



**Poisons and Therapeutic Goods  
Regulation 2008**

**Regulatory Impact Statement**



# **REGULATORY IMPACT STATEMENT**

**TITLE OF REGULATORY PROPOSAL:** **Poisons and Therapeutic Goods Regulation 2008**

**PROPONENT:** **NSW Department of Health**

**RESPONSIBLE MINISTER:** **The Hon Reba Meagher MP  
Minister for Health**

**RELEVANT ACT:** **Poisons and Therapeutic Goods Act 1966**

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## 1. Why is the regulation being reviewed?

The *Poisons and Therapeutic Goods Regulation 2002* (the Poisons Regulation) facilitates the operation of the *Poisons and Therapeutic Goods Act 1966* (the Poisons Act). The Poisons Regulation thereby contributes to the overall control of scheduled poisons and medications in New South Wales.

The *Subordinate Legislation Act 1989* provides for regulations to have a limited life. In most cases, regulations are automatically repealed after 5 years. When a regulation is due for repeal, the responsible agency must review the regulation, its social and economic impacts, and the need for the regulation. The agency must then make a decision about whether the regulation should be remade. The results of this review are required to be published in a Regulatory Impact Statement (RIS) and submissions invited from the public.

This RIS proposes that the existing Regulation be remade.

## 2. Approach taken in this regulatory impact statement

The RIS first considers the objectives of proposed *Poisons and Therapeutic Goods Regulation 2008* (the proposed Regulation). The RIS then considers the basis and rationale for each of the matters contained in the proposed Regulation. The RIS also examines the following options:

- Allowing the Regulation to lapse;
- Remaking the Regulation with amendments to facilitate and promote self-regulation by industry; and
- Remaking the Regulation without substantive amendments.

Submissions about the proposed Regulation can be made to:

Legal and Legislative Services Branch  
NSW Department of Health  
Locked Bag 961  
NORTH SYDNEY 2059

Submissions may also be made via email to [legalmail@doh.health.nsw.gov.au](mailto:legalmail@doh.health.nsw.gov.au)

### **3. Operation of the Legislation**

#### ***3.1 The Poisons and Therapeutic Goods Act and the Regulation-Making Power***

The Poisons Act was enacted to regulate, control and prohibit the availability of poisonous substances, including pharmaceutical drugs and domestic, agricultural and industrial chemicals. Its objectives are facilitated by the Standard for the Uniform Scheduling of Drugs and Poisons" (the SUSDP). Part 4 of the SUSDP divides substances into eight schedules that provide a basis for graded levels of control. Scheduling is not in strict accordance with the toxicity of the substance. Toxicity is only one of a number of important scheduling criteria, which also include the proposed use, potential for abuse, safety in use and the need for a substance. Part 2 of the SUSDP contains standards for labels and containers of scheduled substances and Part 3 contains standards for advertising, sale and supply, and storage.

The Poisons Act is written so that much of the control is achieved through the Poisons Regulation, rather than by the Act itself. Regulation-making powers are extensive and, depending on the schedule, may cover such matters as supply (including dispensing, selling and distribution), manufacture, packaging and labelling, possession, prescription requirements, and administration of the substances.

#### ***3.2 National and International Considerations***

The NSW Poisons List adopts the national schedules of the SUSDP such that Schedules 1 to 8 of the NSW Poisons List are substantially the same as Schedules 1 to 8 of the SUSDP. Parts 2 and 3 of the SUSDP have been substantially incorporated into the Poisons Regulation so that their provisions can be enforced in NSW.

Adoption of the SUSDP has relevance for Australia's commitment to three international United Nations Conventions: the Single Convention on Narcotic Drugs 1961; the Convention on Psychotropic Substances 1971; and the Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances 1988. These conventions aim to prevent the misuse and abuse of drugs by setting standards and measures for the manufacture, possession, supply, prescription and distribution of drugs of addiction and certain other restricted substances. National uniform scheduling of poisons and drugs as per the SUSDP provides a sound basis for the implementation of these conventions in Australia.

All Australian jurisdictions have similar legislation in force that governs the availability of drugs and poisons in accordance with these national and international considerations. In this way such matters as possession, prescribing, labelling, storage and record keeping of drugs and poisons are controlled throughout Australia.

#### ***3.3 Relationship with the Drug Misuse and Trafficking Act 1985***

The Poisons Act and Regulation have an important relationship with the NSW Drug Misuse and Trafficking (DMT) Act 1985. Under the DMT Act it is an offence to

manufacture, supply, possess and use certain prohibited drugs, unless licensed or authorised under the Poisons Act and Regulation. The list of prohibited drugs includes a number of scheduled substances with a legitimate medical, veterinary or dental use (such as morphine and pethidine). Without a Poisons Regulation the possession, administration and supply of these substances by medical practitioners, dentists, pharmacists, nurses, midwives, optometrists, podiatrists and veterinary surgeons would be prohibited unless exemptions were developed under the DMT Act.

