups. Inclusion of Schedule 4 reportable medicines such as benzodiazepines may identify additional persons; however as drug dependence is often associated with poly drug use it is expected that many may have already been reported.

Stakeholders did identify concerns regarding appropriate identification of people with dependency. Capture of this information on the electronic reporting system outlined in section 3.13 will assist in identification of doctor shoppers and drug dependent persons.

If a person were previously on the Register, they would now be reported as drug dependent. The regulations need to be designed to include the same people and provide the same protection afforded by the Notification Regulations. The major difference is that individuals will be informed, have the opportunity to refute any erroneous claims and a chance to fully understand the implications of being reported.

Provision of clear guidance on removal from the record and having the flexibility to construct removal criteria will meet stakeholder concerns generated during consultation. One stakeholder voiced concern that reporting could lead to potential retribution against a medical practitioner. Due consideration must be given to such concerns when developing the Department's operational processes to administer the requirements of the Act



3.13 Electronic Real Time Controlled Drug Reporting

3.13.1 Background

The Commonwealth Government has proposed a national system called the Electronic Reporting and Recording Controlled Drug (ERRCD) system. Such a system could potentially provide real time access to the prescriber, at the time of prescribing, of a patient's past history of Schedule 8 dispensing. The Act contains provisions to allow the collection and sharing of data via a system like ERRCD.

3.13.2 Current Regulations and Issue Identification

The 1965 Regulations require that all pharmacies send their Schedule 8 dispensing information to the Department within 7 days of the end of the month. The information is collected and stored by the Department in an electronic database. This forms the basis of a prescription monitoring program. This is used to plan, monitor and evaluate services for the control of the supply of prescription of Schedule 8 medicine in WA. This system allows:

- Identification of persons receiving prescriptions for more than 60 days and requiring authorisation;
- Monitoring of items which have been prescribed to people who are recorded as dependent;
- Identification of people seeing more than one prescriber at a time e.g. doctor shopping; and
- Identification of medical practitioners prescribing beyond their authorisation.

Technology exists that would support the secure collection and transmission of this information in real time. This would provide the ability to respond to instances of oversupply and similar issues. As well as the Department being able to monitor this information, it could also be provided securely to health practitioners in real time, to use in clinical decision-making. By providing this information to the prescriber or dispenser, practitioners will see an up to date history of medication use, and be better prepared when making therapeutic judgements about legitimate supply. This would also assist practitioners with compliance around controls for Schedule 8 medicines and Schedule 4 Reportable medicines.

For example:

- At present, if a medical practitioner wishes to obtain a prescription history they must ring the Department telephone advice line during normal business hours. When faced with a new patient outside these hours there is no ability to obtain the same information to assist in making a decision whether or not to prescribe.



If this information were provided in real time, the treating medical practitioner would be able to identify any medication of relevance prescribed by another practitioner, and the pharmacist may be able to identify medication had been previously dispensed by another pharmacy. Where these supplies are suggest that there are different conflicting treatments in place at once, or that supplies are too frequent based on expected needs, then clinical decisions can be made in real time in the best interest of the patient.

Current issues regarding Electronic Real Time Reporting can be summarised as:

- **A need to establish a system for the collection of information on prescribing and dispensing of Schedule 8 (and Schedule 4 reportable) medicines and the sharing of this information with health practitioners to support improved patient care; and**
- **Actions to reduce doctor shopping, oversupply, misuse and abuse of prescription medicines.**

3.13.3 Proposed Regulations

The Act requires the Department to keep a record of information relating to the supply and prescription of drugs of addiction. Regulations need to outline the details of how this information will be obtained including, what information needs to be supplied, how it is supplied and when it is supplied. Regulatory control will ensure that as far as practicable, patients are identified prior to prescribing in an attempt to identify oversupplied or drug dependent persons.

If a real time system is implemented the expectation will be that the clinician will access this system and utilise the information to ensure that prescribing and dispensing of medicine is in compliance with the legislation.

It is proposed that the same information is provided as is already currently collected from community pharmacies however, this information should be provided in real time and in an electronic format compatible with the system in place.

Proposed regulations regarding Electronic Real Time Reporting can be summarised as:

- **Providing a regulatory framework to establishing a system for the collection of information on prescribing and dispensing of Schedule 8 (and Schedule 4 Reportable) medicines, and the sharing of this information with health practitioners.**



3.13.4 Impact Analysis

All Australian jurisdictions have adopted some form of monitoring of prescription of drugs of dependence. Of note, Tasmania has implemented a clinical regulatory interface to allow real time monitoring. The evidence from Tasmania suggests that this approach has contained the harms arising from the increasing prescribing of opioid analgesics.⁹⁷

The increased transparency afforded to prescribers provides assistance with clinical decision-making and direct benefits to patient care. There is no impact on the person who is taking medicine as prescribed. For the person that is seeing multiple practitioners it allows identification early to assist in prevention of dependency.

Peak medical groups are *“supportive of rollout of a real time prescription drug database to reduce the number of people dying from prescription drug related overdoses”*⁹⁸. Stakeholders were strongly supportive of the role of an ERRCD type system to assist in monitoring and regulating the supply of medicines:

- *“... supports the use of a real time reporting mechanism”*⁹⁹;
- *“This needs to be implemented as a matter of urgency, if we do not act despite having the ability to do so we are complicit in the ongoing harms”*¹⁰⁰;
- *“...supports and urges the immediate implementation of a national recording system for controlled drugs (ERRCD)”*¹⁰¹.

It was commented that if such a system could capture veterinary use of animal remedies, it would not provide any increased utility, and should not apply to this particular sector.

