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# Final Report Part B

January 2001

**National Competition Review  
of  
Drugs, Poisons and Controlled  
Substances Legislation**

**Final Report Part B\***

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**December 2000**

**\* Part A is bound separately**

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## **SECTION 1 INTRODUCTION**

### **1.1 Structure of the report**

For ease of discussion and clarity, the Report has been presented in two parts: Part A brings together the analysis and recommendations, and Part B provides supplementary information and more detailed analysis. The two parts should be read in conjunction. In presenting Part B, it has been assumed that the background material presented in Part A Chapter 1 has been read.

#### **1.1.1 Terms of Reference**

The Review's Terms of Reference are in Part A Attachment A1. Because of the overlap between the issues covered by the Review's General and Specific Terms of Reference, the Report does not attempt to follow them in sequence. However, the General and Specific Terms of Reference that are covered under each Section are indicated, as appropriate, at the beginning of the Section. The Review was charged with reviewing drugs, poisons and controlled substances legislation with regard to both general and specific requirements. The General Review Issues in the Terms of Reference require the Review to:

1. clarify the objectives of the legislation;
2. identify whether and to what extent the drugs, poisons and controlled substances legislation and regulation restrict competition;
3. identify the nature and magnitude of the health problems that the drugs, poisons and controlled substance legislation seeks to address;
4. analyse the effect of variation of legislation and regulation across jurisdictions;
5. analyse the drugs and poisons interface with other legislative regimes;
6. identify relevant alternatives to drugs, poisons and controlled substances legislation and regulation, including non-legislative and less restrictive approaches;
7. analyse the likely effect of the restrictions on competition and on the economy in general;
8. examine mechanisms for increasing the overall efficiency, including minimising the compliance costs of drugs, poisons and controlled substances legislation and regulation;
9. assess and balance the costs and benefits and overall effects of drugs, poisons and controlled substances legislation and regulation and alternative less restrictive approaches;
10. consider, where uniformity exists or is achieved as a result of this review, a framework for maintaining uniformity in the future; and
11. list the individuals and groups consulted during the review and outline their views.

The numbers have been added for ease of reference throughout the report.



Further Specific Review Issues were also requested, with the Terms of Reference stating that, 'Having regard to the above (general requirements), the review should specifically address the following main issues':

Specific Issue 1: Relationship between the processes and arrangements for decisions on drugs and poisons scheduling and drugs and poisons regulation

Specific Issue 2: National uniformity of regulation and administration of that regulation

Specific Issue 3: The number and range of Schedules, having regard to public access to substances, cost, simplicity of compliance by industry and professions and the optimisation of public health

Specific Issue 4: Interface with related legislation to maximise efficiency in the administration of legislation regulating this area

Specific Issue 5: Manner of supply by professionals of drugs, poisons and controlled substances.

The Terms of Reference explicitly exclude a range of matters from review, being:

- legalisation of illicit drugs;
- interface of drugs, poisons and controlled substances regulation with harm minimisation strategies (e.g. needle exchange programs);
- who has professional prescribing (including possession, administration and supply) rights and the extent of those rights;
- pharmacy ownership and the circumstances under which a pharmacist may practice; and
- criteria for listing in Schedules.

It will be observed that

- General Terms of Reference 1, 2, 6, 7 and 9 constitute the standard requirements for conduct of a review under the 1995 Competition Principles Agreement, Clause 5(9).
- General Term of Reference 11 is purely a process item.
- General Terms of Reference 3, 4, 5, 8 and 10 are elaborations or particularisations of elements in the standard review requirements.
- General Terms of Reference 4, 5, 8 and 10 overlap significantly with the specific review issues, especially with Specific Review Issues 2, 4 and 5.
- Within the context of the General Terms of Reference, the Review is told to give special emphasis to the Specific Review Issues.

The Review noted that it has been asked to conduct an administrative review as much as it has been asked to complete a competition review. The Review must address both elements and they must be rendered consistent. In this context it is significant that, in general, the submissions to the Review did not specifically address the National Competition Policy framework. While some of the discussion in the submissions and

face-to-face meetings raised competition aspects, only limited new data on costs or benefits have been provided to inform the final response of the Review to the general Terms of Reference.

### **1.1.2 Case studies**

This Part of the Report includes seven case studies that illustrate different aspects of the analysis and factors considered in the analysis. A number of these case studies originated from submissions to the Review while others emerged from research undertaken by the Review Secretariat. Those case studies originating from submissions to the Review are identified as such, and were factually extracted without further research.

### **1.1.3 Appendixes**

Three Appendixes at the end of the Report include a brief summary of the amendments to both State and Territory and Commonwealth legislation which would be needed if the Review's recommendations were adopted (the recommendations can be found in the executive summary of Part A of this Report); proposed functions of the recommended Medicines Scheduling Committee (MSC) and the Poisons Scheduling Committee (PSC); and the current and proposed revised Terms of Reference for the National Coordinating Committee on Therapeutic Goods (NCCTG).

## **1.2 The analysis**

### **1.2.1 Rationale for the approach taken**

Initially the Review sought to compare the particular legislative provisions in each jurisdiction corresponding to the controls in this area. This would have been helpful in identifying the exact nature of the different controls applied by each jurisdiction, assessing their relative benefits and costs, and framing more specific recommendations for change. However, with the resources available to the Reviews this proved an almost impossible task on a fully comprehensive basis because of:

- the complexity of the legislative framework;
- the broad scope of the different legislative instruments;
- the differences in the scope of the various legislative instruments;
- the different ways in which the various legislative instruments are framed;
- the different drafting techniques used in the legislation by jurisdictions; and
- the fact that some controls are imposed through Ministerial Orders or other delegated legislation.

Nevertheless, where these issues are manageable, the Report does directly address the issues of jurisdictional differences, including several comparisons against specific controls. In other cases, differences are discussed in more general terms without direct reference to the specific legislative sections and regulations involved. Where appropriate, the Standard for Uniform Scheduling of Drugs and Poisons (SUSDP) is used as a point of reference to discuss the controls in general because it is the point at

which commonality can be achieved in the different jurisdictions. Consequently, many of the recommendations in Part A of this Report relate to the generic nature of the change that should be sought in each jurisdiction. An outline of the legislative changes required to implement the recommendations is provided in Appendix B1.

### 1.2.2 Scope of the analysis

Drugs, poisons and controlled substances legislation places controls on a wide number of substances used by the Australian community. These controls limit access to some of these substances by restricting who may supply them and the circumstances and conditions under which they may be supplied. The legislation includes many types of control and these overlap and interact in complex ways with each other and with related legislation. The forms of control identified include access, labelling, packaging, storage, handling, sampling, record keeping, reporting, licensing, advertising as well as scheduling itself, including controls (often prohibitions) set out in SUSDP Appendixes and applied in jurisdictional legislation by various means.

The direct legislation under review forms part of a broader national framework of controls over these substances. For example, the *Therapeutic Goods Act 1989* and the *Agricultural and Veterinary Chemical Code Act 1994* also impose controls for the safety and efficacy of products containing these substances. Many of these controls are similar to those imposed by the legislation under review (e.g. labelling, packaging, and advertising).

There is also other legislation that is closely linked to the controls under review. For example, the potential benefits from the legislative controls that restrict the access to medicines, rely heavily on the legislation regulating professional practice, which assumes that there will be an appropriate level of professional intervention (e.g. by doctors, pharmacists, veterinarians) to address the information asymmetry between consumers and industry.

### 1.2.3 Stakeholder contributions to the analysis

In the written submissions, there was a wider response from stakeholders in the human medicine sector than from those in the areas of agvet<sup>1</sup> and household chemicals. Overall there was very little discussion of the current controls in terms of National Competition Policy Principles and there was a disappointing amount of quantitative data (particularly Australian data) from any sector, although some additional data were provided upon request of the Chair. Despite the general lack of quantitative data, the submissions did provide extensive discussions and examples of the costs and benefits of specific controls. One submission suggested that it is difficult to demonstrate the benefits of a system that is working well. In other words, it would be easier to establish if the system were not functioning effectively in that there would be widespread evidence of problems apparent.

No stakeholder proposed total deregulation and there was strong support for the objectives of the current legislation. A few questioned the inclusion of quality use of

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<sup>1</sup> agvet broadly covers agricultural and veterinary products.

medicines as an objective, but most submissions strongly agreed that this is, and should remain, an objective of this legislation. There were also suggestions that the protection of animal health and the Council of Australian Governments National Competition Policy Principles should be included as objectives. The Review considered that protection of animal health should be incorporated in the objectives of relevant components of the legislation. It also considered that any amendments to the legislation should be consistent with the Council of Australian Governments National Competition Policy.

In general, the current form and level of controls were considered effective in promoting the a benefit to the community as a whole (especially by protecting public health and safety), but the benefit of some specific controls was doubted and the way in which the controls are applied was queried with respect to duplication, inefficiency and transparency. Across all submissions from all sectors, the single topic that was raised most often was a lack of uniformity across jurisdictions and the costs this imposes on industry and, to a lesser extent, health professionals and through them on consumers.

Some of the issues stakeholders raised, although related to the subject areas encompassed by this Review, were outside the Terms of Reference. In particular, many submissions related to areas specifically excluded from the Review. Yet other submissions related to technical decisions, such as the appropriate Schedule for a particular substance, which the Review considered it was not appropriate to address.

In addition to extensive research by the Secretariat, this Report has drawn on stakeholder contributions to inform the analysis. A brief summary of the written submissions and consultations between the Chair and stakeholders is in Part A Attachment A2.

#### **1.2.4 Options paper**

The Options Paper drew on information provided in the first round of consultation. It was intended to provide a focus for further discussions between the Chair and stakeholders and to elicit additional information to help the Review examine the controls imposed by drugs, poisons and controlled substances legislation.

The Options Paper presented a range of alternatives and set out the costs and benefits of the different options. However, the paper did not attempt to comprehensively analyse these, but encouraged stakeholders to provide additional data to help in that analysis. In general, stakeholders appreciated this approach, although unfortunately it only elicited few additional data. Nonetheless, response to the Options Paper has been helpful in framing this report, and references to the submissions on the Options Paper are made, where relevant, throughout this Report.

The options considered in the Options Paper, as well as a number of other alternatives, have been analysed and that analysis is presented in this Part of the Report.



## SECTION 2 THE EXTENT OF THE PROBLEMS

**Terms of reference addressed:** General issue 3.

To assess the extent of the benefit the legislative controls deliver, it is first necessary to consider the nature and extent of the harm being addressed. This is also required by the Terms of Reference.

Consumption of medicines and use of household chemicals are very common. The substances in these products present medium to high risk and, in combination with the high exposure to the public, create a significant hazard. Over two-thirds of the population will use at least one medicine in any two-week period, most of which will be over-the-counter (OTC) medicines. Older Australians are likely to use more than one medicine concurrently, with 83 per cent of those over 85 years of age using three or more medications, and 40 per cent of those using four or more (Australian Bureau of Statistics, 1997).

While comparable data on the extent of use of agvet and household chemicals were not presented, the Review considered that most Australians would have daily contact with one or more of these substances because of their wide range of uses (garden pesticides, veterinary products, household cleaning agents, disinfectants, paints etc).

Given the potential toxicity of medicines and poisons, their wide level of use, and their ready accessibility in the home and other community settings, some adverse effects are inevitable.

The adverse effects arising from the unregulated use of drugs and poisons include accidental (unintentional) poisoning, intentional poisoning, medicinal misadventure, abuse and diversion for abuse. These adverse effects lead to hospital, medical and social costs. Regulation seeks to reduce such adverse impacts and enhance benefits.

### 2.1 Accidental poisoning

Three recent articles published by the Victorian Injury Surveillance Unit group at Monash University Accident Research Unit provide an up-to-date summary of the data on poisoning in that State (Routley, Ozanne-Smith and Ashby, 1996; Ashby and Routley, 1996; Routley, Ashby and Lough, 1999). These articles state that there were over 600 hospital admissions for childhood poisonings per year in Victoria where it was the second major cause of hospital admissions in the age group, after falls. Of the emergency department attendances, 71 per cent were due to medications and 45 per cent of these cases were admitted. Deaths were very rare (Routley, Ozanne-Smith and Ashby, 1996). Poisoning by a chemical accounted for 26 per cent of poisoning admissions and 29 per cent of presentations.

National data from the National Injury Surveillance Unit at Flinders University Research Centre for Injury Studies are consistent, suggesting that the Victorian data are representative of the whole of Australia. For children under five years old, there were 3 775 admissions to hospital because of accidental poisoning in 1997–98, of which 71 per cent were for poisoning by a medicine (O'Connor, 2000; National Injury Surveillance Unit statistics). On these figures, it could be expected that approximately

0.3 per cent of the population of children in this age group will be admitted to hospital annually because of poisoning.

The medical costs associated with poisoning in small children are estimated to be \$29 million to \$36 million per annum. When the indirect costs of lost productivity and lost capacity for productivity are included, the total lifetime costs of these poisoning episodes are estimated at \$46 million to \$58 million (National Injury Prevention Advisory Council, 1999).

The Review also noted that nearly 90 per cent of childhood poisonings occur in the home, mostly from unsupervised access to commonly used products, such as paracetamol or cough mixtures, or household chemicals, such as mothballs, rat bait, or dishwasher detergent (alkaline salts)(Victorian Injury Surveillance Unit data). This is consistent with a recent study of parental awareness that showed that most parents underrate the toxicity of medicines and household poisons (Peterson cited in Syron, 1994).

While recognising that many of these situations are clearly beyond the scope of legislative control, the Review considered that this does not remove the need for legislative control. Rather the Review considered that there was a need for research to establish the extent to which the controls could be improved to reduce this problem. The Review saw controls over:

- access (to address the information asymmetry);
- packaging, particularly child-resistant packaging (to reduce access by children); and
- labelling to better inform the user, and particularly the parent, on how to use and store the product safely, and the appropriate action in the case of poisoning;

as delivering a net **benefit** to the COMMUNITY AS A WHOLE despite the continuing incidence of childhood poisoning.

The Review did, however, identify alternatives to some of the specific elements of the controls that would improve their effectiveness. For example, the Review noted:

- research which indicates that the current warning statements need to be simplified to make them more easily understood and more likely to be read (Ley, 1995);
- anecdotal evidence to suggest that because of the difficulty of undoing child resistant closures, these may not always be re-secured after use, or that some child-resistant closures can be readily opened by small children.

Research should be undertaken to improve the effectiveness of the label information in communicating the precautions to be taken when using medicine and poisons. Research is also needed to develop more user-friendly, but effective, child-resistant closures. Education of parents about safe use and storage of medicines and household chemicals can also play an important role in preventing poisoning. However, the Review does not see these measures as alternatives to the current controls but rather that they will enhance and complement the current controls.

While definitive information is not readily available to establish why such poisonings occurred (e.g. was the child-resistant packaging left undone, was it ineffective or had the householder repackaged the chemical?), it is not unreasonable to assume that the number of poisonings would be considerably higher without such controls. These benefits are discussed in Section 5. The collection and analysis of data on the reasons for poisonings could, in theory, enable the effectiveness of the controls to be more specifically evaluated. This sort of exercise would require a time-frame and level of resources which it was outside the capacity of this Review to undertake.

## **2.2 Deliberate poisoning**

About two-thirds of poisoning in adults is intentional. Benzodiazepines, alcohol and tricyclic antidepressants were among the leading agents at all levels of severity. Paracetamol is also a significant agent in suicide attempts. It is implicated in 40 per cent of cases in the United Kingdom (Prince et al., 2000) and has an insidious side effect in that those who apparently recover, can sustain permanent liver damage if treatment is not given within a short time of the poisoning incident.

The health cost of suicide and self-inflicted injury is estimated at \$72 million and the total direct and indirect cost is estimated at \$2 billion (Pharmacy Guild of Australia and Pharmaceutical Society of Australia) but only a proportion of this is related to ingestion of medicinal products. It has not been possible to separate the cost related to scheduled substances.

However, Whitlock (1975) found that the number of Australian suicides fell when access was restricted following the introduction of stringent restrictions on the Australian Pharmaceutical Benefits Scheme which significantly reduced the number of prescriptions for barbiturates. While in some cases other medications were substituted for barbiturates (benzodiazepines and tricyclic antidepressants), the acute toxicity of these substances was less than that of barbiturates.

Prince et al. (2000) reported positive outcomes (in relation to intentional poisoning with paracetamol) from United Kingdom restrictions on the sale of paracetamol that were introduced in September 1998. The sale of paracetamol was restricted to 8g per event without the approval of a pharmacist. Since that date, the frequency of severe damage to the liver (taken from hospital data) has been substantially reduced. The Research considered a range of factors that might also have led to that reduction, but concluded that, overwhelmingly, the major contributing factor was the controls placed on the ready access to large quantities of paracetamol.

## **2.3 Medicinal misadventure**

Drug-related medicinal misadventure is a major source of morbidity and sometimes mortality. A number of submissions referenced studies that provide information about the cost of misadventure related to the use of medicines.

For example a number of studies point to a significant decline in the level of serious kidney damage after controls on the use of phenacetin in OTC medicines were introduced (Duggin, 1996; Nanra, 1993; Gleeson, 1988). Note that phenacetin is now a prescription only medicine.



More recent data estimate the total cost to the health system from medicinal misadventure incidents as \$401 million (Mathers and Penm, 1999). Roughead (1999) estimated that at least 80 000 hospitalisations annually are medication related. She estimated the cost of these at \$350 million in hospital costs alone. Based on her analysis, she concluded that half of these are potentially preventable.

Comparison of these admissions with those where there was a primary diagnosis of diabetes (17 488), congestive heart failure (33 477) and asthma (50 522) gives some perspective to the size of the problem (Roughead, 1999).

Not surprisingly, given their higher toxicity, the potential for interactions and the medical conditions being treated, the bulk of these hospital admissions relate to medicines in *Schedules 4* and *8* (Dartnell et al., 1996; Blackbourn, 1991; Hewitt, 1995).

One small study (Roughead, 1999) found that 10 per cent of hospital admissions related to non-steroidal anti-inflammatory drugs (some of which are *Schedule 2* or *3* medicines). The Secretariat of the Adverse Drug Reactions Advisory Committee relayed that, although there is a significant number of adverse drug reports involving *Schedule 2* and *3* medicines, the proportion is small in comparison to prescription medicines. Of those OTC medicines involved in hospital admissions and in reports of adverse reactions, the most significant are analgesics, particularly aspirin, paracetamol and non-steroidal anti-inflammatory drugs (Gleeson, 1988; Larmour et al., 1991; Stanton et al., 1994; Ng, 1996).

Given the potential harm which could result from inappropriate use or drug interactions and the range and complexity of the substances involved, it is difficult for the average consumer to understand when and what precautions need to be taken. Several submissions have also made the point that one of the significant gaps in consumers' information is the capacity to know when they do not know. There is clearly a presumptive role for mechanisms to address such information asymmetry. This could be achieved in a number of ways – by education (general or specific at the time of supply) and by provision of appropriate written and oral information or a combination of these, as well as by introducing informed intermediaries under legislation.

In addition, the Review noted that there are a number of potential drug interactions which can significantly limit the effectiveness of particular treatments. This would add to treatment and other costs for consumers and governments. For example, enzyme-inducing drugs may cause failure of combined oral contraceptives by increasing their metabolism and clearance. This effect is also well established for a number of anti-epileptics, e.g. griseofulvin and rifamycin (Martindale 32). In these circumstances, unless alternative contraceptive measures are taken, pregnancy may result. The review was unable to identify the extent of the costs which flow from such interactions.

## 2.4 Dependence and diversion

Some medicines can cause physiological and psychological dependence. While these medicines have a number of beneficial effects (e.g. relief of pain, anxiety) they are frequently abused. These may be used alone or in combination with illegal drugs (e.g.

heroin, cannabis). To provide a general perspective on the problem, Table 2.1 sets out the extent to which medicines are used for non-medical purposes, as identified by the National Drug Strategy Household Survey 1995.

**Table 2.1: Overview of drug use in Australia 1995**

Drug	Drugs ever tried (for non-medical purposes) %	Drugs recently used (for non-medical purposes) %	Tried prior to age 16 years %	Concurrent use with alcohol %
tobacco	63	26	–	–
alcohol	86	76	–	–
marijuana	31	13	24	–
<b>analgesics</b>	<b>12</b>	<b>3</b>	<b>46</b>	<b>21</b>
<b>tranquillisers</b>	<b>3</b>	<b>0.6</b>	<b>22</b>	<b>46</b>
<b>steroids</b>	<b>0.6</b>	<b>0.2</b>	<b>22</b>	<b>40</b>
<b>barbiturates</b>	<b>1.2</b>	<b>0.2</b>	<b>23</b>	<b>70</b>
heroin	1.4	0.4	14	–
<b>amphetamines</b>	<b>5</b>	<b>0.4</b>	<b>7</b>	–
at least one illicit	37	17	–	–
injected illegal drugs	1.8	0.6	–	–

**Note:** Medicinal drug data have been highlighted in **bold** type for ease of reference.

**Source:** National Drug Strategy Household Survey (1995)

These data indicate that there is a reasonably significant use of medicines for non-medical purposes. It is relevant perhaps to note that the highest level of such abuse is in the area of analgesics, products that are generally widely available in the community. Of particular concern is the high proportion of people under 16 years of age who have used readily available medicines, such as analgesics (e.g. from a supermarket), for non-medical purposes. The use of medicines in combination, particularly with alcohol, is also of concern.

There are other medicines, which are diverted to illicit manufacture. For example, pseudoephedrine, which is a common ingredient in OTC cold and flu medicines, can be used to manufacture amphetamines. There have been a significant number of thefts of pseudoephedrine from wholesalers and pharmacies.

Police also advise that illegal manufacturers pay a premium for large quantities of pseudoephedrine tablets that have been removed from their blister packaging – such quantities are generally obtained by a person visiting a number of pharmacies. The Review noted that in response to such problems, the National Drugs and Poisons Schedule Committee has recently introduced stricter controls on pseudoephedrine products, with large packs moving from *Schedule 2* to *Schedule 4*.

Australia is a party to three United Nations Conventions (Single Convention on Narcotic Drugs, Convention on Psychotropic Substances, and Illicit Trafficking Convention) which establish an international system of controls to permit access to these medicines while limiting their abuse and diversion. The Conventions require Australia to put in place certain controls, including limiting supply to prescription for many of these substances and, for certain substances, to monitor their use.

For some substances, there is no requirement in the Conventions for supply to be limited to a pharmacy or on the prescription of a medical practitioner. These substances include combination analgesic products containing small doses of codeine and pseudoephedrine that are used to provide relief from a number of common minor conditions (e.g. headache, colds, hayfever) which can be safely self-diagnosed. However, quite apart from abuse and diversion problems, these substances can also cause harm (e.g. gastric bleeding, interactions with anti-hypertensive drugs) when inappropriately used. In general, products containing these substances are included in either *Schedule 2* or *Schedule 3*, where professional standards require that pharmacists satisfy themselves that there is a genuine need for these products.

## 2.5 Costs

Dollar costs to the health system from each of these, as assessed by the Australian Institute of Health and Welfare, are set out in Table 2.2.

**Table 2.2 External causes of injury health system costs (\$m) and PYLL-75 by sex, 1994**

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

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

**Source:** Mathers and Penm (1999)

Total cost of injury by poisoning has been estimated as \$600 million, including direct costs of over \$150 million (Moller, 1998). Even if this estimate is, say, as much as even double the true value, it is a clearly a substantial burden. Of course these data reflect the present system, not the circumstances that would apply in their absence or under alternative arrangements.

## 2.6 Availability and quality of data

The Review noted that there is no systematic and efficient system of collecting and analysing data that would identify the extent of the problems caused by misuse and abuse of medicines and poisons in Australia.

Such information would need to include:

- the volume of medicines and poisons sold in Australia, differentiated by class or products; and
- specific data on the principal source of harm for morbidity and mortality data.

It would be particularly useful if the quality of data from Poisons Information Centres were improved by ensuring consistency in the way in which data are collected. The Review also noted that lack of resources meant the data currently recorded by Poisons

Centres is not collected in a way that enables any comprehensive large-scale analysis to be done of the reasons and circumstances in which poisonings occur.

The Review also noted that sales volume data for medicines and poisons could be used with other information to help identify the extent to which the use of a particular product results in harmful consequences for the consumer. For example, if 20 hospital admissions resulted from use of a product that had sold over 100 000 packs, this could indicate a far more significant problem than would 20 hospital admissions resulting from use of a product, of which over two million packs had been sold. The degree of harm caused to individuals involved in such hospital admissions would of course be another significant consideration in assessing the level of harm associated with use of a particular product.

Sales data are generally not available to government or come at a considerable cost. There are also only limited resources allocated to identify the harm caused by drugs and poisons. Recent studies (e.g. Roughead) have concluded that many hospital admissions arising from the use of medicines are avoidable. But, without more specific data to identify the harms and their costs, as well as the reasons for them, appropriate and targeted cost-effective measures to overcome them are difficult to design.

As indicated, the sort of information outlined above is either not available, or not readily extracted from the currently collected health data. Even where there is funded research looking at particular aspects of the harm caused by improper use of medicines and poisons, there is no systematic means of ensuring such research is fed into a national database. Further, data from different sources may not be compatible.

A national database and a national strategy for collecting such data would enable governments to better evaluate the costs and benefits that accrue from particular controls and other strategies. This in turn should lead to more targeted measures to reduce the harms at the minimum level of restriction to industry, consumers and governments.

## **2.7 Summary**

In summary, three general classes of harm have been identified, which occur in distinctly separate populations. These are accidental poisoning, most common in children; medicinal misadventure, most common in adults (particularly the elderly) from prescription medicines; and suicides and self-inflicted injury, most common in working-age adults. Diversion for abuse or use in the illicit manufacture of drugs, is also a cost to public health.



## SECTION 3 IMPLICATIONS FOR NATIONAL COMPETITION POLICY OF THE PRESENT LEGISLATIVE FRAMEWORK

**Terms of reference addressed:** General Review Issues 2, 3, 4, 5 and 7.

### 3.1 Objectives

When drugs, poisons and controlled substances legislation was developed, its primary objective was to redress what is now termed the market failure arising from asymmetry of information (knowledge and understanding) of the risks and hazards associated with consumer access to and use of poisons which lead to increased incidence of accidental poisoning and medicinal misadventure. With the increase in the range of substances the community uses and the expansion of their use, the number of substances subjected to the controls increased, as did the range of controls. In many cases the lack of other suitable legislative vehicles meant that drugs, poisons and controlled substances legislation was used for controls which went beyond the original scope of the legislation. In the last decade or so legislation has been enacted to address some of these specific areas, particularly at a national level.

#### Step 1

Clarify objectives of legislation

#### 3.1.1 Objectives of the overall framework

The legislation under review, along with more recently introduced mechanisms and related legislation, provide a framework aimed at promoting and protecting the health and safety of humans and animals in relation to the use of drugs, poisons and controlled substances. However, no comprehensive analysis of the relationship between these legislative instruments and drugs, poisons and controlled substances legislation has been undertaken.

While not specifically listed for consideration, the Review is required to consider related legislation with a view to improving the efficiency of the legislative framework. It is therefore helpful to consider the objectives of some of the other legislative instruments in this overall framework. For example, the objectives of the *Therapeutic Goods Act 1989* (Section 4) are to:

... provide a national system of controls relating to the safety ... of therapeutic goods supplied in Australia ...

and the *Agricultural and Veterinary Chemicals Code Act 1994* preamble states that:

Recognising (a) that the protection of the health and safety of human beings ... is essential to the wellbeing of society and can be enhanced by putting in place a system to regulate agricultural chemical products and veterinary chemical products;

and the objectives of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Section 3) which state that:

... aiding in the protection of the Australian people and the environment by finding out the risks to ... public health and to the environment that could be associated with the importation, manufacture or use of the chemicals.

### **3.1.2 Objectives of drugs, poisons and controlled substances legislation**

Although the objectives are not generally stated explicitly in the drugs, poisons and controlled substances legislation, they can be deduced from the legislation and surrounding parliamentary deliberations as being: to provide a legislative framework for promoting and protecting the health and safety of humans and animals, in relation to the use of drugs, poisons and controlled substances.

Drugs, poisons and controlled substances have a variety of uses and, when used appropriately, can have considerable benefits. However, as they are often toxic substances, their use or misuse can lead to significant costs for the individual (including death) and the community (e.g. hospital, medical and social costs).

The controls currently imposed by drugs, poisons and controlled substances legislation have contributed to the objectives of the broader overall framework of legislation in this area of protecting public health and safety by:

- reducing unintentional poisoning, of which most identified cases are acute poisonings in childhood;
- reducing intentional poisoning, most of which are adult suicides or attempted suicides;
- contributing to quality use of medicines by reducing medicinal misadventure (much of which is believed to be related to prescription drugs, particularly in the elderly) and facilitating appropriate selection and effective use of medicines; and
- reducing abuse and diversion for abuse.

These are the objectives accepted by the Review. As indicated, these objectives can be seen as deriving from concern over market failure in this field. Basically, many of the products are complex in their effects, consumers lack familiarity with these effects, risks to individual health from incorrect use can be serious and effects on third parties can also be important. For these information and spillover reasons, free markets may be perceived as providing less than optimal outcomes for society in relation to the use of such substances. The objectives of legislation are derived from seeking to overcome these market failures.

In responses made to the Review, there was general agreement with these objectives.

## 3.2 Extent of the restrictions

The extent to which the restrictions impact on competition goes to the heart of National Competition Policy. Those controls in the legislation under review that principally impact on competition can be categorised as restrictions that affect market access and restrictions that affect market (or business) conduct.

### Step 2

Identify nature of restriction on competition

### 3.2.1 Market access

The system of ‘scheduling’, as applied by the legislation under review, in conjunction with legislation for professional activities or licensing, restricts those who may compete to supply drugs, poisons and controlled substances to the public. This is a process of restriction on who may compete for market access.

Access is restricted to:

- prescription only medicine (human and animal *Schedules 4* and *8* and SUSDP Appendix D);
- sale by or under the supervision of a pharmacist (*Schedule 3* and *Schedule 2*);
- sale to an authorised person (*Schedule 7*);
- significant restrictions (SUSDP Appendix G); or
- prohibition or significant restrictions on supply (*Schedule 9* and SUSDP Appendixes C and J).

There are also restrictions through licensing, which limit legal supply of a substance to those so licensed. Restrictions on who may supply some or all of a market represent a restriction on competition. This means there are fewer competing producers and/or suppliers able to contend for custom and able to compete over the terms of supply, including price and other aspects of the products or services. For instance, supermarkets, health food stores, general convenience stores etc. are prohibited from competing with pharmacies for scheduled substances.

In considering the restrictions on access in drugs, poisons and controlled substances legislation, the use of schedules mandates supply of many such products through professional service providers such as general practitioners, pharmacists and veterinarians in various ways, depending on the product concerned. Also, all therapeutic goods and agvet chemicals are required to be on the relevant register<sup>2</sup> before being supplied in Australia. For certain controlled substances (i.e. those likely to be abused or used illicitly) there are also restrictions on import, export and

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<sup>2</sup> Australian Register of Therapeutic Goods (ARTG) under the *Therapeutic Goods Act 1989* and the National Chemical Registration Information System (NCRIS) under the *Agricultural and Veterinary Chemicals Code Act 1994*. To be included on these registers the products must meet certain safety and other standards (e.g. quality and efficacy).



manufacture.<sup>3</sup> This means the Review must also take account of restrictions on access imposed by other legislation within the legislative framework.

### **The schedules**

Restrictions on access according to schedule placement are imposed by State and Territory legislation. These restrictions are intended to ensure users have been provided with sufficient information to enable safe and effective use (in economic terms, to address information asymmetry), although the aim goes further than just the possession of information. A person must have sufficient information, understanding and skill to select and use a product safely and effectively. Access is restricted where general knowledge and label information are not sufficient to overcome the consumer's lack of knowledge. Generally the level of restriction increases with the level of knowledge and expertise required for safe and effective use of the product. Additional restrictions are imposed where the substance is likely to be diverted for abuse or manufacture of illicit drugs.

The controls specify who may sell or supply, which customer may have access, and the amount and form of the product supplied – all based on the level of risk potentially associated with use of the product. These restrictions generally flow from the schedule in which a substance is included or, in some instances, the SUSDP Appendixes (e.g. Appendix C). The National Drugs and Poisons Schedule Committee (NDPSC) determines the schedule in which a substance is included. Adoption of the NDPSC decisions by the States and Territories then determines the controls that apply to any given substance and the products containing that substance. The restrictions that apply to the various schedules are discussed individually in Section 4.

### **Licensing of sellers**

A further elements of access restriction is the licensing of producers and sellers of scheduled medicines and agvet and other chemicals. Licensing complements other controls on access by ensuring that those supplying or dealing with the substances have the necessary skills and competencies to produce or handle the products safely and effectively and the probity to comply with the relevant regulation. The need to obtain a licence limits market entry to those who meet the necessary requirements. Details of when the benefits of imposing licensing requirements outweigh the costs are discussed in Section 5.

Beyond the licensing of those suitable to supply certain substances to the public (e.g. pharmacists, medical practitioners), scheduling dictates some ancillary licensing linked to facilities, manufacture, distribution and to training for fitness to sell agvet poisons and related substances. In all cases, legislation operates to reduce the range of persons who can freely participate in the supply of these products.

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<sup>3</sup> Customs (Prohibited Import) Regulations, Customs (Prohibited Export) Regulations and the *Narcotic Drugs Act 1975*

### 3.2.2 Business conduct

Other restrictions in the legislation under review limit competition by controlling the permissible forms of competition in a range of business behaviours. These include advertising, supply, labelling, packaging, storage and handling, supply of promotional samples, record keeping and reporting.

#### Advertising

Restrictions on competition here operate by prohibiting direct to consumer (DTC) advertising for prescription and some *Schedule 3* medicines, and restrictions on the disease states for which a medicine may be advertised to the consumer.

Advertising is controlled by:

- Scheduling in the SUSDP with its adoption in State and Territory legislation<sup>4</sup>, that prohibits advertising of prescription only medicines (*Schedules 4* and *8*, both human and veterinary) and some pharmacist only (*Schedule 3*)<sup>5</sup> medicines;
- restrictions on the types of diseases/conditions for which medicine may be advertised. However, these controls are often very dated and rarely used
- The *Therapeutic Goods Act 1989* and Regulations also include prohibitions on advertising prescription medicines and those *Schedule 3* medicines not included in SUSDP Appendix H. The *Therapeutic Goods Act 1989* underpins the Therapeutic Goods Advertising Code (TGAC), which restricts the disease conditions for which a product may be advertised. The TGAC is a coregulatory code managed, in the main, by the medicines industry itself, with occasional recourse to the Therapeutic Goods Regulations when the self-regulatory arm of the coregulatory arrangement fails. States and Territories duplicate these controls to varying degrees. The complexity and confusion caused by this duplication adds to costs for industry.

Limits on advertising of medicines reduce competition by narrowing the range of behaviours permitted by existing or prospective suppliers in the field. Firms that wish to expand market or market share through advertising activity are not able to operate with full commercial flexibility.

#### Supply

Restrictions on competition operate where certain forms of supply are restricted, such as supply of medicine samples, hawking, supply through vending machines, and interstate supply of *Schedule 8* medicines where the medical practitioner is not registered in the State or Territory from which the supply is made. A number of submissions to the Review also saw a need for extended controls on other methods of supply particularly mail order pharmacies and Internet pharmacies.

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<sup>4</sup> Not all jurisdictions adopt the SUSDP advertising restrictions although all have similar controls.

<sup>5</sup> All jurisdictions have not yet adopted Appendix H which exempts certain products containing the substances listed from the advertising prohibition.

## Other controls

There are also controls on labelling, packaging, storage and handling, and there are requirements for record keeping and reporting. These controls limit the acceptable forms of competition and they raise costs so that, at the margin, some competitors can no longer be sustained in the market place and some consumers find purchases beyond their reach. For those wishing to participate in this market, the costs associated with these controls may be a barrier to entry.

## Conclusion

The Review concluded that provisions of the drugs, poisons and controlled substances legislation and regulation restrict competition, both in reducing market access to, and in market conduct in, the supply of such substances. The controls that restrict competition represent an extensive framework for regulating drugs, poisons and controlled substances, and operate through a complex system of scheduling, licensing, information control and restriction on the manner and means of supply.

## 3.3 Effect on competition and the economy in general

### Step 3

#### Analyse effects of restriction

The restrictions under review clearly impede competition in markets for therapeutic and related goods. Alternative manufacturers, wholesalers and retailers are not able to enter the market beyond those prescribed or licensed for the purpose. This reduces price competition and non-price competition in terms of access, convenience, service etc.

Restrictions on advertising direct to the consumer reduce the information, both persuasive and functional, that can be provided to consumers. This restriction also reduces the capacity of suppliers to promote and differentiate their product by advertising in a manner that is common in most business – including some product areas with clear consequences for public health and safety. For example, it is possible to promote a vehicle on the basis of its speed and acceleration performance even though excessive speed is known to be a major factor in vehicle accidents with obvious public health implications.

Other restrictions (e.g. storage) may raise costs for all market participants. While such restrictions may apply across the board to all suppliers, the overall increase in costs can reduce the number of competitors at the margin. Some firms that could survive in a lower cost-structure environment fall by the wayside with a higher cost base imposed. Their own market share becomes inadequate to recoup costs. These costs could also deter some companies from entering the market.

In general, competition keeps costs and prices down and encourages innovation in service, quality and products. With reduced competition in the industry, the sector's potential size and dynamism are likely to be reduced; hence its contribution to the national economy may be smaller than it could be with increased competition. However, no evidence permitting precise and detailed quantification of the effects of industry regulation on the level of economic activity were available to the Review.

Some submissions considered that increased competition in this field might not be as beneficial for the economy (quite apart from broader interpretation of the public interest) as standard economic principles usually allow. They pointed particularly to high levels of concentration among potential competitors in a deregulated environment (e.g. supermarkets), which may mean that expected price reductions might not eventuate.

However, the Review noted that the 1999 Report of the Joint Select Committee on the Retailing Sector found that the retail sector was highly competitive with consumers benefiting through lower prices. The Committee found that retail integration and economies of scale afforded the major supermarket chains advantages in pricing practices and that rigorous competition between supermarkets ensures that prices are competitive across the full range of products traded.

Relaxation of advertising restrictions might simply increase supply costs without price benefit as oligopolistic firms chase market share.

It should be noted that, even where the products are homogeneous and straightforward and where producers are unregulated in relation to training and market entry (e.g. barley or wheat), divergences can occur in evaluating public benefit arising from regulation in National Competition Policy reviews (e.g. the contrast in various state reviews of barley marketing regulations). This is even more likely to be the case for markets with immense product complexity, major public health concerns and with an overlay of oligopolistic industries whose market entry and conduct are heavily regulated (e.g. pharmaceutical manufacturers). In these circumstances even general market analysis is complex, let alone adding the further elements of evaluating non-market criteria, such as equity.

The Review acknowledges that restriction on competition can come at some cost in efficiency in some instances (e.g. excluding potentially lower cost competitors). In evidence provided to the Pharmacy Review, the Pharmacy Guild calculated that prevention of competition from supermarkets in relation to sales restricted to pharmacies might cost consumers something in the order of \$97 million annually through foregone economies of scale. Accepting that such estimates are subject to challenge, the even harder task is attributing such losses to specific controls (e.g. scheduling versus pharmacy ownership versus professional licensing). The almost impossible further task is then matching these attributes against other public interest criteria, such as personal trauma or tragedy.

The Review's approach has been to respond to these considerations by proceeding on a case-by-case basis, in relation to individual controls, in terms of the specific issues put to it for resolution.

### **3.4 Costs and benefits assessment**

It is not possible to definitively assess all costs and benefits quantitatively, as fully adequate empirical analysis and data are not available. Nevertheless, costs and benefits are identified and compared across alternatives and form a basis for recommendations. The Review's approach is to do this in

**Step 4**

**Analyse  
benefits and  
costs**

relation to individual controls, but some general discussion is also provided.

In general, the costs of controls include:

- costs to government in developing, administering and enforcing legislation;
- costs to government and individuals related to harms, including hospital, medical and social costs;
- costs to industry due to increased cost of market entry and business conduct; and
- costs to consumers through denial of access to some products and increased prices due to reduced competition.