### **3.4 The Poisons List**

A description of the eight schedules of the Poisons List is given in Table 1 below. Pharmaceutical medicines and drugs are contained in Schedules 2,3,4 and 8. Of these, Schedule 4 drugs are defined in the Poisons Act as restricted substances and Schedule 8 as drugs of addiction. Domestic, agricultural and industrial poisons are contained in Schedules 5,6 and 7.

Some medicinal and household products escape scheduling altogether, provided they comply with specific conditions, or because they present no real hazard. For example, paracetamol is unscheduled in tablets or capsules containing 500 milligrams of paracetamol or less without any other therapeutic ingredient, and enclosed in blister strip packaging, or in a child resistant container containing not more than 25 tablets or capsules and labelled with specific cautions and warnings. Household liquid bleaches (otherwise contained in Schedule 5) are unscheduled provided they contain less than 2 per cent chlorine or contain between 2 and 4 per cent chlorine and are labelled with a specific warning. Others products such as common detergents are not scheduled in any concentration.

#### **TABLE 1 Schedules 1-8 of the Poisons List**

##### **Schedule 1:**

Substances which are extremely dangerous, the supply of which must be strictly controlled.

##### **Schedule 2:**

Substances which are dangerous to life if misused or carelessly handled, but which should be available to the public for therapeutic use or other purposes without undue restriction.

Examples are cough syrups, cold and flu tablets, acne products and many stronger pain-killers.

NB. Schedule 2 substances are generally only available from pharmacies.

##### **Schedule 3:**

Substances which are for therapeutic use and:

1. about which personal advice may be required by the user in respect of their dosage, frequency of administration and general toxicity;
2. with which excessive unsupervised medication is unlikely;
3. which may be required for use urgently so that their supply only on the prescription of a medical practitioner or veterinary surgeon would be likely to cause hardship.

Examples are Ventolin, insulin and some anti-histamines which cause drowsiness.

NB. Schedule 3 substances are generally only available from pharmacists in person.

**Schedule 4 (Restricted Substances):**

Substances for therapeutic use that in the public interest should be supplied only upon the written prescription of a medical practitioner, nurse practitioner, midwife practitioner, dentist, optometrist or veterinary surgeon.

Examples are antibiotics, contraceptive pills, blood pressure tablets, and tranquillisers.

**Schedule 5:**

Poisonous substances of a dangerous nature commonly used for domestic purposes which should be readily available to the public but which require caution in their handling, use and storage.

Examples are household bleaches above a certain strength, kerosene, methylated spirits, and some domestic insect sprays.

**Schedule 6:**

Substances which should be readily available to the public for agricultural, pastoral, horticultural, veterinary, photographic or industrial purposes or for the destruction of pests.

Examples are most insecticides and pesticides.

**Schedule 7:**

Substances of exceptional danger which require special precautions in their manufacture or use.

Examples are strychnine and cyanide.

**Schedule 8 (Drugs of Addiction):**

Substances which have therapeutic use in controlled circumstances but which are addiction producing or potentially addiction producing.

Examples are pethidine, morphine and methadone.

### ***3.5 Administration and Enforcement of the Poisons Act and Regulation***

The Pharmaceutical Services Branch of the Department of Health administers the Poisons Act and Regulation. In support of the legislation, the Branch takes responsibility for:

- licensing and regulating manufacturers and wholesale distributors of drugs of addiction;
- regulating compliance with the legislation by health professionals, veterinary surgeons and distributors of medicines and poisons generally;
- advising on the packaging and labelling of human and animal medicines and poisons covered by the legislation;
- issuing (or refusing to issue) authority to obtain, use, supply etc. a wide range of medicines, poisons and drugs, including in connection with the NSW Opioid Treatment Program;
- withdrawing the right of any authorised individual (including health professionals) to obtain, prescribe, possess, supply or use drugs of addiction;

- monitoring wholesale and retail transactions in drugs of addiction including prescribing.

Pharmaceutical Services Branch promotes compliance with the Poisons Regulation through educational brochures, inspections and the provision of advice. While it investigates a number of breaches of the Poisons Regulation each year, the majority of these are minor and due to ignorance of the legislation. In these instances, the Branch adopts an attitude of education first and the matters are usually resolved through consultation with the concerned parties. However the most serious or flagrant breaches of the legislation are prosecuted. A summary of prosecutions for 2006 indicates that 4 individuals were prosecuted for a total of 12 offences.

The maximum penalty for a breach of the Regulation relating to most poisons and restricted substances in schedules 1-3 and 5-7 is generally 10 penalty units (\$1,100), for restricted substances (schedule 4) the maximum penalty is generally 15 penalty units (\$1,650), although for those schedule 4 restricted substances listed in Appendix D of the Poisons Regulation (prescribed restricted substances) the maximum penalties are usually 20 penalty units (\$2,200), and for offences involving drugs of addiction (schedule 8) the maximum penalty under the Regulation is generally 20 penalty units (\$2,200). The Poison Act also provides for terms of imprisonment of up to 2 years for offences under the Act.