⁹⁷ National Drug and Alcohol Research Centre. A Review of Opioid Prescribing in Tasmania: A Blueprint for the Future 2012. http://www.dhhs.tas.gov.au/__data/assets/pdf_file/0019/137062/A_Review_of_Opioid_Prescribing_in_Tasmania_A_Blueprint_for_the_Future_NDARC_2012.pdf

⁹⁸ Royal Australian College of General Practitioners. GPs call for real time prescription drug database in bid to save lives. 2015 <http://www.racgp.org.au/yourracgp/news/media-releases/prescription-drug-database/>

⁹⁹ CRIS submission 21

¹⁰⁰ CRIS submission 28

¹⁰¹ CRIS submission 39



3.14 Destroying Drugs of Addiction

3.14.1 Background, Current Regulations and Issue Identification

The 1965 Regulations currently require that poisons not be disposed of in any place or manner likely to constitute a risk to the public. There is risk that upon completion of use of a medicine or poison that any remainder may be discarded in a way that allows access by another person, who uses or ingests that substance, which results in unintended harm.

Destroy, in the context of a drug of addiction (including Schedule 8 medicines) means to make it unavailable or unusable for legitimate supply to any other person. This means it would not be available to be reused by an authorised person. For example, tablets may be crushed, ampoules may be broken, or liquid containers may be emptied. The substance in that medicine still needs to be disposed of in a safe manner. The Department currently recommends that all pharmaceuticals be ultimately disposed of by high temperature incineration, as the only method internationally accepted as being environmentally sound.

Only an authorised person can destroy a Schedule 8 medicine. A person authorised to possess a drug of addiction is also authorised to destroy. Destruction is only permitted if there is a valid reason, such as not being suitable for use because a product has expired, is contaminated or damaged. Records must be made of the medicines and quantities destroyed. These records must include details for the authorised person destroying the medicine, why it was destroyed and include a witness to confirm that the destruction. For this reason an authorised person can destroy a Schedule 8 medicine, but they must have a second person who is also authorised to act as a witness to confirm that this destruction did indeed take place as stated

The presence of an authorised witness ensures that drugs of addiction Schedule 8 medicine cannot be diverted through the destruction process. Destruction in this manner ensures that highly sought after Schedule 8 medicines cannot enter the illicit market from licit sources. Stakeholder feedback indicated that destroying and witnessing requirements for Schedule 8 medicine are too restrictive to be practically achieved in many practice settings. This is especially so where there are limitations on the number or type of authorised persons available to participate in that destruction. Currently, the persons approved to act as a witness is a more restricted subset of the persons approved to destroy a Schedule 8 medicine. They must also be of a different professional class to the person destroying the medicine.

For example:

- A veterinary practice may have to contact a policeman to witness destruction of medication; or
- A residential care facility does not have pharmacists available to witness destruction and a nurse is not sufficient.



Current Issues regarding Destroying Drugs of Addiction can be summarised as:

- **Existing regulatory requirements are too restrictive to be practically achievable in normal health practitioner settings.**

3.14.2 Proposed Regulations and Impact Analysis

To ensure appropriate destruction it was recommended that witness requirements for drugs of addiction be modified to enable all persons authorised to handle a Schedule 8 medicine (including those who may be working with or for another authorised person), to be a witness to this destruction. Although this type of destruction is infrequent, the current requirements mean it is expensive and time consuming when performed. Increasing acceptable witnesses is anticipated to be more efficient and reduce costs within small health practitioner businesses. It will also reduce the occasional unnecessary use of public resources, such as police or authorised Department officers required to witness destruction.

This may also prevent stockpiling of unusable medicines at these practices and result in the more frequent destruction of small quantities of medicine in a timely manner. Regulations will continue to require the authorised person only destroy a medicine for specific allowable reasons, do so safely and create an accurate record. This must still be performed in front of an appropriate witness.

For example:

- In a veterinary practice destruction of a Schedule 8 could be done by a registered veterinary surgeon and witnessed by another registered veterinary surgeon; and
- In a residential care facility a registered nurse could dispose of a Schedule 8 and be witnessed by another registered nurse or enrolled nurse.

This should ensure greater compliance with regulatory requirements. The required records will provide ability to monitor and enforce appropriate destruction practices. In the event that the destruction process is used to divert medicines, collusion (destroyer and witness acting together) or wrongful doing by the destroyer, would be evident through these records.

Stakeholder feedback from the Consultation RIS indicated this it is an acceptable approach to continue to require protections around destruction and that increased in flexibility and practicality of the process would be welcome:

- *“This should ensure greater compliance with regulatory requirements. In the event that there is an offence committed destruction records should provide ability to investigate for evidence of collusion (destroyer and witness acting together) or wrongful doing by the destroyer”¹⁰².*

¹⁰² CRIS submission 38



Stakeholders did however request that the Department greater clarity around the mechanisms for disposal of drugs. The scope of the regulations does not outline the mechanism for disposal. Rather it seeks to define who can destroy and how to record this destruction. The Department currently provides guidance on secure, safe and environmentally acceptable methods of disposal. These are considered adequate for purpose and that further regulation is not necessary.

Proposed regulations regarding Destroying Drugs of Addiction can be summarised as:

- **Modification of regulatory requirements to enable all persons authorised to handle Schedule 8 medicines to act as a witness to their destruction.**



3.15 Storage and Transport of Schedule 8 Medicines

3.15.1 Background

Current community concerns over the misuse of prescription medicines related to Schedule 8 medicines are well documented in the medical literature and public media. A specific concern is that inadequate security measures around the legal storage and supply of these medications for legitimate therapeutic purposes does not break down and lead to diversion of high grade pharmaceutical drugs into the illicit market, thereby contributing to this misuse.

In the period since the inception of the *Poisons Act 1964* the range of Schedule 8 medicines, the quantities stored, the types of practitioners handling them, and the range of practice settings they are used in have all increased markedly. For example there are 92 separate types and formulations of Schedule 8 opioid medications currently marketed for medical use in Australia¹⁰³. The rate of prescribing of oxycodone preparations in Australia increased dramatically from 35 per 1000 population to 89 per 1000 population between the years 2002 and 2008.¹⁰⁴ The result is that there are more Schedule 8 medicines in circulation, which increases potential public exposure and also requires surety of adequate protections against theft or misuse.

The 1965 Regulations already contain stringent storage and handling requirements for Schedule 8 medicines. These are designed to ensure there is little opportunity during their progress through the legal supply chain to be diverted into illicit use. These requirements are clearly important to remain and it is vital that these medicines remain well regulated. However the rules around their legal handling and use do need to be practically achievable and appropriate for current practice use settings.