Benefits of the controls include:

- benefits to governments (and hence taxpayers) from reduced hospital and medical costs through reduction of inappropriate and unsafe use;
- benefits for the community through safer and more cost effective use of medicines;
- benefits to the community through improved health outcomes because of improvements in professional standards. (In this case the benefit is dependant on amendments to legislation and procedures regulating professional practice which are outside the Terms of Reference for this review); and
- benefits to the community though reduced illicit use of medicines.

The Review has identified a number of areas in relation to individual controls where costs can be reduced by:

- removing some controls;
- imposing less restrictive controls; and
- coregulation.

But each alternative may have its own new costs and benefits and these have been factored in individually when assessing the alternatives. On the one hand, benefits can be achieved through the flexibility that non-prescriptive measures can provide in terms of promoting innovative and cost effective approaches to meeting identified public health outcomes. On the other hand, there can be costs to industry if there is uncertainty or confusion about what needs to be done to meet identified public health outcomes.

For some controls, where alternatives do exist to redress information asymmetry and achieve the objectives (e.g. professional regulation), recommendations are intended to ensure that the most effective mechanism is applied.

### **Overall degree of cost and benefit**

One approach would be to take the cost–benefit analysis for each control, seek the optimal policy, and aggregate the net benefit for each policy to estimate the total gain

to society from appropriate intervention. However, such an approach is not feasible in this area.

Consider, for instance, the individual issue of controls on advertising prescription medicines directly to consumers. Case study 1, below, provides helpful data from United States experience relevant to this issue. Putting aside the many differences in public health systems between the United States and Australia, it is notable that even in United States terms there are powerful offsetting costs and benefits of their relatively unique experiment in direct to consumer drug advertising. Attaching dollar values to each of these benefits and costs so as to deduce a net balance on this one control is not simple and the data are not available. Instead qualitative judgements must be made to form the ultimate basis for review of this individual control.

**CASE STUDY 1: Assessing drug advertising**

The complexities in assessing the consequences of liberalisation of advertising controls for poisons, drugs and controlled substances are well illustrated by United States experience.

In August 1997 the United States Food and Drug Administration permitted drug makers to specify the uses of their prescription remedies in their radio and television advertisements. The pharmaceutical industry could use their direct to consumer marketing for prescription medicines.

Some of the relevant industry facts since that time are:

- direct to consumer advertising spending has risen from US\$844 million in 1997 to an estimated US\$2 300 million in 2000;
- medication and proprietary remedies have broken into the top five categories of advertising expenditure – along with cars, retailing, movies and financial services;
- polling data show that 21 per cent of consumers found ads for prescriptions always unclear or confusing;
- marketed products, such as the allergy remedy Claratyne, the anti depressant Prozac, and Premaratin (for osteoporosis), have had soaring sales; and
- one-third of adult Americans polled had spoken to their physicians about specific advertised medicines.

However, by the end of 1999:

- marketing to professionals still dwarfs direct to consumer expenditure by a ratio of 10:1 in almost all therapeutic areas;
- consumer marketing by firms has been largely focused on only five therapeutic areas: allergies, arthritis, contraceptives, diabetes and HIV;
- only seven of the top 20 pharmaceutical companies were supporting more than two products with direct to consumer campaigns;
- the product range supported by direct marketing had fallen in 1999 to 48 products, down from 51 in 1997; and
- of 163 million adult Americans who had seen direct to consumer pharmaceutical advertising, 13 per cent were moved to speak to their physician about their conditions for the first time.

The adaptation of these insights to Australia and to long-term outcomes makes the assessment even more complex.

**Source:** Aitken and Holt, *The McKinsey Quarterly*, 2000(2), 82–91.

### 3.5 Alternatives

The detailed analysis of each control that is applied through drugs, poisons and controlled substances legislation is in Section 5, and identifies possible alternatives to the existing controls. These alternatives include removing current controls, providing education and information in place of current controls, industry self-regulation and coregulation.

**Step 5**

**Consider alternatives and recommend**

The submissions made to this Review fell into two groups – those from industry generally sought self or coregulation where change was proposed.<sup>6</sup> No-one sought complete deregulation of the market. The submissions from governments, generally the agencies responsible for administering the legislation, and the professions, on the other hand, generally supported the status quo, arguing that it had served Australia well, and there was insufficient evidence for change. However, there was little or no economic analysis for any of the arguments and, as required by National Competition Policy, it is up to those arguing for retention of the controls to establish their benefits.

Some professional groups were highly critical of self-regulatory and coregulatory arrangements, such as the recent deregulation of some *Schedule 3* advertising. They pointed out that, in their view, the advertising that had resulted was high on promotion and low on information, creating the opposite situation to that which might justify the argument that the advertising was in the public interest.

### 3.5.1 Options for reform of individual controls

Few submissions to the Review suggested or even discussed any options, other than maintaining the status quo, and increased efficiency through uniformity and improved integration with related legislation.

The Review considered that, irrespective of any unanimity amongst stakeholders, each control under existing regulation required re-examination in terms of its net benefit to the community as a whole and how it compared to alternative ways of achieving the objectives. This is what is required for a National Competition Policy review in any case.

The presumption in a National Competition Policy review is to favour the least restrictive option, unless evidence showing a net community benefit from greater controls can be produced. This contrasts with a common presumption in the public health field, which is to avoid undue risks and to seek protection of health and safety as the absolute priority. These two approaches are conditioned and instinctive, as well as each having its own knowledge and discipline base. The Terms of Reference for this Review reflect elements of both.

Resolution of these approaches is to be found in the public interest provisions of National Competition Policy. These acknowledge the possibility of market failure or non-market criteria (e.g. equity), as relevant in justifying divergence from free and open market competition in any specific field. In the area of drugs and poisons the Review has stressed that the combination of asymmetric information in the presence of often irreversible and tragic risk create conditions where simple unfettered market competition will be both inefficient and inequitable.

It bears repeating that the products under consideration are complex in their effects, consumers lack familiarity with these effects, risks to individual health from incorrect

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<sup>6</sup> As is stated on a number of occasions throughout this report there were many controls where no changes were suggested or only such changes as were necessary to achieve uniformity or improved efficiency through integration with related legislation.

use can be serious and sometimes irreversible and fatal, and effects on third parties can also be important.

The Review also considered whether generic regulation would be appropriate to deliver an optimal regulation regime specific to the drugs and poisons area. The Review noted that generic regulation, such as consumer protection laws or torts law, only comes into effect after the event (i.e. they respond to adverse occurrences after they have occurred). The Review considered whether their application would serve as an adequate deterrent to short-sighted, wilful and opportunistic risk-taking behaviours or lead product suppliers to take adequate measures to minimise simple accidents and medicinal misadventure.

The Review noted a number of codes of practice and codes of conduct which industry associations have adopted and the mechanisms for ensuring compliance with those codes. Consideration was also given to coregulation. For example, the coregulatory controls for advertising under the *Therapeutic Goods Act 1989* were considered both as alternatives to the current advertising controls and as models of a coregulatory approach in other areas.

Further, within the spectrum of area-specific options available, the Review concluded that only limited reliance will be possible in relation to 'light-handed' options, such as education, as these too cannot usually be complete and comprehensive across the population. Many individuals remain impervious to such 'messages' so that more direct and mandatory approaches may be needed as well as, or instead of, such approaches. Nonetheless the Review considered that such measures could improve the effectiveness of legislative controls and, in very limited circumstances, may remove the need for particular controls (e.g. see Advertising in Section 5).

The focus in this Review has been to concentrate upon regulatory reforms that minimise any restrictions on competition and costs on business.

The Review also considered a number of non-regulatory means to improve the effectiveness of the controls. These approaches include professional standards and cooperative approaches with industry such as through development of codes of practice.

### **Professional standards**

The key to the effectiveness of the controls on drugs, poisons and controlled substances in redressing the information asymmetry between consumers and industry, is the assumption that health professionals will ensure consumers have sufficient information on the safe and effective use of medicines and prevent abuse and diversion to illicit drug manufacture. The various health professional organisations have codes of practice and standards that relate to the way in which professional services should be supplied. In particular, these relate to the way in which professional services deliver a benefit through counselling and supervision.

A requirement to counsel is rarely included in drugs, poisons and controlled substances legislation and then only in relation to *Schedule 3* medicines. However, submissions included a strong presumption that the restrictions imposed by the legislation should lead to appropriate counselling, not just for *Schedule 3* medicine,



but for other scheduled medicines as well. In general, compliance with professional standards and codes of practice are managed through those Acts that regulate professional practice (e.g. Pharmacy Acts). The suggested options look at improving the effectiveness of the links between compliance with professional standards and the controls imposed by drugs, poisons and controlled substances legislation.

From the limited data available, the quality use of medicines appears to deliver benefits by reducing hospital and medical costs resulting from medicinal misadventure and by enhancing the cost-effective use of medication. This has been taken into account when considering alternatives to individual controls. In particular, one option to the current restrictions on advertising prescription medicines to the consumer puts forward a scheme that would enable a more flexible approach and is consistent with the education strategies of the quality use of medicines policy.

### **Cooperative arrangements with industry**

The Review considered coregulatory approaches as options for achieving the objectives in relation to several controls. Such measures seek to minimise the costs to industry and government while maintaining appropriate levels of control on substances with the potential for misuse. For example, the Review identified a range of different controls that apply to the supply of clinical samples to health professionals across the jurisdictions. After considering these controls and the risks they were intended to address, the Review concluded that the objectives of the controls could be achieved by development of an industry code of practice, which was underpinned by legislation to ensure compliance.

Again, the Review has further considered a ‘package’ of alternatives, embracing a mix of educative, incentive and regulatory interventions against the individual controls (see Section 5 for discussion).

Under this approach each control is reviewed individually, however, their complementarity must also be stressed. For example, the controls on packaging (e.g. child-resistant closures), labelling (e.g. warning statements), and access (from a pharmacist who can give advice) seek, amongst other things, to minimise the risk of accidental poisoning in children. Achieving the objective may not be attributed to any single control, but instead to the suite of controls.

Moreover, for each control there is clearly no presumption that, even though the free market is rejected in most instances as a viable option because of market failure in this area, the status quo is therefore the necessary alternative. Rather, various degrees of restriction, based on a tailored approach to the public interest, are seen as the guiding principle for detailed recommendations as appropriate in this Review.

The options suggested against the individual controls elsewhere in this Review include a combination of these approaches. There are limited data to enable a conclusive cost–benefit analysis of the various options to be undertaken. Therefore analysis of the options needs to be based on a number of assumptions and judgements. These include the assumptions that:

- health professionals will and do take steps to redress the information asymmetry between consumers and industry; and

- consumers will follow the advice of health professionals, read and follow the directions and warnings on labels and replace child-resistant closures properly.

Also, some proposals will be dependent on changes to other legislation, acceptance of responsibility by other government organisations or professional groups and the willingness of various groups to work together. Where these are unlikely to occur, there could be reduced benefit in pursuing these options.

### 3.5.2 Options for improving efficiency

Consistent with its Terms of Reference, the Review considered means of improving the efficiency of the regulatory controls over drugs, poisons and controlled substances. Improved efficiency should reduce costs to industry and lead, in turn, to increased competition with benefits to consumers as well as the community as a whole. Greater uniformity in the regulatory controls across jurisdictions was identified as the most significant means through which to achieve greater efficiency.

The Review also examined ways in which greater integration of drugs, poisons and controlled substances legislation with other legislation covering these areas could lead to greater efficiency.

A second approach is simply to compare whole alternative systems and deduce their aggregate difference in net public benefit and cost for each individual system component. Thus one submission to this Review compared data from some United States and Australian hospitalisation rates for pharmaceutical-related admissions, in which Australian rates were found to be lower. Hospital admission costs were assigned and used as a savings measure derived from scheduling, advertising and pharmacy ownership provisions in Australian regulation.

The resultant estimate was a net annual public benefit in the range of \$78 million to \$140 million. However, the estimate depended crucially upon the assumptions that:

- abolition of scheduling in Australia would lead to reclassification of a large number of *Schedule 3* medicines as prescription medicines; and
- all United States–Australian hospitalisation differences were attributable to tighter Australian pharmacy regulation.

Unfortunately, the reclassification estimate is hypothetical for Australia and the United States–Australian differences may also owe much to excluded differences ranging from other direct regulation (e.g. pharmacy professional training) through medical and hospital systems to demographics and social attitudes. In addition, these estimates ignored a number of other factors including the very different health-care system, including the comprehensive subsidisation of medicines and medical treatment in Australia.

However, this Review’s task is to examine each element of the Australian approach to regulating drugs, poisons and controlled substances. The aggregate United States evidence cannot provide detailed guidance on individual controls for this purpose.

The Review therefore concluded that, in relation to assessment of the balance of costs and benefits in regulation in this area, a case-by-case review of individual controls

was required (see Section 5). Of necessity this is often a qualitative as much as quantitative exercise, given the limited array of hard analytic cost–benefit data in this field and qualifications that apply to some of the available data. Of course, interdependencies between individual controls and, indeed, with other regulations, are explicitly recognised as required.

### 3.5.3 The changing regulatory framework

An important consideration was the changing environment and regulatory framework in which drugs, poisons and controlled substances will be used and supplied in the future. Many of the factors that contributed to the original drugs, poisons and controlled substances legislation continue to be valid, however there have also been significant changes. Some of the features conditioning the original legislation that have changed over time include:

- Protecting public health was viewed as a State responsibility, not a matter for national policy.
- There was no Commonwealth legislation established for evaluating products.
- Emphasis was on substances, and is now more on products. Often the substance was the product, whereas now the same substance can be used in different products, in different strengths, combined with other ingredients, in different packaging, and intended for different uses.
- Consumer access was limited to the physical presence at retail outlets, whereas now there is increased access through distance supply mechanisms, such as the Internet.
- Comparatively fewer substances and less diverse products were available than are now, especially those intended for aged care.

Other changes include the balance of power between the patient and the doctor, the pharmacist, the nurse etc. Patients want to be more involved in decisions about their health care. Consumers are generally more educated about health issues these days and have more information available about medicinal products, either through advertising (where that is permitted) or other media sources.

The composition of our population is changing as the proportion of older people in the community increases. Health costs continue to escalate and governments must look for ways to improve the efficiency of their operations.

There is increased emphasis on the global market – agencies are identifying many areas where mutual recognition or harmonisation is possible. Agricultural and veterinary chemicals have been granted a permanent exemption from the Trans-Tasman Mutual Recognition Agreement, while therapeutic goods and other chemicals have only a temporary exemption. The practice of pharmacy is also changing. The emphasis is much less on the compounding of medicines and much more on supplying the patient. In some pharmacies there is greater emphasis on advising patients to optimise their use of medicines with the intention of improving the quality use of medicines. However, many pharmacies appear to place greater emphasis on, and give the bulk of their floor space to, products which put them in competition with supermarkets and department stores.

Over the last decade, there has also been considerable change in the impact of information technology on our lives. This has opened up a number of choices for us, including where and how we obtain information, and where and how we purchase our health care products and even our health care advice. It provides governments with more efficient options for delivering services and monitoring use.

While it is not possible to predict the future, these, and a number of other trends, are likely to influence the risks and benefits associated with using drugs, poisons and controlled substances over the next decade or so. In developing alternatives, and in considering the costs and benefits of those alternatives, the Review has taken account of changes in the regulatory framework for drugs, poisons and controlled substances and the changing environment in which these substances will be supplied and used.

### 3.6 Jurisdictional differences

One of the most common issues raised with the Review was the lack of uniformity in legislation and regulation across jurisdictions. In all cases this trans-border variation in regulation was seen as detrimental because:

- there are increased costs for business, of multiple standards required for labelling, storage, handling, etc;
- the costs of establishing what the standards are in all the jurisdictions in which a company wishes to operate;
- there are inhibitions and problems for those health professionals moving across borders, especially for those practicing near state borders;
- there are confusions and frustrations for consumers in a mobile society (associated with migration and travel) in identifying and using drugs and poisons safely and effectively; and
- there are costs for government of duplication of regulatory agencies in designing and monitoring standards and inefficiencies in administering those controls.

These differences arise because of the variation in legislative instruments used, including primary and subordinate legislation, variations in the definitions which determine the scope of the controls and the range of controls included and the interpretation arising from the way in which the legislation is drafted.

The consequence is seen to be higher production costs for business and government, higher training costs for professions and higher prices to consumers with reduced certainty in production and consumption for all participants. Spillover to reduced international competitiveness was also identified.

While not provided in any representation to the Review, it is possible to argue for some positive benefit from diversity in regulation and its administration. This argument would be that diversity encourages innovation and competition in regulation so that experimentation allows better regulation to be identified and rewarded by responsive business or consumers. This is a variant of the ‘competitive federalism’ argument if it applies. In practice, overseas countries should reveal evidence of better

regulation in federal versus unitary systems. The Review was unaware, however, of any evidence to support such a theoretical proposition, which is in contrast to the array of case study and anecdotal evidence placed before it that support uniformity (see Section 6).

The Review concluded that the weight of evidence suggests that variation in legislation and regulation across jurisdiction has increased costs by reducing simplicity, clarity and transparency in the regulatory system to the detriment of businesses, professionals, consumers and taxpayers.

The question of the process of establishing more uniform regulation is a matter for examination in Section 6. What can be said from this discussion is that care needs to be taken in arriving at the optimal standardised level of regulation. Standards that are uniformly too high or too low are themselves costly. The system by which uniformity is produced, monitored and revised is therefore also as highly important as the pursuit of uniformity. Uniformity is not desired for its own sake, but as a vehicle for reducing the costs of diversity.

## SECTION 4 SCHEDULES OF DRUGS AND POISONS AND RELATED CONTROLS

**Terms of Reference addressed:** General issues 1, 2, 5, 6, 7, 8 and 9; Specific Review Issues 1, 3 and 4.

### 4.1 Description of the scheduling control system

The controls imposed by drugs, poisons and controlled substances legislation flow from the schedule in which a substance is included. As described earlier, the schedule of a substance is decided by the National Drugs and Poisons Schedule Committee and is published in the SUSDP. Controls on market access and, to a lesser degree, on market conduct, come into effect when these Schedules are adopted into State and Territory legislation, or placed in a different schedule.

The Schedules fall into two broad categories – those that relate to medicines (*Schedules 2, 3, 4 and 8*) and those that relate to poisons (*Schedules 5, 6<sup>7</sup> and 7*). In addition, *Schedule 9* covers substances that are prohibited.

#### 4.1.1 Schedules covering medicines

- *Schedule 2* includes substances that are considered to be able to be used safely when available from a pharmacy where professional advice is available. These substances include analgesics<sup>8</sup> (e.g. paracetamol) and antifungal preparations.
- *Schedule 3* products require the supervision of a pharmacist in their supply to advise the consumer on their safe and effective use. Substances covered in *Schedule 3* include some medicines to relieve the symptoms of asthma and some antihistamines.
- *Schedule 4* products require the intervention of a doctor, veterinarian or other authorised prescriber to diagnose the condition and prescribe the most effective treatment for that patient. These products include medicines to treat conditions such as infections (antibiotics), heart disease and depression. Once prescribed, these medicines can only be obtained from a pharmacy.
- *Schedule 8* covers products where, in addition to the *Schedule 4* controls, further access restrictions are placed on the prescribing of large quantities, prescribing for long-term treatment or in treating drug addiction. These substances include narcotics (e.g. morphine) and drugs to treat attention deficit disorder (e.g. methylphenidate).
- *Schedule 9* includes substances that are generally designated as illegal substances that are subject to abuse, the use, possession and supply of which is prohibited.

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<sup>7</sup> Some *Schedule 5* and *6* substances are also used in medicines.

<sup>8</sup> Small packs of some analgesics are not restricted and may be purchased from supermarkets and other general outlets.

In addition to the schedules, the SUSDP includes a number of appendixes. The appendixes fall into two broad categories, those imposing controls and those that are equivalent to the schedules. For example, Appendix F sets out warning statements to apply to certain substances while Appendix C includes a list of substances that are totally prohibited but are not the illegal drugs associated with *Schedule 9*. The appendixes are adopted variably by the States and Territories although most jurisdictions impose similar controls to those covered by the appendixes. For medicines the relevant appendixes are:

- Appendix A includes a number of general exemptions from the scheduling controls such as foods, and radioisotopes;
- Appendix C includes substances, other than those included in *Schedule 9*, of such danger to health as to warrant prohibition of sale, supply and use;
- Appendix D includes additional controls on the possession or supply of substances included in *Schedule 4* or *8*;
- Appendix E includes first aid instructions;
- Appendix F includes warning statements and safety directions;
- Appendix G relates to dilute preparations;
- Appendix H designates those *Schedule 3* substances permitted to be advertised; and
- Appendix K designates those drugs required to be labelled with sedation warnings.

#### 4.1.2 Schedules covering poisons

*Schedule 5* and *6* products include agricultural, veterinary and household chemicals such as pesticides, herbicides, swimming pool chemicals, growth promotants for animals, household cleaning agents, disinfectants and hair dyes.

- *Schedule 5* includes substances with a low potential for causing harm, the extent of which can be reduced through using appropriate packaging with simple warnings and safety directions on the label.
- *Schedule 6* contains substances with a moderate potential for causing harm, the extent of which can be reduced through using distinctive packaging with strong warnings and safety directions on the label.
- *Schedule 7* includes substances with a high potential for causing harm at low exposure and which require special precautions during manufacture, handling and 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.

Some of the SUSDP appendixes also impose controls in addition to those imposed on poisons by *Schedules 5, 6* and *7*. The relevant appendixes are:

- Appendix A (described above);
- Appendix E (described above);

- Appendix F (described above);
- Appendix I sets out the Uniform Paint Standard, and
- Appendix J sets out conditions for availability and use for *Schedule 7* poisons.

The controls that flow from scheduling may be seen to operate in two broad areas:

- restrictions on access (i.e. who can supply and who can be provided with the substances); and
- business conduct (i.e. the manner in which the substances can be supplied and covers areas such as packaging, labelling and storage).

#### 4.1.3 Restrictions on access

Restrictions on access only come into operation when the NDPSC decisions are adopted into the drugs, poisons and controlled substances legislation of the States and Territories. Restrictions on access are supported by a number of specific controls (see Section 5) which are aimed at delivering a public health benefit to the community by preventing poisoning, medicinal misadventure and diversion for abuse or use in the illicit manufacture of drugs of abuse. Access to medicines is also controlled under a number of other legislative instruments, including the Customs (Prohibited Import) Regulations, the *Narcotic Drugs Act 1975*, the *Therapeutic Goods Act 1989* and the *Agricultural and Veterinary Chemicals Code Act 1994*.

The access controls in drugs, poisons and controlled substances legislation reflect the level of professional advice and counselling necessary to overcome the information asymmetry between consumers and sponsors of products. The way in which the professional advice is provided and the quality of that advice depends on the standards of the profession involved. Compliance with the standards expected of health professionals are managed through complementary legislation regulating professional practice.

The level of restriction on access applied by the current drugs, poisons and controlled substances legislation is based on the hazardous properties of the substances and the risks associated with supplying and using products containing them. The level of risk is assessed by the NDPSC and is reflected in its scheduling decision (inclusion in a schedule or appendix of the SUSDP) and any additional requirements (e.g. warning statements on the product label). The factors to be considered by the NDPSC in reaching a decision are set out in Section 52E of the *Therapeutic Goods Act 1989*.

The Review noted the recent Victorian legislation that provides for accreditation of traditional Chinese medicine practitioners and the consequential introduction of a *Schedule 1* to the Victorian schedules. This Victorian *Schedule 1* designates the traditional Chinese medicines to which these practitioners will have access. The Review considered that it would be appropriate to consider the outcomes of this legislation after two years of operation, with a view to establishing if there is a net benefit in implementing a similar approach for other herbal medicine modalities.



#### 4.1.4 Restrictions on business conduct

As indicated previously, for medicines, there are a number of restrictions placed upon business conduct, particularly in the areas of advertising, labelling, packaging, recording, reporting and storage and handling. These restrictions are discussed in detail in Section 5.

For *Schedule 5* and *6* substances, the major controls relate to labelling and packaging. Apart from the signal heading, the labelling controls are largely substance- or category-of-substance-specific. These issues are discussed in detail in Section 5.

## 4.2 Scheduling controls

### 4.2.1 Objectives

#### Step 1

#### Clarify objectives of legislation

Implicit in the scheduling decision is an assumption that consumers cannot, on their own, make informed judgements about what products to select and how to use the selected products. On this basis, interface with a suitably qualified professional is seen to be an essential prerequisite for the supply of medicines covered by these schedules.

Scheduling seeks to ensure, amongst other things, that the use of these products is supported by adequate information to enable consumers to select, in the case of OTC medicines, and use all medicines safely and effectively. Currently, the restrictions are intended to facilitate this information being provided by:

- health professionals, especially medical practitioners at the time of consultation and pharmacists at the time of supply; and
- written information, including product labelling and Consumer Medicine Information (CMI).<sup>9</sup>

The objectives of the controls on access are to contribute to the overall objectives of medicines and poisons legislation, by allowing opportunities for redressing the information asymmetry that can lead to harmful or ineffective use of medicines. Use of the schedules to apply controls is intended to achieve the level of control that is appropriate for the degree of risk posed by the substance. More specifically, the objectives of restricting access are to:

- prevent medicinal misadventure and to prevent poisoning by ensuring that, where the consumer's lack of knowledge and understanding could lead to significant harms, professional advice and counselling are available to redress that information deficit; and
- ensure adequate supervision of the supply of substances which are likely to be abused or diverted to the illicit drug market.

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<sup>9</sup> The *Therapeutic Goods Act 1989* requires that CMIs be available for all *Schedule 4* and *8* medicines and some *Schedule 3* medicines.

The concern is that, while wishing to ensure the benefits from using medicines and poisons can be realised, and indeed maximised, the concomitant harms that can come from misuse and misadventure are also minimised. Since the complex nature of these products and their effects in application are often difficult to properly understand without considerable expertise and training, the legislation seeks to overcome the resultant information deficit of consumers – in this case through scheduling controls.

For medicines, the legislation aims to establish a partnership between the product user and health professional, where varying degrees of intervention by professionals are necessary to redress the consumer's lack of information and understanding. The level of intervention needs to relate to the extent to which the consumer's lack of knowledge and understanding undermines his or her capacity to select and use the medicine safely and effectively. In this way, the costs that flow from the controls will be outweighed by their benefits to the community as a whole.

The objectives of the controls on business conduct are to complement and support the controls on access. The specific objectives of the different controls on business conduct are discussed in detail in Section 5.

## 4.2.2 Nature of the controls

### For medicines

The access controls attached to scheduled medicines can be broadly described as:

- Those which restrict supply to a pharmacy (or, in some rural areas, a licensed poisons seller) where the product may be supplied over the counter without a prescription. These products are those included in *Schedules 2* and *3* of the SUSDP, where *Schedule 3* requires the pharmacist to be involved in the supply. The extent of the required involvement varies across jurisdictions.
- Those where the medicines can only be obtained from a pharmacy<sup>10</sup> on the prescription of a doctor, dentist, veterinarian or other authorised prescriber. These products are included in *Schedule 4* of the SUSDP.
- Those where additional restrictions over and above the need for a prescription are imposed. For example requirements:
  - for registration of the patient and authorisation to prescribe, controlled substances, (i.e. those likely to cause dependence or be abused). These products are covered by *Schedule 8*, some by *Schedule 4* and Appendix D of the SUSDP;
  - restricting those who can prescribe certain substances to certain specialists (e.g. dermatologists, physicians); or

#### Step 2

Identify nature of restriction on competition

<sup>10</sup> In some instances these products may be supplied by doctors, veterinarians or other authorised persons.

- limiting the circumstances in which it can be prescribed (e.g. where the prescriber has ensured that the possibility of pregnancy is excluded prior to prescribing.)<sup>11</sup>

In addition, there are certain substances that are regarded as being so toxic or highly likely to lead to dependence that they are unsuitable for therapeutic purposes. The supply and use of these substances (*Schedule 9* and Appendix C) are totally prohibited. Most jurisdictions do not adopt *Schedule 9* and Appendix C although all include similar provisions.

The controls on business conduct determine how a product is to be labelled, packaged and advertised, who can supply the product and the way in which that supply is to be managed (e.g. recording, reporting, storage and handling requirements that suppliers must meet).

### For poisons

State and Territory drugs and poisons legislation imposes restrictions on the labelling and packaging of *Schedule 5, 6* and *7* poisons. In some States and Territories the legislation imposes restrictions on access to products containing *Schedule 7* substances.<sup>12</sup> In this context, it should be noted that Appendix J identifies the access restrictions that should apply. The Review noted that while only three jurisdictions (Western Australia, Tasmania and the Northern Territory) have adopted Appendix J, although there is generally provision for similar access controls. It is difficult to identify the exact nature of the controls given the varying way in which these controls are applied in each jurisdiction.<sup>13</sup>

### 4.2.3 Effects on competition and the economy

#### Step 3

#### Analyse effects of restriction

These controls, particularly those on market access, create substantial barriers to market entry, which significantly reduce competition. These controls tend to increase the cost of goods, both through a lower level of price competition and through the time, cost and trouble to access qualified professionals to get them.

The clearest impact in this process is the restriction on who can supply drugs, poisons and controlled substances and under what circumstances. For example, the PRESCRIPTION ONLY schedule for products mandates a medical practitioner prescribe<sup>14</sup> and a pharmacist<sup>15</sup> for supply. PHARMACY ONLY proscribes non-pharmacy retailers

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<sup>11</sup> See Appendix D.

<sup>12</sup> In some jurisdictions these controls are included in agevt legislation rather than drugs and poisons legislation.

<sup>13</sup> In several jurisdictions these controls are applied through delegated legislation which empowers a senior official (e.g. the Chief Executive of the Health Department in Queensland) to authorise the possession and use of these products in certain circumstances.

<sup>14</sup> Veterinarians, dentists or other health professionals may be also authorised to prescribe.

<sup>15</sup> In some circumstances these products may be supplied by the doctor, veterinarian or other authorised person.

from competing with pharmacies in any way for supply of products so scheduled – no matter whether such other suppliers could do so with greater convenience or more economical pricing.

In the case of poisons, while there are some restrictions on access (for *Schedule 7* substances) the principal restrictions relate to business conduct (discussed in some detail in Section 5).

For *Schedule 2* medicines, the pharmacist is expected to exercise a level of supervision to prevent diversion and be available to provide advice. For *Schedule 3* medicines, the level of access is further restricted in that the pharmacist needs to be involved in the sale of the product. There are variations between jurisdictions in the way in which that involvement is specified in their drugs and poisons legislation. The expectation is that the limitation on access will elicit an appropriate level of intervention by the health professional. So, for *Schedules 2* and *3*, the intention of the various requirements is that the pharmacist will use his or her professional expertise to determine whether or not:

- that particular consumer has a therapeutic need for that medicine;
- that medicine is the most appropriate one to treat that consumer's condition; and
- there are drug interactions or other contra-indications which make it unsafe or inadvisable for that consumer to use the medicine.

If the pharmacist determines that a particular medicine is not safe or effective for that consumer, the pharmacist has an obligation not to sell the medicine to the consumer. Where the pharmacist does supply the medicine(s) he or she has an obligation to ensure the patient understands how to use it safely and effectively.

For all *Schedule 4* and *8* medicines, the consumer must obtain a prescription from a doctor or other authorised health professional (e.g. dentist, veterinarian),<sup>16</sup> to obtain the medicine from a pharmacy. Restricting medicines to supply on prescription means the consumer incurs costs in attending a practitioner to obtain a prescription and in obtaining the product from a pharmacy. By requiring that a prescription be obtained for the medicine, the intention is to overcome the consumer's lack of knowledge and understanding to:

- diagnose the condition from which he or she is suffering;
- determine the most appropriate treatment; and
- use the product safely and effectively.

In the first instance, the responsibility to diagnose and prescribe appropriate treatment falls on the doctor or other prescriber. Where medicine is prescribed, the doctor veterinarian or other prescriber also has a responsibility to ensure the consumer understands how to use the medicine safely and effectively. This may include providing written, as well as oral, information. Further, by then requiring the prescription to be filled by a pharmacist, there is a presumption that the information provided by the doctor (or other prescriber) will be reinforced and expanded by the

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<sup>16</sup> The health professional may also supply the medicines directly to the patient in some circumstances.

pharmacist at the time of supply. The intention is that the pharmacist will accurately dispense the medicine, provide written instructions on how the product is to be used<sup>17</sup> and provide written and oral advice to enable the consumer to use the medicine safely and effectively.

The controls restrict the nature of supply for these products and impose conditions of supply different from an open market in the absence of such legislation. The controls may also constrain innovation. The effects of the supporting controls on business conduct are discussed in Section 5.

#### 4.2.4 Costs and benefits of the controls

##### Step 4

##### Analyse benefits and costs

The costs and benefits of the controls related to access are discussed in detail later in this Section against each of the specific areas of control provided by the scheduling system. Section 5 discusses the costs and benefits of the controls affecting business conduct.

In general terms, the costs of the existing access controls are that consumer choice is limited, competition between suppliers is constrained and, as a result, it is reasonable to assume that costs are higher than those that would apply in an open market.

In relation to business conduct controls, the **costs** that relate to INDUSTRY are compliance requirements. In many instances (e.g. labelling controls) the major costs relate to the complexity of the controls rather than the controls per se. GOVERNMENT also incurs **costs** associated with administering and enforcing the controls. The **costs** to industry and to government are, in turn, passed on to CONSUMERS and the GENERAL COMMUNITY respectively.

The principal benefits of the controls relate to preventing poisoning, medical misadventure, abuse and diversion for illicit manufacture of drugs. These **benefits** result in savings to CONSUMERS in terms of medical and social and financial costs. There are also **savings** to GOVERNMENT and the GENERAL COMMUNITY in terms of reduced medical and hospital costs and income support.

#### 4.2.5 Alternatives

##### Step 5

##### Consider alternatives and recommend

The intention of the restrictions on access is that the information asymmetry will be redressed and adequate supervision provided. The Review has considered alternative approaches to redress this information asymmetry. These approaches include:

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<sup>17</sup> These instructions should be included on the prescription by the prescriber. Vague directions such as 'as directed' or 'prn' do not enable the pharmacist to give the best advice to the consumer as he or she cannot determine, from such instructions, the prescriber's intention. This can lead to unsafe or ineffective use and should be seen as a breach of the prescribers professional obligations and dealt with appropriately by the relevant professional board.

- improved label information, including warnings, cautionary statements and first-aid instructions;
- increased use of Consumer Medicine Information. Currently, this is only required by the *Therapeutic Goods Act 1989* to be provided for all prescription medicines and any new *Schedule 3* medicines entered on the Australian Register of Therapeutic Goods (ARTG) after 1994;
- increased education or information strategies, such as specific education campaigns (e.g. on vaccination) and information/counselling services (e.g. consumer medicine information telephone services, support group information services); and
- enhanced professional standards.

The Review also considered whether reliance could be placed on generic regulation, e.g. consumer protection, trade practices law, mutual recognition and law of damages to achieve the desired objectives. Such alternative approaches are discussed as appropriate in Section 5, under the individual controls.

## Labelling

Labels have been identified as a source of information for consumers by providing warning and cautionary statements to assist with the safe use of the products. Under the current scheduling arrangements, some substances are not scheduled or are included in a lower schedule when the product labelling is assessed by the NDPSC as providing adequate information on the safe and effective use of the product. This provides greater access for CONSUMERS and increases the capacity of INDUSTRY to compete in that market.

However, where this is not possible, the NDPSC determines the level of professional intervention required to overcome consumers' information deficit, and allocates the substance to the schedule where the limitation on access is intended to ensure that such professional intervention occurs. This reduces the capacity of INDUSTRY to compete and may prevent market entry for some businesses. It also adds to **costs** for CONSUMERS and GOVERNMENT (for subsidised medicines).

If the effectiveness of labels can be improved, the NDPSC (or its replacement) may consider that such labels are adequate to redress the information asymmetry between consumers and industry and down-schedule an increased number of products (see discussion below). This would **benefit** INDUSTRY by reducing their costs and increasing competition and CONSUMERS by making the products available at a lower price, while still achieving the objectives of the legislation.

## Consumer Medicine Information

Consumer Medicine Information is required under Therapeutic Goods Regulation 9A to be made available for all prescription medicines and those *Schedule 3* medicines approved for registration after 1 January 1993. The CMI is based on the Product Information, which is also required for these medicines. It provides comprehensive

balanced information about the product including possible side effects, potential interactions and directions for use.<sup>18</sup>

For those products required to have a CMI, there is no requirement to have the CMI included in the packaging. The doctor may distribute the CMI at the time of writing a prescription or the pharmacist may distribute it at the time of dispensing the medicine but there is no guarantee that the CMI will in fact be provided by either the doctor or the pharmacist.

The Review was told of problems caused by unavailability of electronically generated copies on the databases used in some pharmacies. Even where copies of the CMI are available (in either hard copy or electronic form) the Review was told that some pharmacists expected to be paid for supplying them.

If the CMI is not made available, the Review noted that the consumer may obtain a copy by contacting the product sponsor but the consumer does often not know this or the consumer is not clear who the sponsor is or how to contact them (see Case study 2). Consequently, the consumer can find it difficult to gain access to CMIs if indeed they are aware that such information is available.

The Review considered whether it should be mandatory to include the CMI as a package insert in all medicines for which the CMI is required. However, the Review noted that such inserts would remain in the pack for the duration of the product's shelf life of perhaps three years. In such cases the CMI could not be updated with new information as it becomes available or at least not without conducting expensive and disruptive nationwide product recalls to enable the packs to be reprocessed. The Review considered that the most effective method of distributing CMIs is electronically. The product sponsor would be responsible for updating the CMI regularly, and the doctor or pharmacist would be responsible for providing the consumer with a copy of the current CMI when prescribing or dispensing a *Schedule 3, 4 or 8* medicine.

The Review noted that the recently concluded Third Community Pharmacy Agreement recognised the duty of pharmacists to supply consumers with information but does not specify the nature of the information, e.g. whether it needs to be in the form of a CMI.

The Review considered that CMIs had the potential to play a particularly important role in providing consumers with the necessary information to enable them to use medicines safely and effectively, thus over time reducing the need for the existing system of controls on access. For this reason, the Review believes that a concerted effort needs to be made to ensure CMIs are not only available but are provided to consumers, as appropriate. Ideally distribution would be at the time the medicine is either prescribed or dispensed.

The Review considered that, given their privileged position, doctors and pharmacists have an obligation to ensure consumers have access to accurate, comprehensive and

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<sup>18</sup> *Schedules 12 and 13* of the Therapeutic Goods Regulations set out the requirements for these documents.

balanced written information about the products they are taking. In particular, they should ensure the consumer has been provided with a CMI, where a CMI is mandated to be available for a product.

The Review also noted that CMIs might come within the definition of an advertisement if made widely available (e.g. included on a company website or distributed unsolicited to persons not prescribed the particular medication). The Review considered that this restriction should be clarified to enable the benefits of the control<sup>19</sup> requiring CMIs to be available for certain medicines to be achieved. This issue is discussed further under Advertising in Section 5.

To a lesser extent, the availability of CMIs may also enable a product to be down-scheduled but only from *Schedule 4* to *Schedule 3* as, under the current arrangements,<sup>20</sup> CMIs are not required for *Schedule 2* products.

#### **CASE STUDY 2: Availability of CMIs**

In a complaint the medical department of Bristol-Myers Squibb Pharmaceuticals received, a patient advised that he had had an allergic reaction to Diclocil, which contains dicloxacillin – a penicillin-type antibiotic. The patient knew he had an allergy to penicillin and claims he brought it to the attention of both the doctor and the pharmacist. Despite this, the doctor prescribed dicloxacillin and the pharmacist dispensed it. Fortunately the patient recovered from the allergic reaction.

The CMI for Diclocil states, 'You should not receive Diclocil if you have ever suffered a serious reaction to penicillin or other antibiotics'. Neither the doctor nor the pharmacist gave the patient the CMI so the patient had no opportunity to discover for himself that the product contained a penicillin-type antibiotic.

**Source:** Bristol-Myers Squibb Pharmaceuticals communication.

### **Education and information initiatives**

The Review considered whether there was scope to reduce access restrictions in conjunction with an education initiative. To be effective, such initiatives would need to be comprehensive and ongoing.

The Review noted that there could be particular value in establishing an independent, credible, well-resourced, readily accessible, consumer information service on the quality use of medicines. This could be a telephone service and/or an interactive website on the Internet.

The Review heard of several small consumer information telephone services which have been funded by Commonwealth and State governments to provide information on the quality use of medicines. As the funding is limited, and there is no guarantee of continuation, the effectiveness of such services is limited. Despite these problems, the services have been well patronised and well received.