Where a health professional has breached the Act or Regulation, and there is concern about the competence/ability of that person to continue in practice, a complaint of unsatisfactory professional conduct or professional misconduct may be laid before the relevant registration board or disciplinary body.

## **4. The Objective of the Regulation**

### ***4.1 The Objective***

The overall objective of the Poisons Regulation is to establish standards and safeguards for the packaging, labelling, administration and distribution of poisons and medicines so as to maximise their benefits to the community and minimise morbidity and mortality that may result from drug misuse, drug abuse and poisoning.

### ***4.2 The Nature, Extent and Cost of Drug Misuse, Drug Abuse and Poisoning***

Drug misuse arises when people inappropriately use medication for medical purposes. Common types of drug misuse include not heeding the correct dosage and using a drug for a medical purpose for which it was not intended. Examples of these are excessive use of asthma sprays and taking combination analgesics containing paracetamol and codeine (Schedule 2) to treat chronic (long-term) pain when their purpose is to provide short-term pain relief only.

Drug abuse arises when people intentionally take drugs for non-medical purposes such as for recreational purposes or to satisfy an addiction. Drug abuse is not confined to those drugs classified as Schedule 8 (drugs of addiction). A number of Schedule 4 prescription drugs such as tranquillisers and anti-depressants can be subject to abuse, as can Schedule 2 and 3 preparations such as cough mixtures and

travel sickness medication. The type of drug abused varies with the age of the abuser. Adolescents tend to be abusers of Schedule 2 and 3 substances since they are available over the counter, while older people abuse the stronger Schedule 4 and 8 substances.

Poisoning occurs through the inappropriate ingestion, inhaling or touching of a poisonous substance. It is usually accidental but can be intentional. The risk of poisoning from a particular substance is a function of the person's exposure to that substance. Hence children are most at risk of poisoning from substances found in the home, such as medicines and domestic cleaning agents. Adults may be additionally exposed to agricultural and industrial chemicals in the workplace.

Accurate quantification of the incidence of drug misuse, abuse and poisoning (due to scheduled substances) is hampered by inaccurate and incomplete data. Drug abuse is particularly difficult to quantify since abusers rarely seek professional treatment in relation to that drug abuse. Drug misuse and poisoning causing serious illness would be expected to lead to hospital admission, attendance at accident and emergency centres (not leading to hospital admission) or GP attendance.

Hospital admissions data is available for NSW, but is of limited value in relation to determining the incidence of drug misuse and poisoning in the community. The classification categories for admissions are broad and where an admission is identified as being related to drug misuse or poisoning the data does not distinguish between scheduled and unscheduled substances. Furthermore, the data does not indicate whether the admissions were due to accidental or deliberate action.

However, the Chief Health Officer's Report for 2006 indicates that in 2004-05, there were 3,716 hospitalisations of NSW residents due to unintentional poisoning, giving a rate of 54.8 per 100,000 residents. Children aged 0-4 years have the highest rates of hospitalisation for unintentional poisoning, followed by young adults aged 15 to 29 years and elderly people aged 85 years and over. Fifteen percent of unintentional poisoning hospitalisations were of children aged 0-4 years. The rate of hospitalisation in this age group was 127.3 per 100,000, more than double the rate for all ages. This rate has decreased, however, from 210.8 per 100,000 in 1989-90.

Amongst poisoning hospitalisations for children aged 0-4, over the period 1998-99 to 2004-05, the most common category of agents specified were sedative-hypnotic and psychotropic drugs (including anti-depressants) (18.8%) and non-opioid analgesics (including paracetamol) (15.0%). In young adults aged 15-24 years, the most common specified agents of poisoning were sedative-hypnotic drugs (31.9%) and narcotics and hallucinogens (16.6%). A further 6% percent of hospitalisations were due to alcohol poisoning. The most common category of agents specified for those aged 65 years and over was sedative-hypnotic and psychotropic drugs (16.4%) Child-resistant packaging is a substantial measure in reducing the risk of poisoning of young children<sup>1</sup>.