Storage, drug safes, transport and handling requirements can vary greatly based on the practice setting. For example a complex institution such as a very large teaching hospital has thousands of health practitioner staff who may need to handle Schedule 8 medicines. A wholesaler with very large quantities of Schedule 8 medicines has a very high, but also very specific risk. Both of these are quite different to the risks posed by a small medical or veterinary surgery operated by a sole health practitioner.

Regardless of the setting, all authorised persons must be able to track and account for these medicines and take adequate steps to prevent their unauthorised access. Under new regulations that seek to account for expanding health practitioner roles (see Section 3.4), it is expected that more health practitioners, rather than less, will seek to store Schedule 8 medicines for legitimate patient care related needs. It is then important that regulations address these risks, while continuing to be achievable and of least regulatory burden.

¹⁰³ Australian Medicines Handbook Pty Ltd. Australian Medicines Handbook. 2015.

¹⁰⁴ Roxburgh A, Bruno R, Larance B, Burns L. Prescription of opioid analgesics and related harms in Australia. *Med J Aust* 2011; 195 (5): 280-284.



3.15.2 Current Regulations

The current storage requirements for any quantity of Schedule 8 medicine require the use of a large safe, weighing 500 kilogram or more. There is a facility for exemption from these requirements that would allow differing security arrangements to be applied in specific circumstances. An exemption must be applied for individually and assessed by the Department as continuing to be appropriate for the safe storage of the medicines and quantities involved.

Additional controls that apply to use of drug safes for storage of Schedule 8 medicines include:

- A safe access device (key) must be kept by or only known by (combination) an authorised person;
- Safes must be kept locked at all times, except when in use;
- Safes must not be located in public areas of a practice;
- Above a certain specified quantity of Schedule 8 medicine there are additional security requirements which apply
 - e.g. monitored alarm systems; and
- A safe must always be under control of an authorised person.

There are some exceptions as to when Schedule 8 medicines are not required to be stored in a safe. These are only intended for very small quantities, when required for emergency uses. In these instances, the authorised person must still take all reasonable steps to keep the Schedule 8 medicines secure.

For example:

- A small quantity of morphine stored in a “Doctor’s Bag” for emergency use.

The objectives regarding regulation of transport requirements of Schedule 8 medicines are to make sure that items are not diverted during transport:

- By taking reasonable steps to:
 - Use proper and reliable means of transport;
 - Appropriately package and label items when in transit;
 - Minimise opportunity for loss or theft;
 - Ensure true delivery to the intended destination through proof of receipt; and
- Identify, report and investigate items lost or stolen in transit.

Currently the 1965 Regulations stipulate Schedule 8 medicines are to be transported without visible identifiers and must be receipted on arrival. The 1965 Regulations refer to use of a “common courier”, although the term is not well defined.



3.15.3 Current Regulatory Issues

Stakeholders have consistently identified the current “one size fits all” approach to handling of Schedule 8 medicines in the 1965 Regulations is not always achievable. In particular, it was suggested that the very stringent requirements are not practical to accommodate within the increasing instances and variety of settings where these medicines are stored, handled or transported. Stakeholders do accept and agree that reasonable measures need to be in place to prevent theft or loss. They also acknowledge that authorised persons must be accountable for the storage and movement of the medicines.

The 1965 Regulations do not currently take into account factors such as health and safety risks posed at a specific setting, practicality and cost issues in achieving some requirements or “current industry standards”, and the overall and specific public health risk involved.

For example:

- Many veterinary practices hold smaller quantities of Schedule 8 medicines. The Department must issue an exemption for each individual practice from the large safe requirements prescribed in the regulations; and
- Due to certain bottle sizes, some veterinary practices end up keeping just slightly over the threshold in the 1965 Regulations for applying additional security requirements. There is limited flexibility to adjust quantities to meet practice needs but remain below this threshold.

Regulations require the taking of an inventory at regular intervals to monitor Schedule 8 medicine stock levels. Currently all records of Schedule 8 medicine including inventory registers need to be kept for 7 years. Additional inventories are required when the control of the drugs are handed over to another authorised person.

For example:

- A pharmacy must keep all Schedule 8 records and Registers for 7 years and have these available for inspection at any time;
- An inventory once a month at a busy hospital, where many administration transactions take place every day, is not adequate to detect and respond to loss or theft that may have occurred at some time during the one month period.

Current regulations provide limited guidance for, or regulatory oversight of, secure transport requirements. There is confusion over the obligations of an authorised person with regard to reporting of losses or theft of a Schedule 8 medicine. The reporting of anomalies in inventory counts, where there is no evidence of theft, represent a significant and growing burden on Police, who in practice will not investigate such minor concerns.



Current issues regarding Storage and Transport requirements for Schedule 8 medicines include:

- **Drug safe and storage requirements are inflexible and may not be appropriately matched to individual risk;**
- **The duration for keeping of records is excessive; and**
- **There is a lack of clarity regarding transport and associated records, taking of inventory, and requirements to report losses or theft.**

3.15.4 Proposed Regulations

It is proposed that storage of all Schedule 8 records be amended to five (5) years. Although this is shorter than the current seven year time period, it is in alignment with other industry norms and similar to other business requirements such as taxation records. This is also consistent with the national Schedule 7 poison record keeping requirements and those required in some other Australian jurisdictions. Although it remains longer than the two year record keeping requirement for Schedule 4 medicines, it is considered proportionate with the higher risk of diversion and harm associated with Schedule 8 medicines.

It should be also be acceptable to keep these records in an electronic form, so long as they are a true and accurate copy of the actions that took place and of any original hard copy record.

Regulations regarding transportation of Schedule 8 medication are required to mandate the reporting of medicines which do not arrive at their intended destination after transportation. This needs to apply to those Schedule 8 medicines which are moving between authorised persons, rather than members of the public and their own dispensed medications in general.