The Review also noted the success of the National Prescriber Service in providing independent, credible, up-to-date information for prescribers and its planned expansion into a consumer information service. The Review believed consumers would benefit if support were given to establishing such services for consumers. Consideration could be given to funding such a service through a levy on industry.

<sup>19</sup> Therapeutic Goods Regulation 9A.

<sup>20</sup> Under the *Therapeutic Goods Act 1989* CMIs are only required for prescription medicines and some *Schedule 3* medicines.



Such a service is also essential if DTC advertising of prescription medicines, which is promotional rather than informational by definition, is to be contemplated at some further time (see Section 5.1).

The Review recognised that there would be **costs** for GOVERNMENT and INDUSTRY in funding such a service. There would, on the other hand be **benefits** to INDUSTRY, CONSUMERS and GOVERNMENT through reduced medical, hospital and social costs deriving from the quality use of medicines. The Review anticipated that if such an information service were available, it could lead to some substances being down-scheduled thereby reducing a barrier to competition for INDUSTRY and increasing access for CONSUMERS.

The Review also considered that such a service had the potential to overcome the lack of face-to-face professional advice in those circumstances where medicines are home delivered, or supplied through mail order or the Internet. Further, by providing consumers with information to help them select and use medicines safely and effectively there would be **benefits** to GOVERNMENT in reduced hospital and medical costs as a result of reduced poisoning or medicinal misadventure.

### Professional standards

Professional licensing (implied by registration under the relevant registration regulatory practices) and associated professional practice, posed interesting challenges for this Review. Formally they operate under separate legislation which is subject to separate competition policy review. Yet their efficacy in professions such as medical and veterinary practice and in pharmacy is central to the beneficial operation of the system of restrictions over drugs, poisons and controlled substances.

By mandating that the medicines can only be supplied on prescription, and/or that they can only be obtained from a pharmacy (or, for some medicines, a licensed poison seller),<sup>21</sup> there is a presumption that there is benefit in doing so. This benefit only arises if there is an opportunity, or indeed an obligation on the doctor, veterinarian, pharmacist (or other health professionals) to redress consumers' information and understanding deficit.

As has been discussed, the primary objective of the schedules and the restrictions which flow from the Schedules is the need to address the information asymmetry between consumers and industry to enable the product to be used safely and effectively. There is a presumption that in restricting access to these substances, an appropriate level of professional intervention will occur to redress that information asymmetry. Where this occurs, the benefits of the restrictions are to reduce the level of poisoning, medicinal misadventure and diversion and the associated medical, hospital and social costs.

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<sup>21</sup> Several submissions commented that the standards imposed on health professionals do not apply to licensed poison sellers. (Licensed poison sellers can supply some *Schedule 2* medicines when the location is outside a fixed distance from a pharmacy, see Section 5) and that this deficiency should be redressed.

The reality is, such counselling does not happen to the extent desirable. This is partly because some pharmacists fail to meet the expected standards and partly because there are situations in the current pharmacy setting which preclude it happening (e.g. many pharmacies do not have a private counselling area where consumers are prepared to discuss intimate health details).

The Review was advised of occasions where, because of the failure of some professionals to meet the expected professional standards, the NDPSC has imposed more stringent restrictions on access to a particular substance, in order to minimise the harm and its associated costs. (For example, large pack sizes of pseudoephedrine products were recently rescheduled from *Schedule 2* to *Schedule 4* because, despite warnings from Pharmacy Boards, some pharmacists continued to supply them in breach of their professional standards. The result was that these packs – then *Schedule 2* – were diverted to illicitly manufacture amphetamines.)

In some instances, opportunities for liberalisation of drugs and poisons controls may exist with tighter professional practice. Counselling is of particular pertinence here. The Review does seek in these instances to indicate the potential for change in controls under its own consideration predicated upon changes elsewhere. It cannot presume, however, that such changes can or will happen.

In this context pharmacists in particular, have an important role to play. They are often the first contact for consumers with health problems. For those presenting prescriptions, the pharmacist needs to reinforce the advice given by the prescriber, address any concerns that have arisen as a result of the visit to the prescriber<sup>22</sup> and provide additional oral and written information to support and help the consumer use a medicine safely and effectively.

### **Distance counselling**

An issue raised by the Pharmacy Guild of Australia and the Pharmaceutical Society of Australia, as well as a number of other professional groups, was that of mail order and Internet pharmacies. Some stakeholders considered a key deficiency of these methods of supply was the supplier's inability to provide face-to-face counselling. These stakeholders saw face-to-face counselling as the ideal way of redressing the information asymmetry between industry and consumers.

In this context, the Review noted that in a number of traditional retail pharmacies face-to-face counselling does not take place, or does not take place regularly and consistently. This may be for a number of reasons other than the failure of pharmacists to meet their professional obligations (although the Review was advised that such failures occur more frequently than they should). For example, there are a number of supply situations where face-to-face counselling cannot take place. These include where a medicine is home delivered, generally by a pharmacy assistant, or is

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<sup>22</sup> These may arise for a number of reasons. For example it may be that the consumer has forgotten the advice given by the prescriber, or has subsequently thought of a question in relation to the condition from which they are suffering, or is unclear about the instructions given. It is a matter of professional judgement whether the pharmacist can provide the information or whether referral to the prescriber is necessary.

collected by an agent (neighbour, family member) for the patient or where the consumer declines such counselling.

As our population ages, and use of the Internet and other supply mechanisms become more common, the number of occasions when face-to-face counselling is not possible are likely to increase. There is clearly a balance to be struck between the cost and benefits of direct pharmacy transactions with the intended patient and a more open or less restrictive supply chain that can deliver alternative benefits, such as lower costs and greater convenience.

The Review noted that the Quality of Care Standards, provide only minimal requirements for distance counselling, and then only for OTC medicines.<sup>23</sup>

The Review saw considerable potential **benefit**<sup>24</sup> to the CONSUMER and GOVERNMENTS, particularly reduced hospital admissions, from expanding pharmacists' professional standards to cover such situations and implementing compliance measures to ensure they are practised. While this would impose additional **costs** on PHARMACISTS, the Review considered that these costs were outweighed by the **benefits** to the COMMUNITY AS A WHOLE.

The Review was also told of a comprehensive process for distance supply at some pharmacies. The pharmacist ensures the consumer knows when the medicine should arrive and then follows up with a phone call to check that it has arrived and that the consumer has all the necessary information to enable safe and effective use of the medicine. The Review considered that this type of procedure should be considered for inclusion in a distance supply standard.

In this context also, the Review also noted that a number of pharmacies have introduced a range of services to improve the quality use of medicine. These include changed procedures that benefit the consumer by making the pharmacist more accessible to the consumer. A number of pharmacists have set aside areas with reference material and computer access for the pharmacist to check a consumer's medication history thereby enabling the pharmacist to alert the consumer to any potential interactions and generally improve the quality of the advice given. Other pharmacies offer a range of supplementary services (e.g. childcare nurses, smoking cessation programs, medication reviews) to support the dispensing services and supply of OTC medicines.

### **Enhancement of professional standards for pharmacists**

The Review has noted that in many cases the risk to the individual purchasing a *Schedule 2* product may be as high or higher than the risk of a person purchasing a *Schedule 3* product. There may be a number of reasons for this, including the age of the consumer, his or her health status, other medicines being used, and his or her literacy levels. For these reasons, the Review sees the risk in relation to OTC

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<sup>23</sup> Standard 2.2 of the Pharmaceutical Society of Australia *Standards for the Provision of Pharmacist Only and Pharmacy Medicines in Community Pharmacy* deals with indirect supply.

<sup>24</sup> Research should be undertaken to identify the extent of such benefits.

medicines as relating more to the individual circumstances of the consumer and the way in which that consumer uses the medicine than to the toxicity of the substance.

This goes to the heart of quality use of medicines where a partnership approach between the consumer and the relevant health professionals is promoted as the most effective way to optimise the use of medicines. The Review considered that, by focusing attention on the substance first, the current two-schedule system might well act as a barrier, preventing pharmacists from giving primacy to the needs of the individual consumer.

A number of submissions supported this ‘risk based’ approach for OTC medicines.

The Review noted that the Third Community Pharmacy Agreement has introduced a new Pharmacy Development Program which has allocated funding to encourage pharmacists to provide quality services for the benefit of consumers. The Review also noted that the Pharmacy Development Program represents a shared commitment between Government and pharmacy to work together on quality initiatives that are intended to benefit the community. The initiatives include delivery of quality assurance and professional counselling standards, and provision of quality use of medicines information to consumers.

Counselling of patients about the medicines they are taking is a normal duty of care requirement of the pharmacists’ professional role of dispensing and supplying medicines. The new Pharmacy Development Program initiatives have the potential to enhance that professional role and increase the availability of quality information on medicines. If such an improvement does occur it might be expected to lead to improved health outcomes, including reduced medicinal misadventures.

The Review noted that \$15 million of the Pharmacy Development Program funding has been set aside for research and development activities related to the objectives of the Program. The Review considered that it would be appropriate for part of this \$15 million to be used to develop the OTC ‘risk-based’ standards proposed above and to expand the professional standards for pharmacists more generally. In assessing levels of risk and expanding the standards, attention should be paid to developing standards which cover situations where face-to-face counselling with a pharmacist (for both OTC and prescription medicines) is not feasible, e.g. the distance-supply of medicines by methods such as home delivery or mail order. The standards should, of course, be developed by consultation between pharmacy organisations, Pharmacy Boards, other professional organisations and consumers.

Development of standards covering supply of medicines generally should be supported by independent research to establish the extent to which health and other outcomes are improved by the initiatives in the Third Community Pharmacy Agreement. This will also provide the basis for a system for continuous improvement in the level and quality of counselling services pharmacists provide for all medicines and their responsiveness to changing circumstances.

The Review considered that development and implementation of these measures was vital. Given:

- the increasing number of medicines on the market;

- the increasing reliance on medicines for treatment;
- the trend toward self-medication and our ageing population; and
- the potential for drug interactions,

the need for professional intervention, particularly by pharmacists, to ensure safe and effective use, will become increasingly important.

Without adequate research and ongoing evaluation, the Review considered that it would be extremely difficult to ensure and maintain the benefits of the restrictions. Baseline data needs to be collected urgently to provide the basis for evaluating current initiatives, establish which controls are effective and enable modifications to meet the changing needs of the community. The Review is not aware of any proposal under the Third Community Pharmacy Agreement to collect such data. Therefore, the Review considered that funds should be allocated from the Pharmacy Development Program to enable independent evaluation of the extent to which the enhanced level and quality of professional intervention by pharmacists benefits consumers, particularly through improved health outcomes.

The results of the research should be made available to the National Coordinating Committee on Therapeutic Goods which report through the Australian Health Ministers Advisory Committee to the Australian Health Ministers Conference on the effectiveness of these standards. This will help Health Ministers consider whether or not *Schedules 2* and *3* should be combined (see discussion below).

### 4.3 Number and range of Schedules

**Terms of Reference addressed:** Specific Review Issue 3

The SUSDP sets out eight schedules (i.e. *Schedules 2* to *9*), as discussed above. The controls are applied to substances according to the schedules in which they are found in State and Territory legislation, the jurisdictional schedules and related controls generally being based on the SUSDP schedules.

Jurisdictions do not generally adopt the SUSDP Part 3 Recommended Controls but the legislation in each jurisdiction includes similar controls. While all jurisdictions adopt *Schedules 2* to *8*, there are variations as to the legislation into which they are adopted,<sup>25</sup> especially with *Schedule 8* which, in some jurisdictions is adopted into their drugs and poisons legislation, while in others it is included under controlled substances legislation. For *Schedule 7* the controls, other than the signal heading, may be included in drugs and poisons legislation or in agvet legislation. *Schedule 9* is not adopted by all jurisdictions, although all prohibit the use of certain substances.

In recent years, there has been a significant devolution of prescription medicines to lower levels of control, thereby increasing consumer access. This has seen a number of medicines move from *Schedule 4* to *Schedule 2* or *Schedule 3*, but rather fewer go

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<sup>25</sup> In those jurisdictions that do not adopt the SUSDP by reference, the number allocated to the schedule may be different from the SUSDP Schedule number.

to open sale, thus not significantly changing the number of OTC medicines available on the open market.

The trend to down-schedule substances reflects the NDPSC assessment that following exposure in the more restricted prescription market, certain products no longer require the intervention of both an authorised health professional and a pharmacist. In these cases the NDPSC has decided that the substance can be safely and effectively used with a lower level of intervention (*Schedule 3*) or general oversight (*Schedule 2*), still by a learned intermediary (the pharmacist), to redress the consumer's lack of knowledge.

The NDPSC may decide that a product, or form of the product, can be included in a lower schedule or even be unscheduled where:

- the level of risk of poisoning is reduced because of its pack size;
- the way in which a product is packaged, e.g. child-resistant packaging, can reduce the risk of accidental poisoning;
- warnings, cautions and first aid instructions are included on the label;
- the intended use of the product reduces the level of risk (e.g. where the substance in a product is to be used topically, reducing the risk compared to ingestion); and
- the formulation of the product reduces the risk of poisoning or misadventure. For example, if the product includes a bittering agent or is combined with other substances (e.g. some antihistamine products also contain an anti-tussive or expectorant substance) which reduce the likelihood of abuse, diversion or misuse.

To facilitate consideration of the number of schedules, the issues are discussed under three broad headings: OTC medicines (i.e. those medicines covered by *Schedules 2* and *3*); prescription medicines (i.e. those medicines included in *Schedules 4* and *8*) and poisons (those substances covered by *Schedules 5, 6* and *7*).

### 4.3.1 Over-the-counter medicines (Schedules 2 and 3)

#### Objectives of controls on OTC medicines

The underlying objectives of the controls on OTC medicines are:

- to ensure consumers have adequate information and understanding to enable them to select the most appropriate medicines for their condition and to use them safely and effectively, taking into account their health status; and
- to reduce the risk of these medicines being diverted for abuse or for illicit manufacture of drugs of abuse.

Step 1

Clarify  
objectives of  
legislation

The Review considered both objectives to be sound.

## Nature of current access controls relating to OTC medicines

### Step 2

#### Identify nature of restriction on competition

The most significant controls related to *Schedules 2* and *3* are restrictions on access. Consumers can only access *Schedule 2* and *3* products through a pharmacy or, in limited circumstances a licensed poisons seller. Other controls, which relate to these schedules, are storage and handling, and recording requirements. These controls are discussed further in Section 5.

*Schedule 2* covers substances that are deemed to be able to be used safely when available from a pharmacy where professional advice is available. Professional standards determine the level of intervention which a pharmacist is expected to exercise when supplying these products.

*Schedule 3* products are considered to require the pharmacist's intervention in their supply to enable the product to be selected appropriately and used safely and effectively. While the level of pharmacist intervention in the supply of *Schedule 3* products set out in drugs, poisons and controlled substances legislation differs across jurisdictions, the general intent of the requirement is that the pharmacist will establish that the consumer has a therapeutic need for the product. This means the pharmacist has an obligation to refuse to supply a *Schedule 3* product where he or she is not satisfied the consumer is suffering from a condition for which the product is appropriate. There is also a presumption that the pharmacist will provide advice about interactions, contra-indications and the way in which the product should be used.

## Effect of current OTC schedules on competition and the economy

### Step 3

#### Analyse effects of restriction

The Review noted, that restricting access to pharmacies of a significant range of products, reduced competition in that non-pharmacists could not sell such products. Restrictions on competition generally lead in turn, not only to higher prices, but also may impact adversely on consumer choice and convenience.

For *Schedule 3* products it may also mean that the consumer is denied access to the product if the pharmacist judges that the use by a particular consumer of a product is inappropriate. Currently, mail order and Internet pharmacies require a prescription before supplying these medicines since it is not possible for the pharmacist to personally intervene in the supply. This adds to costs for the consumer and for government (in subsidising the doctors' visits).

It is worth noting that, apart from the United States, all comparable countries restrict access to some OTC medicines. The United Kingdom has only one OTC schedule with restrictions on access that are similar to those of *Schedule 3*, and both New Zealand and Canada have two OTC schedules. The Review noted that in the United States, where there is no intermediate control between prescription medicines and general sales, a prescription is required to obtain a number of substances that are available from a pharmacy without a prescription in Australia (and New Zealand).

## Costs and benefits of retaining existing OTC schedules

The **costs** of maintaining OTC Schedules for CONSUMERS relate to the limitations on accessibility – that is, these products can only be obtained from pharmacies and it may be inconvenient, particularly in rural locations<sup>26</sup> for consumers to visit a pharmacy. Consumers may also pay higher prices as a result of the lack of competition that non-pharmacy retail outlets could be expected to provide if there were no restrictions on access to OTC products.

### Step 4

Analyse  
benefits and  
costs

For INDUSTRY, the **costs** relate to the fact that they are constrained in the manner in which they can supply their products and this in turn may lead to lower total sales volume than would be possible in an unregulated market. Increased sales volumes may produce economies of scale, which may make their businesses more profitable and/or lead to reduced prices for consumers.

For GOVERNMENTS, there would be some reduction in administrative **costs** if the present OTC schedules were abolished although these would probably not be significant.

By limiting access to a pharmacy, there is a **benefit** to CONSUMERS in having advice and counselling on the selection, and the safe and effective use of these medicines available (*Schedule 2*), or provided (*Schedule 3*), at the time of purchase.

If this advice and counselling leads to the safer and more effective use of medicines, then there are **benefits** to GOVERNMENT in terms of avoiding unnecessary hospital and medical costs as well as related productivity costs (e.g. lost work days).

For INDUSTRY, there may be **benefits** in having the use of their products supported by appropriate professional advice in that, if this advice leads to the more effective use of the product, then this could be expected to assist in promotion and sales of their products. This in turn would **benefit** CONSUMERS through lower prices.

## Alternatives

Alternatives to the current restrictions for OTC medicines the Review considered were:

- no OTC schedules, i.e. essentially abolishing *Schedules 2* and *3*;
- abolishing *Schedule 2*, i.e. the criteria<sup>27</sup> for *Schedule 3* would remain essentially the same, as would the controls that apply; and

### Step 5

Consider  
alternatives and  
recommend

<sup>26</sup> Some *Schedule 2* medicines may be obtained from licensed poison sellers (see also Section 5).

<sup>27</sup> The Review is precluded, by its Terms of Reference, from examining the criteria for scheduling.



- combining *Schedules 2 and 3* with new criteria<sup>28</sup> and changing the controls, which restrict access to focus on the consumer's need for information rather than the toxicity of the substance.

### No OTC schedules

#### *Nature of the control*

Under this alternative there would still be a number of substances where consumer access was restricted, such that a prescription was needed to obtain the product and a further restriction that these products could then only be obtained from a pharmacy. The remainder of the medicinal products would be available from a range of general outlets, such as supermarkets and service stations.

#### *Effect of the control on competition and the economy in general*

This approach is essentially the system that operates in the United States. The experience there is that a number of products, which in Australia are available over-the-counter from pharmacies, are only available with a prescription from a doctor or other authorised prescriber. The extent to which this would occur in Australia would depend on the criteria<sup>29</sup> for *Schedule 4* and the way in which the Scheduling Committee interprets it. However, it could be expected that this would also result in improved consumer access to a number of medicines. This would reduce the restriction on market access for industry for these products. Further, by removing the restriction on who can supply some of the products, competition would be increased for supply of those medicines no longer restricted to supply through pharmacies.

#### *Cost and benefits of the control*

The costs and benefits for industry, governments, consumers and pharmacists of abolishing both OTC Schedules are, in general terms, as identified in the preceding sub-section dealing with the costs and benefits of maintaining the existing scheduling arrangements.

More specifically, for SUPPLIERS, the **benefits** resulting from removing the restriction on who could supply these products would be that supermarkets and other general suppliers would be able to enter the market. For MANUFACTURERS the **benefits** would be increased sales of their products. The **benefits** for CONSUMERS would be increased access to a wider range of medicines. The price of these medicines to consumers may also be reduced through increased competition.

As indicated above, the **costs** to both CONSUMERS and GOVERNMENT of abolishing the OTC Schedules would increase poisonings and medicinal misadventures and diversion for abuse and illicit manufacture of drugs for abuse. These in turn would lead to increased hospital and medical costs for consumers and governments and lost productivity (work days lost) for the community.

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<sup>28</sup> The Review is precluded, by its Terms of Reference, from examining the criteria for scheduling.

<sup>29</sup> The Review is precluded, by its Terms of Reference, from considering the criteria for scheduling.

Also, some *Schedule 2* substances may be diverted for abuse, or for illicit manufacture of drugs of abuse if adequate supervision is not provided. There could also be additional costs to CONSUMERS (to obtain a prescription and the dispensing fee) and GOVERNMENT (for subsidised doctor visits) if some substances which are presently in the OTC schedules were to become prescription only.

Drawing on the United States experience, and based on a number of assumptions,<sup>30</sup> one stakeholder estimated that the net public benefit (benefit–comparative cost) of the scheduling and advertising provisions relating to *Schedules 2* and *3* at between \$78.4 million and \$138.9 million. While the Review considered that a number of less tangible factors, such as the different health systems operating in the United States and Australia, were not taken into account in reaching this estimate it considered there would be a **net benefit** to the COMMUNITY AS A WHOLE in restricting access to some OTC medicines.

In this regard, the Review’s conclusion that restricting access to at least some OTC medicines results in a net benefit was reinforced by information from the United Kingdom, where a substantial benefit to the community was demonstrated by restricting access to large packs of paracetamol to pharmacies only (previously these were unrestricted and available in supermarkets) (see Case study 3).

In Australia, there were 6 600 admissions to hospital for poisoning by paracetamol in people over 15 years of age in the period 1996–98 (based on Victorian data), which is approximately 17 people per 100 000 per annum affected (Routley, Ashby and Lough, 1999). In the United Kingdom, where a more liberalised paracetamol sales regime applied, there were almost 70 000 admissions per annum for intentional paracetamol poisoning (117 people per 100 000 per annum) (Turvill et al., 2000). While it is recognised that United Kingdom and Australian figures may not be directly comparable because of differences in data collection methodologies, it is clear that the United Kingdom incidence of poisoning from paracetamol was much higher than for Australia. Such figures provide a presumptive case for caution in relation to the public health risks of allowing deregulation of scheduling restrictions to take place.

Quite apart from the benefits of having advice available to redress the information asymmetry, several stakeholders also raised another potential benefit for consumers of restricted access. Their contention was that such a restriction acted as a trigger to alert consumers to the fact that these were not normal items of commerce.

While the Review has some sympathy for this view, the extent to which this in fact affects consumer’s attitudes and behaviour is unknown although some research suggested that consumers do view prescription medicines as being more toxic and

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<sup>30</sup> These assumptions included:

- the proportion of substances currently included in OTC schedules which would require a prescription if the two OTC schedules were abolished and the controls on advertising prescription medicines relaxed;
- the increased level of poisoning and medicinal misadventures that would result from abolishing the two OTC schedules; and
- the proportion of hospital admissions which can be attributed to differences in scheduling and advertising controls between Australia and the United States.

therefore requiring greater care in their use (Elliott and Shanahan, 1990). However, less clear from the research was the extent to which restricting supply to a pharmacy influenced consumer attitudes to OTC medicines. Further, the Review noted that the distinction between pharmacies and supermarkets is often not clear with many pharmacies, particularly the larger ones, selling a range of products such as foods, washing powders, china, shoes and toys. The Review considered that this blurring of the boundaries might be an influential factor in relation to consumers' perception of OTC medicines and the way in which they should be used and treated.

**CASE STUDY 3: Paracetamol availability in the United Kingdom**

In response to concerns about the incidence of paracetamol poisoning, the United Kingdom government introduced legislation in September 1998 to limit the amount of paracetamol which could be sold without the approval of a pharmacist. Only 8 grams (equivalent to a 16-tablet pack) was permitted to be sold over the counter in a supermarket, while pharmacies were able to sell 32 tablet packs. A prescription was required to obtain more than 100 tablets. It should be noted that for some years Australia has restricted the pack size available outside pharmacy to 25 tablets or capsules of 500 mg or less when packaged in blister packaging. There is no restriction on the pack size available in pharmacy.

In the United Kingdom, paracetamol poisoning was the most common cause of liver failure. The incidence of paracetamol poisoning was considered to be related to its availability, rather than ignorance of its complications, with it being implicated in 40 per cent of cases of intentional self-poisoning.

A study examined the records of patients referred to the liver unit in a major hospital, and also the number of requests for registration with the national liver transplantation authority, before and after September 1998.

The median monthly number of referrals to the hospital liver unit fell from 2.5 before that date, to one afterwards. Although in the three years prior to September 1998 the annual rate of referrals to the liver unit was falling by 4.5 patients per year, after the legislation change the rate fell by 10 referrals per year.

The median monthly referrals to the national transplantation registry from paracetamol poisoning fell from 3.5 to two. In the three years prior to introduction of the legislation, the referral rate to the registry had actually been increasing by an average of 7.5 patients per year.

The study noted that the nature and severity of overdose remained constant over the 'before' and 'after' periods, as did the referral patterns, leading to the conclusion that the reductions in liver failure were due to the legislative changes limiting the sale of paracetamol.

**Source:** Prince et al., *The Lancet* 2000(355) 2047–49

## **Abolish Schedule 2<sup>31</sup>**

### *Nature of the control*

The Review noted that by far the largest proportion of OTC medicines come under *Schedule 2*. Therefore abolishing *Schedule 2* would mean there would be considerably fewer substances to which access was restricted (i.e. only those included in *Schedule 3*). Thus, under this alternative, a much wider range of substances would be available through general outlets such as supermarkets and service stations. The restriction on access for those substances in *Schedule 3* would continue to require supervision or intervention by the pharmacist in the sale of the product to ascertain, as a minimum, that the consumer had a therapeutic need for that product.

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<sup>31</sup> In considering the abolition of *Schedule 2*, the Review assumed that the criteria and controls for *Schedule 3* would remain unchanged. (The Review is precluded from considering the scheduling criteria.)

### *Effect of the controls on competition and the economy*

The abolition of *Schedule 2* would lead to a considerable increase in access for consumers, free up market entry for suppliers and improve market access for manufacturers in relation to a large number of products. However, these restrictions would remain for those OTC products included in *Schedule 3*. At the margins, this may prevent a few firms entering the market. These restrictions would also add to the price of goods for consumers.

### *Costs and benefits*

The Review noted that the major proportion of OTC medicines fall under *Schedule 2*. Thus the Review considered that, in the main, the costs and benefits discussed above in relation to abolishing both OTC schedules would also apply to abolishing *Schedule 2*. Consequently, the Review considered that abolishing *Schedule 2* would not provide a **net benefit** to the COMMUNITY AS A WHOLE nor would it achieve the objectives of the legislation.

### **Combining Schedules 2 and 3 into a single OTC schedule**

#### *Nature of the control*

The criteria for a single OTC schedule would need to be determined.<sup>32</sup> Similarly, the controls on access to apply to the single schedule would also need to be determined, depending on the criteria for the Schedule. That is, the level of professional intervention the combined schedule would require of the pharmacist would need to be identified, together with associated controls, such as storage, handling, recording and advertising. However, the Review considered that the objective of restricting access to products containing substances included in the new schedule (i.e. that consumers had sufficient information to use the product safely and effectively) would best be achieved by placing greater emphasis on the needs of the consumer as the trigger for the pharmacist's intervention rather than on the substance.

#### *Effect of the control on competition and on the economy*

The extent to which the single schedule reduces the current restriction on access for consumers and market entry for manufacturers will depend on the criteria for the new schedule. It could be expected, however, that there may be some **costs** for INDUSTRY where relabelling is required when products move from *Schedule 3* to *Schedule 2* to the new OTC schedule, although this would be a one-off cost and is not expected to be significant.

The Review considered that if, as discussed above, the controls which are intended to flow from the single schedule are implemented, the information asymmetry between consumers and industry would be more effectively addressed than under the current two-schedule system. The single schedule would place more responsibility on the pharmacist to exercise their professional skills.

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<sup>32</sup> The Review is precluded by its Terms of Reference from examining the scheduling criteria.

### *Cost and benefits*

A number of submissions strongly argued that to combine *Schedules 2 and 3* would lead to an increase in **costs** because:

- as noted above, some medicines currently in *Schedules 2 or 3* could be consequently rescheduled to prescription only (*Schedule 4*), because of the perceived risk of use without professional advice from a pharmacist. This would result in additional costs for GOVERNMENTS (subsidised doctor visits), inconvenience to CONSUMERS (attending a doctor to obtain the prescription) and reduced market access for INDUSTRY; and
- it may lead to some currently scheduled substances being de-scheduled so information on safe use, other than what is on the label, is no longer available. If this occurred there would probably be an increase in the number of adverse events related to the use of these medicines resulting in additional medical and hospital costs for CONSUMERS and GOVERNMENTS.

In considering these submissions the Review noted that these arguments were based on a number of assumptions about the level of control that would apply to the new single OTC schedule and the criteria to be applied for including a substance in the schedule. The Review did entirely share the views expressed in these submissions. However, it noted that both the controls and the criteria would need to ensure the agreed objectives of the legislation could be met.

In this context, the Review considered the importance of appropriate and effective standards for pharmacists that ensured the intended objectives of the restrictions on access (i.e. to redress the information asymmetry between the consumer and industry) were realised. These standards were discussed earlier in this Section.

The Review did not anticipate that a single OTC schedule approach would lead to OTC substances being rescheduled to *Schedule 4*. In terms of **benefits**, the Review noted that combining *Schedules 2 and 3* should reduce INDUSTRY costs for labelling (especially where there are changes of schedule or differences between the jurisdictions), for compliance costs (in establishing the schedule that applies to a product)<sup>33</sup> and in preparing applications for rescheduling. For CONSUMERS, the Review saw considerable potential **benefits** (more ‘risk based’ counselling<sup>34</sup> as discussed above). This in turn should lead to fewer medicinal misadventures with their associated hospital and medical cost for GOVERNMENTS and CONSUMERS.

The effect on the viability of pharmacies, if *Schedule 2* were abolished, was raised in several submissions. Rural pharmacies were seen as being particularly vulnerable if this occurred and closure of these pharmacies would add to the **costs** for the RURAL COMMUNITIES. If indeed such a situation was to arise, consumer access to the professional services (especially dispensing of prescription medicines) and advice available through pharmacies would be reduced.

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<sup>33</sup> Many of the schedule entries are complex, particular for multi-ingredient products.

<sup>34</sup> This is based on the assumption that the current professional standards, which are based on *Schedules 2 and 3*, would be replaced with a single risk-based counselling standard.

However, it should be noted that the Review has not proposed abolishing *Schedule 2* but rather has canvassed the possibility of there being a single OTC schedule. The criteria for this schedule,<sup>35</sup> and the controls that apply to it, should be such that the objectives of the legislation will continue to be met. It is therefore difficult to predict the extent to which this proposal will impact on the viability of pharmacies although, as the objectives of the legislation have not changed, the Review would not expect this effect to be significant.

Several stakeholders also commented that pharmacists do not charge for the advice given and that, in some cases, the advice may lead to no product being sold. They argued that this was only possible from a business perspective because of their exclusive right to sell *Schedule 2* medicines. The extent of the **cost** to PHARMACISTS of providing advice is unclear, however, verbal advice is often ‘bundled’ with processing of sales as a ‘joint good’ and so does not take more time than a sale itself. No evidence was provided on the ‘extra’ time required for this function. The Review was made aware of a few pharmacies that have designated counselling areas. This would be a cost to those pharmacies.

Some submissions, including those from police, discussed the benefits of pharmacists’ supervision in preventing diversion of *Schedule 2* and *3* medicines for abuse or manufacture of illegal drugs. The Review considered that in this case there would be a clear **net benefit** to the COMMUNITY AS A WHOLE in restricting access to these substances. However, the Review saw no reason why that benefit could not be achieved with a single OTC schedule.

### **The need for data**

The Review noted that in 1996 the Industry Commission, in its Review of the Pharmaceutical Industry, found difficulty in supporting the retention of both *Schedule 2* and *Schedule 3*. The Commission recommended that:

... both *Schedule 2* PHARMACY ONLY and *Schedule 3* PHARMACIST ONLY be retained, pending **further research into the role of pharmacist counselling in ensuring improved health outcomes and monitoring the extent of such counselling ...**<sup>36</sup>

The Review is concerned to note that while some effort has been made to examine the extent to which counselling occurs,<sup>37</sup> no effort has been made to undertake any research to evaluate the effectiveness of counselling in delivering improved health outcomes.

The Review was similarly hampered in its evaluation of the costs and benefits of retaining both *Schedules 2* and *3*. The Review noted that the Third Community Pharmacy Agreement,<sup>38</sup> provides that, after a phase-in period, a financial incentive

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<sup>35</sup> The Review is precluded, by its Terms of Reference, from considering the scheduling criteria.

<sup>36</sup> Recommendation 15.1 Industry Commission report on the Pharmaceutical Industry, 1996 (emphasis added).

<sup>37</sup> Development of the Guild PSA Standards.

<sup>38</sup> This agreement sets out the agreement for remunerating pharmacists for supplying medicines under the Pharmaceutical Benefits Scheme.

will be paid to pharmacies which comply with the recently developed Pharmacy Guild Quality of Care Standards.

The standards are also being adopted by Pharmacy Boards, which may discipline pharmacists who fail to meet them. These standards are based on a limited risk-based approach, which relies heavily on *Schedules 2* and *3* to identify the level of risk for OTC medicines,<sup>39</sup> and thus the extent to which counselling is required. The Review considered that this initiative had considerable potential to overcome some of the criticisms of the current system (i.e. that the level of intervention by pharmacists falls far short of the expected standard). Evaluation of the extent to which this initiative improves health outcomes should provide the basis on which to establish whether there is a net benefit to the community as a whole in retaining both *Schedules 2* and *3*.

The Review believed that an evaluation strategy (including collection of baseline data) should be put in place immediately to establish the extent to which these standards, their associated incentives and the legislative controls deliver improved health outcomes. The Review considered that this evaluation should be funded from the money allocated to the Research and Development Program under the Third Community Pharmacy Agreement. The evaluation report should be made available to the Australian Health Ministers Conference through the National Coordinating Committee on Therapeutic Goods (NCCTG) to assist with ongoing monitoring of the effectiveness of the controls imposed by the legislation.

#### 4.3.2 Prescription medicines (Schedules 4 and 8)

Both *Schedules 4* and *8* require a prescription before being supplied by a pharmacy. *Schedule 8* imposes additional restrictions on access and business conduct. These are identified below and in Section 5 respectively.

##### Objectives of restrictions on prescription medicines

###### Step 1

###### Clarify objectives of legislation

The objectives underlying these restrictions on prescription medicine are to ensure:

- the condition from which the consumer is suffering is diagnosed correctly;
- the most appropriate treatment is prescribed; and
- the consumer has enough information and understanding to enable him or her to use the medicine safely and effectively.

The Review considered there would be benefits in making explicit reference in relevant legislation to the objectives underlying the controls on prescription medicines.

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<sup>39</sup> It is noted that the standards do not include any specific provision in relation to risk-based counselling for prescription medicines.

## Nature of current restrictions on prescription medicines

The restrictions, which attach to *Schedules 4* and *8* and Appendix D significantly, limit the opportunities for competition by restricting market entry. This in turn generally leads to increased costs for industry, consumers and government (for subsidised medicine and medicines where a doctor's visit is required to obtain a prescription).

### Step 2

Identify nature of restriction on competition

## Effect of current restrictions on prescription medicines

For medicinal products covered by *Schedules 4* and *8*, supply can only occur when it is authorised by a doctor, veterinarian or other authorised prescriber and the supply obtained from a pharmacy.<sup>40</sup> *Schedule 8* imposes additional controls over and above the requirement for a prescription (see Controlled substances below). Apart from the need to manage the risks associated with some substances and the diseases for which they are used, there are requirements, under United Nations drug treaties, that certain substances only be supplied on the written prescription of a registered medical practitioner (or other authorised person). Many of these restrictions are included the controls that attach to *Schedule 8* (controlled substances) but may also be included in *Schedule 4* or Appendix D.<sup>41</sup>

### Step 3

Analyse effects of restriction

The restrictions applied by these controls relate to:

- who can authorise the purchase of the goods (by prescription, although this Review is not to address prescribing rights);
- who can sell the goods at retail level, to whom they can be sold and under what circumstances;
- supply by wholesalers and distributors (peripheral to the controls on consumer access and dealt with in more detail below); and
- in some cases, who can administer the medicines.

## Costs and benefits of restrictions on prescription medicines

In the case of prescription medicines, the restrictions on access impose significant **costs** on CONSUMERS and GOVERNMENT associated with:

- the need to attend a doctor, veterinarian or other authorised prescriber to obtain a prescription; and
- the need to attend a pharmacy to obtain supplies.

### Step 4

Analyse benefits and costs

<sup>40</sup> Special restrictions apply where these products are supplied or administered in a hospital.

<sup>41</sup> As discussed above, these schedules may be adopted into drugs and poisons legislation, or controlled substances legislation, and Appendix D may not always be adopted or the restrictions may be included in other ways. Currently Appendix D only imposes additional restrictions on a few substances.



The **costs** to INDUSTRY relate to the fact that the market for their products is significantly constrained, thus denying them potential profits through increased sales volumes and associated economies of scale that could be provided in the manufacturing process. These costs to industry may limit market access by some companies and this in turn would reduce the levels of competition in the market place for the supply of medicines.

The **benefits** of the controls for CONSUMERS and GOVERNMENT relate to avoiding hospital, medical and social costs of poisoning, medicinal misadventure or diversion and abuse. These benefits are illustrated by:

- the prohibition placed on thalidomide (previously available OTC in pharmacies) when the serious and frequent risk of birth defects from its use was identified; and
- the restriction requiring a prescription for products containing phenacatin when it was identified as causing severe kidney damage (see Case study 4).

**CASE STUDY 4: Stricter control on access to potentially damaging products**

In the 1960s a range of combination analgesic products containing phenacetin and other analgesic substances was freely available from general retail outlets including supermarkets and service stations. Research then identified phenacetin as causing serious kidney damage known as analgesic nephropathy. As a result of that research, products containing phenacetin were rescheduled to PRESCRIPTION ONLY.

In response to these restrictions, alternative analgesic products were developed. While this resulted in some initial costs to industry, the longer-term benefits to industry (removal of a threat of liability and the capacity to replace the products with safer alternatives) helped to offset those costs.

Following the imposition of these strict controls on access to products containing phenacetin, there was a significant decline in new patients with analgesic nephropathy entering dialysis waiting lists in Australia. Although there is some dispute about the exact extent to which imposition of these controls contributed to the decline in analgesic nephropathy, there is general agreement that it made a significant difference

**Source:** Duggin, 1996; Nanra, 1993; Gleeson, 1988.

Another **benefit** which flows from the restrictions arise through intervention by appropriate experts to ensure the effectiveness of a medicine is not affected by interactions with other medication. For example, enzyme-inducing drugs may cause failure of combined oral contraceptives by increasing their metabolism and clearance. This effect is well established for a number of anti-epileptics, griseofulvin and rifamycin antibacterials and has also been suggested for some antivirals and for modafinil. In these cases, unless alternative contraceptive measures are used, unintended pregnancy may result. This would impose **costs** on the CONSUMER and the COMMUNITY AS A WHOLE.

There are also public health **benefits** for the COMMUNITY AS A WHOLE in restricting access to some medications. For example, there is widespread community concern over the development of antibiotic-resistant organisms, many of which have occurred as a result of the overuse and inappropriate use of antibiotics. If antibiotics were more readily available, the rate at which resistant organisms developed would escalate significantly. This could see the re-emergence of many diseases which have been largely brought under control in Australia, e.g. tuberculosis. This in turn would see medical and hospital costs increase considerably.

## Controlled substances

Controlled substances are those that cause dependence, are abused or may be diverted to the illicit drug market. These substances are generally included in *Schedule 8* although there are some controlled substances in *Schedules 2, 3 and 4*. In general all jurisdictions apply additional restrictions for controlled substances, over and above those that apply to all prescription medicines. These substances are mostly covered by the three United Nations drug treaties.<sup>42</sup> However, other substances, such as anabolic steroids, which are abused may be included in controlled substances legislation in some jurisdictions.

## Objective of restrictions on controlled substances

The objective of these additional restrictions is to prevent abuse, medical dependency and diversion of these substances to the illicit drug market. Given the nature of the substances, the risks of such events occurring are very high.