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<sup>1</sup> (O'Connor P. *Accidental poisoning of preschool children from medicinal substances, Australia*. Injury Research and Statistics Series. Australian Institute of

The Report of the Review of Drugs Poisons and Controlled Substances Legislation (the Galbally Report) provides some national data relating to the incidence of illness and injury from the misuse and abuse of drugs and poisons. Included in that information is the assessment that 0.3% of Australian children under the age of 5 years will be admitted to hospital due to poisoning each year, and of these children 71% will have been poisoned by a medication. The Report goes on to state that the cost associated with poisoning in small children is estimated as between \$29 and \$36 million per annum.<sup>2</sup> The Galbally Report also attempts to estimate the annual costs to the Australian health system from poisoning, medicinal misadventure and suicide and self inflicted injury (including drug abuse). The findings of the Report are contained in the following table<sup>3</sup>:

Table 2: External causes of injury health system costs (\$m) and PYLL-75 by sex, 1994

**Note:** PYLL = person years life lost

**Source:** Mathers C and Penm R *Health system costs of injury, poisoning and musculoskeletal disorders in Australia 1993-4*, Australian Institute of Health and Welfare, Canberra, 1999.

	Total Cost \$m	Males			Females		
		Total costs	Deaths	PYLL-75	Total costs	Deaths	PYLL-75
<b>Poisoning</b>	26	13	211	8,506	13	115	3,746
<b>Medical misadventure</b>	401	194	28	417	207	23	256
<b>Suicide and self inflicted injury</b>	72	35	1,891	63,844	38	454	13,994

These figures indicate that the community as a whole bears a substantial annual cost from the misuse or abuse of poisons and medications. It is important to note also that this burden arises in the context of existing levels of control over medications and poisons and not an unregulated environment.

#### **4.3 The Alternatives**

Three alternatives have been considered as a means to achieve the objective of the Regulation. These are:

1. Allowing the existing Regulation to lapse without replacing it.
2. Self-regulation by the industry and related health professions.

Health and Welfare cat no. INJCAT 39. Canberra: AIHW, 2001. Available at: [www.nisu.flinders.edu.au/pubs/reports/2001/injcat39.pdf](http://www.nisu.flinders.edu.au/pubs/reports/2001/injcat39.pdf)

<sup>2</sup> Galbally R, Final Report Part B, *Review of Drugs Poisons and Controlled Substances Legislation*, Therapeutic Goods Administration, Canberra 2000, pages 7-8. Available at:

<http://www.health.gov.au/tga/docs/pdf/rdpfinb.pdf>

<sup>3</sup> *ibid.* page 12.

3. Re-making the existing Regulation with minor updates.

## **5. The Proposed Regulation**

The Regulation is based on the premise that in a free market for drugs and poisons, consumers would make poorly informed decisions about purchasing and using these substances. Those poorly informed choices could lead to illness and death. To address this market failure, the Regulation restricts the general availability of drugs and poisons in the community, and establishes mechanisms to ensure that people who do obtain them are provided with sufficient information to be able to use them appropriately and safely. The varying levels of control placed on each substance are too detailed to be recounted here, but a summary is provided below.

### **5.1 Summary of Controls on each schedule**

#### **5.1.1 Schedule 1**

There are no substances listed in Schedule 1.

#### **5.1.2 Schedules 2,3,4 & 8**

Pharmaceutical drugs (Schedules 2, 3, 4, and 8) are subject to varying levels of control, but one common factor is that substances in these schedules are generally only available for purchase from pharmacies. This restriction enhances their image as medicines not to be used indiscriminately, and means that purchases are subject to more specialised supervision than would be the case if they were available through supermarkets and other retailers.

**Schedules 2 and 3** are intermediate schedules. The substances listed in these schedules are only available from pharmacies, although their purchase does not require a prescription. Schedule 2 substances can be purchased from the general shop area of a pharmacy and consumers may self-select the substances they require, but their supply is under the general supervision of a pharmacist who is always on hand to provide advice about the product. Schedule 3 drugs must be kept out of public access and therefore customers must specifically ask for them, thus ensuring involvement with the pharmacist and supervision of the purchase.

**Schedule 4** drugs are only available from pharmacies on the written prescription of an authorised health professional. In this way they are restricted to people who have a legitimate health care need for them. Specific requirements are made for record keeping and the writing and filling of prescriptions to help ensure that they are not inappropriately obtained, and that the patient is appropriately instructed in the use of the drug.

**Schedule 8** drugs (drugs of addiction) are fully regulated with accountability being a major facet of their regulation. Possession without authority is an offence as is manufacturing without a licence. Greater controls exist over prescribing and dispensing these drugs than for drugs listed in Schedule 4 to help ensure that abusers do not inappropriately obtain them. For example, prescription forgery is

addressed by a requirement that the dispensing pharmacist must know either the patient or the handwriting of the prescriber.

### **5.1.3 Schedule 5, 6 & 7 poisons**

Domestic, agricultural and industrial poisons are classified using Schedules 5, 6 and 7.

**Schedule 5** substances are the least regulated of all the scheduled substances. These poisons can be purchased from any type of retail establishment. The inappropriate use of Schedule 5 poisons is almost solely controlled through packaging and labelling requirements.

**Schedule 6** substances have greater packaging and labelling controls. In addition, these substances must generally be stored at least 1.2 metres above the floor (to help prevent access by young children), or otherwise packaged in a manner designed to prevent access by children. These restrictions are designed to prevent accidental poisoning.