An adequate audit trail of transported medicines is necessary to prevent loss and to ensure that any medicines that are lost or stolen can be rapidly identified. Tracking of high value goods in transit is now a routine occurrence and therefore places no exceptional additional burden on businesses to achieve. It is in the best interest of the general public to ensure Schedule 8 poisons cannot be diverted during distribution to points of supply.

For example:

- If a shipment is lost in transit, the Department must be informed.

Mandated requirements for storage are another method of preventing unauthorised and unwanted public exposure to medications. Minimum drug safe requirements are still necessary. However, these need to be more flexible than “one size fits all” and must be based on the level of risk posed by the type and quantities of medicines held for use in different settings. Where there are other security measures in place or a higher level of supervision, the risk of diversion may be considered somewhat lower. The suggested approach is outlined in more detail in Table 9. This proposes a continuum of different storage requirements for Schedule 8 (and Schedule 9) substances commensurate to risk. This is based on practice setting, authorised person, and quantities held. Table 10 further defines specific safe requirements.



Table 9: Suggested requirements for storage of Schedule 8 and 9 substances

Setting		Quantity	Reasonable steps	Hardwood cupboard or drawer	Small safe	Large safe	Strongroom or safe	Conditions ^{\$}	Additional security
		Number of individual dose units [#]		Securely fixed, lockable	AS/NZS 3809:1998 Resistance Grade I / Table 2, Level 1	AS/NZS 3809:1998 Resistance Grade II / Table 2, Level 2	AS/NZS 3809:1998 Resistance Grade VII		Monitored alarm system and movement detectors
During mobile patient treatment	“Doctor’s bag”	Minimum required	✓					Authorised person is responsible	
	Veterinary surgeon	Minimum required for one day	✓						
	Ambulance	Minimum required	✓						
Patient care area: Hospital / Health care facility	Supervised* 24/7	Any		✓					
	Not supervised* 24/7	≤ 250			✓				
		> 250			✓				✓
Health practitioner: Doctor’s surgery / Dental surgery / Veterinary practice		≤ 250			✓				
		250 to 500			✓				✓
		> 500				✓			✓
Schedule 8 / Schedule 9 medicines permit (researcher, analyst)		≤ 250			✓				
		250 to 500			✓				✓
		> 500				✓			✓



Setting	Quantity	Reasonable steps	Hardwood cupboard or drawer	Small safe	Large safe	Strongroom or safe	Conditions	Additional security
Pharmacy / Hospital pharmacy	Any		Securely fixed, lockable				opening hours only / authorised person on site	
	Any				✓			✓
Manufacturer / Wholesaler	Any					✓		✓
Electronic Supply Unit: Hospital / Health care facility	≤ 250		Equivalent protection [%]					
	250 – 500			Equivalent protection [%]				
	> 500			Equivalent protection [%]				Equivalent protection [%]

Explanatory Notes

[#] Dose means the usual human therapeutic dose. For example, a 50 mL multi-dose vial of ketamine (as used by veterinary surgeons) would be considered to constitute 25 doses of 200 mg and a 10 mL multi-dose vial of 10mg/mL butorphanol would be considered to represent 50 doses of 2mg.

^{*} Supervised means that an authorised person is physically on the premises near where the Schedule 8 medicines are stored and in control of the safe. 24/7 means that this supervision occurs 24 hours a day, 7 days a week.

[%] Equivalent protections means other security features that are assessed as providing the same level of protection as offered by the hardwood cupboard, drawer, safe or additional security measures

^{\$} All receptacles to be kept locked when not in immediate use for accessing the medicine.



Table 10: Safe specifications

	Level 1	Level 2
Cabinet/Body	<ul style="list-style-type: none">• Made from solid steel plate at least 10mm thick or a steel skin with concrete fill 50mm thick.• Continuous welding of all joints.	<ul style="list-style-type: none">• Made from solid steel plate at least 10mm thick or steel skin with concrete fill 50mm thick.• Continuous welding of all joints.
Door	<ul style="list-style-type: none">• Made from steel plate at least 10mm thick or a steel skin with concrete fill 50mm thick.• Flush fit.• Maximum clearance of 1.5mm when closed.• Hinge system such that hinge removal would not allow the door to be opened.	<ul style="list-style-type: none">• Made from steel plate at least 10mm thick or a steel skin with concrete fill 50mm thick.• Flush fit.• Maximum clearance of 1.5mm when closed.• Secured with at least 2 locking bolts of 32mm diameter.• Hinge system such that hinge removal would not allow the door to be opened.
Lock	<ul style="list-style-type: none">• 6 lever key, type 2 UL rated, or• 4 wheel combination or electronic (digital), group 2 UL rated.	<ul style="list-style-type: none">• 6 lever key, type 2 UL rated, or• 4 wheel combination or electronic (digital), group 2 UL rated.
Mounting	<ul style="list-style-type: none">• To brick or concrete wall and/or floor with at least four bolts of at least 12 mm in diameter.• If mounting to brick or concrete wall and/or floor is not possible, safe must be securely mounted to structural elements of the building such as studs or floor joists.	<ul style="list-style-type: none">• Directly to concrete floor with a 16mm diameter expanding bolt, installed by a person licenced under the <i>Security and Related Activities (Control) Act 1996</i> to install safes.• Safes weighing over 1 tonne are not required to be bolted.
Weight	<ul style="list-style-type: none">• No minimum weight.	<ul style="list-style-type: none">• Minimum weight 250kg.

Proposed regulations regarding Storage and Transport of Schedule 8 Medicines s of Addiction can be summarised as:

- **More flexible drug safe and storage requirements matched to health practitioner, setting of use, quantity of medicines held and individual risk;**
- **Reduction of duration for keeping of records; and**
- **Greater clarity regarding transport and associated records, taking of inventory, and requirements to report losses or theft.**

3.15.5 Impact Analysis

The flexible approach to storage requirements will provide increased clarity for stakeholders. Stakeholders indicated the proposed regulations will:

- *“Alleviate confusion around existing security infrastructure and systems that may be considered equivalent”¹⁰⁵.*

Health practitioners and licence and permit holders will be able to identify their own personal situation and readily identify the minimum requirements to achieve. The inclusion of an increased number of storage options will allow a reasonable and appropriate solution for the risk posed by an individual practice setting. The preferred option will be more achievable for most settings. In many cases they will be cheaper. These requirements will still ensure that there are minimum standards to be met and that storage is adequate to prevent authorised access and diversion.