## Nature of restrictions on controlled substances

The controls at State and Territory level may be imposed either under drugs, poisons and controlled substances legislation or by separate controlled substances legislation or by both controlled substances legislation and drugs and poisons legislation. Where jurisdictions have separate controlled substances legislation there is considerable variation in the scope of the controls included in that legislation. The controls may include.<sup>43</sup>

- all controls applied to controlled substances (*Schedule 8*, some *Schedule 4* and some precursor chemicals which may or may not be included in the schedules);
- the controls imposed by Appendix D or similar controls;
- the prohibitions on certain substances (*Schedule 9* but generally not those included in Appendix C);
- other controls affecting the supply of medicines such as those over manufacture, distribution, reporting, handling, and storage;
- treatment restrictions for those dependent on drugs;
- harm minimisation measures, such as the supply of needles;
- and various offence provisions.

The controls related to storage, handling, recording and reporting are discussed further in Section 5. The controls are also closely related to controls in the various State and Territory crime acts.

In some jurisdiction controlled substances legislation may impose controls on other substances such as those in *Schedule 7*.

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<sup>42</sup> The Single Convention on Narcotic Drugs, 1961; The Psychotropic Substances Convention, 1972 and the Illicit Trafficking of Narcotic Drugs and Psychotropic Substances Convention, 1988.

<sup>43</sup> The Review is precluded from examining those controls which apply to harm reduction or legalisation issues.

### Effect of restrictions on controlled substances

The controls place significant restrictions on access. In some cases, not only is a prescription required but the prescriber must seek special permission to prescribe one of these substances for a patient. For some controlled substances access is prohibited (e.g. heroin, cannabis).<sup>44</sup> Strict record keeping and reporting provisions also apply to all controlled substances in *Schedule 8*. In some jurisdictions recording and reporting restrictions also apply to some other controlled substances (i.e. those in *Schedule 4*). Specific storage and handling controls also apply to controlled substances (see Section 5 for further discussion).

### Costs and benefits of restrictions on controlled substances

The restrictions on access impose **costs** on the CONSUMER to obtain the prescription (for *Schedule 4* and *8* medicines) and to attend a pharmacy to obtain supply of the medicine. Where a prescription is required there are also **costs** for GOVERNMENT in funding the visit to the doctor and in subsidising the medicine.

The need for a prescription from a doctor registered in the same jurisdiction as where the supply was to take place was seen as a barrier, particularly for mail order and Internet pharmacies. In these cases, consumers in other jurisdictions are not able to take advantage of the reduced prices offered by these pharmacies. Such considerations raise issues relevant to the *Mutual Recognition Act 1992*, including its provisions for referral of anomalies.

As in the case of all prescription medicines, the **costs** to INDUSTRY and the CONSUMER relate to the fact that the market for their products is constrained, thereby leading to higher prices. In the case of controlled substances, the extent of the constraint is even more severe than that applying in the case of all other prescription medicines. These constraints, as indicated above, deny suppliers potential profits through increased sales volumes and associated economies of scale that could be provided in the manufacturing process. These costs to industry may limit market access by some companies and this in turn would reduce the levels of competition in the marketplace for the supply of medicines. These costs are passed on to the consumer.

One of the issues raised by a number of stakeholders was the dual requirements for prescription and authorisation, which were seen by some consumers and doctors as confusing, unnecessary, cumbersome, costly and as imposing an additional restriction on access. All jurisdictions impose additional restrictions on access to controlled substances over and above those applying to all prescription medicines. In certain cases (e.g. long-term use, use of large quantities), the prescriber is required to obtain authorisation to prescribe these substances. Similar authorisation to prescribe these substances may also be required from the Health Insurance Commission (albeit for a different purpose, namely to reduce costs).

The **benefits** of these controls are that the level of abuse, medical dependence and diversion to the illicit drug market are reduced thereby reducing hospital, medical and

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<sup>44</sup> These prohibitions will not be discussed as the Review is precluded from examining issues related to legalisation.

social costs for CONSUMERS and GOVERNMENTS. The Review has been unable to quantify these benefits although some stakeholders advised the Review that without these controls they considered that the level of medical dependence would be high.

There appeared to be no alternatives to the current controls which would achieve the objectives set out above, although there did appear to be some scope to reduce some of the costs by improved uniformity and greater efficiency in the way the controls applied. These are discussed under the specific controls in Section 6.

This requirement for additional authorisation adds to the costs for the consumer as well as the prescriber, and imposes additional administrative **costs** on GOVERNMENT authorities (see Case study 5).<sup>45</sup> While these costs may be balanced by reduced costs from abuse, dependence and doctor shopping, the Review has been unable to quantify these.

While recognising that the reasons for the Health Insurance Commission requirements (to reduce the cost of subsidising doctor visits and prescriptions) and those of State and Territory governments (to reduce the level of abuse) are different, the outcome of both controls is similar. Therefore the Review was not convinced there was need for these dual controls and considered there would be a **benefit** in the Health Insurance Commission and State and Territory governments exploring options to rationalise these restrictions thereby reducing costs for GOVERNMENT, PRESCRIBERS and CONSUMERS. Greater use of electronic prescribing should assist in reducing the costs of these controls.

The costs and benefits of other restrictions which apply to controlled substances, such as recording, reporting, storage and handling are discussed in Section 5.

## Appendix D

The Review did note that SUSDP Appendix D imposes additional controls for *Schedule 4* or *8* substances (e.g to make possession without authority illegal or to limit those with authority to prescribe certain substances)

The Review also noted that the New South Wales Schedule legislation provides an interim level of control between *Schedules 4* and *8*. This provides a mechanism which in some circumstances can avoid the need to move the substance to a higher schedule. In this context, it is also noted that some substances that are *Schedule 8* in other jurisdictions, are less restricted in New South Wales, where they are *Schedule 4*. No evidence was brought to the Review's attention to indicate that the New South Wales approach resulted in a higher level of harm (more dependence, abuse or diversion) than in jurisdictions with greater controls.

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<sup>45</sup> Reference, in Case Study 5, to the Victorian drugs, poisons and controlled substances legislation: Victorian Health authorities advise that, with respect to treating cancer pain with opioid analgesics, Steps 1 and 2 are achieved in one action by completing and submitting the relevant form (DP2) and Step 7 is not necessary as notification of treatment is required only once (i.e. it does not need to be made again).

The Review considered there would be a **net benefit** to the COMMUNITY AS A WHOLE in expanding Appendix D, or an equivalent provision, to provide greater flexibility in meeting the objectives of the legislation, thereby enabling the minimum restriction necessary to be applied.

#### **CASE STUDY 5: Schedule 8 medicines**

The current legislative and regulatory requirements with which general practitioners and specialists outside public hospitals and hospices must comply to enable the prescribing of sufficient quantities often result in less than optimal care. This issue can be highlighted by considering the steps required by a general practitioner to prescribe regular controlled sustained release morphine 40 mg twice per day with morphine 2 mg/1 mL mixture for breakthrough pain, a very common scenario.

The general practitioner or specialist must:

1. Give notice of this drug use to the Drugs and Poisons Unit of the Department of Human Services under s35(2A) of the *Drugs, Poisons and Controlled Substances Act 1981*.
2. Complete and post Form DP2 'Treatment with Schedule 8 Drugs'.
3. Write three separate prescriptions, as the patient requires 10 mg, 30 mg and 2 mg/1 mL strengths of morphine, and annotate the prescriptions with quantities and strengths in words and figures.
4. Obtain prior approval from the Health Insurance Commission to prescribe more than the maximum quantity before the drug can be dispensed, this can be done by phone or post. Posting the Authority Prescription Form to the Health Insurance Commission results in a delay of at least 10 days prior to dispensing. For immediate approval and supply the Health Insurance Commission Authority Service can be contacted by phone but, in this case, no repeat authorisation will be approved. These additional tasks are further disincentives to prescribing.
5. Obtain a separate authorisation from the Health Insurance Commission for each prescription strength of opioid required: three in this scenario.
6. Repeat steps 3–5 at least every month as no repeats authorisations are granted by the Health Insurance Commission for phone approvals and whenever a dose is changed.
7. Repeat steps 1–5 whenever an opioid is changed, for example, morphine to oxycodone. This would occur frequently.

It is common for these bureaucratic hurdles to be circumvented by the prescribing of small quantities of paracetamol/codeine (30 mg) in place of morphine. The consequences of this is that patients receive a less efficacious medication and in quantities that last only three days (only 20 tablets are allowed on a regular Pharmaceutical Benefits Scheme prescription), with resultant poor pain control as patients often ration tablets accordingly.

The steps described above not only deter a busy general practitioner from prescribing suitable therapy by requiring significant organisational and time commitments but also reinforce misconceptions that morphine and other opioids are dangerous or may be abused by cancer patients. Patients have significant concerns regarding taking opioids in any case, and are often further dissuaded as they become aware of these restrictive requirements. The overall result is that in many cases patients needlessly endure pain as a direct consequence of inadequate prescribing and the difficult approval process of the most appropriate therapy.

**Source:** Peter MacCallum, Cancer Institute submission.

### **4.3.3 Need for a schedule for herbal medicines**

Two broad issues were raised with the Review in relation to the scheduling of herbal medicines: access to scheduled herbs by those best trained to prescribe them and the appropriateness of NDPSC to make decisions about herbal substances.

The issue of access to prescribe and administer scheduled herbs is really one of prescribing rights, which is outside the scope of this Review. Petitioners for herbal prescribing rights argue that orthodox practitioners do not have adequate training to safely prescribe or administer herbal medicines. They argued that those with an appropriate level of training in the safe and effective use of herbs were better placed to offer such advice. Certainly, the schedule restrictions do preclude market entry for

herbal practitioners without the ‘necessary’ qualifications, i.e. those determined for orthodox allopathic medicine.

The Review noted that Victoria recently introduced a schedule of substances to which accredited traditional Chinese medicine will have access. Development of this additional schedule allows for greater access to potentially harmful substances to those with recognised qualifications.

The Review considered that there may well be a net benefit in similar accreditation or registration systems for other modalities of herbal medicine and subsequent access to scheduled herbal substances. The Review considered that the outcomes of the Victorian legislation should be analysed after two years operation to assess the costs and benefits with a view, if appropriate to introduce a similar scheme for other complementary medicine modalities and to their introduction in all jurisdictions.

#### 4.3.4 Schedules for veterinary medicines

The Review noted that the issue of separate regulation of human medicines and agvet and household chemicals has long been an issue. It was first raised by the National Health and Medical Research Council in 1954 when the NDPSC was established. Later reviews, including the Inquiry into the Pharmaceutical Industry (Industry Commission, 1996) and the A Review of the Poisons Scheduling Process in Australia (Wall, 1996) also recommended separation of the scheduling of human medicines and of agvet and household chemicals.

The objective of restricting access to veterinarian medicine is to protect both animal and human health.

Separate regulation of agvet products was much canvassed in submissions to this Review. Considerable concern was expressed that, unless public health protection from agvet and household chemicals was controlled by health portfolios, the **benefits** to the COMMUNITY afforded by the current system (i.e. reduced poisoning, medicinal misadventure and diversion to the illicit market and their associated hospital, medical and social costs) would be eroded. This was particularly so with veterinary medicines, especially those containing controlled substances or other substances likely to be abused (e.g. anabolic steroids) or to have significant adverse effects on human health if used inappropriately (e.g. antibiotics).

The controls on scheduling agvet and household chemicals impose a **cost** on INDUSTRY and reduce the capacity of some companies to compete in the marketplace, particularly in veterinary medicine. There are also **costs** to FARMERS and PET OWNERS in the restrictions on access to veterinary medicines. The controls on agricultural and household chemicals relate mainly to labelling and packaging (discussed in more detail below and in Section 5).

The Review examined the **benefits** for the COMMUNITY of retaining the same level of control over veterinary medicines as over human medicines, as part of the overall scheduling process. The Review noted that many of the substances used in veterinary medicines were the same as those used in human medicines. Further, the Review noted that there has been considerable diversion of animal medicines for abuse purposes, particularly of substances such as steroids. The other concern raised with

the Review related to antibiotic resistance and the extent to which antibiotics used in animals contributed to this. On this basis, there was considered to be real **benefits** for the COMMUNITY (less diversion for abuse and reduced level of antibiotic resistance) in maintaining a system of controls, through scheduling of veterinary products and especially those containing steroids and antibiotics.

More generally, the Review noted the **benefits** for the CONSUMER and GOVERNMENT (preventing poisoning, medicinal misadventure and abuse and the associated hospital, medical and social costs) which could flow from retaining the same level of control over veterinary medicines as for human medicines. However, the Review recognised that this could add to costs for farmers particularly if this imposed additional controls to those that might be imposed under a separate system. On the other hand, separating the regulation of agvet chemicals may increase **costs** for GOVERNMENT and INDUSTRY by duplicating enforcement efforts.

However, the Review saw no reason why the schedule decision making could not be achieved through separate but closely related processes.

The Review also noted that medicines exclusively for veterinary use are regulated separately and are specifically identified in the schedules in New Zealand and a number of other countries. The Review considered that there may be **benefits** for INDUSTRY and GOVERNMENT in veterinary medicine being separately listed within the schedules. This is an administrative measure which should have no cost impact but one which would facilitate trade with New Zealand.

### 4.3.5 Poisons (Schedules 5, 6 and 7)

#### Introduction

Chemicals included in *Schedules 5, 6 and 7* of the SUSDP are used in household products and agvet products as well as a few medicines. The schedules designate the level of risk attaching to the substance. Part 2 of the SUSDP sets out some labelling requirements, particularly the signal heading and the packaging requirements which should apply generally and to certain substances and groups of substances included in the schedules. Appendixes E and F set out the warning and first aid statements which must be included on the label<sup>46</sup> of specific substances or groups of substances. Appendix J sets out restrictions on access which should apply to the supply and use of those highly toxic chemicals in *Schedule 7*.

All jurisdictions adopt *Schedules 5, 6 and 7* and Part 2 of the SUSDP and while most also adopt Appendixes E and F there are a few that do not, or which qualify the way in which they are adopted. In those jurisdictions that do not adopt Appendixes E and F, there are generally similar provisions within the legislation although they do not have exclusions for agvet chemicals which are included in Appendixes E and F.

The situation with Appendix J is more variable and also overlaps with the conditions imposed by the National Registration Authority for Agricultural and Veterinary

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<sup>46</sup> Appendixes E and F of the SUSDP exclude agvet products labelled in accordance with the requirements of the *Agricultural and Veterinary Chemicals Code Act 1994*.

Chemicals. Section 93 of the *Agricultural and Veterinary Chemicals Code Act 1994* provides that the NRA may declare a chemical to be ‘restricted chemical product’. Products declared to be restricted chemical products may only be supplied to authorised persons and must be labelled to reflect this.<sup>47</sup>

In some cases this creates considerable uncertainty as to the extent and nature of the controls that apply to the use and possession of products containing some Schedule 7 substances. There is clearly a need to rectify this situation. The Review considered that this could be achieved if all jurisdictions adopted Appendix J.

*Schedule 5* poisons are substances which, because of the relatively low toxicity, concentration or hazard of the chemical(s), have limited potential to cause minor adverse effects in human beings when used normally, but which require caution in handling, storage or use. *Schedule 6* poisons have moderate to high toxicity and may cause severe injury or death if ingested, inhaled or come into contact with the skin or eyes.

Many of the substances used in agvet and household chemicals are also used in industrial chemicals that are regulated under occupational health and safety legislation. Where a new chemical<sup>48</sup> is included in these the products, the chemical is required to be included on the National Industrial Chemical Notification Assessment Scheme.

There has been some confusion for industry where products may be used in domestic, therapeutic and industrial settings. This is discussed further below and under labelling in Section 5.

Internationally, there are initiatives to develop a globally harmonised system for labelling and packaging hazardous chemicals. Australia has been participating in those initiatives. However, the extent to which these recommendations will apply to domestic chemicals is unclear at this stage.

### **Objectives of controls on poisons**

There are a large number of poisons used for agricultural, veterinary and household purposes.

The objective of the controls is to prevent accidental and deliberate poisoning, particularly in children by agricultural, veterinary and household products..

**Step 1**

**Clarify objectives of legislation**

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<sup>47</sup> See Sections 94 and 95, *Agricultural and Veterinary Chemicals Code Act 1994*.

<sup>48</sup> A ‘new chemical’ in this context is one which is not currently included in a product on the Australian market



## Nature of restrictions

### Step 2

#### Identify nature of restriction on competition

Scheduling of household chemicals ensures appropriate labelling and packaging, with adequate safety and storage directions at the time of sale. Some of these products are also used widely in industry where they are subject to occupational health and safety legislation. Household chemicals do not have a registration scheme like that for therapeutic goods and agvet chemicals, nor does there seem to be a strong case for one.

The Review noted that the current restrictions do not require household chemicals to include full details of their ingredients on the label.

## Effect of restrictions on poisons

### Step 3

#### Analyse effects of restriction

The restrictions on poisons impose certain labelling and packaging requirements on product manufacturers. For some *Schedule 7* substances there are restrictions on the level of access<sup>49</sup> – generally, these restrictions are intended to ensure the products are used only by those who are appropriately qualified. The considerable variability in the way in which these controls are applied<sup>50</sup> across jurisdictions makes it difficult to assess the extent to which this restricts market entry and limits competition.

The Review noted the concern expressed by some industry stakeholders that the use of the signal heading POISON posed a significant barrier to competition as this signal heading acted to deter potential customers in some circumstances. The Review was also advised that this signal heading was inappropriate for use on veterinary products as owners of animals were reluctant to give their animals a product so labelled. The signal heading for *Schedule 5* has also been identified as being of uncertain meaning to consumers (Ley, 1995) and the Review considered that a more specific warning relating to the actual hazard is called for.

The Review noted the labelling project currently being undertaken by the Therapeutic Goods Administration and the Review of the Model Labelling Regulations being undertaken by the National Occupational Health and Safety Commission (NOHSC), and sees potential in the outcomes of these projects to improve the effectiveness of labels for *Schedule 5, 6* and *7* poisons.

The nature of the signal heading is a technical issue that is not appropriate for the Review to address. Nonetheless, in considering opportunities for greater efficiency through closer alignment with related legislation, the Review has proposed that the possibility of closer alignment of the labelling requirements under occupational health

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<sup>49</sup> In some cases, these restrictions are included in agvet legislation and not in drugs and poisons legislation.

<sup>50</sup> In some jurisdictions these restrictions are imposed by regulation but in other they are imposed through delegated legislation by officials (e.g. the Executive Direction of Health in Queensland) issuing an authorisation.

and safety legislation and drugs and poisons legislation be explored. This is discussed in more detail below.

## Cost and benefits of the controls

The **costs** for INDUSTRY and GOVERNMENT of the controls relate mainly to the cost of labelling and packaging and their administration. These issues are discussed in more detail in Section 5.

### Step 4

Analyse  
benefits and  
costs

There are also costs for industry in establishing the requirements that apply where these differ across jurisdictions.

In general, the jurisdictional differences in this area are minimal. There may also be a cost in establishing whether a product comes under drugs and poisons legislation or under occupational health and safety legislation. However, the Review did not see these costs as significant. This matter is discussed further in Section 5.

The Review noted that industry is willing to accept the cost of regulation where safety issues are concerned. One industry submission stated:

Compliance with safety regulations is a basic cost of doing business. If companies, small or large, are unable or unwilling to comply with safety requirements, they should not be participating in the market. (Australian Supermarket Institute)

A more significant **cost** for INDUSTRY, which was brought to the Review's attention was the impact on competition which flows from the requirement for *Schedule 6* products to carry the signal heading POISON. The Review has discussed options for minimising this cost, below.

The **benefits** to the CONSUMER and to GOVERNMENT which flow from the controls are that the level of poisoning is reduced thereby reducing medical and hospital costs. Experts in the field of childhood poisoning consider that the packaging restrictions which require products to be in a child-resistant packaging offer considerable benefits in reducing the number of childhood poisonings. This is discussed further in Section 5. Although no evidence was provided to the Review, the requirements that first aid instructions be included on the labels of certain products would seem to provide a benefit by potentially minimising the extent of the harm that may occur where a poison is ingested.

These requirements add marginally to the **costs** for INDUSTRY of bringing the product to market in that product sponsors need to establish the details required on the label and the nature of the packaging. There is also an impact on competition in that the product sponsor has limited capacity to differentiate their product from others on the market.

The fact that the current restrictions do not require manufacturers to include full ingredient details on household chemical labels can delay treatment or lead to unnecessary hospital admissions for observation because it is not immediately possible to assess the likely harm and advise the appropriate treatment. The Review considered that, were more information made available on the composition of these products, the number and cost of precautionary hospital admissions would be reduced.

## Alternatives

### Step 5

#### Consider alternatives and recommend

The Review considered whether the restrictions that apply to *Schedule 5, 6 or 7* were necessary or whether the objective of the legislation – to prevent poisoning – could be achieved by other less regulatory means. Given the toxicity of these substances and their potential to cause significant and possibly fatal harm, the Review considered that removing all regulation was not an appropriate option as some industry members would not package or label the product in a way that minimised the risk of poisoning. Without these controls the Review considered there would be increased medical and hospital **costs** for CONSUMERS and GOVERNMENTS as a result of an increased number of poisonings, particularly among children.

The toxicity of *Schedule 7* poisons is such that the Review considered they should only be supplied and used by those who were trained in their use. Consequently, the Review could not see any alternative to the current *Schedule 7* controls that would achieve the objectives of the legislation. However, the Review did note the varying way in which the controls flowing from inclusion of a substance in *Schedule 7* are imposed by the jurisdictions. These may be applied through agvet legislation, drugs and poisons legislation or a combination. Further there is considerable variation in the instruments used to impose the controls.

For *Schedule 5* and *6* substances, the Review also considered whether there were alternatives to the present regulatory controls to ensure products were labelled and packaged in way that enabled the product to be used safely and effectively. The Review considered whether self-regulation through industry codes of practice was an appropriate option. However, because of the range of products covered and the fact that many businesses do not belong to industry associations the Review considered that it would be difficult to ensure compliance. As noted previously, non-compliance may involve quite considerable **costs** to CONSUMERS and to GOVERNMENT through accidental poisonings. Further, the Review considered that with legislative underpinning the code would be little different to the current standard.

Similarly, the Review considered that relying on consumer protection legislation would reduce the **benefits** to the COMMUNITY of the control because a number of businesses would not have the resources to properly identify the appropriate requirements for labelling and packaging their product to prevent poisonings. Further, any action under general consumer protection legislation will be after the event. Thus a significant number of poisonings could occur before action is taken. The Review considered that there was **net benefit** to the COMMUNITY AS A WHOLE in maintaining the controls associated with *Schedules 5* and *6*.

### Need for three poisons schedules

Consideration was also given to the need for three poisons schedules. If it were possible to reduce the number of schedules, there may be some benefits to industry in terms of simplifying the labelling requirements. The costs of this simplification would depend largely on how particular substances were classified under a system that had only one, or at most two, schedules. While the Review is precluded from examining the criteria for scheduling, it noted that if a significant number of substances were to

be placed in a lower schedule this might lead to an increase in accidental poisonings with consequential **costs** to CONSUMERS and GOVERNMENTS. In this context the Review noted that consumers were likely to take greater care to use a product according to directions if it was labelled POISON than if it had the *Schedule 5* signal heading of CAUTION (Ley, 1995).

If, on the other hand, a significant number of substances were placed in a higher schedule, there would be **costs** to INDUSTRY in terms of reduced access to their products or, as described above, consumer resistance to using a product labelled POISON.

Few submissions commented on the need to retain *Schedules 5* and *6*, although there was some support for a simpler more appropriate system. The major issue of concern was the inappropriateness and lack of flexibility of the signal heading for some products as discussed above. The Review noted that the key difference in the controls centered on the different signal headings which flow from the schedule in which a substance is included – CAUTION for *Schedule 5* and POISON for *Schedule 6*. These designate the level of hazard related to the substance. However, if a more flexible system of signal headings were to be adopted, it may be that *Schedules 5* and *6* could be combined to provide a single schedule that designated those substances to which special labelling and packaging restrictions applied. The particular restrictions that apply to each substance would continue to be designated as they are at present through Part 2 of the SUSDP and Appendixes E and F.

In this context the Review noted international initiatives aimed at introducing a harmonised classification and labelling system for industrial chemicals. This issue is discussed further in Section 6.

Several submissions also commented that there was a public health risk if inconsistencies arose because agvet chemical products carried different warnings to household chemical products containing the same substance. One submission said that the risk related mainly to the substance, irrespective of the product in which it was contained. The Review does not support this view, as there are a number of factors that can influence the risks. For example, if one product contains a bittering agent while the other does not, the likelihood of poisoning with the first product is likely to be considerably less than with the second. Similarly, the formulation of a product can influence whether or not the product is likely to be absorbed either from the skin or if swallowed or it can affect its volatility which may affect the likelihood of it having a corrosive effect on the eyes.

The Review considered that there was a **net benefit** to the COMMUNITY in retaining *Schedule 7* to designate those substances that are highly toxic and need special restrictions on access for their safe use. To do otherwise would lead to increased hospital and medical **costs** for CONSUMERS and GOVERNMENTS.

In summary, the Review considered that, at present, there were **net benefits** for the COMMUNITY AS WHOLE in maintaining the existing three schedule system for poisons because of the flexibility it provided in terms of being able to categorise substances according to their levels of risk. However, the issue of retaining both *Schedules 5* and *6* should be reconsidered if a more flexible system of signal headings is developed.

## Full disclosure of ingredients for household chemicals

The need for a mandatory requirement that labels on all household poisons include a full list of ingredients and other relevant details (e.g. the pH of the product) was raised with the Review. At present, when a poisoning occurs the Poisons Information Centres<sup>51</sup> are unable to determine the most appropriate treatment (which may well be observation at home for 24 hours) if the product consumed does reveal its chemical composition. Where details of the composition of a product are not readily available, the Poisons Information Centre is likely to err on the side of caution and refer the person to emergency outpatient departments at public hospitals, thus leading to avoidable hospital costs.

It has been suggested to the Review that cooperation between the Poisons Information Centres and the relevant industry associations could identify ways of overcoming these difficulties. One approach could be that material data safety sheets, which, by law, should be available for these products under occupational health and safety legislation, should be made available to Poisons Information Centres and hospitals.

The Review considered that there would be a **net benefit** to the COMMUNITY AS A WHOLE from this cooperative approach as the **costs** for INDUSTRY and GOVERNMENT (for administration) of mandating that all ingredients be included on the label could not be justified.

The issue of the scope to achieve greater integration with the hazardous chemicals requirements under industrial chemical health and safety legislation is discussed in Section 6.

## 4.4 NDPSC and the current scheduling system

As noted previously, under the current system of regulation, drugs and poisons that pose a potential risk to public health (e.g. OTC and prescription medicines, household and industrial chemicals, pesticides, veterinary medicines, cosmetics, paints etc) are scheduled by the NDPSC.

The intrinsic hazard (toxicity), purpose of use, potential for abuse, safety in use and the need for the substance are all considered when substances are classified into schedules. The probability of harm to vulnerable groups, such as children who may be at risk of accidental poisoning because of accessibility, is also an important consideration.

The primary rationale for these controls is to redress the information asymmetry between consumers, on the one hand, and industry on the other which, if not appropriately managed, could lead to significant and possibly fatal outcomes for consumers.

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<sup>51</sup> These centres provide emergency and other information about poisons to consumers, doctors and hospitals. To be able to provide this service, the Poisons Information Centres need the full details of the ingredients of a product so the appropriate advice on treatment can be given.

Each schedule attracts a set of specific requirements that are mainly applied at the point of sale. These include conditions of access (to whom it may be sold and under what conditions) and labelling for dispensed medicines. Controls also apply to labelling and packaging and to various elements of business conduct (e.g. storage). The controls on business conduct have largely been put in place to support and complement the limitations on access.

The scheduling of substances, and the corresponding controls, are consolidated by the inclusion of the scheduling decision of the NDPSC in the SUSDP. There are also additional controls that are specific to a substance in a particular presentation and quantity, which may be set out in the SUSDP Appendixes.

The current scheduling processes are summarised in Figure 4.1.

Membership of the NDPSC includes representatives of all Australian jurisdictions and New Zealand, relevant Commonwealth and New Zealand government agencies, industry, consumers and professionals as well as relevant experts.

The processes of the NDPSC were codified in amendments to the *Therapeutic Goods Act 1989*, proclaimed in April 1999.

The NDPSC makes scheduling decisions in relation to new substances, new presentations of substances already in the schedules (new strengths, different combinations, or uses etc) and rescheduling of substances currently in SUSDP.

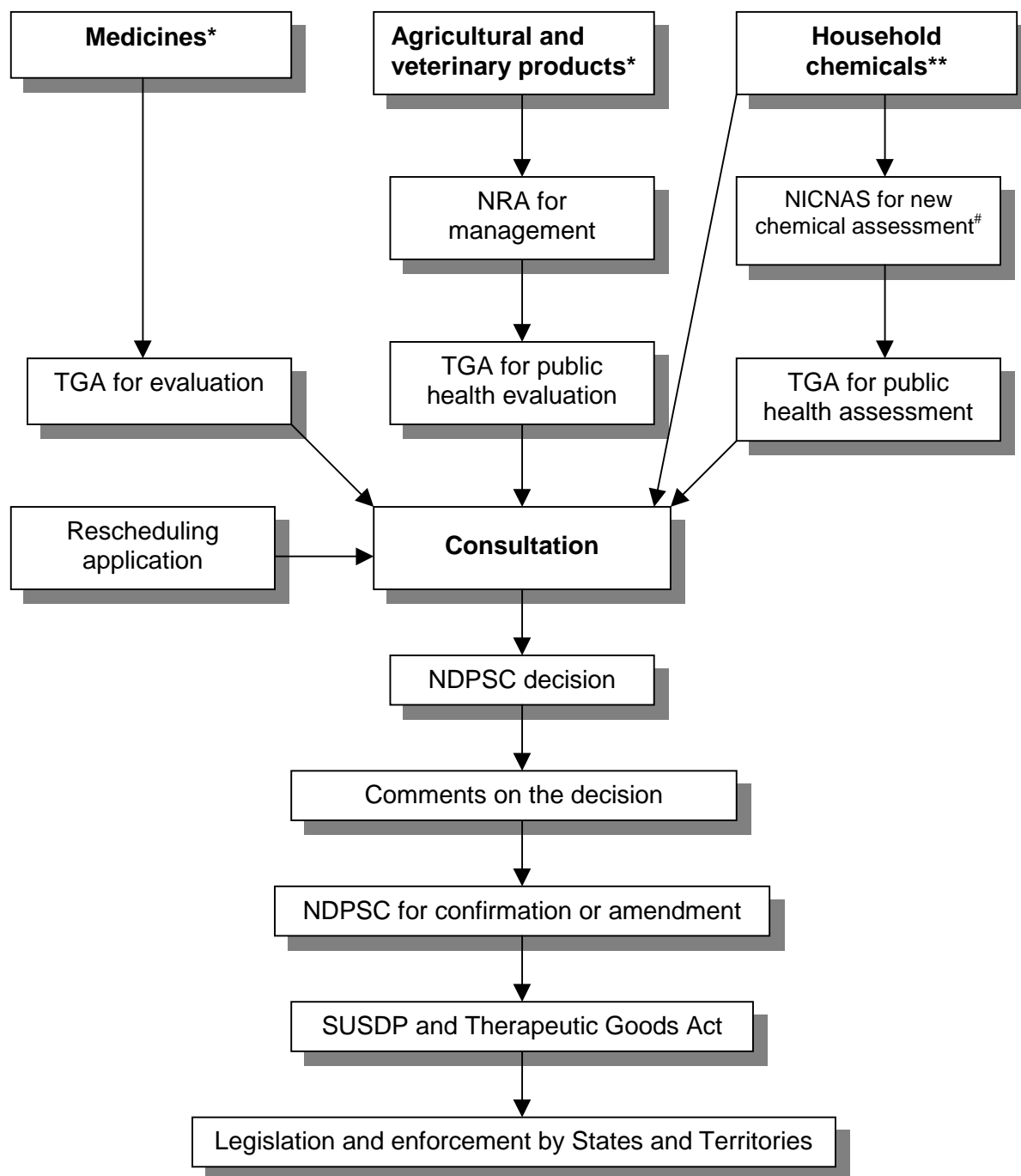
The *Therapeutic Goods Act 1989* amendments, proclaimed in April 1999, codify the matters to be taken into consideration in reaching a decision, by having them established under relevant Commonwealth legislation. Details of the criteria to be applied are set out in the *National Drugs and Poisons Scheduling Committee Guidelines* (pp. 17–31).

As required by the *Therapeutic Goods Act 1989* the NDPSC actively seeks stakeholder input. All proposed scheduling decisions are gazetted before the meeting, all decisions made at meetings are gazetted, and further comments on those decisions are invited after which the decisions are reviewed and amended or confirmed (see figure 4.2).

Generally, all States and Territories adopt NDPSC decisions, either by reference or by orders published in the Gazette of the relevant jurisdiction, within three months of the NDPSC decision seven months after notification that the Committee is to consider a substance.

The NDPSC processes are considered cumbersome and anti-competitive by some, but the Review noted that the present arrangements have achieved a high level of consistency in scheduling across the States and Territories.

Figure 4.1: Present arrangement for scheduling drugs and poisons



**Notes:**

- \* Medicines and agvet chemicals: all products are required to be evaluated.
- \*\* Household chemicals: only evaluated when an issue of concern is brought to the attention of the NDPSC.
- # National Industrial Chemicals Notification and Assessment Scheme (NICNAS) also has a program to assess the safety of chemicals on a priority basis.

#### 4.4.1 Standard for the Uniform Scheduling of Drugs and Poisons

The SUSDP referred to above contains the recommendations of the NDPSC. It provides a model for the States and Territories to maintain the uniformity of their poison schedules and includes other model provisions. The purpose of the SUSDP is to promote uniform scheduling of substances and uniform labelling and packaging requirements throughout Australia. It is published as a paperback document four times per year as the NDPSC decides amendments.

The schedules recommend substance classification according to the general description given in the introduction. The first schedule is currently not used. *Schedules 2 and 3* are for human non-prescription medicinal substances and *Schedule 4* is for prescription human and animal medicinal substances. *Schedules 5 and 6* are for domestic, agricultural and veterinary substances ranked lower to higher risk. *Schedule 7* contains dangerous poisons requiring special precautions; *Schedule 8* contains medicinal substances requiring stricter controls; and *Schedule 9* substances are prohibited for manufacture, possession, sale or use.

The Part 2 of the SUSDP and some of the Appendixes include definitions and recommendations on a number of matters related to scheduling, including:

- labelling (e.g. warning statements, first aid instructions);
- packaging (e.g. pack size, child resistant closures, blister packs); and
- advertising; and
- additional restrictions (e.g. substances which should be totally banned).

The SUSDP Appendixes supplement the *Schedules* by setting out additional controls, and qualifications and exemptions that should apply to some substances. These controls include to whom some products may be sold and under what conditions. Controls on advertising are covered in SUSDP Part 3 and Appendix H.

There are multiple references to the SUSDP in this report and it must be stressed that the controls applied through the recommendations of the SUSDP are those applied in the States and Territories legislation through adopting the SUSDP. The legislative and administrative differences between the jurisdictions means that uniform application of the Schedules and recommended standards is not always achieved. However, there is sufficient uniformity in the Schedules for them to provide a convenient starting point for discussion.

#### 4.4.2 Scheduling processes and arrangements

The NDPSC is a statutory committee established under the *Therapeutic Goods Act 1989*. Its functions are to determine the classification and schedule of substances<sup>52</sup> for inclusion in the SUSDP. The process for determining the SUSDP schedule is set out

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<sup>52</sup> Generally medicines are included in *Schedules 2, 3, 4* and *8* while other poisons are included in *Schedules 5, 6* and *7*. *Schedule 9* includes prohibited substances.



in the *Therapeutic Goods Act 1989* and Regulations. This process includes two rounds of public consultation and voting procedures. NDPSC decisions must include support from a majority of the jurisdictions as well as a majority of the committee.

NDPSC decisions generally have no effect, i.e. the controls do not come into operation until they are included in State and Territory legislation.<sup>53</sup> The controls, which apply to a substance, are largely determined by the schedule in the SUSDP in which it is included.<sup>54</sup> The way in which NDPSC decisions are adopted into State and Territory laws varies. In some jurisdictions the decisions are adopted automatically by reference (unless action is taken not to accept a specific scheduling decision) while the remaining jurisdictions require specific action before it can come into force (e.g. gazettal of the decisions).

Currently, there is no nationally agreed mechanism for determining the controls to apply to the schedules, for accepting the additional measures included in the SUSDP or ensuring consistency of the controls across jurisdictions. However, when the NDPSC was given legal status under the *Therapeutic Goods Act 1989*, the NCCTG was invested with responsibility for providing policy direction to the Committee.

One submission from an industry peak body argued that scheduling was within the Commonwealth's power and should become a Commonwealth responsibility. While this may be so in relation to the scheduling decisions for medicines and agvet chemicals, and for some household chemicals, it is the application of the controls which flow from scheduling a substance, particularly as they impact on access, that is the critical issue. The Review was advised that the Commonwealth does not have the Constitutional power, in most cases, to limit access to products.

Several comments from industry related to the variability in the time of adoption and the timeliness with which scheduling decisions were adopted although the Review has been unable to identify any significant differences in the time of implementation across jurisdictions. One industry submission argued for a longer lead time for changes on the basis that this additional time was need to change labels. Timeframes for the different steps in the scheduling process are set out in Figure 4.2.

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<sup>53</sup> There are a few exceptions, e.g. the restrictions on advertising in the *Therapeutic Goods Act 1989* are based on the SUSDP *Schedule* of a substance

<sup>54</sup> In general, the schedule of a substance in State and Territory legislation is closely related to its schedule in the SUSDP.

**Figure 4.2. Scheduling process timetable**

TIME	ACTION REQUIRED
Week 1	1. Submissions must be received by the Secretariat at least 16 weeks before the meeting at which the decision is to be considered. <sup>55</sup>
Week 11	2. At least five weeks before the date of the scheduling meeting, the Chair of the NDPSC must give notice of the meeting and details of the substances to be considered and invite submissions. <sup>56</sup>
Week 15	3. Submissions close a week before the scheduling meeting provided that at least 4 weeks have been allowed for submissions. <sup>57</sup>
Week 16	4. NDPSC meets to consider scheduling decisions.
Week 20	5. Notices of amendments to the SUSDP are published approximately six weeks after the scheduling meeting. The notice gives the date on which the amendment is to come into force and further submissions from those who made submissions in response to the pre-meeting notice are invited. <sup>58</sup>
Week 22	6. Persons making a further submission, as mentioned at Step 5, must do so within two weeks of the publication of the notice making the invitation. <sup>59</sup>
Week 29	7. At the next meeting of NDPSC, the decision taken at the previous meeting is confirmed, amended or replaced. <sup>60</sup>
Week 33	8. If the decision is amended in any way, a notice giving details of the amended decision is published and consultation begins again at Step 6.
Week 42	9. SUSDP decision generally becomes effective and also comes into effect under State and Territory legislation. <sup>61</sup>

#### 4.4.3 Discussion

The Review has identified a number of problems with the current scheduling processes and with the relationship between the scheduling processes and the regulatory system that flows from the schedules. These problems are:

- the lack of uniformity in the uptake of the SUSDP and controls that apply to the schedules, and of a mechanism to develop and maintain uniform controls. This is discussed further in Section 6;
- the inefficiency of the NDPSC arrangements where one committee is responsible for regulating both medicines and poisons (particularly given the

<sup>55</sup> The Secretariat must receive matters for scheduling decisions that arise from the evaluation process for human medicines (under the *Therapeutic Goods Act 1989*) or avet chemical products (under the *Agricultural and Veterinary Chemicals Code Act 1994*) at least seven weeks before the meeting at which they are to be considered so agenda papers can be prepared and the notification required under Therapeutic Goods Regulation 42ZCU given.

<sup>56</sup> These times are set out in the Therapeutic Goods Regulation 42ZCU.

<sup>57</sup> These times are set out in the Therapeutic Goods Regulation 42ZCU.

<sup>58</sup> This notification and invitation to persons who made a public submission in relation to the substance to make a further submission is required by Therapeutic Goods Regulation 42ZCY.

<sup>59</sup> See Therapeutic Goods Regulation 42ZCZ.