**Schedule 7** substances have far more stringent packaging and labelling controls. In addition, due to their extreme toxicity, these substances must be stored out of public access with supply occurring following a specific request only.

### **5.1.4 Packaging and labelling**

All scheduled substances are required to be packaged and labelled in accordance with the Standard for Uniform Scheduling of Drugs and Poisons (SUSDP), which is adopted in the Regulation by reference. The SUSDP makes general requirements that substances must be packaged in resealable, impervious, leak-proof containers. All substances must have labels that clearly identify the substance, its quantity and strength and the name of the manufacturer or distributor. Labels must be clearly written in English in accordance with size, font and colour specifications. All substances must be labelled with "Keep out of the Reach of Children". In addition to these general requirements, the SUSDP sets further substance-specific requirements for labelling (including first aid instructions and/or warning statements), packaging and containers which address specific risks. For example, to impede (or slow) access, some substances must be packaged in child-resistant closures, and some medication must be enclosed in unit dose packets.

Corbett et al demonstrated effectiveness of child resistant containers in *Accidental Poisoning in the Domestic Environment*<sup>4</sup>. This report describes a decline in the number of admissions to hospital for accidental poisoning in the 0-4 year age group between 1979 and 1984. According to the report, the decline followed the introduction between 1979 and 1981 of mandatory child resistant packaging for paracetamol, salicylamide, iron compounds, hydrocarbon liquids, hydrochloric acid, methylated spirits and sodium hydroxide containing products. Corbett's findings are

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<sup>4</sup> Corbett et al, "Accidental Poisoning in the Domestic Environment", Report to the NH&MRC Working Party on Domestic Chemicals, July 1991.

supported by more recent research from the United States<sup>5</sup> which reported a 45% reduction in childhood deaths from poisoning following the introduction of child-resistant packaging for oral prescription drugs.

## 6 Other Options

### **6.1 Allowing the Regulation to lapse without replacing it**

Given that the efficacy of the Poisons Act relies on the existence of the Poisons Regulation this option cannot achieve the objective of minimising illness and death resulting from drug misuse and abuse and from poisoning. To allow repeal of the existing Regulation without replacing it would leave little control over the availability of legitimate drugs and poisons. This would undoubtedly result in a significant increase in drug abuse and misuse and poisoning. It is axiomatic that this will lead to increased illness and death.

The level of general and specific knowledge in the community about drugs and poisons is not sufficient to allow individuals to make safe decisions about their use without the backing of a Poisons Regulation. The ability to determine the most appropriate drug to treat a particular medical condition and how to use that drug appropriately, are skills that can only be attained with specific training. Furthermore, even if it is widely understood that some pharmaceutical drugs may be dangerous and addictive, there will be individuals who are unable to resist abusing them.

Compounding this, the conduct of manufacturers and suppliers of scheduled substances cannot, in the absence of a Regulation, be guaranteed to be in the public interest. Indeed there are likely to be cost and profit incentives promoting action to the contrary (such as abandoning child resistant closures and warning labels, and supplying poisonous products to anyone who can pay for them, regardless of legitimate need).

This option would also mean abandoning the SUSDP's uniform national standards for the packaging and labelling of poisons and drugs, in contravention of the State's previous agreement. In the absence of further controls in other legislation this approach would also place NSW at risk of breach of the three United Nations Conventions on drug misuse and abuse. Furthermore in the absence of amendments to the Drug Misuse and Trafficking Act health professionals, who in their professional capacities have legitimate reasons to possess, use or supply drugs of addiction, could find themselves guilty of serious criminal offences.

### **6.2 Self-regulation by industry and health professions**

Self-regulation by the industry and related health professions, whether backed by regulation or not, would be incapable of achieving the objective of minimising illness and death resulting from drug misuse and abuse and from poisoning, primarily due to the sheer size and scope of the industry and professional groups. Together these groups encompass every individual or business entity that manufactures, supplies,

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<sup>5</sup> Rodgers GB, *The safety effects of child-resistant packaging for oral prescription drugs*, Journal of the American Medical Association, 275(21): 1661-1665.

retails, dispenses, administers, possesses and uses scheduled substances. They include chemical and pharmaceutical companies, medical practitioners, veterinary surgeons and dental surgeons, registered nurses, midwives, podiatrists, optometrists, pharmacists, supermarkets and other retailers, hospitals, clinics, nursing homes, pest controllers and farmers.

The number of associations and bodies involved is so large and with such diverse interests that it would be unlikely for them to voluntarily agree to a standard set of guidelines or a code of conduct. Even if they could, membership of these associations is far from universal and does not provide effective sanctions against those who breach an industry or professional code. Furthermore, differences in the relative strengths of representative bodies and the under-representation of consumer groups would make such a process unlikely to serve the public interest. A further point to consider is that industry and professional associations are not necessarily interested in upholding the State's obligation to adopt the SUSDP, or Australia's commitment to the United Nations conventions on drug misuse/abuse.