Use of “number of doses” as the cut-off for specific controls, rather than total weight as currently used, will better assist practitioners to identify which requirements they must personally meet. The number of doses more accurately reflects risk of diversion than total weight. This is particularly true for high potency drugs like fentanyl or high volume veterinary drugs like ketamine.

For example:

- A veterinary practice could use a ‘small safe’ where they hold less than the equivalent of 250 human doses. This could include a relatively standard inventory of 2 x 50mL multidose vials of ketamine 100mg/mL (100 doses), 1 x 10 mL multidose vial of butorphanol 10 mg/mL (50 doses), 20 x buprenorphine 300 mcg/mL ampoules (20 doses), 10 x morphine 10 mg/mL ampoules (10 doses) and 10 x morphine 5 mg/mL ampoules (10 doses).

Feedback on the Consultation RIS suggested that the standard veterinary dose varies greatly according to the animal. The doses contained in a product when calculated for a cat would be very high and very low if considering a horse.

The preferred option is premised on the street value or incentive to divert these medicines for illicit human use. The public health risk with these medicines is through the theft or unauthorised access by humans into the illicit drugs market. This option also uses a single and practical standard human dose for assessing the risk of diversion.

¹⁰⁵ CRIS submission 44

The existing weight threshold of 8 grams realistically allows no more than one ketamine vial before other security measures are necessary. The preferred option would mean that although secure storage in an adequate safe is necessary, these thresholds would not be triggered until in excess of 5 and then 10 vials are held, respectively.

Department records indicate that in total there were 848,152 prescriptions filled in 2014 for opioids and stimulants through community pharmacies^{106,107}. In addition, in the 2014/2015 financial year there were over 2.7 million separate dose unit transactions for Schedule 8 medicines in WA public hospitals¹⁰⁸. These figures do not account for Schedule 8 medicines used in humans in private hospitals, medical and dental practices, or elsewhere. These figures might suggest that there is a very large amount of Schedule 8 medicine use, and therefore risk, in human use settings, where the preferred option will be of highest regulatory benefit.

There was stakeholder concern voiced that registered veterinary surgeons identified medicines by the doses related to animal treatment, rather than by human therapeutic doses. It was also stated that researchers using these substances tend to measure quantity by weight, not dose. It is acknowledged that this may require stakeholder education and guidance for some sectors on what is considered to be a 'human therapeutic dose'. This would allow individuals to calculate themselves and then appropriately comply with the legislation. The use of dose cut offs is a common approach in other Australian jurisdictions and has been proven effective.

Similarly, there was comment that vehicle security for veterinary surgeons (and medical practitioners) visiting patients was important and required suitable controls. While potentially a minor component of total circulating Schedule 8 medicines, guidance on vehicle security is important to assist practitioners to take all reasonable steps to keep these medicines secure while in transit.

Requirements for pharmacies are proposed to be higher than other health related practices. Pharmacies generally maintain larger stocks and frequently supply Schedule 8 medicines. Pharmacies as an open retail store have potentially less control over who is on the premises at any one time. Other health practitioners (veterinary surgeons, medical practitioners, dental practitioners) generally use appointment systems and medicines are stored in areas separated from publicly accessible areas. Very few pharmacies have completely closed dispensary areas where the Schedule 8 safe may be located. Drug safes, wherever practicable, should be located out of public access. Due to the nature of their business, pharmacies appear to be known targets for burglaries and hold-ups compared to other practitioner groups.

As all pharmacies should already be compliant with existing legislation there is no new cost of compliance. The proposed requirements for pharmacies maintain the status quo, with the exception that the minimum safe weight is reduced to 250 kg to make this comparable with standards outlined by other jurisdictions. This reduction is not believed to make a discernible difference to the risk of the entire safe being stolen, but can potentially reduce costs for business. However, in practice many pharmacies may require a heavier safe simply to provide adequate internal volume to hold the quantity of Schedule 8 medicines they keep to meet prescription demand.

¹⁰⁶ Department of Health and Ageing Office of Chemical Safety: NDS Transaction Data 2013. Unpublished data.

¹⁰⁷ WA Health. Western Australian Stimulant Scheme Regulatory Scheme 2014 Annual Report. 2015.
ww2.health.wa.gov.au/~media/Files/Corporate/general%20documents/medicines%20and%20poisons/Word/Updated-report-2014-1015.ashx

¹⁰⁸ WA Health. iPharmacy 2015. Unpublished data.

Hospital inpatient wards can use a cupboard, but other patient care areas that are not operational 24/7 need to use a safe. Stakeholders supported this requirement indicating that as Schedule 8 volumes are increasing in hospitals, the use of locked cupboards will be welcomed in high activity areas. Health care facilities with inpatients (or residents) will usually have staff on site 24/7. However, unless there are authorised persons (staff) in the vicinity of the storage area for the Schedule 8 medicines 24/7 (such as the case on a normal inpatient ward), a safe rather than a cupboard is required to reduce the risk of theft when staff are not present. This means a ward set up for day cases only, which is closed overnight, will require a safe rather than a cupboard.

Benefits to business of the introduction of these proposed regulations are that they are easier to understand, which should aid in compliance. They also have cost benefits in that the cheapest safe that will meet the Department requirements can be utilised by business.

3.16 Shipping and Vessels

3.16.1 Background

Ships and vessels have an established need to possess and use medicines for the treatment of medical conditions and emergencies when at sea. This includes some Schedule 8 medicines. The 1965 Regulations have historically provided the ability for ships and vessels to lawfully obtain and use medicines.

There have been several recent laws enacted federally which influence the regulatory requirements in this area. The *Marine Safety (Domestic Commercial Vessel) National Law Act 2012* (Commonwealth) was passed in August 2012 and implemented on 1 July 2013.