<sup>60</sup> See Therapeutic Goods Regulation 42ZCZ.

<sup>61</sup> In those jurisdictions that adopt the scheduling decisions of the NDPSC by reference the effective date will be the same as the effective date of the NDPSC decision. In other jurisdictions there may occasionally be a delay if the necessary administrative action to adopt the decision has not been taken. However, in general, these decisions also come into effect on the same day as the NDPSC decision.

wide range of substances involved and the variety of ways and settings in which they are used);

- the composition of NDPSC does not adequately represent stakeholders – its processes are seen as inefficient and its voting system has been criticised because the weight given to the vote of all members is not equal;
- that for those products which are subject to evaluation under other legislative processes, the efficiency and timeliness of the scheduling process could be improved by closer integration with those evaluation processes; and
- that the timeliness and efficiency of the current consultation processes could be improved.

### Separate regulation of medicines and poisons

The Review noted that separate regulation of drugs and poisons was first proposed by the National Health and Medical Research Council in 1954. It was also raised in more recent reviews of drugs and poisons scheduling<sup>62</sup> and was an Industry Commission recommendation in the Report on the Pharmaceutical Industry in 1996.<sup>63</sup> The Commission saw this as an important step in improving the efficiency of scheduling decision-making processes for medicines.

The Review noted that, in all other comparable countries, medicine and poisons are regulated separately.

The opinion of stakeholders was divided on whether the benefits of establishing two separate committees to schedule medicines and poisons outweighed the costs. Industry was generally in favour of separating medicine scheduling from poisons scheduling.

Regulators raised concerns, however, that such a separation might also lead to inconsistency in the way a substance is regulated (e.g. when included in agvet products and when included in household chemicals). The Review noted that, to some extent, this concern appears to arise because of confusion over whether it is products or substances that are being regulated and an assumption that consumers are not able to appreciate that different products containing the same substance may have different risk profiles.

Several government agencies and one professional group suggested that, rather than separating into two different committees, it would be preferable to establish two subcommittees of the NDPSC, with NDPSC providing coordination and consistency between the two.

The Review noted that the proposal to establish sub-committees would add considerably to administrative **costs** for GOVERNMENT and would be likely to extend

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<sup>62</sup> e.g. *Review of the Poisons Scheduling Process in Australia*, Wall B (1996) recommended a separate committee for scheduling agvet chemicals.

<sup>63</sup> See vol 1 pp. 404, 433 and 435: the Commission stated that ‘drugs are different to other poisons and require careful consideration of risk–benefit trade-offs, including the risk associated with undue restriction of availability’ (p. 433).

the time taken to make a decision thereby increasing INDUSTRY costs and potentially delaying access to new substances for consumers. The Review did not consider that these additional costs were justified.

While costs should certainly be an important factor in considering the number of Committees that should operate in this area, the principal concern is about the level of public health protection the scheduling process supports.

The Review noted in this regard, that over the last decade Australia has developed a comprehensive national system requiring all medicinal and agvet products to be regulated under Commonwealth legislation<sup>64</sup> which requires the products to be assessed for safety. The Review noted that the scheduling system pre-dates the introduction of this national system of product assessment. These assessments are based on the toxicological assessment of the substance(s) in the products as well as taking into consideration a number of other matters including the purpose for which the substance is to be used and its efficacy for that purpose.

While, as noted previously, there is no comparable national registration scheme for household chemicals, all new chemicals must be assessed for safety under the National Industrial Chemicals Notification Assessment Scheme before being introduced<sup>65</sup> in a product marketed in Australia.

Therefore, given the changes to the regulatory framework as well as the increased range of substances covered by drugs, poisons and controlled substances legislation, and their increased use, there are strong arguments that efficiency would be improved by at least partial separation of the regulation of medicines and poisons. While there may be a need for consistency<sup>66</sup> in some cases, this should be only one factor taken into consideration when deciding the controls that should apply to a substance or product. Further, the Review considered that these concerns could be addressed if the Secretariat of the two committees remains with the Therapeutic Goods Administration and formal processes of communication between the two committees are established.

The Review considered that separating the regulation of medicine and poisons may also facilitate moves towards harmonisation with New Zealand of the regulatory controls in this area. The partial separation proposed by the Review involves disbanding the NDPSC and replacing it with two committees, one to address scheduling matters related to human medicines and the other those scheduling matters related to poisons, including agvet chemicals. This proposal would also facilitate improved efficiency through closer integration of the scheduling decision-making with the evaluation process for medicines and agvet products.

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<sup>64</sup> *Therapeutic Goods Act 1989* and *Agricultural and Veterinary Chemicals Code Act 1994*

<sup>65</sup> 'Introduced' is defined as 'the importation or manufacture in Australia of the chemical' under the *Industrial Chemicals (Notification and Assessment) Act 1989*

<sup>66</sup> There is concern that different controls (e.g. different warning labels, different packaging requirements and different signal headings) applied to products containing the same substance may cause confusion to consumers, which could lead to them ignoring warnings and precautions and result in harm, such as poisoning. While these products will not always have the same risk profile because of the formulation or way in which they are to be used, there is merit in ensuring that, where appropriate, the controls applied to the same substance are as close as possible.

## Committee membership and processes

The Review noted the concerns of stakeholders that the current membership did not include expertise or representatives of all relevant sectors. In considering these concerns, the Review noted that the current Committee is quite large<sup>67</sup> and that to increase its membership further could make its deliberations difficult and management of its processes less cost effective.

The Review also noted that the experience and expertise of some representatives and experts was primarily focused on either human medicines or agvet and household chemical areas. Therefore the Review considered that the involvement of all committee members in the full range of scheduling decisions was not the most cost-effective use of their time and expertise. For these reasons, the Review considered that two Committees would enable the membership of the committees to be more specifically focused.

More generally the Review also considered what the overall composition of Committee should be. In doing this the Review considered the nature of the decisions the committee makes, the effect of those decisions on different sectors of the community, other NDPSC processes for reaching a scheduling decision and who had responsibility for implementing the decisions.

The Review considered that, while a committee composed solely of experts would provide governments with independent advice, a committee of experts may not adequately reflect or give due weight to the responsibilities of State and Territory governments in protecting public health and safety. Similarly, the decisions of a committee comprised solely of jurisdictional representatives would be less robust because they would be made without the benefit of input by and debate with a broad range of experts and representatives. While the jurisdictional members would have the benefit of public submissions, the Review considered that this would not always elicit the full range of matters that the committee needed to consider. Therefore, the Review concluded that committee membership which incorporated a balanced mix of perspectives and expertise would be best placed to consider the scheduling proposals and weigh up the submissions received in relation to scheduling medicines and poisons.

The voting procedure of the NDPSC was one of the more contentious issues raised by stakeholder representatives in the course of the Review's consultations. Moreover, the Review was aware that this issue pre-dates the Review. There were very strong objections from a number of interested parties about the current arrangements whereby the final decisions requires the support of a majority of the jurisdictional members.

The Review considered whether it was in the best interests of the community as a whole for decisions to be made by a majority vote of the whole committee. The Review noted that, ultimately, the responsibility for the scheduling a substance

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<sup>67</sup> Currently membership is 20 members comprising 10 jurisdictional members (i.e. one from the Commonwealth, each State and Territory and New Zealand) four experts and six representatives of various community sectors and government organisations.

depends on the adoption into State and Territory legislation of the NDPSC decision. Adoption by all jurisdictions of all scheduling decisions is a crucial element of a uniform scheduling system. Therefore the Review concluded that, on balance, the scheduling system and the community as a whole was best served by a voting system that allowed all committee members to play a role in the decision making but with jurisdictional members having the key voting power. Consequently the Review considered that the current voting system set out in the *Therapeutic Goods Act 1989* should be retained.

### **Closer links between evaluation processes and scheduling**

Some stakeholders suggested that there would be improved efficiencies if there were a closer link between the scheduling decision and the evaluation processes for those products, which undergo evaluation. This would also be consistent with the New Zealand approach and as such could contribute towards meeting the objectives of the Trans Tasman Mutual Recognition Arrangements.<sup>68</sup>

The Industry Commission Inquiry into the Pharmaceutical Industry (1996) stated that it considered:

... there are sound reasons for unifying the registration and scheduling processes. In particular:

- as scheduling and registration decisions are essentially about management of risk, consistent criteria would reduce the cost of delay, lack of uniformity and errors ...<sup>69</sup>

The Review recognised that the focus of the two assessments differs, with the emphasis of product evaluation being on the safety and efficacy of the product, while the emphasis in scheduling focuses more broadly on safety from a public health perspective. Nonetheless, for new products much of the data considered will be the same. For human medicines and agvet products responsibility for many labelling and packaging controls (e.g warning statements, child-resistant packaging) are already addressed under the product evaluation processes of the *Therapeutic Goods Act 1989* and the *Agricultural and Veterinary Chemical Code Act 1994* respectively.

The Review therefore considered that efficiency would be improved if a recommendation is made by the evaluator during the product evaluation process for a new substance or a new formulation or other factor that significantly alters the risk profile, and that this would provide **benefits** to INDUSTRY and GOVERNMENT. The guidelines for product evaluation will need to be expanded to include the NDPSC scheduling criteria and guidelines.

Incorporating substance scheduling with product evaluation will also enhance the capacity for harmonising the SUSDP with the New Zealand schedules, by inclusion of decisions on what is currently known as reverse scheduling in the evaluation process. Reverse scheduling is the exemption to a lower schedule or removal from the

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<sup>68</sup> Therapeutic goods and industrial chemicals have temporary exemptions from these arrangements while agricultural chemicals have a permanent exemption.

<sup>69</sup> Industry Commission report on the Pharmaceutical Industry 1996, pp. 432–33.

schedules, for a substance in a particular product type, meeting criteria for risk reduction, such as reduced pack size, or additional warnings on the label. These exemptions are for product characteristics, not the substance per se, and could be efficiently decided within an evaluation of the product.

The recommendations of the evaluating agency would be advised to the relevant Scheduling Committee (MSC or PSC) which would advertise the decision inviting submissions. The remaining scheduling process followed by the MSC or PSC would then be similar to that currently followed by the NDPSC, except that some of the assessment for public health and safety, which is currently duplicated to a certain extent in evaluation, would not be necessary.

## Consultation

There are currently several ways in which stakeholders can provide input to scheduling decisions. Firstly, the membership of the NDPSC includes representatives of a number of stakeholder sectors, although, as noted previously, some stakeholders would like this representation increased. In addition, stakeholders are afforded the opportunity to make submissions in relation to matters to be considered by the NDPSC and for those who do so, there is a further opportunity to comment on those decisions.

Some industry stakeholders have commented that the current NDPSC processes take too long, although one wanted more lead-time (to make label changes). Closer links with the evaluation processes should improve the timeliness of the decision making in those cases where substances are included in a product being evaluated. Also, if the labelling and packaging controls for medicines and agvet products are transferred to the Commonwealth, the number of scheduling decisions is expected to decrease because scheduling of a substances will no longer be dependent on the labelling or packaging of the product in which it is contained.<sup>70</sup> This should lead, in turn, to **benefits** for INDUSTRY and GOVERNMENTS.

One of the key factors in the time taken for a decision is the consultation processes to ensure stakeholder input. Given that scheduling decisions affect a number of stakeholders, their input is essential in ensuring that the NDPSC (or its replacement) is aware of, and is able to weigh costs and benefits for all stakeholder sectors involved, or likely to be involved. However, the consultation process should be cost effective for both stakeholders and regulators.

While industry and professional stakeholders were critical of the current processes, they did not put forward a detailed alternative. One industry association did suggest that there was no need for a second round of consultation where the NDPSC decision was to either accept or reject the proposed decision advertised in the pre-meeting Gazette. Only where decisions differed from that advertised would they be subject to

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<sup>70</sup> It is anticipated that these warning statements will be included in a Therapeutic Goods Order for labelling or packaging or in the guidelines for evaluating these products.

a second round of consultation and this should be open to all stakeholders.<sup>71</sup> This presupposes that the proposed decision will be published as part of the consultation process. Currently this is not the case as to do so may extend the consultation process where every time a different decision is reached further consultation is required.

Transparency of decision making is also an important factor, and one raised especially by industry stakeholders. A single round of consultation prior to the scheduling decision will ensure the NDPSC (or its replacement) has before it all the relevant information to enable it to make a robust decision. Further, given that the Committee includes members representing a wide range of stakeholder interests the Review saw no particular benefit in a second round of consultation and indeed considered that the costs associated with the additional time this added to the decision-making process were not justified. This would not preclude the NDPSC (or its replacement) from seeking additional input either directly or indirectly from stakeholders by deferring a decision or publishing a proposed decision.

### **Introduction of charges for re-scheduling applications**

While the measures outlined for some preliminary scheduling decisions to be made during the evaluation process should only add marginally to the cost of evaluation, adoption of these measures will ease the calls on NDPSC's limited resources. However, the Review believed this will be insufficient to address the calls for increased efficiency by the NDPSC in assessing applications for re-scheduling in a timely manner. Consequently, the Review considered it would be appropriate to include provisions in the *Therapeutic Goods Act 1989* to enable the costs of processing re-scheduling applications to be recovered. (Cost recovery is already associated with new product evaluations and related scheduling decisions.)

## **4.5 Other matters**

### **Veterinary medicines**

The objectives of the restrictions placed on access to veterinary medicines are to protect the health and safety of humans as well as of animals. Many of the substances used to treat animals are the same as those used to treat humans and so are included in the same schedules as for human medicines. The Review was advised of instances where animal medicines, most notably anabolic steroids, have been diverted for abuse by humans. This issue was seen as a significant problem. There is also concern that the overuse of antibiotics in animals may lead to cross resistance in humans, which may reduce the armory of drugs available to fight serious infection.<sup>72</sup> The restrictions on access are seen as minimising those risks.

Health and veterinary professionals as well as government regulators expressed concern that if veterinary medicines were regulated separately to other medicines, the

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<sup>71</sup> Currently only stakeholders who have made a submission in response to the pre-meeting notice may make a submissions after a decision has been made. These submissions must be against the reasons for the decision. See Therapeutic Goods Regulation Section 42ZCU and 42ZCY.

<sup>72</sup> Joint Evaluation Technical Advisory Committee on Antibiotic Resistance (JETACAR) Report



level of protection for human health may be reduced, which would in turn lead to significant social, medical and hospital **costs** for the COMMUNITY. These costs would arise from diversion to human use leading to dependence or other problems (e.g. the misuse of anabolic steroids can result in the user becoming excessively violent and causing serious injury and even death to others).

Veterinarians also expressed concern that owners did not always have the requisite knowledge and understanding to diagnose and treat their animals safely and effectively. Ultimately this could lead to unnecessary suffering for the animals and higher costs for the animal owner for treatment. There was also concern that in separating veterinary products from human products veterinarians may be denied access to prescribe human medicines for animal use. This is a matter of prescribing rights<sup>73</sup> but the Review saw no reason why separating regulation of agvet products from human medicines should change the current range of substances which veterinarians are permitted to prescribe.

The practice of veterinarians supplying and prescribing veterinary medicines was raised, particularly by pharmacists and consumers. While supplying a veterinary product without giving the purchaser the opportunity to obtain it from another supplier, i.e. a pharmacy or a supermarket could be considered anti-competitive, the Review noted that drugs and poisons legislation does not prevent pharmacies competing for this business. The Review therefore considered that this was really a Trade Practices issue and that any specific concerns could be taken up with the Australian Competition and Consumer Commission.

### **Links to food regulation**

Drugs and poisons legislation does not apply to foods, unless the food is a vehicle for administering a medicine or is a food additive but where it is not actually incorporated into a food.

In some cases, however, a food may contain the same substance as that contained in a medicine.

For food products, there would be a need to comply with the relevant Food Standard<sup>74</sup> whereas in the case of the medicines, the level of control would be determined by the schedule under which the substance was listed.

Stakeholders raised concerns about apparent inconsistencies in the way in which a particular substance may be treated under Australian New Zealand Food Standards and how it is treated under drugs and poisons legislation. For example, the Food Standard for Formulated Supplementary Sports Foods restricts the content of inorganic selenium to not more than 52 micrograms per day (organic selenium is limited to not more than 26 micrograms per day), whereas until recently, any medicine containing selenium required a prescription.

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<sup>73</sup> The Review's Terms of Reference precluded it considering prescribing rights.

<sup>74</sup> Australia New Zealand Food Standards Code

The Review is aware of the current initiatives at the food–medicine interface to improve liaison between the respective advisers and decision-makers. Improvements have been made in the discrimination of products for regulatory purposes at the interface, such as for dietary supplements. The Review noted that liaison over the risk assessment of substances in common between foods and medicines has also improved, particularly where herbal derivatives and minerals are used in specialist foods.



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## SECTION 5 The appropriate levels of controls

### 5.1 Advertising

**Terms of reference addressed:** General Issues 1, 2, 4, 6, 7, 9 and 10; Special Issue 2.

#### 5.1.1 Introduction

Direct-to-consumer advertising of human and veterinary prescription medicines and some non-prescription medicines is prohibited in Australia. These prohibitions are included in State and Territory drugs, poisons and controlled substances legislation.<sup>75</sup> Similar prohibitions are included in the *Therapeutic Goods Act 1989*. While prescription products (*Schedule 4* and *Schedule 8*) may not be advertised to consumers, advertising to health professionals and to wholesalers is permitted for such products by both State and Territory legislation and the *Therapeutic Goods Act 1989*.

Since 1998 consumer advertising has been permitted for some pharmacist-only medicines (*Schedule 3*). Only those *Schedule 3* substances included in Appendix H may be advertised. To be included in Appendix H, the applicant must demonstrate a public health benefit in advertising being permitted. For example, non-sedating antihistamines were seen as offering a public health benefit (less drowsiness when driving and operating machinery). In addition to compliance with the provisions of the TGAC<sup>76</sup> all advertisement for these products must also carry advice that the pharmacist will advise whether or not this medicine is suitable.

The Review noted that general advertising to consumers has never been prohibited for 'pharmacy-only' over-the-counter medicines (*Schedule 2*), provided it is done according to the requirements set out in drugs and poisons legislation and in the *Therapeutic Goods Act 1989*, associated regulations and the TGAC. In addition to the restrictions on advertising prescription medicines, the primary control exercised by these requirements is to restrict the disease conditions for which a product may be advertised. The Commonwealth regulations also set out the process to be followed for different types of advertisements to consumers (e.g. pre-clearance of all mainstream media advertisements).

While the definition of advertising in State and Territory drugs and poisons legislation and the Commonwealth Therapeutic Goods Act varies across jurisdictions, all definitions cover a wide range of material and behaviours.

As a result of these definitions, price lists for medicines from a supplier; the CMI (in some circumstances); press releases; and even some of the information included on the label of products (e.g. pictures, claims) come within the scope of the controls on

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<sup>75</sup> For veterinary medicines these prohibitions may be included in other legislation such the *Stock Medicines Act 1989* (New South Wales).

<sup>76</sup> The Therapeutic Goods Advertising Code is part of a coregulatory system underpinned by the *Therapeutic Goods Act 1989*.

advertising. These forms of advertising are prohibited if they refer to prescription medicines or *Schedule 3* substances not included in Appendix H.

The definitions in both the Therapeutic Goods Act and drugs and poisons legislation cover all forms of advertising including the use of print and electronic media.

Currently, in the industrial countries it appears that only the United States and New Zealand allow DTC prescription medicine advertising. DTC advertising for prescription medicines in New Zealand is not restricted. However, when medicines subsidised by the government's national drug benefit plan, Pharmac (equivalent to Australia's Pharmaceutical Benefit Scheme) are advertised, the advertisements come under Pharmac's strict scrutiny for potential breaches of the advertising code. New Zealand is currently reviewing its position on DTC advertising of prescription medicines.

Canada is examining the issues with respect to their restrictions, especially in the light of exposure of Canadians to American media. The European Commission has commenced a review of members' legislation prohibiting DTC advertising, taking note of the huge expansion in the availability of information and advertising opportunities through electronic means. While submissions to the EC have closed, no decision has yet been announced.

In Australia, in response to the options put forward in this Review, two of the key industry bodies supported removal of the blanket prohibition on advertising prescription medicines, but submissions from professional associations, professional boards, consumer groups and some individual pharmaceutical companies supported continuing the prohibition.

In relation to prohibiting advertising of veterinary medicines, the Review noted that there does not seem to be the same public pressure for change. Not even the industry associations put forward a case for change and the professional groups argued for retention of the current restrictions, as did the police.

### 5.1.2 Objectives

#### Step 1

#### Clarify objectives of legislation

The restrictions on advertising many *Schedule 3*, and all *Schedule 4* and *8* medicines, is intended to promote and protect human (and animal health) by ensuring that the use of medicines is based on objective, expert advice. In particular, the medicines selected need to be appropriate for the individual consumer and the condition(s) from which that consumer is suffering.

The current limitation for advertising of prescription medicines is intended to allow marketing of commercial products, but with advertising only permitted to health professionals, i.e. those with the capacity to evaluate the material using their training and knowledge. Balanced and complete information is necessarily in the form of complex data, given the nature of medicines, their interactions with complex body systems, their potential for interaction with other medicines and foods and the limitations of clinical trials in predicting responses in individuals.

Restrictions on advertising are not intended to deprive consumers of information about medicines to which, indeed, they have a right. The current situation incorporates the provision of the ‘learned intermediary’, a medical practitioner and/or a pharmacist as a source of information to redress the asymmetry.

The restrictions on the disease states for which a product may be advertised are intended to require consumers, who are unlikely to have the knowledge, understanding or experience to correctly diagnose a particular condition (e.g. cancer) and to determine the safest and most effective treatment, to seek advice from a health professional.

The restrictions on advertising medicines for certain disease states apply regardless of whether the medicine contains a substance included in *Schedules 3, 4* or *8*. By way of illustration, advertising of Vitamin E is not prohibited per se, but it cannot be advertised for treating heart disease or cancer on the basis that consumers would not be in a position to diagnose and treat such serious health conditions.

### 5.1.3 Nature of restrictions

Advertising controls included in all State and Territory poisons legislation fall into two broad categories – those totally prohibiting advertising of certain substances and those restricting the content of the advertisements.

**Step 2**

**Identify nature of restriction on competition**

#### Prohibitions on advertising certain substances

State and Territory poisons legislation prohibits any person from advertising directly to the consumer medicines containing substances listed under *Schedules 4* and *8* as well as many *Schedule 3* substances, i.e. except those *Schedule 3* substances for which the NDSPC has supported advertising.<sup>77</sup> The ban on advertising these products includes those used for veterinary purposes.

In addition to State and Territory legislation, there are similar controls restricting DTC advertising in the Commonwealth Therapeutic Goods Regulations. Regulation 6(1) states:

A person must not publish an advertisement about goods for therapeutic use ...

(d) that refers to goods included in *Schedule 3, 4* or *8* to the Poisons Standard, except goods mentioned in Appendix H of the Standard.

It is noted, however, that State and Territory drugs and poisons legislation does not prohibit advertising to health professionals. Similarly the Commonwealth legislation also permits advertising to health professionals of products containing *Schedule 3, 4* and *8* substances. Thus it is possible to advertise these products to professionals and in trade journals. The Review noted that health professionals have a gatekeeper role in relation to supplying these medicines. On this basis, suppliers are not prevented from competing in the market place of the decision-makers.

<sup>77</sup> Substances in *Schedule 3* which the NDSPC considers can be advertised to the consumer are included in Appendix H of the SUSDP.

## Restrictions on the content of advertisements

Apart from the above State and Territory restrictions on advertising certain substances, there are also, as noted previously, disease-based controls on advertising, including controls which would effect affect, among other things, *Schedule 3, 4 and 8* products should such advertising be permitted. Similar controls are imposed under the TGAC, which is adopted, in part, by the Therapeutic Goods Regulations. These controls restrict the advertising of products for a range of serious medical conditions (e.g. cures cancer or heart disease). These restrictions apply even where a medicine is approved for that condition. The *Therapeutic Goods Act 1989* also prohibits advertising of therapeutic goods that are not included in the ARTG for that purpose.

The list of disease states varies across the jurisdictions although all include similar controls. In all States and Territories other than New South Wales, which adopts the *Therapeutic Goods Act 1989* by reference, the controls have not been amended for some time. Further, the Review was not made aware of any recent occasions when the States and Territories have exercised these disease state controls. The Review noted that some of the disease state controls in State and Territory legislation are inconsistent with the disease state controls included in the TGAC.

In this context the Review also noted that recent amendments to the Therapeutic Goods Regulations and the associated Therapeutic Goods Advertising Code have expanded the list of conditions which may be advertised provided the required level of evidence to support those claims is held.<sup>78</sup>

### 5.1.4 Effect of restrictions on competition and the economy

#### Step 3

#### Analyse effects of restriction

The restrictions on advertising act as a constraint on competition in that manufactures and suppliers are prevented from promoting their products in a way that might maximise the consumption of those products. This in turn could be expected to limit the profits of manufacturers and suppliers with flow-on consequences to the economy as a whole.

Restrictions on advertising drugs, poisons and controlled substances have the potential to inhibit competitive innovation in inventing and bringing to market new therapeutic products.

By their nature, the advertising restrictions prevent firms from using advertising-based product differentiation as a freely available competitive tool for the pursuit of market advantage. It is noted in this regard that there is no absolute prohibition on advertising other products where over consumption can lead to health problems (e.g. alcohol and foods with a high fat content).

For the economy, more resources are directed into advertising with no restriction, and fewer with the restriction. Free entry of resources, including advertising, is accepted as valid for most markets, since it is seen as serving free consumer choice where individuals filter all messages as they wish and spend their own monies accordingly.

<sup>78</sup> The nature of the evidence to be held is specified in the TGAC.

In the ‘medicines market’, however, it is the taxpayer rather than the consumer, who pays for a major proportion of consumption of prescription medicines, through the Commonwealth Government’s Pharmaceutical Benefits Scheme. Under this arrangement, the use of the taxpayer’s funds is supported by expert advice in pharmaceutical classification for public subsidy with well-trained general practitioners and pharmacists acting as gatekeepers to ensure appropriate, prescribing and use of publicly-subsidised products.

### Restrictions on the substances that may be advertised

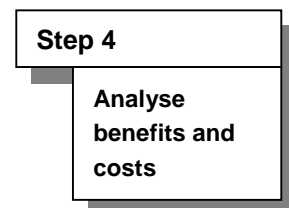
The current system of restricting the advertising of certain substances, i.e. those included in *Schedules 8, 4 and 3* (unless included in Appendix H) is one of total prevention of certain circumstances occurring. The restriction depends heavily on the assumption that doctors know how to evaluate medicine information provided by advertisements (and through other marketing and promotional activities) and will act in the interests of patients. Thus the consumer is denied information in the form of advertisements that certain substances are available. This restriction does not prevent information reaching consumers in a variety of other ways including media articles, and from health professionals.

### Restrictions on the content of advertisements

These restrictions apply to all OTC medicines<sup>79</sup> whether or not they are included in the schedules. These restrictions limit the ability of manufactures or suppliers of these products freely to market their products. Competition is thus restrained. If manufacturers and suppliers were able to market their products freely, the more successful ones could be expected to increase their profits with flow-on effects to the economy as a whole.

#### 5.1.5 Cost–benefit review of current restrictions

The Review noted that particular controversy arises in the case of assessing the costs and benefits of advertising prescription medicines directly to consumers.



There is considerable debate around the world in the effort to estimate the benefits and costs of such advertising. Regulators in various countries have not been able to determine whether the potential harm outweighs the benefits for DTC advertising of prescription medicines. There is not much historical evidence as, either DTC has been totally prohibited or, in the countries where it is permitted, advertising of these products on a large scale has been a recent phenomenon.

As indicated previously, there are **costs** to INDUSTRY in their not being able freely to advertise and promote their products in a way that would maximise sales and profits. There may also be **costs** to CONSUMERS in that the lack of competition may lead to

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<sup>79</sup> Prescription medicines cannot be advertised, so the restrictions on the content of advertisements does not come into play.



higher prices than would otherwise apply in a free market situation. However, the extent of those costs is difficult to assess because there is no restriction on suppliers advertising their products to health professionals, i.e. the gatekeepers or decision-makers.

The converse could, however, be true in that lifting the restrictions on advertising may in fact increase the **costs** to INDUSTRY because they would feel pressured to spend considerably more on advertising than they do at present. Any such additional **costs** as a result of increases in the advertising budget may be passed on to CONSUMERS in the form of higher prices.

The **benefits** of the current restrictions flow largely to CONSUMERS and GOVERNMENT on the basis that removing the restrictions may lead to increased problems caused by the inappropriate selection of medicines prompted by the claims made by advertisers in promoting their particular products. As noted previously, consumers would not generally have the knowledge or skills to critically evaluate the claims product sponsors might make in promoting their medicines.

As a general point, it is noted that the arguments for permitting advertising of prescription medicines are based on the assumption that doctors act as the perfect gatekeeper, with up-to-date knowledge, a capacity to evaluate promotional material and to communicate about the treatment with patients. If this were the case, DTC advertising should not lead to medicinal misadventure and the consequential medical and hospital costs. A similar argument could apply to the role of pharmacists as gatekeepers of the supply of OTC medicines.

One submission argued that consumers assume that if a medicine is advertised, it is safe, and therefore resented the pharmacist's intervention to establish the therapeutic need for the product. While there is no definitive evidence to support this contention, the Review considered that there was enough anecdotal evidence to conclude that this is the case, at least for some consumers.

The Review considered that such an attitude in consumers would create a particularly risk-laden situation especially when the relevant professional standards are not met. This in turn would result in consumers not being provided with the necessary counselling and available written information (e.g. the CMI) to overcome their information deficit.

Advertising prescription medicines is reported to have led to increased costs in the United States and New Zealand as a consequence of increased problems caused by the misuse of medicines. The Review was, however, unable to identify data on the extent to which this misuse of medicines has resulted from the failure of health professionals to provide the level of intervention, including counselling and information, expected by their professional standards. Further, because the health systems and the cultures of these countries differ from Australia the available United States data have been used as indicative only.

From research so far in the United States, there is some evidence that patient behaviour does alter in response to advertisements (Mintzes, 2000; NIHCM, 1999; Wilkes et al., 2000). It appears that when a prescription medicine is advertised, there is an increase in sales as a result of people going to their doctors, discussing and

requesting advertised medicines, and receiving prescriptions. There has not been sufficient research to determine whether this activity in the United States leads to benefits in terms of improved health outcomes for consumers or whether there are costs to consumers and to governments as a result of the misuse of medicines.

### 5.1.6 Alternatives and their costs and benefits

The Review examined a range of alternatives to both the prohibition on advertising prescription medicines and some *Schedule 3* medicines and the restrictions on disease state advertising. The alternatives to the prohibition on prescription advertising which were considered included:

#### Step 5

Consider  
alternatives and  
recommend

- no regulation;
- self regulation/coregulation; and
- a system that permitted certain classes of advertisements.

#### No regulation

If there were no regulation, the only consumer protection available would be through trade practices and consumer protection legislation.

The Review recognised that there may be **benefits** to CONSUMERS if they had access to more information about certain medicines in that it could mean they receive appropriate treatment (through either prescription or pharmacist-supplied OTC medications) for conditions which previously have gone untreated. In such cases, the decision to seek treatment would have been prompted by the consumer seeing an advertisement for a particular product. In this context, the Review noted that where ‘under-treatment’ is a significant public health problem, governments and relevant consumer organisations frequently mount campaigns that encourage those most at risk to seek appropriate medical assistance (e.g. diabetes, heart disease, and high blood pressure). The role of government in this area is discussed further, below.

In terms of the **costs** of not regulating the advertising of prescription medicines, the Review considered that these would include:

- for GOVERNMENT, higher expenditure on subsidised medicines if advertising led to increased consumption of subsidised prescription medicines through the Pharmaceutical Benefits Scheme; and
- for GOVERNMENTS and CONSUMERS increased hospital and medical costs and lost productivity (days of work lost) if the advertising resulted in changes in the behaviour of consumers and suppliers such that the inappropriate use of medicines led to a higher level of poisoning and medicinal misadventure.

#### Self regulation or coregulation

An intermediate alternative between no regulation and the status quo, would be self-regulation or coregulation where advertising prescription and pharmacist-only medicines would be permitted in accordance with a code of practice, possibly with legislative underpinning (coregulation).

Depending on the nature of the code and the effectiveness of the compliance measures, this approach may provide some assurance of truthfulness and balance, but may not provide confidence that consumers will gain sufficient information to enable them to make fully informed choices. The Review noted that it might not only be the manufactures of products, which would advertise these products but other suppliers such as pharmacists, doctors and veterinarians. Consequently, the Review considered that such an alternative would not manage the risk to the public purse from switching to newer, high cost drugs if that is seen as a problem. Stakeholders voiced dissatisfaction with the effectiveness of self-regulation of press releases, the recent exploitation by some companies of the limitations of the controls<sup>80</sup> and the promotional nature of some *Schedule 3* advertising. The Review concluded that self-regulation is not a viable alternative for regulating advertising of prescription medicine, as it is unlikely to achieve the objectives of the control.

The Review considered the possibility of allowing advertising under a system of regulatory approvals, provided the informational side could be enhanced and the advertising adequately controlled.

However, the Review noted that such advertising is:

- by its nature, promotional;
- addressing complex issues (adverse effects and the need for correct diagnosis); and
- addressing only one product rather than setting out the range of treatment options.

The Review considered that the criteria for approving advertisements for prescription medicines would need to include support for the advertisement in the form of a national education strategy related to a priority health issue (e.g. vaccination). This would add significantly to the **costs** for:

- INDUSTRY to fund an effective national public education campaign;
- GOVERNMENT for administrative costs in approving the advertisement or public education campaign (or industry if these costs were recovered by government); and
- CONSUMERS for increased prescription costs or for GOVERNMENT (for subsidised medicines) when these costs were passed on by industry.

The Review could see only limited **benefits** in permitting such advertising. For INDUSTRY there may be increased sales of the advertised product. For the COMMUNITY, they may be made aware of the availability of products, but the

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<sup>80</sup> A number of advertisements highlighting a disease state without mentioning a product or the company that sponsored the advertisements have been brought to the Review's attention. The advertisements and surrounding public relations activities have ensured most people were aware which product was being advertised. The advertisements did not breach the advertising regulations and the industry association was unable to deal effectively with the situation particularly where the companies involved were not members of the association.

information is likely to be unbalanced because sponsors or suppliers of related, but cheaper, products might choose not to advertise.

The Review considered a number of other options, including more flexibility for government to solicit advertisements as part of a government education strategy and clarification of the definitions to allow certain advertising (e.g. of prices, the distribution of the Consumer Medicine Information and disease state advertisements). The Review considered that in certain limited circumstances, provided there were adequate safeguards to prevent unscrupulous suppliers from exploiting these advertisements, that such advertisements would provide a **net benefit** to the COMMUNITY AS A WHOLE. The Review therefore proposed that codes of practice be developed for each of these areas and underpinned by legislation.

The **costs** of a system that allowed advertising in these limited circumstances would be to GOVERNMENT through the administrative arrangements that would need to be established to support the system. For INDUSTRY, there would be **costs** in terms of the outlays they may make on advertising budgets. Where these **costs** are not recouped by additional sales, they would be passed to CONSUMERS in the form of higher prices.

The **benefits** to CONSUMERS would be that they would have additional information to assist in their choice of what products to use. These **benefits** could be financial in that price advertising would allow them to select the ‘best buy’ and/or lead to greater competition amongst suppliers with associated price reductions. The benefits to consumers could also be in improved health outcomes if wider availability of product information led to safer, more effective use of medicines and where product advertising associated with public health campaigns led to better health outcomes for the community as a whole.

The **benefits** to INDUSTRY would be that they could compete more effectively in the areas of price and also gain greater market exposure for their products, particularly when advertising is associated with an approved public health campaign.

The **benefits** to GOVERNMENT would flow from any improvements in health outcomes that followed improved consumer knowledge about the medicines they use and improved levels of participation in public health campaigns. Improvements in health outcomes would result in savings in hospital and medical costs.

The Review considered there would be a **net benefit** to the COMMUNITY AS A WHOLE if advertising in the circumstances noted above were to be allowed.

Such a system could be evaluated after, say three years of operation with a view to assessing:

- the extent to which advertising in the designated areas had provided a net benefit to the community as a whole;
- if a net benefit to the community as whole had been demonstrated, the extent to which there was greater scope for industry involvement in a system of either coregulation or even self-regulation operating under the guidelines that had been developed by the National Coordinating Committee on Therapeutic Goods; and
- whether it was desirable to extend the areas in which advertising is permitted.

In relation to disease state advertisements, the Review noted the coregulatory approach taken by the Commonwealth under the *Therapeutic Goods Act 1989*.

### 5.1.7 Advertising veterinary medicines

Also of concern to the Review was the potential ‘spill over’ effect to human medicines if prescription veterinary medicines were allowed to be advertised, particularly as these products generally contain the same substances as used in human medicines. The Review considered that the same costs and benefits would be incurred and that the current controls provide a **net benefit** to the COMMUNITY AS A WHOLE. Further, the Review considered that the alternatives discussed above for human medicines would enable the objectives of the legislation to be met provided the same conditions applied (i.e. the advertisements complied with the relevant code of practice).

## 5.2 Supply of product samples

**Terms of Reference addressed:** General Issues 1, 2, 3, 4, 6, 7, 9 and 10; Specific Issues 2 and 5.

### 5.2.1 Introduction

The supply of samples falls into two broad categories:

- **Clinical samples** are products which are provided to doctors, pharmacists, veterinarians and other health professionals (e.g. dentists, optometrists, nurses) free of charge. They generally contain scheduled substances especially those in *Schedules 4* and *8* but may also contain substances in *Schedules 2* and *3*.
- **Consumer samples** are products supplied directly to the consumer free of charge as a mechanism to promote sale of the product. These may be small packs produced specifically for the purpose of promoting the product or they may be the normal commercial packs which, in other circumstances, the consumer would need to purchase.

### Clinical samples

The supply of clinical samples to health professionals, particularly doctors, is a well established practice, which enables industry to promote new products and provides health professionals with an opportunity to prescribe a trial of these products at no cost to the consumer. Samples are generally, but not always, supplied in small packs, sufficient for a few days’ treatment. The established practice is for company representatives to visit health practitioners with details of new (and sometimes older) products. As part of that information and promotion activity, the representative will provide the practitioner with samples of the product, which the practitioner can trial with appropriate patients.

The controls in place to regulate this practice comprise restrictions on sample packaging, labelling and volumes, as well as how samples may be provided and who may provide and receive samples.

Industry representatives making submissions to the Review used the control of supply of clinical samples to illustrate the overall lack of uniformity in the legislative controls for drugs, poisons and controlled substances. It was said that these controls illustrate the bewildering array of regulations that has developed, even when the schedules themselves may be uniform. It was further indicated that the situation demonstrates the unnecessarily complex controls, for what, from a public health perspective, is generally a lower level of risk than normal commercial supply of these products.

A number of submissions to the Review pointed out the major variation between jurisdictions in the legislation controlling the supply of clinical samples to health professionals and the costs, not only resulting from the variations, but from the controls within some jurisdictions (see Case study 6).

Health professionals commented that there were some benefits to them and consumers in having access to clinical samples, but had concerns over such matters as storage and disposal, especially where company representatives provided large quantities of samples.

The problems which can arise when clinical samples are supplied directly to hospital staff (e.g. overdosing because of poor record keeping) were also raised with the Review. In this case the Review considered that these problems should be dealt with through hospital policies and procedures.

#### **CASE STUDY 6: Variable costs across jurisdictions**

In Victoria, company representatives are not permitted to carry sample, bonus or replacement stock of any scheduled product. Thus, firms need to make special arrangements for the doctors, dentists, pharmacists etc. in that State to obtain their sample stock.

One company has identified its two main areas of additional costs (wages and courier costs) and a third minor area for each scheduled product:

- wages – this costs around \$8 000 per annum for a part-time employee to pack and dispatch any scheduled product; and
- courier costs – about \$17 000 per annum.

The minor area is that of cost to the company of space to store bonus/sample stock. This cost is estimated at 5 sq m at \$150/sq m, i.e. \$750 per annum. Total costs would depend on the number of products and the number of companies involved.

For the two products the company samples nationally, the total additional cost is therefore \$25 750. Based on underlying product costings for every new sample line or bonus, approximately 5 per cent would need to be added on to the costs of meeting the Victorian regulations.

**Source:** Proprietary Medicines Association of Australia Inc., 'One company's experience with the sample laws in Victoria'.