## 7. COST BENEFIT ANALYSIS OF THE PROPOSED REGULATION

### 7.1 Costs

#### 7.1.1 Cost of Administering the Regulation

The Pharmaceutical Services Branch's budget for the 2007/8 financial year is \$2.296M. The Branch has estimated that it spends about 25 per cent of this administering the existing Poisons Regulation (another 50 per cent is spent in administering the Poisons Act itself and the final 25 per cent on other matters).

On this basis, the cost of administering the proposed Poisons Regulation in 2007/8 is estimated to be approximately \$574,000 (25% per cent of the total budget). Table 3 below shows this annual cost to have a net present value (NPV) over the next five years (the expected life of the Regulation) of \$2.495 million (at a discount rate of 7 per cent). Variance of the NPV is shown with a lower discount rate of 5 per cent.

TABLE 3: Net Present Value of Administration Costs

Net present value of administration costs over 5 years	Discount rate of 7%	Discount rate of 5%
	\$2.495 million	\$2.597 million

Source: Pharmaceutical Services Branch, NSW Department of Health

#### 7.1.2 The Costs of Compliance

The poisons and pharmaceutical industries and related health professionals experience costs in complying with the Regulation, and there should be no discernable change. It would be impossible to quantify these costs, since the industry is so vast. However the costs involved essentially comprise the costs of any action taken by any person to comply with the Regulation, which would not have been taken in the absence of the Regulation. Clearly this does not include actions

that would be taken in order to comply with insurance requirements and to meet any other duties to consumers and the public in general.

For manufacturers and suppliers (including health professionals) the costs may include:

- the cost of maintaining records;
- the cost of securing premises and securely storing substances;
- costs associated with administrative procedures such as obtaining necessary licenses and approvals;
- the cost of complying with packaging and labelling requirements;

A further general cost is that controlled access to a product may reduce demand and thereby restrict manufacturers and distributors ability to fully exploit economies of scale. However, regardless of the party that initially incurs these costs they will ultimately be borne by consumers of scheduled substances in the form of higher prices.

### **7.1.3 Other Costs to Consumers**

Costs to consumers include those of physically obtaining products whose availability is restricted. The requirement to purchase Schedule 2, 3, 4 and 8 substances from a pharmacy rather than a supermarket, service station or convenience store may be inconvenient and costly in terms of travel time and the price of the product (for example the high sales volumes of supermarkets may enable them to operate on lower margins than pharmacies and consequently charge consumers less for those products).

Furthermore, the requirement to attend a health professional to obtain a prescription for a Schedule 4 or 8 substance imposes a consultation cost. In the case of prescriptions issued by medical practitioners the average cost of the consultation, \$37.51, is largely borne by the taxpayer through Medicare funding<sup>6</sup>. The average benefit paid for drugs dispensed on prescription under the Pharmaceutical Benefits Scheme in 2005/06 was \$34.00.<sup>7</sup>

While there is a not insignificant cost to patients who are generally required to consult a health practitioner and then separately visit a pharmacy to obtain any medication that is recommended (schedules 2 and 3) or prescribed (schedules 4 and 8) the additional costs involved in attending a pharmacy (rather than a supermarket) are imposed by section 28 of the Pharmacy Act 1964 not by the Poisons and Therapeutic Goods Regulation.

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<sup>6</sup> Health Insurance Commission Annual Report 2006/2007, Medicare statistical table 8

<http://www.medicare.gov.au/about/governance/reports/06-07/stats/mcare8.shtml>  
The figure quoted is the average cost to Medicare of an unreferral consultation with a vocationally registered medical practitioner.

<sup>7</sup> Pharmaceutical Benefits Scheme,  
<http://www.medicare.gov.au/about/governance/reports/06-07/stats/pbs3.shtml>

## **7.2 Benefits**

The proposed Regulation will assist in minimising drug misuse, drug abuse and poisoning. By doing so the Regulation will help to prevent illness and death. These benefits can be measured in terms of the extra resources available to society through treatment cost savings and higher productivity through reduced morbidity (illness) and mortality (death).

In the sections below the different types of benefit of the Regulation are discussed. However, in most cases only the unit benefit per prevented case of drug misuse/abuse/poisoning can be estimated. The total value of each type of benefit cannot be quantified. To do so would require a comparison of the illness and death caused by drugs and poisons under the proposed Regulation with what would occur without any Regulation at all. While we have some indication of the current situation (see section 4.2), we cannot determine what it may be in the absence of any Regulation at all, since the availability of drugs and poisons has been regulated throughout the last century.