The 1965 Poison Regulations define a Certified Commercial Vessel as one registered under *Western Australian Marine Act 1982*. In 2011, the Commonwealth, State and Territory Governments signed the Intergovernmental Agreement for Commercial Vessel Safety Reform to transfer responsibility for the regulation of all commercial shipping to the Federal Government, including design, construction, survey, operations, manning and crew qualifications.

The new regulatory framework in this area is known as the National System for Commercial Vessel Safety and is administered by the Australian Maritime Safety Authority (AMSA). It consists of regulations and marine orders to adopt:

- *National Standard for Commercial Vessels* (National Standards); and
- Regulatory Plans (for vessel and crew treatment).

This means that the WA Government will no longer regulate commercial shipping in the State. Newly built vessels will be regulated by the AMSA, while existing vessels will be 'grandfathered' into the National System.

The National Standards outline the required first aid and medical cabinet supplies to be held aboard different classes of vessels. These include antibiotics, analgesics and related Scheduled medicines necessary for first aid and emergency purposes.

At the same time the Commonwealth Government revised the *Navigation Act 1912*. The replacement *Navigation Act 2012* covers all foreign commercial vessels in Australian waters and Australian commercial vessels undertaking international voyages.

The Maritime Labour Convention, 2006 (MLC 2006) establishes standards for medical care on board ship and ashore. Regulated Australian vessels must carry medicine chests with at least minimum medicines, medical and surgical stores, appliances and antiscorbutic treatments stored according to medical carriage requirements outlined by AMSA. It is an offence under Commonwealth legislation to fail to provide for the medical needs of persons aboard vessels.

3.16.2 Current Regulatory Issues

To meet medical needs aboard ships and yachts, pharmacists and other pharmaceutical suppliers may be requested to supply medicines to complete the required safety equipment for these vessels. The Department commonly fields requests and questions from poisons licence holders and personnel from ships querying the rules on supply to these vessels as outlined in the 1965 Regulations. This suggests that there is generally poor understanding of the current legislative requirements.

Whilst ships and vessels are generally a highly regulated area, the Poisons Regulations are the only legislative tool, which governs the supply management of poisons to ships and vessels. Regulations need to reflect the new medical equipment scales outlined in the national standards for registered vessels. The 1965 Regulations refer to Section 125 of the *Navigation Act 1912*. Since this time the Navigation Act has been repealed and replaced by the *Navigation Act 2012*.

Practical implementation of the MLC 2006 occurs under the authority of the *Navigation Act 2012* and *Marine Order 11 (Living and working conditions on vessels) 2013*¹⁰⁹. These orders refer to the medical carriage requirements on regulations Australian vessels, published by AMSA¹¹⁰ and the International Medical Guide for Ships by the World Health Organisation.

There is a long-standing and accepted need for ships and yachts to carry basic medicines for medical emergencies when away from land. These vessels and their staff may not be health practitioners, nor be suitable to apply for poisons permits due to their place of origin and mobility. However as they should still be authorised to obtain and use poisons for medical treatment purposes, regulations need to outline how they may purchase medicines. In particular, regulations need to clearly describe under what circumstances a pharmacy or pharmaceutical supplier may supply to these persons.

Similarly the 1965 Regulations point to medical requirements for carriage of medicines on board aircraft as required by the named authority: the Department of Transport of the Commonwealth. This authority no longer exists, and therefore these regulations are not current.

The current regulatory issues with ships and vessels can be summarised as:

- **The current regulations refer to outdated legislation and are difficult for users to understand and apply.**

¹⁰⁹ Australian Government. Marine Order 11 (Living and working conditions on vessels) 2013. https://www.comlaw.gov.au/Details/F2013L00841/Html/Text#_Toc356072508

¹¹⁰ Australian Maritime Safety Authority. Medical Carriage Requirements on Regulated Australian Vessels. 2014. <https://www.amsa.gov.au/forms-and-publications/Publications/AMSA438.pdf>

3.16.3 Proposed Regulations

It is proposed that regulations be amended to complement the requirements of the new maritime and/or aircraft legislation and provide improved clarity for pharmacists and wholesalers when supplying to vessels or aircraft. Consistent with the current approach, it is not practical for a poisons permit to be required of the purchaser of the medicines to equip these vessels. Similarly, there should be no need for a medical practitioner to write individual prescriptions to authorise supply to the types of vessels covered by regulations.

Regulations will need to have a mechanism to include definitions of the types and general allowable quantities of drugs which domestic and commercial vessels should be permitted to obtain. These must be aligned with the National System for Commercial Vessel Safety and the Navigation Act / Marine Order 11. In addition, regulations must outline the storage and recording requirements for supply by pharmacists and where necessary, use by ships.

As for any other instance of supply, there must be a valid order outlining the authority to supply to the supplier. Pharmacists and wholesalers should receive a written requisition, signed and dated by the master of the vessel, which includes the following information necessary for supply:

- Name of the domestic commercial vessel;
- Machinery and hull number (M & H number) of the vessel;
- Name and address of the master of the vessel; and
- Medicines required including strength, dosage form and quantity

Schedule 8 transactions involving vessels should be part of collected information on the supply of drugs of addiction and include:

- Date of supply;
- Name of the vessel;
- Name of the ordering person;
- Drug supplied including strength and dosage form; and
- Quantity supplied.

Proposed regulatory changes, for shipping and vessels, can be summarised as:

- **Update the existing regulations to reflect current maritime legislation; and**
- **Outline pharmacists and wholesaler recording requirements.**

3.16.4 Impact Analysis

It is essential that requirements in this area be updated as part of maintenance of existing regulations. Removing regulation in this area will not support national maritime legislation and meet the needs of vessels that need to obtain and use medicines.

Regulations must allow pharmacists and wholesalers to supply medicines to three types of vessels:

- Registered ships;
- Domestic commercial vessels; and
- Yachts participating in offshore races departing from WA.

As pharmacists and wholesalers already have to meet recording requirements for this type of supply there is no additional impact.