### **Consumer samples**

The controls that apply to consumer samples (i.e. unscheduled medicines and poisons included in *Schedules 5 or 6*) also vary considerably across the jurisdictions with supply being totally prohibited in some jurisdictions while in others the Minister may grant an exemption. In general, these provisions fall under the controls addressing supply by methods such as door-to-door sales and hawking. Where the controls apply to unscheduled medicines, they fall outside the scope of drugs, poisons and controlled substances legislation and so are outside the scope of this Review.

The Review considered that the costs of permitting the supply of consumer samples of scheduled medicines and poisons (i.e. increased poisoning, medicinal misadventure) outweigh the benefits to consumers or industry and that the same controls that apply

to supply of all scheduled medicines should apply. The reasons for this are discussed in detail in Section 4 and so are not further discussed here.

### 5.2.2 Objectives

**Step 1**

**Clarify objectives of legislation**

The objectives of the controls on supplying clinical samples are to reduce the costs to the community and individuals by preventing poisoning, diversion or deterioration in the quality of the products supplied free of charge for promotional purposes.

### 5.2.3 Nature of current restriction on competition and the economy

**Step 2**

**Identify nature of restriction on competition**

In general, the objectives of the controls are pursued by controls which:

- limit the volumes of samples in circulation (e.g. in representative's cars);
- limit the volume of unsolicited samples given to doctors;
- impose labelling restrictions; and
- prevent the unsolicited supply of consumer samples.

The nature of the controls differed depending on the jurisdictions. Thus, in one jurisdiction, company representatives need to be licensed; other jurisdictions restrict how clinical samples may be supplied, the quantities that may be supplied and storage, handling and recording requirements.

### 5.2.4 Effects of current restriction on competition and the economy

**Step 3**

**Analyse effects of restriction**

#### Clinical samples

The effect of the controls is to:

- minimise opportunities for theft or loss of samples;
- protect the quality with attention to storage;
- avoid the accumulation of products in doctors' and veterinarians' surgeries; and
- minimise the need for disposal of unwanted samples.

However, the effect of the controls varies considerably across jurisdictions. For example, in Queensland, company representatives distributing samples need to be licensed, in Western Australia there are restrictions on the amount a company representative can carry, and in Victoria carrying samples for prospective supply is prohibited. In New South Wales, which has the least restrictions, there was an expectation that representatives would comply with the Code of Good Wholesaling Practice. However, it is now recognised that this code has limited application to representatives of manufacturers and concern has arisen, particularly about quality

storage of the samples and the possible harmful consequences for patients using products, which have been stored incorrectly. Some jurisdictions require practitioner labelling for amounts of more than a few days' supply, but not for shorter supply.

These controls are a significant source of cost and inefficiency, which is inevitably reflected in the price of goods. This in turn means competitive entry by smaller-scale marginal firms is impeded more than it would be in the absence of such controls. It also means that competition across jurisdictions is impeded by the need to acquire knowledge of different controls, and to incur the higher associated costs. However, equally, divergent controls do in principle allow alternative regimes to be evaluated and pressure to arise for conformity to the best practice so revealed.

### Consumer samples

The effect of the controls is to prohibit the supply of consumer samples of any scheduled samples except in accordance with the general restrictions that apply to supply of such products. Further, the restrictions also apply to consumer samples of *Schedule 5, 6 and 7* poisons, at least when supplied door-to-door or when hawked. This limits the freedom of choice for suppliers in the way in which they can market their products.

### 5.2.5 Costs and benefits of sampling controls

The Review was not able to identify any net benefit from the more restrictive State or Territory regulations. However, it did accept that serious risks of diversion are present, and are significant where representatives are permitted to carry samples of *Schedule 7 or 8* products for prospective supply. Most samples that are supplied are *Schedule 4* medicines, and while the risk to public health is less, it is still significant.

#### Step 4

Analyse benefits and costs

### Clinical samples

Further, no evidence was presented to the Review to demonstrate that the controls in one jurisdiction are more effective in achieving their objective than those in other jurisdictions. This variation in the level of controls across jurisdictions resulted in differences in costs across the jurisdictions. Case Study 6 demonstrates some of the costs to industry in Victoria. In Queensland there were costs in obtaining and maintaining licences for company representatives. In other jurisdictions, where there were limitations on the amount of samples that could be carried, the freedom of the company to freely market their product was curtailed. These jurisdictional difference in the level of control added to costs for firms trading in more than one jurisdiction, to establish the nature of the controls that applied in each jurisdiction and in complying with a range of different requirements.

The Review was told of limited **benefits** to RURAL COMMUNITIES of having clinical samples available for distribution as starter packs by the doctor. These benefits of overcoming the barriers to access for rural communities, occur where there is no pharmacy, or where there is no after hours access through pharmacy depots (e.g. after 8.00 p.m. weeknights and after 1.00 p.m. Saturday at weekends). However, the extent



of the benefit is limited by a number of factors including the lack of a consistent supply of samples/starter packs, the limited range of sample/starter packs available and storage difficulties.

### Consumer samples

The **benefit** for CONSUMERS and the COMMUNITY of the controls that apply to supplying consumer samples is a reduction in the level of poisonings, medicinal misadventure and diversion, which might otherwise result from inappropriate sampling. For *Schedule 5, 6 and 7* poisons, the restrictions on supplying consumer samples reduce the likelihood of poisoning occurring. The **costs** for INDUSTRY which flow from the controls are the constraints on the freedom of companies to choose how they will market their products.

The Review considered that, in the case of *Schedule 7* products, the risk of harm from consumer samples was high so that the **benefits** to the COMMUNITY of retaining the restrictions clearly outweigh the **costs** to INDUSTRY. In this context the Review noted that, in general, the purposes and circumstances in which *Schedule 7* are approved for use under the *Agricultural and Veterinary Chemical Code Act 1994* are limited and, in many instances, restrictions apply as to who is permitted to use these products. However, for consumer samples of *Schedule 5 and 6* products the extent to which the controls provided a **net benefit** to the COMMUNITY AS A WHOLE is not so clear-cut.

## 5.2.6 Alternatives and their costs and benefits

### Step 5

Consider  
alternatives and  
recommend

### Clinical samples

The Review considered whether or not there is a need for separate controls to apply to supplying clinical samples at all. But given:

- the hospital, medical and social costs which can result from unrestricted access to some substances, (e.g. poisoning, diversion to the illicit market, medicinal misadventure);
- the limited control which company representatives are able to exercise over the samples which may be stored at home or in a car, particularly where the representative is operating some distance from the company headquarters (e.g. a representative of a company with premises situated in New South Wales but visiting medical practitioners in Western Australia);
- the circumstances in which samples are supplied (e.g. to group surgeries, rural single practice surgeries, in hospitals); and
- that these samples are unsolicited, often leading to large quantities being supplied which, in turn, can lead to the need to dispose of unwanted or excess samples. The Review noted that, in this context, the doctor has a right to refuse supply.

The Review considered that, there were considerable risks of poisoning and diversion if the supply of clinical samples was unfettered (losses or theft from cars, insecure home storage, representatives' bags etc). This would lead to hospital, medical and

social **costs** for CONSUMERS and GOVERNMENTS. The Review considered that without regulation of the supply of clinical samples, there would be no **net benefit** to the COMMUNITY AS A WHOLE despite some potential improvements in competition. The Review identified and considered the following alternatives:

- educating and training company representatives in the safe management of clinical samples;
- developing and implementing a voluntary code of practice for self-regulation; and
- developing and implementing a mandatory code of practice, coregulation.

### **Education and training**

The Review first considered whether the risks identified above could be overcome by educating and training company representatives. However, the Review considered that there would be ongoing **costs** for INDUSTRY in doing this effectively. Further, without a standard, any training and education would vary with the company doing the training. This could lead to variations in the extent to which the objectives of the controls are met thus delivering only limited **benefits** to the COMMUNITY.

### **Voluntary code of practice**

The Review considered that the **cost** to INDUSTRY and the **benefits** to the COMMUNITY from a voluntary code of practice would be similar to those of an education and training strategy. The level of harm that could occur (poisoning and diversion for abuse), may be unacceptable if companies and representatives fail to comply with the code. Further, as many companies do not belong to an industry association the Review considered that the effectiveness of self-regulation would also be similarly unacceptable. Nor would the professionals, for whom the samples are intended, be in a position to establish whether the company and its representatives had complied with the code.

### **Coregulation**

The code could be developed by industry and underpinned by legislation. The Review considered that the legislative underpinning could be achieved by making compliance with the code of practice a condition of licence for wholesalers and/or manufacturers. For company representatives, the Review considered that a reverse licence is all that is required and that authorised company representatives should be exempted from the restrictions on supplying scheduled medicines, provided they do so in compliance with the code of practice for the supply of clinical samples.

There would be some initial costs to develop the code, but the ongoing **costs** for INDUSTRY should be minimal – any necessary training and education could be incorporated into the product training. There would be some enforcement **costs** for GOVERNMENT but these should be more than offset by the **benefit** to the COMMUNITY of reduced hospital and medical costs from medical misadventure, poisoning or diversion. There may also be some benefits to rural communities through improved access.

### Controlled substances and toxic substances

The Review considered that, because of the very high risk of harm (poisoning, abuse or diversion) associated with the inappropriate use or misuse of *Schedule 7* and *8* samples, the current restrictions, which do not permit them to carry samples for prospective supply of these substances should be retained. However the company representatives would be able to take orders for supply in the normal way.

### Code of good practice for the supply of clinical samples

The code of good practice for the supply of clinical samples would be expected to cover such matters as:

- the volume of samples in circulation (e.g. in representatives' cars);
- the volume of unsolicited samples given to doctors or other health professionals;
- security of the stock representatives hold and carry;
- storage conditions (e.g. where products may be left in cars in hot weather);
- record keeping;
- disposal; and
- labelling.

The code should be developed in consultation between industry, government and health professionals and underpinned by legislation to ensure compliance.

Labelling of samples is addressed later in this Section.

### Consumer samples of poisons

The Review considered that, for scheduled poisons, unless such samples are distributed in a controlled manner, unfettered distribution, particularly of *Schedule 7* poisons, could lead to poisonings and even fatalities.

As discussed above, the Review considered that the current controls provide a *net benefit* to the COMMUNITY AS A WHOLE and did not identify any alternatives which would meet the objectives of the legislation.

In the case of *Schedule 5* and *6* poisons, the Review considered that the **benefits** to the COMMUNITY of the current restrictions on distributing samples of these products were to reduce the number of accidental poisonings resulting in avoidable hospital and medical costs for governments and consumers.

The Review did consider, however, that the objectives of the legislation would be able to be met by a less regulatory approach than at present. The Review was not made aware of any industry code of practice that addresses these issues, but considered that if such a code were developed and underpinned by legislation, the objectives of the legislation would be met. The code would need legislative underpinning because, with the diverse range of people involved, the Review did not consider that the benefits for the community of preventing poisoning and diversion would be achieved by self regulation. The code of practice should cover such matters as:

- which substances are suitable for consumer samples – may require consideration of the uses of the substances, where they are generally used and by whom;
- the requirements for packaging and labelling – in general, these would not differ from the current requirements for these products;
- how the samples are to be distributed (e.g. direct to adults, attached to other products, letter box drops);
- where the samples can be distributed (e.g. shopping centres); and
- who may distribute the samples (e.g. only adults).

The Review noted that there are several industry associations whose members distribute *Schedule 5* and *6* products. The Review considered that it would be appropriate for these organisations to work together with government, consumers and health professionals to develop the code of practice. The Review considered that as many suppliers of these products do not belong to industry associations this code of practice should be underpinned in drugs and poisons legislation to ensure all suppliers comply.

## 5.3 Licences

**Terms of Reference addressed:** General Issues 1, 2, 3, 4, 5, 6, 7, 8, 9 and 10; Specific Issues 2 and 4.

### 5.3.1 Introduction

Licences and similar instruments have been widely used to give effect to the drugs, poisons and controlled substances legislation. They restrict market entry to those who can meet all the requirements necessary to obtain a licence.

There is a variety of licensing requirements in the jurisdictions. Licences may apply to individuals (e.g. one jurisdiction requires representatives of manufacturers to be licensed to supply clinical samples to doctors and other health professionals) at retail level (e.g. poisons sellers) or to wholesalers and manufacturers.

One State licences pharmacies directly under poisons and drugs legislation whereas other States rely simply on the licence under the Pharmacy Act. The National Competition Policy Review of Pharmacy recommended that requirements for registering pharmacy premises be removed.

In addition to licensing by States and Territories, Commonwealth licences are required to manufacture medicines, as well as in the special case of controlled substances, to import, export, and (for narcotics) manufacture are required to comply with Australia's obligations under the three relevant United Nations drug treaties. In this context, the Review noted that drugs and poisons legislation in several jurisdictions includes provisions relating to the import and export of substances.. These provisions would seem to be unnecessary as this is a Commonwealth responsibility.

There was very little comment in submissions to the Review on this issue. Members of the pharmaceutical industry commented on the costs of duplication in licensing between the Commonwealth and the States and Territories. It was suggested that holders of State and Territory licences be deemed to have automatically met those

requirements in common with a Commonwealth licence to import, export or manufacture these substances. The non-pharmaceutical chemical industry suggested the use of industry associations (Avcare or Agsafe) programs as alternatives to State and Territory licensing requirements.

Some concern was expressed about *Schedule 2* poisons licences. The concern was that such licences undermined the quality use of medicines as, unlike supply of these products from a pharmacy, consumers do not have access to pharmacists' advice. On the other hand, the Review heard of the difficulties of remote and rural communities in accessing medicines. In particular, concern was expressed about the difficulties of obtaining prescription medicines and *Schedule 3* medicines at weekends. Several stakeholders suggested that, in these circumstances, community nurses, health centres or other suitably qualified people could be licensed to dispense limited supplies of at least some designated *Schedule 3, 4* or *8* medicines. The Review noted that this does already occur to a limited extent in some jurisdictions.

### 5.3.2 Objectives

#### Step 1

#### Clarify objectives of legislation

The objective of the restriction is to ensure that only those who have demonstrated the necessary competencies in dealing with medicines and poisons, who meet other requirements such as secure storage, and who supply these substances in accordance with the relevant controls, are given a legal right to do so.

In common with much regulation in this area, licensing seeks to provide a means for redressing the problem of information asymmetry in the presence of significant and potentially tragic risk and supports other legislative requirements intended to achieve the same objective. Licensing seeks to ensure that expert knowledge and appropriate procedures be involved in the supply of specified medicines and poisons, and also to ensure there is adequate security and supervision to prevent diversion.

The broad objective is to enhance public health by providing a legislative means to reduce the incidence of harm from misuse of potent medicines and dangerous poisons, in this instance by mandating licensing for supply.

Thus licensing is used to:

- protect public health and safety by ensuring industry (including retail) has the necessary competencies and security to store safely the restricted substances and to supply them in a safe and competent manner; and
- ensure only licensed entities or suitably qualified or authorised people have access to controlled substances.

For manufacturing licences, the objective is to ensure the quality of the product is such that it will not be contaminated or sub-standard thereby making it unsafe or ineffective.

Licensing provides a way to identify sellers of goods with the necessary standards and apply appropriate controls on sale, through licence conditions. In this way, licensing supports the controls on access discussed above.

For *Schedule 2* licences, the objective is to improve the level of access to medium to low risk products for those in remote and rural areas that would otherwise find it difficult to obtain these products or to do so in a timely manner.

### 5.3.3 Nature of restriction on competition and the economy

The risk that is managed through licensing is:

- the sale of substances by persons who do not fully understand what it is they are selling;
- to persons who do not fully understand what it is they are purchasing or how to use it safely; and
- in circumstances where misuse of the product can be harmful or it can be diverted for illicit use.

**Step 2**

Identify nature of restriction on competition

Licence requirements are numerous and varied, covering the manufacture, transport, storage and supply of the great range of products containing scheduled substances.

The circumstances in which a licence is required vary across jurisdictions, as do the requirements for licences for the same activity. In addition, there is some duplication or overlap between licence requirements under State and Territory legislation and those required by the Commonwealth under the *Therapeutic Goods Act 1989*, the Customs (Prohibited Import) Regulations and the Customs (Prohibited Export) Regulations and the *Narcotic Drugs Act 1975*.

### 5.3.4 Effects of restriction on competition and the economy

The consequence of licensing for competition is that the legal entry to the supply of medicines and poisons is restricted to those holding the requisite licences, in those areas where such licensing applies. Not all who would wish to operate in this market, can enter the market to compete. In some cases, e.g. pharmacists, this licence may be implied.<sup>81</sup>

**Step 3**

Analyse effects of restriction

Thus some persons or firms may be excluded by not meeting entry requirements and others, who could meet the standards, may be deterred from entry by the costs of the licensing process itself.

For persons or firms who meet the licensing standards, costs will have been raised by the costs of investment in gaining the necessary characteristics and having them verified and approved. These costs are multiplied where different legislative requirements apply in different jurisdictions.

Entry restrictions and increased costs mean reduced competitive supply and some degree of price increase and possibly harmful restriction of consumption compared to

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<sup>81</sup> The Review noted that if governments accept Recommendation 7 of the COAG Review of Pharmacy (2000), drugs, poisons and controlled substances legislation will give pharmacies an implied or reverse licence to supply scheduled products.

the benchmark of no licensing. It may also restrict other forms of competition, e.g. if particular storage arrangements are a condition of licence, improved storage through alternative or new storage approaches can be inhibited compared to an unregulated market.

The licensing requirements at a retail level impact significantly on the level of access for consumers in rural and remote areas. While *Schedule 2* licences enable consumers who would otherwise find it difficult to do so, to access some medium to low risk products, the licensing restrictions<sup>82</sup> impose a significant barrier on access for consumers in remote and rural communities to prescription and *Schedule 3* medicines.

### 5.3.5 Cost–benefit review of restrictions

**Step 4**

**Analyse  
benefits and  
costs**

The **costs** for INDUSTRY which flow from the existing restrictions include the cost of obtaining a licence (the licence fee), the cost of meeting the licensing requirements and of continuing to comply with those requirements (e.g. storage requirements, probity) and the costs which arise from reduced competition.

That said, it could be argued that many of these costs would be incurred, even without regulatory obligation, in markets without licensing by responsible firms and individuals concerned for duty of care. Extra costs once regulations are in place will be to some extent the province of the less responsible. The Review acknowledges this argument, but noted some more generalised cost effects through reduced competition are still likely to remain.

More importantly, what was more commonly argued to the Review instead was that there were major **benefits** to the COMMUNITY AS A WHOLE which would not occur in a situation of no licensing. Such benefits derive from the reduction in poisoning and diversion that flow from the licence conditions (e.g. storage), and hence, were benefiting INDIVIDUALS who could otherwise suffer serious health consequences. These, in turn, benefit GOVERNMENTS, the taxpayers behind them and the community as a whole through reduced medical, hospital, welfare and other outlays.

For some poisons, the benefits extend to reduced harm to the environment and international trade, e.g. through inappropriate use in stock animals.<sup>83</sup>

But this is not to say some reform of existing provisions should not be considered. For instance, the need to licence sellers of poisons has decreased as the use of highly toxic chemicals has decreased, i.e. as the poisons in common use have themselves become safer through better alternatives, and as a more risk-averse public attitude to such chemicals has developed. This has already led some jurisdictions to revoke regulations requiring sellers of *Schedule 5* and *6* poisons to be licensed.

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<sup>82</sup> In this case, the legislation imposes an indirect licence which prohibits supply from anyone other than a pharmacist, or doctor or other authorised health professional.

<sup>83</sup> The factors may also be controlled by agvet and environmental legislation in the States and Territories.

### 5.3.6 Alternatives and their costs and benefits

The preceding analysis has considered the nature of the existing restrictions in this area, their effects on competition, and the costs and benefits thereof.

#### Step 5

Consider  
alternatives and  
recommend

The Review considered that unrestricted access to medicines and some poisons could lead to significant **costs** for INDIVIDUALS and the COMMUNITY. For example, if untrained persons use toxic pesticides incorrectly; or unauthorised persons insecurely handle some medicines and narcotic drugs which could lead to high social, medical and hospital costs from diversion to the illicit drug market, as well as contravene international treaties. For these reasons, the **costs** to the COMMUNITY arising from a complete absence of licensing in this area would be so high as to eclipse any **benefits** to INDUSTRY.

The Review determined that there was a **net benefit** to the COMMUNITY AS A WHOLE in the present form of intervention compared to no regulation. The next step required under National Competition Policy legislation review is to consider any less restrictive alternative means for achieving the objectives of the legislation. The following alternatives to licensing suppliers of drugs, poisons and controlled substances were identified and considered:

- **self-regulation**, including helping industry develop a code of practice and enhanced consumer information;
- **adopt certification or registration**, rather than licensing, and use minimum standards which indicate expected outcomes;
- **repeal most licensing arrangements**, but retain those required by the Commonwealth under the United Nations drug treaties;
- **reverse or negative licensing**, where regulators detect and remove from the industry those persons and businesses which fail to comply with an industry code of practice; and
- **partial self-regulation**, repeal licensing for low-risk, non-problematic areas, (such as *Schedule 5* and *6* poisons; *Schedule 7* where already required by other regulations e.g. agvet; and at the retail level where suppliers are already required to meet other professional regulations, e.g. veterinarians, pharmacists).
  - This alternative also includes rationalising and eliminating duplication of licensing arrangements or administrative processes between the Commonwealth and other jurisdictions (e.g. Customs import, export and manufacturing licenses), or mutual recognition and acceptance of licence requirements where they overlap.

#### Self-regulation

Self-regulation, whereby the firms in an industry voluntarily regulate their own conduct by setting standards of business practice, is a less restrictive alternative to regulating the market than is licensing. It can improve the operation of the market by, e.g. developing an industry code of conduct, and by providing education and better information to help consumers. In the area of drugs, poisons and controlled substances



licences, self-regulation would apply to the requirements necessary to obtain and maintain a licence, e.g. secure storage. These requirements are discussed later in this Section.

The *benefits* of self-regulation would accrue to INDUSTRY through lower compliance costs and increased flexibility.

On the other hand, where firms (or individual suppliers) did not comply with the voluntary code of practice, the resulting negative impacts would lead to higher hospital, medical and social **costs** for INDIVIDUALS and GOVERNMENT through higher poisonings, medicinal misadventures and diversion for abuse. It is therefore considered that self-regulation, with a voluntary code of practice, would not achieve the objectives of the legislation because there is no effective enforcement mechanism to ensure that scheduled substances are not supplied in a way that leads to poisoning or medicinal misadventure. For substances where the risk of diversion or inappropriate use is less, it could be argued that licences are not necessary.

### **Certification or registration**

Certification provides an indication of standards attained, but without necessarily attempting to set minimum standards; registration requires basic information to be provided about a business with no attempt to regulate standards or inform the public about standards to be attained. Both can include a degree of vetting, such as a check on the probity of the firm or individuals involved. While these have the potential to be less restrictive and more efficient alternatives to licensing, the extent to which this leads to reduced costs would depend on the certification or registration requirements and on the costs of obtaining that certification or registration.

The Review considered that it would be difficult for a system of self-certification to achieve a high level of compliance with a code of practice or legal requirements. This in turn would lead to the same **costs** for the COMMUNITY AS A WHOLE as self-regulation, i.e. higher hospital, medical and social costs through increased poisonings, medicinal misadventures and diversion for abuse.

The **costs** for INDUSTRY of a system of certification or registration that required an external organisation (e.g. an industry association) to certify or register the supplier are unlikely to differ significantly from that of the current licensing system. Any certifying or registering body would need to recover the costs of ensuring that the supplier met the required standard. In addition, there would be **costs** for GOVERNMENT in monitoring the effectiveness of the certification or registration process or for the COMMUNITY if the system of certification and registration failed to ensure the required standards are met.

### **Repealing most licensing arrangements**

Repealing most licensing arrangements, except mandatory licensing for manufacturing, wholesaling and retailing controlled substances (which have the greatest risk of diversion to the illicit market and potential harm through inappropriate use) would minimise intervention in the free operation of the market. **Costs** for some SUPPLIERS would thereby be reduced, while targeting restrictions to the high-risk sector of internationally recognised drugs of abuse.

Retaining licensing for high-risk substances would have a **benefit** for the COMMUNITY AS A WHOLE by exercising control over high-risk products and by maintaining Australia's commitment to United Nations treaties relating to narcotic drugs and other controlled substances. However, the Review considered that repealing much of the licensing system would not adequately protect the community against the illicit diversion or misuse of other scheduled medicines, such as anabolic steroids or pseudoephedrine, misuse of substances, such as antibiotics, or accidental poisoning from unregulated access to toxic substances. This would lead to increased hospital, medical and social **costs** for GOVERNMENTS.

### **Reverse or negative licensing**

Reverse or negative licensing places less emphasis on setting up barriers to entry as a means of dealing with the market problems, and more emphasis on action to remove from the industry those who persistently fail to meet acceptable standards and practices. The Review recognised that a reverse or negative licensing system would reduce the **costs** for INDUSTRY in obtaining a licence and, for GOVERNMENT by providing a more efficient means of removing incompetent and unethical businesses from the industry than does a formal licensing system.

However, such a system would only come into operation once an illicit action had occurred, with possible attendant harm and the consequential hospital, medical and social **costs** to the COMMUNITY. The Review thus considered that, in general, such a system would provide a potentially inadequate alternative to meeting the objectives of the legislation. However, the Review considered that this option would be appropriate where the risks are low and breaches could be managed effectively, and has proposed that it be adopted for company representatives distributing clinical samples.

### **Partial self-regulation**

Partial self-regulation is an alternative that removes the licensing requirements from a number of areas where the risk of diversion or inappropriate use is minimal, and/or where there is duplication with other legislation. Some licensing would be retained in those areas where ensuring security and safety are paramount. However, the burden of licensing on industry would be reduced by using existing mechanisms where available and standardising the requirements for licensing across all jurisdictions to the minimum necessary to achieve the objectives.

One low-risk area is where the major controls on the substances involved relate to labelling and packaging. These controls are imposed on the original manufacturer or sponsor of the product and not on others in the supply chain. However, the Review considered that, where controls on access have been put in place to redress the information asymmetry between the consumer and the relevant health professional (*Schedules 2, 3 and 4*), the limitations on access at the wholesale level should be consistent. These restrictions on access are in place to reduce the number of serious harms which, in turn, lead to hospital, medical and social **costs** for INDIVIDUALS and GOVERNMENTS. Licensing restrictions support the effectiveness of the controls on access.

Therefore the Review believed that retaining wholesaler/manufacturer licences for scheduled substances for which access is restricted at the retail level, provides

**benefits** to the COMMUNITY AS A WHOLE from reduced hospital, medical and social costs through reduced poisonings, medicinal misadventures and diversion for abuse. These licences also provide a **benefit** to GOVERNMENT through a simple and cost-effective mechanism to monitor and enforce other requirements, such as storage and security. The Review considered that removing licences for substances, which do not have restricted access at the retail level, would provide **benefits** to INDUSTRY by removing the costs of licensing and for GOVERNMENT by reducing the administrative costs of the licensing system, but would not necessarily lead to increased hospital and medical **costs** for the INDIVIDUAL or GOVERNMENTS.

At the retail level, where there are other mechanisms to readily identify those with the relevant competencies to supply these products to the consumer, i.e. those with professional qualifications, such as pharmacists, veterinarians, doctors, and dentists, there seems little need for separate licences under drugs, poisons and controlled substances legislation. In this context the Review noted the recommendation of the Council of Australian Governments Review of Pharmacy that pharmacies no longer be registered, but that registration of pharmacists will continue to be required.

The Review identified a number of differences in the requirements for licences across jurisdictions. For example, some jurisdictions require applicants to be ‘fit and proper’ while others do not. Some set out prescriptive requirements for securing licensed premises while others focus more on outcomes. There seems little justification for retaining these different requirements.

Further, administrative efficiency will be significantly improved if these licence requirements are uniform across States and Territories and, where appropriate, there is consistency between those States and Territories licence requirements and overlapping requirements for Commonwealth licences. For example, there would be a reduction in duplication of the necessary checks on security and personnel. These matters are discussed further, in relation to uniformity in general, elsewhere in this report (see Section 6), and relate to provisions of the *Mutual Recognition Act 1997*.

## Alternatives in relation to specific licences

### Schedule 5 and 6 licences

The need to licence sellers of poisons has decreased as the use of highly toxic chemicals has decreased, i.e. as the poisons in common use have become safer through better alternatives, and as a more risk-averse public attitude to such chemicals has developed. For many of these chemicals, safety requirements are imposed under occupational health and safety regulations and agvet legislation. Jurisdictions have generally revoked the regulations, requiring retail sellers of *Schedule 5* and *6* poisons to be licensed, although several still require wholesalers to be licensed.

Given that occupational health and safety controls are in place, and that access at retail level is not restricted for *Schedule 5* and *6* products, the Review considered that there would be a **net benefit** to the COMMUNITY AS A WHOLE in repealing any requirements for *Schedule 5* or *6* licences included in State and Territory drugs, poisons and controlled substances legislation.

## Schedule 7 licences

There is a level of overlap with licences required by other organisations for agvet products in *Schedule 7* (e.g. under agvet legislation in the States and Territories). The Review believes that, where other organisations take responsibility for regulating an activity through licensing or some other mechanism, the objectives of the legislation can be met without the need for these licences to be duplicated under drugs, poisons and controlled substances legislation. This would reduce the **costs** to INDUSTRY without changing the **benefit** of the controls to the COMMUNITY.

## Schedule 2, 3, 4, 8 and 9 licences <sup>84</sup>

For those substances likely to be diverted to the illicit market (*Schedules 8 and 9*), a licensing system provides an efficient and effective way of managing the high cost of diversion at a wholesaler and/or manufacturer level. The Review noted that, in relation to *Schedule 9*, such licences would only be issued in very limited circumstances for research.

Similarly, licensing manufacturers, suppliers and distributors of those *Schedule 2, 3 and 4* medicines that have a higher than average risk of diversion for illicit marketing or illicit manufacture also provides an efficient and effective way of managing the high costs of diversion.

For other scheduled medicines, the arguments are not so strong. However, as discussed above, there is justification for imposing restrictions on access at the manufacture and/or wholesale level that are consistent with the access restrictions applied at the retail level, as defined by the schedule of medicine being handled. In practice, the manufacture and/or wholesale of medicines often involves a range of medicines of different schedules, and to require licences for particular substances that are likely to be abused, or otherwise considered a special risk, would make the system more complex and thus more costly.

The primary **costs** for INDUSTRY arise from the licence requirements, such as those for storage, handling, recording and reporting. These requirements are discussed later in this Section. Therefore, the Review considered that the **costs** for INDUSTRY which relate to obtaining a licence would not be great and would be more than outweighed by the **benefits** to GOVERNMENT of a cost effective mechanism for restricting access, and to the COMMUNITY from reduced hospital, medical and social costs through reduced poisonings, medicinal misadventures and diversion for abuse.

There is some duplication in licensing requirements for the manufacture/wholesale of medicines by the States and Territories (for quality and security) and by the Commonwealth under the *Therapeutic Goods Act 1989* (for quality) and under Customs legislation and the *Narcotics Drugs Act 1975* (for security). This duplication is currently necessary for quality licences in those jurisdictions that do not have complementary legislation, in order to provide the jurisdiction with some ability to

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<sup>84</sup> Not all jurisdictions adopt *Schedule 9* and the number of the schedules may vary across jurisdictions. However, all jurisdictions have controls that correspond to those flowing from the SUSDP schedules so references to the schedules should be seen as references to those controls in all jurisdictions.

take effective public health action against sole traders trading within jurisdictional boundaries. Jurisdictions without complementary legislation are strongly urged to enact this as soon as possible. In the meantime, a requirement in State and Territory legislation that medicines be in the ARTG before being supplied in that jurisdiction would require the sponsor to ensure the required manufacturing standards under the *Therapeutic Goods Act 1989* are met. These measures would reduce **costs** for INDUSTRY without affecting the **benefit** of the restrictions to the COMMUNITY AS A WHOLE.

There will still be some overlap between State and Territory and Commonwealth licenses in this area for quality issues such as storage and handling, but this can be minimised by rationalising State, Territory and Commonwealth licensing requirements. Where possible, licence requirements should be based on accepted codes of practice, such as the Code of Good Wholesaling Practice.<sup>85</sup> Compliance with the code should be deemed to be compliance with the legislative requirements.

Other requirements, which might be imposed as a condition of licence, including security, storage, personnel, record keeping and supply procedures, may overlap in some cases with Commonwealth licence requirements. At a national level, these requirements may be necessary to fulfil obligations to the three United Nations Drug Treaties. However, there seems no reason why these requirements should not be uniform across all States and Territories. If these requirements are also consistent with Commonwealth licence requirements, the Commonwealth should be able to accept a State or Territory licence as evidence of compliance, thus reducing **costs** to INDUSTRY without affecting the **benefit** to the COMMUNITY AS A WHOLE.

### **Schedule 2 poisons licences**

Most jurisdictions make provision for those in rural and remote areas to obtain access to some medicines (generally only designated *Schedule 2* medicines), which might otherwise not be readily obtainable, because of their remoteness from a pharmacy. While the SUSDP sets the minimum distance such stores must be from a pharmacy at 25 kilometres, this distance varies between jurisdictions, as do the restrictions that apply to such poisons sellers (e.g. the substances which may be sold, the quantities that can be stocked).

Some submissions to the Review commented that there are no requirements for these poisons licence holders to provide advice to consumers, as is required of pharmacists selling the same product. However, given the lack of training of these poison sellers, it cannot be expected that they would be in a position to provide expert advice.

The Review considered that these licences should continue, but should be subject to compliance with a code of practice, or guidelines, which establish basic requirements to facilitate the safe and effective use of these medicines. The NCCTG should develop such guidelines for adoption by all jurisdictions. They might include restrictions on the quantities to be stocked, the quantities to be sold to any one customer at any one

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<sup>85</sup> It is noted that this is a voluntary code which only applies to some distributors. It may be necessary to develop more comprehensive codes that apply to the full range of distributors, wholesalers and manufacturers.

time, storage conditions etc. and procedures to ensure customers have access to information about the product.

The Review could see few reasons for licensed poisons sellers not being able to sell the full range of *Schedule 2* medicines. However, to reduce the risk of any social, medical and hospital **costs** for the COMMUNITY, the Review considered that these could be adequately managed if the Medicines Scheduling Committee was charged with establishing those substances which are not suitable for sale by licensed poisons sellers and including these in an SUSDP Appendix (see Appendix B2 for proposed Medicines Scheduling Committee functions). If this is done, the Review considered that the **benefits** of access for CONSUMERS IN REMOTE AND RURAL AREAS would outweigh the hospital and medical **costs** to the COMMUNITY of diversion and medicinal misadventure. The substances to be included in such an Appendix might include those likely to be abused, such as pseudoephedrine.

These licensing provisions, and restrictions on the substances to be sold, should be adopted by all jurisdictions unless there is a strong argument based on local circumstances that justifies not applying them.

## 5.4 Record keeping and reporting

**Terms of Reference addressed:** General Issues 1, 2, 3, 4, 5, 6, 7, 8 and 9; Specific Issue 2, 4 and 5.

### 5.4.1 Introduction

Various regulations governing recording and reporting of the supply of drugs, poisons and controlled substances are in place in Australia. These requirements apply at wholesale, retail and administrative level. The three United Nations drug treaties require that parties to the treaties maintain certain records and provide reports on consumption to the International Narcotic Control Board annually, or on request. These obligations are implemented under Commonwealth legislation<sup>86</sup> and under State and Territory drugs, poisons and controlled substances legislation, along with the other Australian provisions mandating various further recording and reporting requirements.

In analysing these requirements, the Review has sought to distinguish recording requirements from reporting requirements and to specify whether the requirements operate at the wholesale and/or retail level.

Submissions to the Review generally recognised the benefits of recording and reporting requirements for *Schedule 8* medicines. Some stakeholders commented that these records should be able to be kept in electronic form rather than the hand written hard copy currently required. The cost of complying with the *Schedule 8* recording provisions (where they are required in hard copy drug books) has been raised as an issue, particularly for mail order pharmacies where the volumes of records may be considerable. State and Territory authorities indicated to the Review that, while the legislation did not preclude electronic records. The Review was told that in some

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<sup>86</sup> *Customs (Prohibited Import) Regulations, Customs (Prohibited Export) Regulations and the Narcotic Drugs Act, 1975.*

instances where this had been tried, there had been problems with system failures. While the extent to which this problem would occur is not known, delays in accessing records would make it difficult to identify abuses, over-prescribing and forgeries in a timely manner, thereby undermining effective enforcement.<sup>87</sup>

The need to clarify the relative roles of drugs and poisons legislation and professional regulation in relation to recording, particularly in relation to the supply of *Schedule 3* medicines was also raised with the Review. The Review was advised that when recording requirements were repealed in some jurisdictions, these were, in some instances, reimposed administratively by Pharmacy Boards. This situation has now been corrected, but it illustrates the need for clarity in the relative roles of the different legislation.

### 5.4.2 Objectives

**Step 1**

**Clarify objectives of legislation**

At retail level the objective of the recording control for medicine supply is to provide a medication history which is sufficient to:

- facilitate quality use of medicines by enabling the pharmacist to identify potential interactions, over-use or misuse;
- provide an opportunity to intervene where the frequency of purchase suggests abuse or diversion occurring;
- establish, for prescription medicines, that the medicines have been provided in accordance with a prescription and to whom they were provided (for enforcement purposes);
- establish that *Schedule 8* medicines, and other substances of abuse, have not been supplied for inappropriate or unauthorised use, abuse or diverted to the illicit drug market; and
- establish that the person purchasing *Schedule 7* poisons is adequately trained or experienced to use the substance safely.

At wholesale level the objective of the recording requirements is to:

- establish that the medicine or poison has only been supplied to persons entitled to hold or deal with such medicines (i.e. those holding licences to handle those scheduled substances or a pharmacy, medical practitioner or other authorised person);
- establish to whom, and in what quantity, *Schedule 8* medicines and other substances likely to be abused have been supplied to enable effective action to be taken to prevent their abuse, unauthorised supply or diverted to the illicit drug market; and

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<sup>87</sup> The suspicion is that, when a person claims the electronic records are unavailable, e.g. because of a supposed system failure, the records are not up-to-date. In contrast it is immediately obvious if a paper record is not up-to-date.

- provide an effective mechanism for tracking and recalling any products for which a problem is identified.

Finally, the objectives of reporting requirements, as distinct from recording, at the wholesale and retail level, are to prevent diversion of *Schedule 8* and other substances of abuse, or which can be used to illicitly manufacture drugs, and to enable timely and effective enforcement where such abuse or diversion occurs.

Overall therefore, the objectives of legislation mandating various recording and reporting requirements are to ensure that adequate records are kept to monitor who provides these substances to whom, so as to help reduce mis-use and diversion.

### 5.4.3 Nature of current restrictions

#### Medicines

At a wholesale level, records are required for all transactions of scheduled medicines. Also, all jurisdictions require records, at the retail level, of all *Schedule 8* supplies and copies of prescriptions, to be retained. All jurisdictions require all wholesale transactions of *Schedule 8* substances to be reported.<sup>88</sup>

This is managed through an electronic reporting system managed by the Commonwealth (under the DRUMS).<sup>89</sup> This enables interstate trade and imports and exports to be monitored efficiently and effectively. There may be some costs to industry to set up such a system although these would not be expected to be significant. The ongoing costs of reporting should be minimal, once the necessary system has been set up.

The requirement that pharmacists keep a record of all *Schedule 4* prescriptions provides a mechanism to track supply of these medicines should that be necessary for enforcement or other reasons, such as recall of a medicine. More importantly, it also facilitates the quality use of medicines by enabling pharmacists to monitor the prescription drugs used (where the patient always attends the same pharmacy). These records will be even more important as we move towards electronic prescriptions and establishment of databases aimed at improving the quality use of medicines by making information on consumers' medicine usage available to all health practitioners across Australia.<sup>90</sup> It will also facilitate development of a partnership between doctors, pharmacists and consumers to improve the quality use of medicines.

At retail level, reporting requirements vary, with some jurisdictions requiring all narcotic supplies to be reported, while some also require the supply of selected *Schedule 4* medicines, such as benzodiazepines, to be reported. For narcotic medicines, this reporting can link to the DRUMS reports but no such link applies for

#### Step 2

Identify nature of restriction on competition

<sup>88</sup> These reporting requirements are included in the *Narcotic Drugs Act 1975* and the Customs (Prohibited Import) Regulations, but are also required by some States and Territories.