### **7.2.1 Treatment Cost Savings**

The 2004/5 NSW hospital casemix comparative data shows that patients have an average length of stay in hospital, on poisoning cases, of 2.2 days with an average cost of \$1,950. Therefore the NSW public health system saves at least \$1,950 for every hospital admission prevented by the Regulation. For illicit drug related matters the average length of stay is 2.7 days with an average cost of \$1,970.<sup>8</sup> Savings may be more than this due to follow-up outpatient treatment required by patients.

Further treatment costs would also be saved through avoided accident and emergency attendances (not leading to hospital admission). These cannot be quantified, but would save on average \$233 per prevented treatment not leading to admission.<sup>9</sup> Every prevented GP consultation would save on average \$36.95. Furthermore there would be less pressure on other avenues for advice and treatment such as the Poisons Information Centre and the affected person's family and friends.

### **7.2.2 Saved Productivity - Reduced Illness/Time off Work**

Productivity is lost wherever drug misuse or abuse or poisoning leads to time off work, whether due to GP attendance, admission to hospital or home recovery. While the total productivity lost in the absence of the Regulation cannot be estimated, the average cost of a lost week of productivity is estimated below.

The human capital approach approximates the value of an individual's productivity to the labour costs of employing the individual (Hall & Mooney 1991). To estimate the average labour costs of employing an individual, average weekly earnings of \$1,105<sup>10</sup> can be increased by 12 percent for leave loadings, termination payments,

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<sup>8</sup> Figures provided by the NSW Health Casemix Policy Unit.

<sup>9</sup> NSW Health Services Comparison Data Book 1999/2000, volume 2, table 4a, [www.health.nsw.gov.au/pubs/h/pdf/yellowbook\\_vol2\\_99-00.pdf](http://www.health.nsw.gov.au/pubs/h/pdf/yellowbook_vol2_99-00.pdf)

<sup>10</sup> Australian Bureau of Statistics,

superannuation, workers compensation and fringe benefits, to give an average weekly employment cost of \$1,237. Accordingly, the value to society of every week of productivity saved due to averted drug misuse and abuse and poisoning is approximately \$1,237.

**7.2.3 Saved Productivity - Fewer Deaths**

The human capital approach can also be used to estimate the productivity saved through the prevention of premature death from drug misuse or abuse and poisoning. Research Report no 217 (1992) of the Australian Road Research Board estimates the value of future productivity, including both paid and unpaid work, at the time of death of victims of road accidents. Its estimate of the net present value of future productivity (adjusted for growth in average weekly earnings) starts at \$421,621 at birth, rises to a peak of \$1,128,970 at age 25, and then falls to \$891,613 by age 40, \$403,006 by age 60 and to \$95,254 by age 80.

In 2000 the Bureau of Transport Economics estimated that the total economic value (both paid and unpaid employment) of the average life lost in 1996 was \$2 million.<sup>11</sup>

**7.2.4 Saved Resources Specific to Reduced Drug Abuse**

A specific benefit of preventing drug abuse is the extra resources available to the community through averted production and dispensing of substances which are not necessary for maintaining or improving health status (Collins and Lapsley 1991, p.76). However, since the extent of drug abuse cannot be accurately stated, this cannot be quantified.

**7.2.5 Intangible Benefits - Higher Quality of Life**

By preventing drug misuse, drug abuse and poisoning society also benefits from a number of intangible factors including the averted pain and suffering of affected persons and anxiety of their relatives and a generally "safer" society.

**7.3 Summary of Costs and Benefits of the Proposed Regulation**

Table 4 below summarises the costs and benefits of the proposed Regulation. It shows the total monetary value of each component of the costs and benefits where possible. Where this is not possible, the table gives an estimation of the value, or a unit value, or a description of the component. It is clear from the Table that the net present value to society of the proposed Regulation is a large positive.

TABLE 4: Summary of Costs and Benefits of the Proposed Regulation

<b>COSTS</b>	<b>BENEFITS</b>
<b>Administration Costs:</b> \$2.497 million (discounted over 5 years at 7%) for administration of Regulation by Pharmaceutical Services Branch.	<b>Saved Treatment Costs:</b>  <b>Approximately \$2,000</b> in hospital charges

<http://www.abs.gov.au/ausstats/abs%40.nsf/b06660592430724fca2568b5007b8619/ba84bbb55b643021ca2568a90013934e!OpenDocument>

<sup>11</sup> Bureau of Transport Economics, *Road Crash Costs in Australia*, BTE Report 102, Canberra 2000.