Stakeholder feedback indicated a previous lack of clarity regarding requirements in this area. Introduction of new regulations have the benefits of supporting existing regulatory programs for vessels as well as improving the supply to vessels and hence their access for medicines to use for medical purposes. Due to improved regulatory certainty for suppliers there are not expected to be any additional costs to compliance with these regulations. Overall, improved understanding is likely to improve compliance with regulation and decrease regulatory burden.

3.17 Summary of Regulatory Recommendations

This document has been compiled based on feedback from survey of the Consultation RIS, which presented options for the new regulatory framework and posed questions to identify further issues to be incorporated in this document.

In Sections 3.4 through 3.8 and Section 3.16 it proposes regulations to address issues identified regarding: Professional Authority, Structured Prescribing Arrangements, Electronic Prescribing, Electronic Storage and Supply Units, Licencing, and Shipping and Vessels.

The proposed regulatory recommendations for these sections are summarised in Table 11.

Sections 3.11 through 3.15 are concerned with various aspects of Schedule 8 medicines regulation, including prescribing and dispensing of Drugs of Addiction, management of the Record of Drug Dependent Persons, Electronic Real Time Controlled Drug Reporting, Destroying Drugs of Addiction, and Storage and Transport of drugs of addiction.

The regulatory requirements related to medicines and poisons Schedules were also examined in Sections 3.9 and 3.10. In assessing required regulatory control the SUSMP Schedules provide a framework for the level of control in the following areas: labelling, packaging, advertising, storage, record keeping, transport and hawking. The SUSMP guidelines regarding level of control was considered in identifying regulatory issues to be incorporated in the subsidiary legislation.

Proposed changes in regulatory control for Schedule 8 medicines and other medicines and poisons according to SUSMP Scheduling requirements are summarised in Table 12.

Table 11: Summary of Regulatory Issues and Proposed Regulations

Area	Regulatory Issues	Proposed Regulations
Professional Authority	<ul style="list-style-type: none"> • Lack of alignment with registration standards of the relevant National Board. • Certain professions are not named and therefore it is difficult to identify restrictions. • Current regulations are out dated in terms of current practice. • Current authority system does not allow changes in response in professional scope therefore there is inflexibility to changing workforce needs. 	<ul style="list-style-type: none"> • Defining individual professions that need access to medicines and what includes or excludes a person as part of that practitioner group. • Outlines conditions or limitations for any specific authority or group and define what legitimate practice may be for this group. • Define appropriate level of authority in terms of each professions ability to obtain, possess, administer, supply, prescribe, dispense and manufacture medicines and poisons.
Structured Prescribing Arrangements	<ul style="list-style-type: none"> • No current framework to establish Structured Prescribing Arrangements (SPAs). • Regulation currently achieved via various exemption processes, which are inconsistent, slow and difficult. 	<ul style="list-style-type: none"> • Providing a single regulatory framework so health professionals can clearly see their role and responsibilities. • Support development of SPAs from: <ul style="list-style-type: none"> • The Department of Health; • For a health organisation; and • For individual medical practitioners. • Provide clear regulatory guidelines regarding minimum requirements of a SPA. • Ensure safe application and use of SPAs by medical practitioners and other health practitioners.
Electronic Prescribing	<ul style="list-style-type: none"> • Existing regulations are out-dated and do not support the current work practice or future potential of electronic prescribing. • Need to protect or safe guard from misuse or abuse of data e.g. forgeries. 	<ul style="list-style-type: none"> • Regulations will outline details regarding how the electronic systems can be used including: what information needs to be supplied, how it is supplied and when it is supplied. • Electronic prescriptions must meet existing principles of prescription regulations.
Electronic Storage and Supply Units	<ul style="list-style-type: none"> • Regulation is required in this area to ensure benefits realisation of automation and future proofing of regulations. 	<ul style="list-style-type: none"> • Support the requirements set out in the Act regarding vending machines.

Area	Regulatory Issues	Proposed Regulations
Licencing and Permits	<ul style="list-style-type: none"> • Licensees possessing a poison licence or permit may require duplicate registration by a regulatory authority other than the Department. • Inconsistent with national requirements for: <ul style="list-style-type: none"> • Schedule 6 Wholesale licences; and • Pharmacy licence. • No facility to provide an appropriate licence or permit for: <ul style="list-style-type: none"> • Indent trading; and • Use of Schedule 9s. • Need to establish new schedule of fees. • The Act requires licences and permits to be provided with expiry / renewal dates based on the date of issue rather than the same day each year. 	<ul style="list-style-type: none"> • Licensees possessing a recognised licence by a regulatory authority other than the Department would not require an additional licence; <ul style="list-style-type: none"> • Removal of Schedule 7 permit requirements for recognised industrial uses at clearly identifiable industrial locations. • Removal of: <ul style="list-style-type: none"> • Schedule 6 Wholesale licences; • Pharmacy Licence; and • Introduction of: <ul style="list-style-type: none"> • Indent licencing; and • Permits for Schedule 9s. • Establishment of a schedule of fees. • Licences and permits to be provided with expiry / renewal dates based on issue dates.
Shipping and Vessels	<ul style="list-style-type: none"> • The current regulations refer to out dated legislation and are difficult for users to understand and apply. 	<ul style="list-style-type: none"> • Update the existing regulations to reflect current maritime legislation. • Outline pharmacists and wholesaler recording requirements.