<sup>89</sup> Drug Reporting Utilisation Monitoring System.

<sup>90</sup> There have been proposals that consumers be encouraged to participate in such a system on a voluntary basis. Practitioners should only be able to access the records where the consumer authorises the practitioner to do so.



other medicines. The Review noted that, as these requirements are State-specific, there are gaps in the reporting, and the capacity of regulators to take timely action when supply takes place across jurisdictional borders is therefore diminished.

Some jurisdictions require some, or all, sales of *Schedule 3* medicines at retail level to be recorded. This requirement may be imposed directly under drugs and poisons legislation or indirectly through the legislation regulating professional practice, where Pharmacy Boards declare such recording to be a professional practice standard. In this context the Review was told of the success of the asthma card which was introduced in New South Wales. This card acted as a trigger to pharmacists to discuss management of a consumer's asthma with affected consumers.<sup>91</sup> However the Review was also told of problems with this system where consumers from interstate, or those who forgot their card, were forced to pay for a card before being able to purchase their OTC asthma medication.

The role of professional boards in imposing controls such as recording was questioned by a number of stakeholders. The Review considered that where a net benefit to the community can be demonstrated from consistent application of such controls, they should be included in legislation rather than rely on professional standards.

Drugs, poisons and controlled substances legislation imposes prescriptive requirements on:

- the form in which records of *Schedule 8* medicines are to be kept;<sup>92</sup>
- the way in which the records are to be kept (e.g. recording must be done at the time of supply); and
- the frequency and form of the reports that are to be supplied.

These recording and reporting requirements ensure monitoring can be undertaken in a timely and efficient manner and diversion quickly identified and traced to support the restrictions on access.

For recording at both wholesale and retail level (where that is required) for *Schedule 4* and *Schedule 3* medicines, the requirements are less prescriptive. For example, States and Territories may only require wholesalers and retailers to report on the supply of some *Schedule 4* medicines on request (e.g. the movement of anabolic steroids where diversion is suspected).

Jurisdictions also require those who administer medicine to others (e.g. doctors, nurses, dentists, veterinarians) to keep records of *Schedule 8* medicines and, in many cases, *Schedule 4* medicines administered by them.

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<sup>91</sup> It has been estimated that most deaths from asthma (685 Australian deaths in 1998) can be avoided where the asthma condition is appropriately managed (National Asthma Campaign, 1999).

<sup>92</sup> These require recording in a sequential manner in a 'drug book' with numbered pages of the date of supply, the name and address of the person to whom they have been prescribed, the name of the prescriber and the quantity prescribed. A record of all stock received must also be entered sequentially and a running total of the stock on hand kept.

## Poisons

In most jurisdictions there are no specific requirements at the wholesale or retail levels that records be kept for *Schedule 5* and *6* poisons. For *Schedule 7* poisons, the requirement to maintain records may be in drugs, poisons and controlled substances legislation or in other legislation, such as agvet regulation. The form in which these records are kept is not always specified, but there would be an expectation that, if necessary, distribution of these poisons could be traced quickly.

### 5.4.4 Effects of current restrictions on competition and the economy

These recording and reporting requirements for both medicines and poisons serve to limit competition. In particular, these controls give effect to restrictions on who can supply (and purchase) various specified substances. This means they are instruments for ensuring specified restrictions to market participation can be monitored.

#### Step 3

Analyse effects of restriction

They also raise costs, particularly where they are not uniform across jurisdictions, and this can reduce competition at the margin, because of the increase in costs making market entry, or continuation in this sector less attractive. The costs arise from the need to acquire knowledge of the controls and to implement and operate the information systems required to give effect to those controls.

As with other controls, the restrictions can inhibit innovation – in this case, options for record keeping. For example, some submissions to the Review described out-of-date requirements still in place for hard copy record keeping, so raising costs by dual recording and/or inhibiting adoption and improvement of record-keeping processes divergent from those indicated by the controls. For some firms, a recording standard may improve upon otherwise poor business practice, so that an ‘on-balance’ assessment remains. The Review accepts that, on balance, there is a net restriction on competition. However, firms do already have strong incentives to keep adequate records for business competition and for tax and generic corporate regulation. The extra recording required is that sought for public benefit, not extra business efficiency.

### 5.4.5 Costs and benefits of current controls

The Review noted that the administrative **costs** for INDUSTRY and HEALTH PROFESSIONALS in meeting the recording and reporting requirements of the legislation, while not generally high, nonetheless serve to restrict competition at the margins.

#### Step 4

Analyse benefits and costs

The **benefits**, the current recording and reporting achieve, are dependent on the extent to which they prevent diversion, medicinal misadventure and poisoning occurring. Where large quantities of highly addictive substances are involved (generally at wholesale level) the benefits are considerable, particularly in relation to reducing diversion. At the retail level the benefit arises from preventing individual abuse or illegal prescribing and supply by health professionals.

However, the level of these benefits would be less for small quantities of a low concentration of an addictive substance. The Review noted that, under the current system, the level of recording and reporting varies to reflect the level of risk and when coupled with the relatively low cost of these measures, leads to a **net benefit** to the COMMUNITY AS A WHOLE.

### 5.4.6 Alternatives

#### Step 5

#### Consider alternatives and recommend

The Review considered that removal of all requirements for recording and reporting would seriously reduce the capacity to:

- enhance the quality use of medicines by increasing the opportunities for pharmacists, in particular, to check for drug interactions. Recording prescription details enables the pharmacist to monitor a patient's use of medicines so significant harms, or even death, can be prevented. These prescription records can also be accessed by doctors, where the patient authorises that access. This may be of assistance in maintaining the integrity of prescribing decisions where such prescriptions have been written by a different health practitioner;
- inhibit misuse by enabling the pharmacist and/or the regulator to monitor the rate of use of substances, especially those likely to be abused;
- prevent diversion by enabling tracking of substances likely to be diverted from the supply chain to the illicit market or for abuse. The Review noted that it is very rare for drugs to be diverted during the routine movement of these substances through the licit medicine supply chain,<sup>93</sup> partly because such a diversion would be quickly identified by the current monitoring system and tracked in a way that is likely to lead to swift enforcement action; and
- ensure that the records enable any problems related to the product to be monitored or tracked and timely action taken (e.g. if a product needs to be recalled because of a manufacturing problem, or for another product-specific reason).

Consequently, the **costs** for GOVERNMENTS and CONSUMERS of removing all recording and reporting requirements would be to increase social, hospital and medical as a result of increased diversion, poisoning and medicinal misadventure. The Review considered that these costs would significantly outweigh the **benefits** to INDUSTRY, SUPPLIERS and HEALTH PROFESSIONALS of removing the administrative burden of recording and reporting on the movement and use of medicines and poisons.

The Review then considered other alternatives by which the objectives of the legislation might be met. The following alternatives were identified and considered:

- **Implement an information and education strategy** to assist industry to maintain effective voluntary record keeping, and to link in with any voluntary patient medication management programs.

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<sup>93</sup> The diversion that does occur is almost always as a result of a robbery.

- **Implement national industry and professional standards or codes of practice** for record keeping and reporting, while retaining the existing *Schedule 8* requirements.
- **Minimise and rationalise the legislative controls** required, by repealing those for low risk areas and eliminating areas of duplication with Commonwealth legislation; any mandatory requirements to be uniform across the jurisdictions.

### **Education strategies and voluntary codes of practice**

The **benefits** of an education strategy or a voluntary code of practice or standard would be to reduce the regulatory burden for INDUSTRY and HEALTH PROFESSIONALS.

The disadvantage of an education strategy and a voluntary code would be that there would be no consistency in the recording and reporting by different groups in the supply chain. The effectiveness of such recording and reporting in preventing significant harm occurring depends on the accuracy of the records and the timeliness of the reporting, particularly in relation to preventing diversion of substances for abuse. An industry code of conduct or standard for wholesale suppliers may not be compatible with the system developed by health professionals. This would hamper the monitoring and identification of diversion incidents and make intervention to prevent the substances reaching the illicit drug market difficult if not impossible. Thus the objectives of the legislation would not be met and this would lead to increased social, hospital and medical **costs** for GOVERNMENT and INDIVIDUALS through increased abuse, medicinal misadventure and poisoning.

### **Rationalising legislative controls**

The Review did however, identify a number of ways in which the efficiency of the controls could be improved by minimising and rationalising the legislative controls. These are discussed below.

### **Medicines**

The Review considered that records at wholesale level would continue to be required for all *Schedule 2, 3, 4* and *8* substances. This is consistent with the good business practice of recording transactions and so in general, this requirement should not impose any additional costs on industry except those with poor business practices. By mandating recording that all suppliers keep such records the integrity and effectiveness of the system will be maintained.

For *Schedule 8* medicines and other substances likely to be abused or diverted, the recording mode should be specified. This provides a **benefit** to GOVERNMENT regulators and to the COMMUNITY by aiding timely and effective enforcement. However, the Review considered that these records should be able to be kept electronically and that it should be possible to do this in a way that does not hamper the enforcement process or impose significant compliance costs on industry. State and Territory health departments and industry should work together to develop efficient and effective procedures as soon as possible.

No one has questioned the need for adequate recording and reporting of *Schedule 8* medicines at the wholesale level or its cost effectiveness in preventing diversion. This also **benefits** the COMMUNITY by enabling Australia to meet its obligations under the United Nations drug treaties. At a wholesale level, the **cost** to INDUSTRY of the reporting requirements would be minimal once the system has been set up, as these reports can now be submitted electronically to DRUMS. Recording requirements for other medicinal substances, which will enable movement of products to be readily tracked, would be minimal compared to additional costs for industry over and above those necessary for good business practice, provided they are not prescriptive. Further, such requirements would be of **benefit** to CONSUMERS where products can be quickly tracked when there is a problem. Given the critical role these substances play in a person's health care, any problems need to be quickly identified and rectified.

The **benefit** to the COMMUNITY of current reporting for *Schedule 8* medicines at retail level is the reduction in diversion and abuse leading to lower social, hospital and medical costs. The Review recognised that this benefit is reduced where monitoring supply to consumers across State and Territory borders is involved. At present, there is no timely and effective mechanism for monitoring the movement of these medicines across jurisdictional borders.

Nor do the current processes enable 'real-time' monitoring even within jurisdictional borders as under the present system, routine reporting at retail level is not required in all jurisdictions, and where it is, it may be some time after the event before a discrepancy is identified. This undermines the benefits of the reporting requirements. More timely monitoring, including of interstate transactions, would improve the effectiveness of these requirements in meeting the objectives of the controls.

Uniform requirements across jurisdictions and an efficient electronic reporting system should facilitate more effective and timely monitoring and identification of discrepancies. Further, each jurisdiction needs to ensure that their legislation will enable reports to be exchanged with other jurisdictions in a timely manner. The NCCTG should investigate cost effective mechanisms to achieve this. Legislation may be needed to give effect to these mechanisms.

At the retail level, the costs of reporting and recording *Schedule 8* transactions can be onerous for professionals where the volume of transactions is large. Mail order pharmacies in particular pointed to this as a significant cost but one which could be largely overcome by development of an electronic recording system. Ultimately these costs are passed on to consumers. The Review considered that professionals and government should work together to find a mechanism which will enable these records to be kept electronically. This should reduce the costs of record keeping for industry and reduce the costs for government, of any necessary monitoring.

The **benefits** to the COMMUNITY and GOVERNMENT of these recording and reporting requirements for *Schedule 8*, and some other prescription medicines, are that they help prevent diversion and reduce the social, medical and hospital costs which flow from the resulting abuse and dependence. The recording and reporting controls also benefit governments and the community by facilitating effective and timely enforcement of the restrictions on access thereby enabling identification of those abusing or diverting these substances. 'Doctor shopping' has been identified as a significant problem for

the community and government, which could be significantly reduced by ‘real-time’ monitoring.

For prescription medicines, the **benefit** that recording of retail transactions provides for CONSUMERS and the GOVERNMENT is that it facilitates the quality use of medicines, thereby helping prevent medicinal misadventures through checks for drug interactions and duplication of prescriptions. As mentioned above, the effectiveness of this monitoring is undermined where the consumer obtains supplies from more than one pharmacy. However, if there is a timely mechanism to check a patient’s medicine use, appropriate remedial action could be taken to minimise the harm where medicinal misadventure has occurred, or is likely to occur. As the benefits to the consumers and community are better understood, consumers are likely to see the advantages of having their record of medicine use accessible to relevant health professionals. In relation to prescription medicines, recent initiatives to require consumers to provide their Medicare number to obtain Pharmaceutical Benefits Prescriptions should facilitate such monitoring.

For *Schedule 3* medicines, the recording may provide **benefits** for the COMMUNITY in identifying abuse and misuse and in facilitating quality use of medicines. However, this benefit is limited, because there is no requirement for consumers to obtain the product from the same pharmacy. Further, because there is no ‘real-time’ monitoring of these records, their usefulness in aiding enforcement is limited. Therefore, the Review considered that for PHARMACISTS, administrative **costs** to record *Schedule 3* supply and the consequential **costs** for CONSUMERS do not justify such requirements being applied universally.

However, the Review acknowledged that there may be a **net benefit** for the COMMUNITY AS A WHOLE in recording the supply of *Schedule 3* medicines, on a case-by-case basis. For example, the Review considered that, where a person has a chronic disease, such as asthma, which requires periodic monitoring by a medical practitioner, the **cost** to:

- the CONSUMER (in the time taken to complete such records);
- the PHARMACIST (in registering and keeping such records); and
- the GOVERNMENT (for subsidised visits to the doctor for regular monitoring);

would be more than outweighed by the **benefit** to the COMMUNITY of reducing unnecessary hospital and medical costs resulting from preventable events such as asthma attacks.

The Review considered, however, that such a requirement should only be mandated by legislation where the net benefits of doing so can be clearly established. Such cases may also include substances where there is significant abuse or diversion to the illicit drug market or a significant health problem, such as asthma.

The Review did, however, consider that voluntary monitoring of medicine use, as part of a quality use of medicines program, would benefit the consumer and the community and should be encouraged.

In summary, the Review considered that there are benefits in requiring recording of *Schedule 4* medicines (fewer medicinal misadventures, less diversion and more

effective enforcement). However, it sees only limited net benefits for the consumer (preventing diversion) in requiring the supply of *Schedule 3* medicines to be recorded. While the Review can see no net benefit in a general requirement for reporting the supply of *Schedule 3* and *4* medicines, there could be **benefits** to the COMMUNITY (less diversion and abuse), and to the CONSUMER (less medicinal misadventure), in requiring the reporting of specific *Schedule 4* (and a few *Schedule 3*) medicinal substances at the retail level. Where, on a case-by-case basis, the specific benefits for the community of doing so are clearly identified as outweighing the **costs** to the COMMUNITY AS A WHOLE, such requirements should be imposed nationally. Such cases may include substances where there is significant abuse or diversion to the illicit drug market (e.g. anabolic steroids).

## Poisons

There are generally minimal or no requirements for recording *Schedule 5* and *6* poisons. Maintaining such records at a wholesale level would be normal business practice and the Review sees no particular benefit to the community in mandating this.

For *Schedule 7* medicines, the need to maintain records at both the wholesale and retail level could add marginally to **costs** for INDUSTRY at the retail level and these **costs** would be passed on to CONSUMERS. However, the benefits to the community (reduced hospital and medical costs) in preventing unsafe use of these highly toxic chemicals would more than outweigh the costs.

The Review did however, consider that eliminating duplication could reduce the costs for industry, consumers and governments (in enforcing the requirements). Consequently, in those cases where other legislation requires records of such transactions to be kept (e.g. agvet legislation in some jurisdictions requires tracking of the sale of some *Schedule 7* products), the Review considered that provisions in medicines and poisons legislation mandating such recording should be repealed.

In summary the Review has identified some areas where the controls on recording and reporting can appropriately be removed. Also, where the Review proposed that recording and reporting requirements be retained, it considered that the degree to which the legislation needs to prescribe the exact nature of the records to be kept, should be dependent on the level of risk. The Review also identified a number of ways in which the efficiency and effectiveness of the controls can be improved.

For all scheduled substances, the recording/reporting on a case-by-case basis, should be encouraged where there is a net benefit in doing so (i.e. voluntary recording of medicines in line with quality use of medicines or reporting for a medicine or poison for which diversion or abuse has become problematic). Table 5.1 provides a summary of proposed changes to requirements for recording and reporting.

**Table 5.1 Summary of proposed changes to requirements for recording and reporting**

Schedule	Recording				Reporting			
	wholesale		retail		wholesale		retail	
	current	proposed	current	proposed	current	proposed	current	proposed
2	Y	Y	N	N	N	N	N	N
3	Y	Y	varies	N	N	N	N	N
4	Y	Y	Y	Y	N	N	varies	N
5&6	varies	N	N	N	N	N	N	N
7	varies*	Y**	varies*	Y**	N	N	varies*	N
8***	Y	Y	Y	Y	Y	Y	varies	N

\* Requirements may be in drugs and poisons legislation or other legislation such as agvet legislation.

\*\* Where there is no other mechanism, or requirement under other legislation, e.g. agvet legislation.

\*\*\* Reporting of *Schedule 8* medicines is generally a requirement under the *Narcotic Drugs Act 1975* or the Customs (Prohibited Import) Regulations and the Customs (Prohibited Export) Regulations.

## 5.5 Storage and handling

**Terms of Reference addressed:** General Issues 1, 2, 4, 5, 6, 7, 8 and 9; Specific Issues 1, 2, 4 and 5.

### 5.5.1 Introduction

Storage and handling requirements under State and Territory legislation apply at both the wholesale and the retail level. These requirements are applied mainly to prevent the products finding their way on to the market in a way that may lead to poisoning, diversion to the illicit market or to medicinal misadventure.

There are also storage requirements related to quality, such as the temperature at which a product is stored or transported, but these are largely controlled for medicines under the *Therapeutic Goods Act 1989* or for agvet chemicals the *Agricultural and Veterinary Chemical Code Act 1994*.

Few submissions to this Review commented on the restrictions on storage and handling. Those comments that were made related to the lack of uniformity, with the key issues being security and storage of *Schedule 2* and *3* medicines in pharmacies and equity in the requirements for storage of substances at wholesale level (especially controlled substances).

### 5.5.2 Objectives

Storage and handling regulation is intended to form part of, and so complement and support, the suite of controls that restrict access to drugs, poisons and controlled substances. The controls apply at both the wholesale (including manufacturers, distributors) and retail levels.

The objectives of the legislative controls applying to storage and handling legislation are to:

#### Step 1

Clarify objectives of legislation



- prevent poisoning incidents as a result of loss, (e.g. during transport) or of children having ready access from suppliers;
- facilitate the safe and effective use of medicines by promoting, as appropriate, the intervention and supervision by pharmacists to ensure a prescription is provided for *Schedule 4* and *8* medicines and in supporting the use by consumers of OTC medicines (*Schedule 2* and *3*);
- prevent diversion for abuse (e.g. opiates) or misuse (e.g. anabolic steroids) or use in illicit manufacture (e.g. pseudoephedrine), particularly in preventing theft; and
- maintain the quality and safety of products throughout their shelf life.

### 5.5.3 Nature of current restrictions

#### Step 2

#### Identify nature of restriction on competition

Storage and handling provisions relate to the way in which medicines and poisons are stored by wholesalers, distributors, manufacturers and retailers and how they are transported or distributed.

The storage controls cover matters such as where a product needs to be kept on the manufacturer's/wholesaler's/distributor's premises, the level of access allowed for staff, the degree to which public access is restricted and the extent of unauthorised access, such as break-ins, are prevented. At retail level, the controls on public access relate to where and how products are displayed.

Handling controls in the legislation under review covers matters such as transport and the manner of supply up to the point of retail sale, e.g. from manufacturer to distributor to retailer but not to subsequent storage and handling by the consumer.<sup>94</sup>

#### For medicines

All jurisdictions require secure storage for *Schedule 8* products either in a safe or cage at wholesale level and in a safe at retail level. The exact requirements are either specified in the relevant Act or regulations, or imposed administratively. They vary between jurisdictions, often because of the way in which the legislation is phrased or interpreted (e.g. the legislation may be outcomes focused with examples of how the outcome can be achieved or it may be prescriptive). These requirements of necessity provide some flexibility at wholesale level to take account of the levels of risk (e.g. because of the quantities stored).

Storage and handling restrictions at the wholesale level are designed to ensure consumers only have access to scheduled medicines (i.e. *Schedule 2, 3* and *4*) in

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<sup>94</sup> Enforcement of further controls beyond the point of consumer purchase is not feasible given the myriad of consumers and the breaches of privacy that would be involved. However, warning labels may advise the consumer how the product should be stored (e.g. KEEP OUT OF THE REACH OF CHILDREN, OR STORE IN THE REFRIGERATOR AFTER OPENING).

accordance with the restrictions specified elsewhere in drugs, poisons and controlled substances legislation.

At retail level:

- *Schedule 4* products are required to be stored in areas to which the consumer does not have access.
- *Schedule 3* medicines are required to be in a special area under supervision of the pharmacist, with the exact provisions varying across jurisdictions.
- The current requirements for *Schedule 2* medicines vary considerably – some jurisdictions require storage behind the counter or for access to be restricted in some way, whereas others have no specific restrictions.

The SUSDP description of *Schedule 2*<sup>95</sup> and the criteria for inclusion of a substance in *Schedule 2*<sup>96</sup> is that the product is available for self selection in the pharmacy where professional advice is available and sales of excessive quantities can be monitored. Drugs and poisons legislation in most jurisdictions<sup>97</sup> does not specifically set out the storage and display requirements for *Schedule 2* medicines. However, the Review noted that to store or display products in a way that did not facilitate supervision by the pharmacist is likely to be considered a breach of professional standards. In such cases, Pharmacy Boards could take disciplinary action. So, for example, it would not be appropriate for *Schedule 2* products to be put on sale in large containers (dump bins) on the perimeter of the pharmacy in the same way as products such as tissues and toothpaste are commonly displayed.

Other storage issues, such as controls intended to preserve the quality of the product (e.g. the storage temperature), may be addressed in State and Territory drugs and poisons legislation. They are also addressed by other legislation, such as the *Therapeutic Goods Act 1989*, the *Agricultural and Veterinary Chemical Code Act 1994* or by codes such as the Code of Good Wholesaling Practice and the Code of Good Manufacturing Practice. These codes are underpinned by the *Therapeutic Goods Act 1989* for medicines so as to provide an effective mechanism for ensuring compliance.

There are several other legislative controls that impact on storage, including dangerous goods legislation, consumer protection legislation and environmental protection legislation. There is also recourse to common law.

On-farm storage of agricultural and veterinary chemicals is also an area of relevance, but no specific controls are applied under drugs and poisons legislation. In at least one jurisdiction, farms are considered to be workplaces and so must comply with storage and other provisions under occupational health and safety legislation.

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<sup>95</sup> Which is rejected in the State and Territory legislation.

<sup>96</sup> In the National Drugs and Poisons Schedule Committee Guidelines.

<sup>97</sup> In one jurisdiction, *Schedule 2* products must be stored behind the counter while in another they must be under the direct supervision of the pharmacist.

Disposal of medicines and poisons is an issue related to storage. It is also dealt with under drugs, poisons and controlled substances legislation.

Handling of medicinal products also varies across jurisdictions. In some jurisdictions, there is greater reliance on the Code of Good Wholesaling Practice compared to other jurisdictions where the controls are more prescriptive.

### For poisons

Most jurisdictions do not have any specific requirements for storage at wholesale level for *Schedule 5, 6 and 7* products. The Review noted, however, that all these premises would be covered by occupational health and safety legislation.

Some jurisdictions have very specific provisions detailing retail storage of poisons. These specify the height at which certain products must be stored (this is not the same in those jurisdictions where it is specified, e.g. 1.5 metres in one jurisdiction and 1.2 metres in another). Other jurisdictions place the onus on the retailer to ensure the product is stored out of the reach of children without specifying the means by which this is to be achieved.

Where a product is in child-resistant packaging or a large pack (e.g. in excess of two litres) the risk of a child accessing a poison is reduced, although not eliminated. Consequently, the likelihood of poisoning occurring is generally low, and the Review noted that, in these cases, the specific height restriction for storage does not generally apply.

### 5.5.4 Effects of current restrictions on competition and the economy

#### Step 3

#### Analyse effects of restriction

As noted previously, the legislation, in many cases mandates the forms of storage and handling that can apply to drugs, poisons and controlled substances.

The storage and handling regulations restrict competition in that they do not permit those firms that are supplying the drugs, poisons and controlled substances markets to determine for themselves the most efficient (and therefore most profitable) ways of organising storage and handling.

The storage and handling requirements also prevent suppliers from displaying products in ways that could make the selection and purchase of these products by consumers more likely. This restricts the way in which these products can be marketed to the consumer and limits consumer access.

Innovation in storage and handling procedures (finding new and better ways of conducting such activities) is also inhibited or at the least constrained by the legislative restrictions. Innovation will not be as readily pursued because it would involve negotiations with regulators which can be a costly, problematic and time-consuming process, or it will be pursued only in those areas not subject to regulatory controls.

The costs of meeting the storage and handling requirements will be passed on to consumers, thus increasing the prices they pay for products. These industry costs may also act as a barrier to market entry and therefore also reduce the level of competition in the marketplace.

### 5.5.5 Costs and benefits of current restrictions

#### Medicines

For medicines, the main **costs** for INDUSTRY relate to the storage requirements for *Schedule 8* medicines. Depending on the substances stored and the quantities involved, these costs can be quite high, reflecting the level of risk of the products being stolen or diverted to the illicit drug market.

Step 4

Analyse  
benefits and  
costs

Similar costs may also be imposed on wholesalers of some *Schedule 4* medicines (e.g. benzodiazepines and anabolic steroids) and substances that are used in the illicit drug manufacture (e.g. pseudoephedrine in manufacturing amphetamines). The Review noted in this context, that the number of major robberies involving such substances, demonstrated need for secure storage and appropriate handling procedures for these substances.

As indicated previously, these costs may limit the capacity of industry to compete and could, at the margins, prevent some parties from entering the market. There are also **costs** for GOVERNMENTS associated with allocating resources to the tasks of regulatory development, compliance monitoring and enforcement.

For HEALTH PROFESSIONALS, especially pharmacies, there are also **costs** in storing *Schedule 8* medicines, although these are largely the ‘one-off’ cost of installing a prescribed-style safe.

The storage requirements for other prescription medicines impose minimal **costs** on INDUSTRY and PHARMACIES, over and above those that would normally be incurred by any business. It is noted in this regard that the costs to pharmacies of the *Schedule 2* and *3* storage requirements were not raised with the Review as being significant.

The **costs** to PHARMACISTS for storage requirements should be minimal. Moreover, it is difficult to see how a pharmacist can exercise the required level of professional supervision for *Schedule 2* and *3* products if their storage is not segregated in some way from other pharmacy products (e.g. disposable nappies, make-up).

Given the general requirement for *Schedule 2*, i.e. that pharmacist advice be available, the Review does not consider that *Schedule 2* products should be stored in a way that prevents direct consumer access. If the product requires that level of restriction, it is concomitant that the pharmacy should display the product in such a way as to facilitate or encourage the consumer to seek information and enable adequate supervision of the sale of the product to prevent diversion.

The Review appreciated that these changes may mean a number of jurisdictions will need to relax their present storage provisions. The review was not able to identify any

evidence to show that the level of pharmacist supervision and intervention was any greater in those jurisdictions with more stringent storage requirements.

The **benefits** to CONSUMERS of the storage requirements for other medicines are that these requirements facilitate professional intervention that will support the safe and effective use of these medicines.

The **benefits** to the COMMUNITY AS A WHOLE is seen to be that of obliging safer and more secure handling and storage particularly of *Schedule 8* and *Schedule 4* substances than would be adopted in a free market. This in turn leads to reductions in accidental and deliberate poisonings and in the diversion of certain products for abuse or misuse, including in illicit manufacture of harmful or addictive substances. The end result being lower hospital, medical and social costs than would be the case if access to these products were not restricted.

For these reasons, the Review considered there was a **net benefit** to the COMMUNITY AS A WHOLE in retaining the legislative storage and handling controls related to *Schedule 8* and *Schedule 4* substances.

### Poisons – retail level

For *Schedules 5, 6* and *7* poisons, the Review noted that there are **costs** for INDUSTRY in those jurisdictions that impose specific restrictions on the height at which a product may be displayed. Given the retail practice of charging for shelf space, with the prices varying with the height of the shelf used, a prescribed height could, in some cases, lead to additional costs for industry. The Review noted, however, that these costs are likely to be limited to a few products.

There is considerable variation in the requirements, which means the **costs** to INDUSTRY of the control vary across jurisdictions. Variations between jurisdictions in storage and handling requirements can lead to confusion for consumers, health professionals and industry which can add to costs.

So while the current controls do impose a **cost** on INDUSTRY in ensuring the product is stored safely, these costs are not significant but these costs would be reduced by greater uniformity (See Section 6).

The Review considered that the **costs** of prescribing the exact storage provisions for *Schedule 5* and *6* poisons outweighed the **benefits** to the COMMUNITY AS A WHOLE of less accidental poisoning and the associated hospital and medical costs. In particular, the Review noted that the packaging and labelling requirements for these products are the primary means by which the risk of accidental poisoning occurring in the retail setting is reduced.

In relation to *Schedule 7* substances, because of their highly toxic nature and the significant harms that can occur from their accidental or inappropriate use, the resultant hospital and medical **costs** to the CONSUMER and the COMMUNITY of inadequate measures by retailers could be considerable.

Therefore, the Review considered that the less regulatory approaches discussed above for *Schedule 5* and *6* poisons would not be effective in meeting the objectives for

*Schedule 7* substances. The Review therefore considered there were **net benefits** to the COMMUNITY AS WHOLE in retaining the current controls on storage and handling of *Schedule 7* poisons at the retail level. The Review noted that in some jurisdictions these controls are included in legislation other than drugs and poisons legislation.

### Poisons – wholesale level <sup>98</sup>

For *Schedule 5, 6 and 7* poisons there are minimal storage requirements, if any, at wholesale level. These controls would generally come under occupational health and safety legislation.

### 5.5.6 Alternatives to present restrictions

The next step required in a National Competition Policy Review is to consider whether there are alternative means for achieving the objectives of the legislation. The alternatives to the current controls on storage and handling considered by the Review were:

**Step 5**

**Consider alternatives and recommend**

- relying on general consumer protection legislation to achieve the objectives;
- developing codes of practice where compliance is achieved through legislative underpinning; and
- rationalising the legislative controls required, by eliminating areas of duplication with other State and Territory legislative requirements (e.g. occupational health and safety legislation) and with Commonwealth legislation.

In considering alternative approaches to meeting the objectives of the legislative controls on storage and handling, the Review has also noted the desirability of achieving uniformity across jurisdictions in relation to any mandatory requirements in order to minimise the costs to industry of compliance with the controls.

### General consumer protection

The Review considered whether it was possible to repeal the provisions in State and Territory legislation relating to storage and handling and instead rely on general consumer protection legislation and common law protection to meet the objectives of the legislation.

As noted previously, the objectives of the legislative controls applying to storage and handling legislation are to:

- prevent poisoning incidents as a result of, for example, loss during transport or of children having ready access from suppliers;
- prevent diversion for abuse (e.g. opiates) or misuse (e.g. anabolic steroids) or use in illicit manufacture (e.g. pseudoephedrine); and

<sup>98</sup> Wholesalers includes manufacturers, formulators and distributors as well as wholesalers.

- maintain the quality and safety of products throughout their shelf life.

The **benefits** to INDUSTRY of relying on general consumer protection legislation would be that it would provide industry (manufacturers, wholesalers and suppliers alike) with significantly more flexibility in how to handle and store drugs, poisons and controlled substances. Savings could be expected to flow from this increased flexibility which could mean higher profits and/or savings being passed on to CONSUMERS through lower prices. Innovation would also be fostered. There would also be **benefits** to GOVERNMENT in that they would no longer need to meet the costs of administering the present legislative storage and handling requirements.

There would be hospital, medical and social **costs** to CONSUMERS and GOVERNMENTS associated with misuse and abuse of certain products if the present legislative requirements were removed.

General laws relating to consumer protection and duty of care necessarily operate after-the-event. In the case of drugs and poisons and controlled substances, such events may have serious and even fatal health consequences.

The Review was not convinced that general consumer protection laws were sufficient to prevent significant events with adverse health effects occurring in the first place. On this basis, the Review considered that general consumer protection laws need to be supported by preventative measures that are area-specific and apply before the event. In this way, not only is short-sighted and opportunistic behaviour by careless or unethical businesses pre-empted for these purposes, but also so is simple accident and misadventure without attributable or actionable fault.

The Review did however, identify some controls where normal business practices supported by the general consumer protection mechanisms should be adequate to meet the objectives set out above. These controls are those where the risks are largely managed by other controls, such as labelling or packaging.

The Review considered that, in the case of *Schedule 5* and *6* poisons, market forces, such as the common law liability of the retailer for any harm suffered by customers, should be sufficient to meet the desired objectives. While a code of practice developed by the retail industry would make it easier for retailers to identify the standard needed to meet their duty of care, the diversity of the retailers makes it difficult to assign responsibility to one body to develop and enforce any such code. Hence the backstop provided by common law under torts for damages is possibly the most efficient form of necessary intervention available in this instance. In such cases, the Review considered that in those jurisdictions where such controls are presently imposed, the controls could be abolished without leading to additional costs for the community in terms of adverse health outcomes.

### **Codes of practice**

At the wholesale level, the Review considered whether secure handling of substances likely to be abused or diverted to the illicit market could be achieved through a code of practice such as the Code of Good Wholesaling Practice. The Review noted that this code is underpinned by the *Therapeutic Goods Act 1989*.

For *Schedule 8* and some *Schedule 4* substances, and particularly those substances likely to be diverted for abuse or for illicit manufacture of drugs, the Review considered that a code of practice would not be adequate to prevent diversion. The significant illicit manufacture and abuse, which would occur if such a code were adopted, would impact significantly on social hospital and medical **costs** for GOVERNMENTS and the COMMUNITY.

While a self-regulatory approach would ensure proper handling in some cases, there are circumstances where the products pose such a high risk of diversion leading to poisoning or illicit use, that the **costs** to INDUSTRY of a regulatory approach are outweighed by the **benefits** to the COMMUNITY and GOVERNMENT.

A code of practice would provide only general guidance and where the risks to the community from accidental poisoning, abuse or diversion are high, a margin of error in industry taking the most appropriate action cannot be tolerated. It may well be difficult for industry, particularly small businesses, to assess the level of risk and identify the measures, which need to be taken to minimise those risks.

The Review did not believe that a code of practice at the wholesale level would achieve the objectives in cases where the risk of diversion or inappropriate use is high, because there is considerable variation in the products and volume of products handled by those involved.

Similarly, the Review considered that a code of practice at the retail level would lead to increased diversion and medicinal misadventure where high risk medicines such as those in *Schedules 8* and *4* were involved because of the difficulty in maintaining the necessary level of security and supervision. Thus the objectives of the legislation would not be achieved. However, the Review noted that the restrictions relating to storing *Schedule 2* and *3* medicines imposed constraints which made innovation in where and how pharmacies could display these products difficult, if not impossible. The Review considered that for *Schedule 2* and *3* medicines the objectives of the legislation could be achieved by a code of practice.

In this context, the Review noted that the recently released *Pharmaceutical Society Standards for Schedule 2 and 3* (Section 2.22) makes provision for storage of these products. The Review also noted that the Pharmaceutical Society of Australia has been hampered in providing truly national standards by the current differences in jurisdictional legislative requirements. The Review considered that the objectives of the legislation could be better met by the legislation setting out the intended outcomes. This would provide the context in which a code of practice could effectively operate for low risk products and would set a framework in which the more specific controls would operate. If this occurred, the Pharmaceutical Society of Australia Standard could be amended to ensure that storage within pharmacies supported the purpose of the restrictions on access, which flow from including a substance in *Schedule 2* or *3*.

### **Rationalise the controls**

Some jurisdictions have already removed their previous regulatory requirements relating to wholesale storage and handling of *Schedule 5* and *6* poisons. In these jurisdictions, the storage and handling requirements are provided by occupational



health and safety legislation. This legislation is based on national model occupational health and safety regulations.

The Review considered that there would be **benefits** to INDUSTRY and GOVERNMENT if all other jurisdictions were to adopt a similar approach and repeal wholesale storage and handling requirements for poisons in drugs and poisons legislation. Instead, they could rely on occupational health and safety legislation to ensure the safe storage of these products.

## 5.6 Labelling

**Terms of reference addressed:** General Issues 1, 2, 3, 4, 5, 6, 7, 8, 9 and 10; Specific Issues 1, 2 and 4.

### 5.6.1 Introduction

Labelling is an important communication tool that can help consumers select and use products safely and effectively. Effective labelling reduces the need to apply restrictions on consumers' access to particular products.

Labelling controls in State and Territory legislation mandate the information that must be included on the label of the primary pack and sometimes other labels. Labelling provides the consumer with information to assist in the product's safe use by:

- identifying what the product contains and the strength of the ingredients therein;
- advising of any precautions necessary to ensure safe use, through the signal headings, first aid, safety directions and warning statements; and
- identifying for whom the product is intended, directions for use by that person and other information to facilitate its safe use by them, such as use-by date information and storage instructions.

The Review noted that the *Therapeutic Goods Act 1989* imposes a number of labelling controls and standards for products<sup>99</sup> in relation to the use of medicines by humans. These controls are currently being reviewed to improve the efficiency of the regulatory controls and enhance their effectiveness in improving the quality use of medicines.

In most jurisdictions labelling for agvet chemicals is largely controlled under the *Agricultural and Veterinary Chemical Code Act 1994*. The only labelling controls applied under drugs and poisons legislation are the signal headings, which relate to the schedule in which a substance is included, and several general warnings.

Labelling controls imposed by occupational health and safety legislation are also under review and there has been consultation between the health agencies and NOHSC on the review of model regulations to reduce confusion about the requirements for labelling products at the interface between household use and industrial use.

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<sup>99</sup> For example, the Therapeutic Goods Regulations, TGO 48 and the various Guidelines for applications to enter products on the ARTG.

## 5.6.2 Objectives

In general terms, the objectives of labelling controls in drugs, poisons and controlled substances legislation relate to the need to protect public health and safety, particularly in relation to poisoning and medical misadventure, by redressing consumers' the information deficit.

### Step 1

Clarify objectives of legislation

The role of labels is to communicate essential information to:

- consumers to enable them to:
  - select an appropriate non-prescription product, and to use the product safely and effectively;
  - use a prescription product safely and effectively; and
  - select an appropriate agvet or household chemical product and use it safely and effectively; and
- health professionals to enable them to select and dispense or administer medicines correctly and safely.

## 5.6.3 Nature of restrictions

Labelling controls fall into two main categories:

- **product labels** which are affixed to the product by the manufacture or sponsor of the product. They are intended to convey information to the consumer for OTC products (i.e. those which are unscheduled, or included in *Schedules 2, 3, 5, 6 and 7*) or to the dispenser or administrator of the product (i.e. those in *Schedules 4 and 8*); and
- **dispensing labels** which are affixed to the product (generally over the top of the product label), by the pharmacist, doctor, veterinarian or other authorised person.

### Step 2

Identify nature of restriction on competition

The existing restrictions require information and warnings, often in prescribed wording, to appear on product and dispensing labels. Warnings may be about:

- using the product in the safest way;
- avoidance of the product by certain individuals or in certain situations (e.g when driving a motor vehicle); or
- protecting the unwary, particularly children, from accidental consumption or exposure.

For some products there is also a requirement for first aid instructions to advise of the steps to be taken if accidental consumption or exposure does occur.

### Product labels

The SUSDP labelling requirements apply to product labels. The exception (SUSDP Part 3) is that the dispenser must include specific warning statements for certain

substances. For example the sedation warnings for substances listed in Appendix K are the responsibility of the dispenser. These are adopted by all jurisdictions.

All States and Territories adopt the labelling requirements in SUSDP Part 2 which sets out signal headings. Signal headings designate the schedule into which the product falls and provides some indication of its level of toxicity.

Most jurisdictions also adopt the labelling requirements set out in Appendixes E (First Aid Instructions) and F (Warning Statements and Safety Directions) by reference while the remainder include provisions with a similar intention in their legislation. These jurisdictional differences add to costs for industry and consumers by creating confusion, which could have implications for safety.