	<p>for every case of drug use or poisoning related admission to hospital avoided. Plus unquantified costs associated with follow-up treatment.</p> <p><b>Approximately \$233</b> saved for every averted accident and emergency consultation related to drug use or poisoning. Plus unquantified costs associated with follow-up treatment.</p> <p><b>Approximately \$37.51</b> saved for every prevented GP consultation.</p> <p>Additional saved resources through reduced pressure for advice and care from Poisons Information Centre and victim's family respectively.</p>
<p><b>Compliance Costs:</b> Costs of compliance to firms (see section 7.1.2), likely to be passed on to consumers in the form of higher prices.</p>	<p><b>Saved Productivity - Reduced Time off Work:</b> Productivity saved through reduced sickness and less time off work. Worth <b>approximately \$1,237</b> per week of work saved.</p>
<p><b>Other Costs to Consumers:</b> Costs of obtaining therapeutic substances from pharmacists.</p>	<p><b>Saved Productivity - Fewer Deaths:</b> <b>Approximately \$2 million</b> is saved for every prevented death from poisoning and drug abuse.</p>
	<p><b>Other intangibles</b> Saved Production/ Dispensing of Unnecessary Schedule 8 Substances, and Reduced Crime; Higher Quality of Life.</p>
<p><b>NET PRESENT VALUE: LARGE POSITIVE</b></p>	

## **8. Cost Benefit Analysis of the Alternatives**

### ***8.1 The Do Nothing Option***

Without a Poisons Regulation, many of the existing restrictions on the availability of drugs and poisons would be removed and consumers may make inappropriate and hazardous consumption choices. Suppliers could not be guaranteed to act in the public interest and many of the SUSDP packaging and labelling requirements would be likely to be abandoned. Under this approach costs to the poisons industry and health professionals would be reduced, and it is expected that the costs to consumers of obtaining scheduled substances would also reduce. However, with the expected decrease in price and increased accessibility of drugs and poisons it is anticipated that drug abuse, drug misuse and poisoning would increase significantly. The treatment costs and lost productivity associated with ensuing increases in illness and death would be expected to far outweigh any benefits of this alternative. This situation would more than likely require Government to institute alternative controls, for example via the Drug Misuse and Trafficking Act, and far from decreasing costs to industry, practitioners and consumers, this may very well substantially increase those costs.

Since the costs and benefits of the proposed Regulation have been estimated against the base case of "no Regulation", that is the do nothing option, there is no need to perform a separate cost benefit analysis on the do nothing option. The net present value of the do nothing option is, by definition, -1 times the net present value of the proposed Regulation. Since the net present value of the proposed Regulation is a large positive, the net present value of the do nothing option is a large negative.

### ***8.2 Self-Regulation by Industry and Professions***

Self-regulation by the poisons and pharmaceutical industries and related health professionals is expected to have a negative net present value, although whether this would be smaller or larger than the do nothing option is unclear as there may be a need for some form of regulation to facilitate that self-regulation. Under self-regulation the industry and health professionals would incur costs in establishing codes of practice and in endeavouring to enforce compliance with them. However as described in section 6.2, the size and scope of interested parties would be likely to prevent self regulation from adequately preventing drug misuse, drug abuse and poisoning. Drugs and poisons are likely to be more readily available under this option than under the existing or proposed Regulation (although possibly not as available as under the do nothing option). Drug and poison related illness and death would be expected to increase significantly, leading to significant resource costs in terms of lost productivity, higher treatment costs and pain and suffering etc.

## **9. Conclusion**

The analysis in the preceding two sections shows that, of the three alternatives, the proposed Regulation has the highest net present value and will therefore benefit society the most. Both the self-regulation and do nothing options have negative net present values. Clearly the proposed Regulation is the best method by which to achieve the objectives.



## **Appendix A: Organisations to be consulted**

ACCORD Australasia  
Aged and Community Services Association of NSW and ACT  
Australian Medical Association (NSW Branch)  
Australian Veterinary Association  
Health Care Complaints Commission  
Medical Services Committee  
Medicines Australia  
NSW Dental Board  
NSW Medical Board  
NSW Nurses Association  
Nurses and Midwives Registration Board  
Optometrists Registration Board  
Pharmaceutical Society of Australia (NSW Branch)  
Pharmacy Board of New South Wales  
Pharmacy Guild of Australia (NSW Branch)  
Private Hospitals Association  
Veterinary Practitioners Board

## **Bibliography**

Australian Road Research Board, Research Report ARR 217, *Preliminary Costs for Accident Types*.

Bureau of Transport Economics, *Road Crash Costs in Australia*, BTE Report 102 Canberra 2000.

Collins and Lapsley, *Estimating the Economic Cost of Drug Abuse in Australia*, Monograph series No 15, AGPS Press, Canberra, 1991.

Corbett et al, *Accidental Poisoning in the Domestic Environment*, Report to the NH&MRC Working Party on Domestic Chemicals, July 1991.

Galbally R, Final Report Part B, *Review of Drugs Poisons and Controlled Substances Legislation*, Therapeutic Goods Administration, Canberra 2000

Rodgers GB, *The safety effects of child-resistant packaging for oral prescription drugs*, Journal of the American Medical Association, 275(21): 1661-1665.

World Health Organisation, *International Classification of Disease - Clinical Modification*, Version 9.