Table 12: Schedules as outlined in the SUSMP and proposed areas of change

Schedule	Classification	Controls								Summary of proposed changes
		Licencing	Advertising	Labelling & Packaging	Prescribing	Supply	Storage	Recording	Disposal & Transport	
Schedule 1	Not currently in use	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Schedule 2	Pharmacy Medicine	X	X	X	N/A	X	X	X	X	No changes proposed.
Schedule 3	Pharmacist Only Medicine	X	X	√	N/A	X	X	√	X	Pharmacy recording requirements. Labelling changes.
Schedule 4	Prescription Only Medicine OR Prescription Animal Remedy	X	X	X	√	X	X	√	X	Structured Prescribing Agreements. Specialist authority prescribing restrictions. Schedule 4 Reportable e.g. specified drugs such as benzodiazepines.
Schedule 5	Caution	N/A	X	X	N/A	X	√	X	X	Adoption of national controls regarding storage
Schedule 6	Poison	√	X	X	N/A	X	√	X	X	Adoption of national controls regarding storage Removal of wholesale licencing requirements
Schedule 7	Dangerous Poison	√	X	X	N/A	X	X	√	X	Licence changes Duration of record keeping

Schedule	Classification	Controls								Summary of proposed changes
		Licencing	Advertising	Labelling & Packaging	Prescribing	Supply	Storage	Recording	Disposal & Transport	
Schedule 8	Controlled Drug	X	X	X	√	√	√	√	√	Revised Schedule 8 prescribing authorities. Revised professional authorities. Detoxification clinics. Real time electronic recording. Changes to oversupplied and drug dependent persons. Safes. Destruction.
Schedule 9	Prohibited Substance	√	X	N/A	X	N/A	√	√	√	Supply and access changes - permits.
Schedule 10	Strictly Controlled Substances	√	X	N/A	N/A	√	√	√	√	Regulations proposed as new to Schedules.

√ = proposed changes

X = no changes proposed

N/A = controls not applicable to this Schedule

Part 4: Implementation

4.1 Implementation and Transition

The recommendations of this Decision RIS will be implemented via multiple strategies including:

- Development of regulatory guides and teaching materials;
- Education sessions via peak bodies and stakeholder forums;
- Updating and renewing guidance materials available online;
- Letters to people affected by regulations;
- Development of Departmental policies and information circulars;
- Development of published codes where required by regulation; and
- Issue of notices where required under the Act.

Where ever possible, provisions of previous regulatory rules will remain in effect. Where an authority under the prior regulatory scheme is time limited, for example a poisons licence, these will continue apply for the previously approved time period. Specific transition provisions are outlined in the 2014 Act and will be in alignment with the transition provisions written into new regulations.

For example:

- A licence which has been issued for 3 years will not expire till the 3 years is complete, at that time the licensee will be provided with an option to renew or transition to the most appropriate licence type; or
- A health practitioner who has had any authority revoked to prescribe or access medications will also have no authority under the power of the new Regulations.

To enable continuity of patient care with medicines, regulations may provide that any existing authorisation continue to apply till the completion of the expiration date given under prior Regulations. Any authorisation issued to prescribe or supply, such as a prescription written for a patient by an authorised prescriber, must remain valid till the natural duration of the existing prescription.

For example:

- An approved medication order will be honoured;
- A CPOP authority will remain valid under the new regulations; and
- A prescription written under the old regulations will remain valid.

Any authority or approval issued under the power of the 1965 Regulations will be subject to new regulations once expired, reissued or renewed. Where there are modifications to existing regulations that affect an authority which is not time limited, a transition plan will be adopted.

For example:

- Any exemption will remain in effect until such time as the business changes hands, e.g. approval of a small safe at a veterinary practice.

Similarly, an exemption for labelling or packaging of a medicine could be allowed to continue under the new legislation.

For example:

- All poisons supplied need to comply with SUSMP packaging and labelling which includes adherence to standards to poisons bottles. There are instances where exemptions have been granted to manufacturers who are using safety features which have been deemed as being equivalent. It would be unduly expensive for the manufacturer and unnecessary where there are no public safety issues, to enforce a change to new requirements. Therefore, any reasonable exemptions should continue to apply.

The Department will endeavour to inform all identified stakeholders regarding implementation of the new regulations. Consultation indicated that stakeholders would appreciate ongoing communications to provide guidance regarding regulatory matters. Communications requested in the stakeholder survey have included:

- Information sheets for practitioners explaining professional authority;
- Detailed guidance regarding minimum requirements and examples of Structured Prescribing Arrangements; and
- Guidance notes to assist with interpretation of regulations for pharmacists supplying to ships.

The Department will utilise the stakeholder contact list, web site, peak bodies and notices to communicate information regarding implementation of the legislation.

Communication with stakeholders is seen as a key strategy in ensuring appropriate implementation of the new regulations. A comprehensive communication strategy will be developed to ensure this is considered adequately. Current management of regulatory change is standard practice for the branch. Industry briefings, issuing of notices, updating of changes via the website are common practice and targeted information to identified stakeholders (e.g. informing licence and permit holders).

Implementation of Structured Prescribing Arrangements was an area of particular interest to stakeholders. For Structured Prescribing Arrangements issued by the CEO, the Department plans on clearly defining the appropriate governance arrangements and establishing an assessment panel to review structured prescribing needs. Consultation with stakeholders was supportive of the minimum requirements / conditions for Structured Prescribing Arrangements. The Department will issue guidance on the minimum requirements including templates and examples of Structured Prescribing Arrangements. The Department will also commence a program of education and compliance for this new framework.

4.2 Review and Evaluation

The Department is aware that this legislation complements many other pieces of State and Commonwealth legislation. It is likely that some ongoing amendments will be necessary to ensure continued alignment with complementary legislation. Any amendments will need to follow the standard regulatory processes, including any best practice regulatory requirements, gatekeeping or impact assessments.

The Department will be able to monitor the performance of regulations via the following processes:

- Monitoring the records supplied to the department including authorisations and approvals of Schedule 8s or licence and permit applications;
- Accessing the timeliness of completing administrative tasks for the operation of the Act, e.g. time to issue an authorisation or a licence;
- Impact of the regulations in terms of instances of noncompliance identified during audit, voluntary and mandatory reporting, and formal investigations.
- Feedback from stakeholders via information lines, emails and website activities.

In addition, it is proposed that the Department complete a formal review of regulations after 5 years. This review will be required, among other reasons, to assess the impact of the regulations on industry and to consider whether further regulation is required to ensure public health and safety.

Appendices

Appendix 1: Stakeholders

Appendix 2: Discussion Paper: Poisons Regulations 1965

Appendix 3: Discussion Paper: Schedule 8 Opioid Regulations

Appendix 4: Discussion Paper: Poisons Schedules