The warning statements and the first aid instructions included in Appendixes E and F do not apply to agvet chemicals registered by the National Registration Authority. However, there are two jurisdictions which do not adopt Appendixes E and F.

Registered agvet chemicals<sup>100</sup> must be labelled according to requirements under the *Agricultural and Veterinary Chemicals Code Act 1994*.<sup>101</sup> The material which was formerly included in Appendixes E and F for these products is now in the First Aid Instructions and Safety Directions Handbook, a handbook of first aid instructions, safety directions and warning statements for agricultural and veterinary chemicals. This Handbook is a consolidation of recommendations from the SUSDP, the Therapeutic Goods Administration and the National Occupational Health and Safety Commission.

Poison level signal headings for scheduled agvet products as set out in the SUSDP are uniformly adopted and are required as per schedule, but labelling requirements of the SUSDP are not intended for products packed and sold solely for industrial or manufacturing purposes and labelled correctly for workplace requirements. Workplace labelling attracts signal headings, often different, but appropriate for the level of warnings required for workers.

Confusion occurs for industry and regulators when jurisdictions do not classify a farm as a workplace or the same product is used both domestically and in the workplace (e.g. hair dyes). Lack of uniformity arises if the exemption for products labelled according to the National Occupational Health and Safety Commission requirements<sup>102</sup> expressed in the SUSDP is not picked up by each jurisdiction.

The new Code for Labelling of Workplace Substances being prepared by the National Occupational Health and Safety Commission attempts to clarify the interface for industry. It distinguishes labelling requirements, based on use of products in the

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<sup>100</sup> All agvet chemical products are subject to the *Agricultural and Veterinary Chemicals Code Act 1994*.

<sup>101</sup> In those jurisdictions which do not adopt Appendixes E and F by reference the State and Territory requirements would also apply to the agvet products which could be confusing for industry and consumers. In practice this has not proved to be a problem to date partly because the NRA requirements are based on the SUSDP requirements.

<sup>102</sup> The Review was advised that there are differences across States and Territories in the way in which the model occupational health and safety regulations are adopted.

workplace, as either ‘used in the same manner as in the domestic environment’ (poisons legislation suffices) or ‘used in a manner which alters exposure in the workplace’ (different precautions needed). Regulators in the health arena and the occupational health and safety area should work together towards a consistent approach.

## Dispensing labels

The pharmacist usually applies dispensing labels, although other health professionals may also be required to apply specific labels for a particular patient when dispensing a medicine. The labels are intended to:

- identify the patient for whom the medicine is prescribed;
- state the dose prescribed by the doctor, veterinarian or other health professional;
- give safety and quality information (e.g. use-by date, storage instructions);
- provide necessary warnings (e.g. sedation warnings set out in Appendix K); and
- other information, such as the name of the pharmacy supplying the medicine.

The labelling requirements in Part 3 of the SUSDP and Appendixes E and F are not adopted by all jurisdictions and there is some variation in the requirements for warning labels to be applied by pharmacists and the requirement to include the expiry date on the dispensed label.. However, in general the level of variation in the requirements for dispensing labels across jurisdictions is minimal.

## 5.6.4 Effects of restrictions on competition and the economy

### Product labels

As indicated previously, labelling controls mandate the information for inclusion on the label of the immediate container and, in some instances, other labels. Labelling provides consumers with information to help them use the product safely and provides handlers and professional workers with guidance for complying with the appropriate controls on, for example access and storage.

Step 3

Analyse  
effects of  
restriction

However, the controls are anti-competitive in that suppliers are limited in competing for custom with product appeal through labelling. Suppliers are prevented from using their own initiative for content of, and manner of conveying, information in ways divergent from regulatory requirements. This limitation does not totally prevent creation of corporate image and individuality, but the necessity to add features such as additional warnings can create problems in this regard.

### Dispensing labels

Dispensing labels are intended to provide information to enable the consumer to use the medicines safely and effectively. The specific label instructions for use by the person or animal for whom the medicine is prescribed are determined by the prescriber of the medicine and help that consumer use the medicine most effectively.

The effect of the restrictions is to constrain the extent to which a particular supplier can distinguish the products they supply from those of other suppliers. This may reduce the level of innovation in dispensing labels.

The requirements for labelling clinical samples when supplied by the doctor or other health professional to the consumer differ across the jurisdictions (see the discussion of the controls applying to clinical samples earlier in this Section). In some jurisdictions dispensing labels are not required where the supply is for less than three days. The Review noted that some companies include a blank panel on clinical samples to allow the prescriber to include instructions. The Review was advised that on some occasions consumers would seek the advice of a pharmacist because they had forgotten the instructions the doctor gave them when the sample was supplied and the pack had not been labelled.

### 5.6.5 Costs and benefits of current controls

#### Step 4

#### Analyse benefits and costs

#### Product labels

The **costs** to competition for INDUSTRY of imposing labelling restrictions under legislation are a reduced freedom for suppliers to choose flexibly, without constraint, how they would wish to market, display and present their product in the drugs, poisons and controlled substances area. There are also administrative costs for GOVERNMENT. These costs need to be set, however, against the **benefits** to CONSUMERS.

The **benefits** of the current controls for CONSUMERS are that the controls impose a standard, which enables consumers to compare the nature of over-the-counter products and to understand product characteristics. The labelling information also supports the safe and effective use of products, both over the counter and prescribed. As indicated previously, information is central to the safe and effective use of the products concerned. The consequent prime benefit is enhanced consumer safety and welfare in using potent medicines and dangerous poisons thereby limiting unnecessary avoidable hospital and medical costs.

When labelling requirements differ across jurisdictions, firms operating across markets incur greater costs of investigation and implementation than under a single uniform approach. In addition, sponsors frequently seek exemptions from the prescriptive labelling requirements for reasons such as package size or scheduling changes. These exemptions currently have to be separately obtained in each jurisdiction. While an exemption granted by one jurisdiction might be acceptable to other jurisdictions, the sponsor seeking such an exemption has no certainty that this will be the case ( see Case Study 7). Industry has identified this as an unnecessary cost. Improved efficiency and uniformity are discussed in more detail Section 6.

Labelling laws may also serve as some protection for industry in meeting their liabilities to consumers in marketing potential poisons, by way of provision of necessary, reliable information

## Dispensing labels

The Review considered that the person supplying a medicine (including clinical samples) has an obligation to ensure the consumer understands how to use the medicine effectively and safely. This is best achieved if the patient has written instructions to remind them of the oral advice they have been given.

Thus the labelling requirements lead to safer use of medicines, more timely identification of the product in the event of poisoning or diversion and prevention of accidental poisoning through use of the wrong medicine.

While this imposes a small **cost** on the HEALTH PROFESSIONAL, the Review considered that the **benefits** to CONSUMERS, i.e. avoiding confusion particularly in the chronically ill or elderly, outweigh, even justify, those costs.

### 5.6.6 Alternatives and their costs and benefits

The Review considered that if products containing potentially harmful substances were supplied without providing any mandated information about the risks to consumers, there would be an increase in the level and severity of accidental poisonings and medicinal misadventures leading in turn to higher medical and hospital costs. There are obvious benefits to consumers and governments in avoiding these costs.

#### Step 5

Consider  
alternatives and  
recommend

As discussed above, the **costs** to INDUSTRY of the label restrictions are not high and therefore the Review considered that the controls offered a **net benefit** to the COMMUNITY AS A WHOLE over no regulation.

Further, as stated above, effective labelling can provide benefits to consumers by redressing their information deficit. However, the Review must also consider whether there are alternative ways in which the objectives could be met.

The Review considered that removal of the labelling controls would not provide a **net benefit** for the COMMUNITY AS A WHOLE, as labelling controls are a key mechanism for overcoming the information asymmetry to enable consumers to select and use medicines safely and effectively.

Removing the controls could be expected to result in an increased emphasis on persuasive promotion of a product rather than on balanced and factual information being contained on a product label. This would, at a minimum, make the information necessary to enable consumers to use the products safely and effectively difficult to identify and would, in some cases, lead to at least some of that information not being included on the label. The consequence of this would be to increase the **costs** of the current controls for CONSUMERS and the GOVERNMENT through increased poisoning and medicinal misadventure leading to hospital and medical costs for the consumer and governments.

A further consequence would be that this sort of situation would lead to some products being moved to a higher schedule to redress that information asymmetry. Moving substances to a higher schedule could be expected to decrease consumer

access, increase the price of the goods for consumers and increase the restrictions on market entry for industry.

### Generic consumer protection legislation

The Review believed that generic consumer protection and trade practices legislation were not adequate to ensure the objectives of the legislation are met as these methods of redress only come into operation after an adverse event or a number of adverse events have occurred. Moreover, tests of truthfulness and capacity not to mislead are only part of the demands for useful labels. The consumer requires a range of information (e.g. how and when to use the product, the amount to use and precautions to take) to enable him or her to use the substance safely and effectively.

In this area, where public health and safety are at issue, limited criteria and retrospective remedies are inadequate. They do not reduce harms sufficiently in this field and are too late for those so harmed – though they remain a useful complement to area-specific regulations. Consequently, the Review considered that many of the costs associated with removing the controls would also apply so that this alternative would not deliver a **net benefit** to the COMMUNITY AS A WHOLE and would not achieve the objectives of the legislation.

In considering less restrictive alternatives, the Review noted that labelling requirements in many cases provide an alternative to including a substance in a higher schedule with the additional restrictions on access that would then be incurred. Thus the consideration here is between the costs imposed by labelling restrictions and those costs resulting from more restrictive controls on access.

Some of the **costs** for INDUSTRY and CONSUMERS imposed by labelling were discussed in Section 4 together with the costs associated with the restrictions on access imposed by the controls, which flow from the Schedules. The Review considered that, for any particular substance, the costs of labelling controls are considerably less than would occur if the substance was rescheduled to a higher schedule.

Other alternatives the Review considered were:

- the means for product labels to be improved as communication tools through the use of performance-based regulation and reconsideration of the role of signal headings; and
- simplifying the labelling requirements by making the requirements uniform – in some cases this could be achieved through moving the requirements for medicine labels and for agvet chemical products from drugs and poisons legislation (leaving household poisons) to Commonwealth legislation and concurrently repealing State and Territory labelling. In other cases (e.g. household chemical labels and dispensing labels), uniformity could be achieved through States and Territories adopting by reference model legislation. These issues are discussed in depth in Section 6.

## Performance-based regulation

Under this alternative, the present prescriptive requirements relating to labelling would be replaced with, or set in the context of, a performance-based system of regulation.

Under a performance-based system of regulation, the legislation would identify the outcomes that need to be achieved together with performance criteria to help product sponsors meet the specified outcomes.

The **benefits** to INDUSTRY of this system are that it would provide flexibility, encourage innovation and may in any event provide greater effectiveness in achieving the objectives of the legislation.

The Review noted that the objective of the legislation might not always be realised under the current very prescriptive approach to the requirements for labelling. Consumers may not always comprehend the required warnings or other mandatory statements, including the signal headings (Ley, 1985; Rush Social Research, 1995).

If performance-based regulation led to improved effectiveness of labels as a means of communicating important information to consumers about the safe use of a product this may enable a few substances to be moved to a lower schedule, thus improving access.

Further, identification of the performance standard will provide greater transparency and equity, particularly where exemptions are sought from the legislative requirements.

The Review noted that the labelling project the Therapeutic Goods Administration (TGA) is currently undertaking is exploring the extent to which performance-based regulation will be cost effective for labelling requirements for medicines and how best to implement such an approach.

### 5.6.7 Other matters

Some stakeholders raised concerns over the interpretation of labels by those with low literacy skills and the use of consistent dosing formats was recommended (e.g. for children by weight or by age). Research on the labels on poisons (Ley, 1995) found that warnings to KEEP OUT OF REACH OF CHILDREN were considered ineffective with respect to safe storage (particularly in the home and farm), and differentiation between 'less toxic', 'highly toxic' and 'lethal' products were recommended along with an education campaign about safe storage. Some stakeholders also raised the problems of the visually impaired.

The Review noted that for medicines, these issues are likely to be addressed by the current TGA review of labelling. Depending on the outcome of that review, there could be benefits for the community in the National Registration Authority for Agricultural and Veterinary Chemicals (NRA) (for agvet products) and the NCCTG (for household chemicals) considering the outcome of the TGA review with a view to making changes in the requirements for labels for agvet and household chemicals.



The choice of wording of signal headings is a problem, which was also raised. For example, use of POISON for *Schedule 6* veterinary products appears illogical for a product to be ingested, even though by animals only. While the Review considered that this was technical issue beyond the scope of this Review, it did note that the requirement for this signal heading did impose a cost on industry and consumers by deterring some consumers from purchasing these products. The Review considered that it would be appropriate for the NCCTG to direct the PSC to review this heading with a view to providing more a more appropriate signal heading(s) for veterinary products in *Schedule 6*.

## 5.7 Packaging

**Terms of reference addressed:** General Issues 1, 2, 3, 4, 5, 6, 8, 9 and 10; Specific Issues 2 and 4.

### 5.7.1 Introduction

Packaging controls in this field refer to the requirements that are imposed on the primary pack for scheduled medicines and poisons, including its closure, the immediate container and the immediate wrapper. Scheduling decisions are sometimes conditional upon the design of a container or closure. For example, the packaging of some cockroach baits and the use of child-resistant packaging for some poisons makes them less accessible. Appropriate packaging restrictions can allow a substance to be available on a lower schedule than would otherwise be the case, thereby improving access without compromising safety.

Packaging is one of the suite of controls used to ensure safe use of drugs and poisons within the community. Packaging controls are a complex web of regulatory requirements, sometimes imposed through the drugs and poisons legislation (in the case of agvet and household chemicals) and sometimes through related legislation.

Child-resistant packaging for medicines is imposed by the *Therapeutic Goods Act 1989*, not by State and Territory drugs and poisons legislation. Thus, sole traders trading intrastate in those jurisdictions without complementary therapeutic goods legislation may not be required to comply with packaging restrictions.

In recent years, recommendations on Trans-Tasman harmonisation of labelling and packaging of medicines and poisons have been implemented, although there is now some uncertainty as to whether harmonisation of the labelling of household chemicals in particular can be achieved, because Regulations to the New Zealand Hazardous Substances and New Organisms Act have yet to be implemented.

The major comments made in submissions to the Review in relation to packaging were to call for uniform controls and to suggest that products that are assessed for safety, including packaging, under other legislation (e.g. *Therapeutic Goods Act 1989*), should also have the packaging restrictions under that legislation (e.g the *Agricultural and Chemical Code Act 1994*).

Injury surveillance units and university researchers were strongly in favour of all products being included in child-resistant packaging. However, consumer organisations and groups representing those with chronic illnesses pointed to the difficulty some people, particularly the elderly or some of those with disabilities have

in opening products with current child-resistant packaging. Industry argued that the need for child resistant packaging should be considered on a case by case basis.

### 5.7.2 Objectives

The overall objectives of packaging controls are to protect public health and safety by:

- reducing accidental use of medicines and poisons;
- reducing the risk of abuse, over-use, dependence and illicit use;
- minimising the risk of medicines being used in intentional overdose; and
- minimising the possibility of product contamination and tampering injurious to public health.

**Step 1**

**Clarify objectives of legislation**

### 5.7.3 Nature of restrictions

Packaging restrictions fall into two broad categories:

- those restricting pack size which affect the schedule in which a substance is included, with smaller pack sizes being included in a lower schedule or being unscheduled; and
- the way in which the good is packaged. In particular, this relates to child-resistant packaging or blister packaging and tactile containers (e.g. with ribbing or embossed with the word POISON) used for some poisons. This packaging is intended to make it more difficult for children in particular to accidentally ingest a medicine or a poison. Some goods (e.g. essential oils) are very difficult to package in this way because the contents may dissolve some of the materials used to make these closures. The Australian Standard for Child Resistant Closures places responsibility on the sponsor of the goods to ensure the contents of the container do not affect the effectiveness of the closure.

**Step 2**

**Identify nature of restriction on competition**

### 5.7.4 Effects of restriction on competition and the economy

The packaging restrictions limit the opportunities for competitors to use this form of product differentiation as flexibly as they could be expected to do in the absence of such controls. Product differentiation is very much a vehicle for competition between firms using non-price mechanisms. The constraint upon competitive behaviour can extend to inhibition of innovation in packaging, since potential innovators with approaches that do not conform to existing controls face the time-consuming, costly and uncertain task of convincing regulators to change their policies to accommodate an alternative. Such a process also risks losing ‘first mover’ advantages from innovation in packaging, i.e. innovators will fear that in the process of seeking regulatory amendment there is a chance that their innovation will be shared with competitors. This too will inhibit competition through packaging.

**Step 3**

**Analyse effects of restriction**

This could prevent small suppliers, who do not have the technical capacity to establish whether or not their product requires child-resistant packaging, from participating in the market, thereby limiting the extent of competition.

Controls on pack size restrict seller participation in a particular market segment (e.g. supermarkets in the sale of packs of 25 or more analgesics tablets/capsules). The intention is to reduce the amount of medicine available for misuse, abuse or diversion, thereby minimising the harm. In theory, however, where the smaller packs are unscheduled and therefore available from supermarkets, there is nothing to stop someone buying several packs of an analgesic from a supermarket, though the price will be likely to be higher than if they bought one large pack from a pharmacy. In practice, the evidence indicates that this does not occur, and indeed, limiting the pack sizes freely available from supermarkets has been shown to lead to less poisoning (Prince et al (2000)).

There is a further consequence of some of the existing approaches to regulating packaging. Restrictions on pack sizes available in some retail outlets, e.g. supermarkets, limit the achievement of economies of scale in such outlets, so reducing availability of some product configurations and raising prices for those that are available.

### 5.7.5 Costs and benefits of current controls

#### Step 4

#### Analyse benefits and costs

The controls for child-resistant packaging add to **costs** for INDUSTRY but stakeholders indicated that these costs were not significant.

Submissions did not provide any detail of the costs associated with the different packaging controls, although several commented that the costs of requiring all drugs, poisons and controlled substances to be in child-resistant packaging could not be justified. Of course the difficult judgement here is what the degree of harm would be in the absence of regulation.

A further cost of the control, which is difficult to estimate, is the inconvenience for some consumers, particularly the elderly and disabled who have difficulty accessing their medicines when provided in child-resistant packaging. The Review was not able to identify any specific costs in this area although a number of stakeholders identified it as a problem.

Currently, it is estimated that there are around 3 500 admissions to hospital for childhood poisonings annually (O'Connor, 2000; National Injury Surveillance Unit statistics). Experts in this area advise that the number of admissions, and the associated hospital and medical costs, would be considerably higher if the current restrictions were relaxed. A review of the effectiveness of child-resistant packaging in the United States found that the introduction of child-resistant closures resulted in a 45 per cent reduction in childhood deaths from poisoning by prescription medicine (Rodgers, 1996). Although there are difficulties in extrapolating from the United States data, the extent of the benefit is such as to indicate that the requirements for child-resistant packaging in Australia do provide a significant **benefit** to the

COMMUNITY – perhaps as much as \$44 million per year (based on United States results) – through preventing poisoning in children.

Of course some poisonings will occur despite these controls, and funds need to be allocated for research to identify the reasons for these cases and to help develop a full range of cost effective preventive measures to improve the effectiveness of the current controls. If this does not occur, there may be calls for substances implicated in a high proportion of poisonings to be rescheduled to a higher schedule.

The Review considered that there are considerable **benefits** for the COMMUNITY (reduced hospital and medical cost as a result of poisoning) in requiring that, where the risk of poisoning is high, products be presented in child-resistant packaging. These **costs** are passed on the CONSUMERS and to GOVERNMENT (for subsidised medicines).

### 5.7.6 Alternatives and their costs and benefits

The Review is concerned that, without a specific mandatory requirement, some businesses may choose not to use such packaging without fully appreciating the impact this can have on the likelihood of poisoning, especially in children. Relying on the market to regulate this through pressure from legal liability claims could significantly increase the number of poisonings requiring admission to hospital.

#### Step 5

Consider alternatives and recommend

While a subsequent legal damages action may provide compensation and deter others, the legal process can be slow and imperfect and consequently does not provide an adequate incentive to ensure that suppliers package their products in child-resistant packaging when there is a risk of childhood poisoning. Moreover, it still leaves the burden of control over potentially severe health damage with victims – an unjust and inequitable method of sole regulation in this area. The Review did not consider that the objectives of the legislation would be achieved by removing packaging controls.

The Review considered, however, that general consumer protection mechanisms formed a useful complement to more comprehensive preventative regulation. The Review considered whether abolishing area-specific regulation altogether and leaving packaging controls to be implemented under the general safety provisions of the *Trade Practices Act 1975* or State and Territory consumer protection legislation, would achieve the objectives of the legislation.

However, the Review formed the view that relying on these mechanisms may lead to significant hospital and medical **costs** for CONSUMERS and GOVERNMENT occurring before any preventive action is taken. Further for certain substances, or in certain circumstances, the risk of such harm occurring is high.

The Review's further task is to examine other options to reduce the restrictions on competition to determine if there are potential improvements possible to the existing legislative approach. The Review considered the following options in this context:

- community information and education campaigns on safe storage and use of medicines and poisons in the home and place of work;
- taxes or subsidies for dangerous or safe packaging; and

- voluntary industry code of practice covering child-resistant packaging.

The Review considered whether the objectives of the legislation could be met through such alternative approaches. However, for the reasons set out below, the Review did not consider that these alternatives would enable these objectives to be met.

### **Community information and education campaigns**

To be effective, community information and education campaigns would need to be comprehensive and ongoing. This would involve allocation of considerable resources and so would involve significant **costs** to INDUSTRY and/or to GOVERNMENT.

### **Taxes or subsidies**

Taxes or subsidies may induce behaviour in desired directions in the public interest, but unless the level of tax or subsidy is significantly higher than the cost of supplying the product in a child resistant closure they cannot guarantee sufficient up-take or response for adequate preventative coverage. There would be **costs** to GOVERNMENT and to INDUSTRY in developing a system of taxes and/or subsidies aimed at influencing the way in which drugs, poisons and controlled substances were packaged without any certainty that this system would result in the objectives of the controls being met. Consequently, the Review considered that there would not be a **net benefit** to the COMMUNITY AS A WHOLE.

### **Voluntary industry code of practice**

In assessing the potential role of a voluntary industry code of practice, the Review noted that the range of persons involved in supplying drugs, poisons and controlled substances is diverse, ranging from large multinational companies to small sole traders. Moreover, many suppliers do not belong to industry associations. This would limit the effectiveness of industry codes of practice unless there was legislative underpinning.

Moreover, the Review noted that many small businesses would not have the resources and expertise to identify which products should be packaged in child-resistant packaging. While the additional costs for industry of special packaging do not appear to be overly onerous they can be significant for small business. To leave the decision about when to use special packaging (including child-resistant packaging) to the product sponsor, would place a considerable burden on industry, especially small business, in deciding when special packaging was necessary and consumers may well be disadvantaged where adequate protection against poisoning does not occur.

The Review further considered that the need to refer all new substances to industry for consideration about the nature of the packaging control to apply could add significantly to the time taken to bring a product to market as such a decision would be subsequent to the scheduling decision. These delays would add to INDUSTRY **costs**. The Review considered that there were **benefits** to the COMMUNITY, CONSUMERS and to INDUSTRY in having packaging decisions made during the scheduling process as this process is:

- open and transparent, providing all stakeholders with an opportunity to comment on the decision; and
- timely in that the process is not additional to the scheduling process.

Therefore, apart from recommendations to achieve greater uniformity of the controls and to improve their administrative efficiency (see Section 6), for the reasons above the Review considered that the current packaging controls provided a **net benefit** to the COMMUNITY AS A WHOLE and there were no alternatives that would meet the objectives of the legislation.

### 5.7.7 Child-resistant packaging

The Review identified a number of problems associated with child-resistant packaging including:

- the difficulty that some elderly consumers reportedly have in undoing the containers; and
- proposals for the packaging of all medicines and poisons to be child resistant.

A number of stakeholders especially injury surveillance units, argued strongly that child resistant packaging should be mandatory for all medicines and poisons.

The Review did not consider that the **costs** to INDUSTRY and CONSUMERS from mandating child-resistant packaging for all medicines and poisons could be justified in terms of the benefits to the community through reduced poisonings. Moreover, requiring child-resistant packing for all medicines and poisons would very likely increase the problems older people and those with disabilities have in handling products packaged in this way.

The Review strongly urges industry and governments to allocate resources to finding more effective child-resistant packaging which the elderly and the disabled can more easily use while providing protection to the community from accidental poisoning, particularly among children.

## 5.8 Other matters

**Terms of Reference addressed:** General Issues 2, 6 and 9; Specific Issues 4 and 5.

The Review is required to consider the manner of supply by professionals of drugs, poisons and controlled substances.

For the purposes of this Review, ‘supply’ is defined as: provision of a drug, poison or controlled substance to a company, person or organisation for use by that company, person or organisation.

‘Administration’ is where a person administers that medication to another person (e.g. by injection) for immediate consumption or application or when, on a single occasion, one or more medicines is given to a person.

While supply is generally controlled under drugs, poisons and controlled substances legislation, administration may be controlled under professional regulation or under institutional (e.g. hospital) or organisational (e.g. teachers) standards or a combination of these.

### 5.8.1 Administration of medicines

Administration of medicines is closely linked to prescribing rights (which are excluded from this Review) where the health professional that prescribes the medicine also administers it.

There are situations, however, where administration can be distinguished from prescribing rights. These situations include administration:

- of medicines to children in schools;
- by nurses to patients in hospitals;
- by nurses or carers to residents of nursing homes, aged care facilities or homes of the patient etc.;
- by nurses or health workers in remote and rural communities; and
- of medicines by parents to children.

Drugs, poisons and controlled substances legislation deals with some, but not all, of these situations. In other instances, such administration may be dealt with by other mechanisms; such as standards for aged care facilities, hospital operating procedures, or professional codes of practice or other legislation. In part, these mechanisms are intended to ensure that these medicines are administered safely and to prevent diversion of substances likely to be abused. In this context, the Review noted recent changes in New South Wales to the *Stock Medicines Act 1989* to require anabolic steroids for veterinary use to be only administered by veterinarians.

Several stakeholders commented on this issue, particularly in relation to administering medicines to residents of aged care facilities. The responsibility of teachers in administering potent medicines to children in schools was also of concern to some stakeholders.

The primary objective of any legislation, or other mechanism, which sets out how, when and who may administer medicine to others should be to protect the safety of the person to whom the medicine is administered. Given the diversity of situations in which medicine is administered by one person to another, the differing knowledge and understanding of those administering the medicine and the understanding of the patient to whom it is being administered, the Review did not consider medicines and poisons legislation to be the most effective tool for regulating administration of medicines. The Review considered it is more appropriate, in most cases, that standards or codes of practice pertaining to the particular circumstances be developed and enforced by the relevant body or association.

For example, hospitals will have standard procedures for administering medicines in those institutions. In remote areas, special protocols would need to be developed, where they do not already exist, to take account of the level of training and skills of

the health workers operating in those communities to reduce the problems caused by lack of access to doctors and pharmacies to obtain required medicines.

The Review considered that a code of practice for teachers (administered by the education department in consultation with the teachers unions) or standards for nursing homes (administered by the accreditation agency) that set out the qualifications and procedures for staff administering medicines would be the most cost effective means of achieving the desired objectives. For parents, it would be inappropriate and unnecessary to apply legislative sanctions as they would be largely unenforceable and as there is a strong presumption that parents will follow the directions of the relevant health professional and the directions provided on the label.

The Review therefore saw no need for controls on administration in these circumstances to be included in drugs, poisons and controlled substances legislation. In many cases, however, the Review noted that the controls are intended to prevent diversion or abuse. In these circumstances the controls not only limit who can administer the medicines but the procedures for doing so, including the records to be kept. The Review considered that, in these circumstances, the controls (particularly in relation to record keeping) should be retained in drugs, poisons and controlled substances legislation.

### **5.8.2 Mail order and Internet supply**

This mode of supply was been raised as an issue in relation to human medicines, although it could also be used for supply of agvet products and household chemicals. All mail order and Internet suppliers operating within Australia are subject to the same controls as all other suppliers of these substances.<sup>103</sup> Suppliers also need to ensure they comply with dangerous goods legislation and with postal regulations. Quality and security issues also need to be considered, particularly for potent medicines and those likely to be abused.

It is important to note that a distinction needs to be made between off-shore Internet suppliers and those operating within Australia. While off-shore suppliers are beyond the control of drugs, poisons and controlled substances legislation, there is concern that supply from such sources can pose a considerable risk to consumers.<sup>104</sup> This is an issue that requires international cooperation to reduce those risks. Therefore, this Review is only considering Internet and mail order supply from within Australia.

However, the Review believed that these methods of supply offer the potential to increase competition and provide consumers with a choice of supplier. They can also provide access for those living in remote communities.

The Review has identified particular areas, where the regulations hamper alternative supply mechanisms, or where alternative measures need to be put in place to ensure

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<sup>103</sup> i.e all the restrictions discussed in Section 4 and Section 5 above apply to mail order and Internet pharmacies,

<sup>104</sup> The risks include counterfeit drugs, poor quality, mis-identification, contamination etc. In general, the consumer has no way of knowing whether the product supplied is the correct one or of establishing the quality of the product.



the benefits of the controls to the community can be delivered by such supply mechanisms. For example, the controls that operate to prohibit these suppliers from advertising the price at which prescription products can be obtained from these suppliers (see earlier discussion). There is also an urgent need to develop professional practice standards for distance supply, particularly in relation to these supply mechanisms (see discussion in Section 4).

Comments from pharmacy organisations in particular were highly critical of mail order pharmacies. Their comments related largely to the inability of such suppliers to offer face-to-face counselling. They were also critical of the advertising used by such businesses and several pharmacists commented that the prices charged by mail order suppliers undermined the viability of regular pharmacies. However, some pharmacists saw this as a challenge to improve the services offered to offset the cheaper prices of mail order pharmacies. The view was also put that pharmacies should be embracing the Internet as a means of delivering new services for consumers, adding convenience and providing more information and better customer service. The Review concurs with this view.

Consumer organisations, particularly those representing the chronically ill, saw considerable **benefit** to the CONSUMER in mail order and Internet pharmacies as they provided a cheaper alternative supplier for regular medication. The Review noted that some Internet or distance suppliers offered excellent counselling and support with calls advising when the medicine would arrive, and following up after its arrival to ensure the consumer knew how to use it safely and effectively.

The need for professional standards to address distance supply (i.e. by mail order, Internet or other forms of delivery which preclude face-to-face counselling) has been discussed elsewhere in this report, as has advertising by such suppliers.

Issues relating to supply of *Schedule 3* medicines by mail order need to be resolved. Because of the legislative requirements for a pharmacist to be personally involved in supplying *Schedule 3* medicines, the Review was advised that mail order pharmacies have required customers to provide a prescription to accompany the order. This adds to the CONSUMER'S **costs** and also involves costs to GOVERNMENT through subsidising a doctor's visit. The Review believed it should be possible, as discussed in Section 4, to develop appropriate standards for supplying *Schedule 3* medicines by mail order or Internet.

*Schedule 8* medicines may only be supplied on the prescription of a doctor (or other authorised prescriber) where that prescriber is registered in the same jurisdiction from which the supply is taking place. This disadvantages some consumers by restricting their choice to access these medicines and restricts some pharmacies from competing for this business (e.g. mail order pharmacies). Given the potential for abuse of these substances, it is important that there is adequate control of prescribing and dispensing. As there is no national system of registration for health professionals, the Review sees no alternative to this requirement at this time.

The Review also noted the difficulty for health authorities in monitoring interstate retail supply of *Schedule 8* medicines via mail order and the Internet and proposed that, where the NCCTG determines there is a benefit in doing so, a mechanism to overcome this should be developed (see Record keeping and reporting, above).

### 5.8.3 Herbal and complementary medicines

Drugs, poisons and controlled substances legislation places restrictions on access to a number of herbal and complementary substances. This is, on the face of it, a restriction on competition, although enacted with a presumption of advancing health outcomes.

Several submissions from the herbal and complementary health care sector argued that it was inappropriate for herbal and complementary medicines to be regulated under drugs, poisons and controlled substances legislation. They commented that many of those who are authorised to supply these medicines did not have the necessary skills and knowledge to do so and that the products should be prescribed and supplied by those trained in their use. This view implies that the benefits for the consumer of the controls are lessened by the restriction on competition.

Many of the issues stakeholders raised relate to prescribing rights that are outside the scope of this Review. However, the Review noted that Victoria has recently passed legislation to accredit practitioners of traditional Chinese medicine and to extend the prescribing rights to accredited practitioners. A special schedule is to be created in the Victorian legislation to identify those substances to which traditional Chinese medicine practitioners will have access.

The Review saw no reason not to regulate herbal and complementary medicines under drugs, poisons and controlled substances legislation in the same way as other medicines. Consumers use these medicines to treat, relieve or prevent various medical conditions in the same way as, or as an alternative to, orthodox pharmaceuticals. The harms that can occur (poisoning, medicinal misadventure and diversion) and the consequential hospital, medical and social **costs** for the CONSUMER and the COMMUNITY are the same. Therefore the costs and benefits of the controls need to be evaluated in the same way.

While the Review recognised that the current restrictions do hamper competition and may prevent some firms from entering the market, the Review considered that the current controls did provide a **net benefit** to the COMMUNITY AS A WHOLE.

This is not to say that the Review did not see ways in which the costs of these controls for alternative medicine practitioners could be reduced. The Review considered that herbal practitioners should follow the lead set by traditional Chinese medicine practitioners in Victoria and develop national accreditation standards which could provide the basis for allowing access to scheduled herbs for suitably qualified practitioners.

That said, the Review considered it important that the NDPSC (or its replacement) have access to appropriate expertise when making decisions about the level of control that should apply to these substances. This matter is discussed further in Section 4.

#### 5.8.4 Dose administration aids

There are a number of dose administration aids (DAA) in use across Australia. These can be seen to fall into three broad categories:

- those filled by the pharmacist when the prescription is supplied. Generally, these aids will be one of several sophisticated blister packaging systems;
- those filled by other health professionals such as community nurses. These are often compartmentalised re-useable plastic containers and will be filled by the health professional from the container dispensed by the pharmacist; and
- those filled by family or friends from the container dispensed by the pharmacist. Again, these are generally compartmentalised re-useable containers.

Drugs, poisons and controlled substances legislation does not regulate the packaging of medicines once they have been dispensed. Pharmacists need to comply with the relevant legislation in relation to labelling and supplying medicines and with the appropriate professional standards.

The Review noted that the Pharmaceutical Society of Australia has developed standards for pharmacists filling blister packs although the Review heard that nurses, who are often responsible for using these aids, do not find these standards acceptable. The nurses are concerned that, where each blister contains multiple medicines, they may be unable to check that they are administering the correct medicine. In this context, the Review noted that development of single product blister packs might overcome this problem but recognised that this would add considerably to **costs** for GOVERNMENT, PHARMACISTS and CONSUMERS.

The Review considered that it may be advisable for pharmacists to revisit their DAA standard in consultation with those who will be administering medicines packaged in this way, including nurses and carers as well as patients. Failure then to comply with the standard should lead to disciplinary action by Pharmacy Boards for a breach of professional standards.

The Review was not made aware of any other standards or codes of practice relating to filling the aids.

Other health professional groups, such as community nurses, that fill DAAs should develop standards for doing so. Compliance with those standards would be managed through professional registration boards.

The Review considered that manufacturers of DAAs, particularly those likely to be filled by family and friends, should provide clear guidance to those who are filling them to reduce the risk of adverse events resulting from their use. Manufacturers should also consider ways in which the design of these products can reduce the risk.

In summary, the Review considered that professional practice standards and information provision arrangements are the best approach to address concerns about dose administration aids, without recourse to further regulation being necessary under drugs, poisons and controlled substances legislation.

### 5.8.5 Veterinary medicine

The issues of veterinarians both prescribing and supplying medicines, and of the supply of certain veterinary medicines only being available from a veterinarian, were raised with the Review.

These restrictions on supply are not mandated by drugs, poisons and controlled substances legislation, or anywhere else that the Review could identify. Therefore, where such restrictions do occur, the issue should be referred to the Australian Consumer and Competition Commission, which is the agency responsible for restrictive trade practices.

For the purpose of this Review, it is concluded that the matter is not one for legislation under review and should be addressed instead through the generic trade practices law.

### 5.8.6 Vending machines

The issue of vending machines and hawking were raised with the Review.

All jurisdictions prohibit these modes of supply for scheduled medicines, although those restrictions may be in legislation other than drugs, poisons and controlled substances legislation (e.g. health acts or therapeutic goods legislation). However, in several jurisdictions there is discretion for the Minister to grant an exemption.

The Review considered that these restrictions for scheduled medicines provided a **net benefit** to the COMMUNITY AS A WHOLE, given the benefits of the restrictions on access discussed in Section 4 of this Report.

However, for unscheduled medicines, the Review could see that, in certain circumstances, the **costs** for CONSUMERS (limited convenience of access) and INDUSTRY (limited capacity to freely market their products) of restricting competition may well outweigh the **benefits** to the CONSUMER and to INDUSTRY. In particular, there may be benefits to the consumer, as well as industry, if vending machines that dispense packs containing no more than two doses of unscheduled medicines were to be permitted.<sup>105</sup>

Restrictions may need to be placed on the products that could be distributed in this way (e.g. simple pain relievers), and the nature of the vending machine, to ensure children were not able to access these products.

### 5.8.7 Rural and remote supply

In rural and remote communities where there may be no, or infrequent access to health professionals, alternative supply mechanisms need to be adopted to provide access to medicines. One jurisdiction raised the role and responsibility of health workers in remote communities where medicines may be administered according to agreed protocols.

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<sup>105</sup> For example a single dose of a mild pain reliever available from a vending machine in a hotel foyer.

The legislation in all jurisdictions recognises the special needs of these communities and includes a number of measures to overcome the problems these communities have in general in accessing health services.

The Review has identified a number of areas where the controls in drugs, poisons and controlled substances legislation should take account of the needs of these communities. These include:

- poisons licences which enable remote communities to access some *Schedule 2* medicines; and
- mail order and Internet supply which can provide cheaper and more convenient access to a full range of medicines.

The Report has also discussed the need for the pharmacy profession to develop standards for providing advice and counselling in situations where face-to-face counselling is not possible – including where medicines are supplied to consumers in remote communities.

Developments in technology are also leading to innovative mechanisms for supplying medicines to those in remote communities (e.g. remote dispensing machines) and for providing access to information about medicines. Any necessary controls should facilitate development and use of such alternative supply mechanisms while achieving the objectives of the legislation.

## SECTION 6 EFFICIENCY OF THE LEGISLATIVE FRAMEWORK

**Terms of Reference addressed:** General Review Issues 1, 2, 3, 4, 5, 6, 7, 8, 9 and 10; Specific Review Issues 2, 3 and 4.

The Review's Terms of Reference also require it to examine ways of increasing overall efficiency in the regulation of drugs, poisons and controlled substances including by:

- reducing compliance costs of drugs, poisons and controlled substances legislation; and
- ensuring the interfaces with related legislation promote efficiency in the administration of legislation regulating this area.

### 6.1 Background

#### 6.1.1 Current legislative framework

State and Territory Governments have long exercised controls aimed at protecting public health and safety from accidental, poorly informed or deliberate misuse of drugs and poisons.

The initiation of drugs, poisons and controlled substances legislation dates back to a time when there were essentially no controls to warn consumers of the hazards of any of these classes of substances. As the use of such substances grew, and as concern over their misuse developed, official controls were increasingly introduced.<sup>106</sup>

Under the Australian Constitution, many of these controls are the responsibility of the States and Territories. Until the mid-1950s, there was little coordination of these controls and consequently there was considerable variation in the level of control across jurisdictions. In 1954 the National Health and Medical Research Council recommended that, in the interests of efficiency and in order to promote national uniformity, there should be national standards for regulating drugs, poisons and foods and that each of these areas should be regulated separately.

In the event, jurisdictions made provision only for the separate regulation of foods with drugs and poisons continuing to be regulated together under State and Territory drugs and poisons legislation. Also, as has been discussed, uniformity was not, and has still not to this day been achieved.

The National Health and Medical Research Council established the forerunner of the NDPSC in 1954 to provide technical advice to facilitate a more uniform approach to

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<sup>106</sup> It could be said that the foundation of the current legislation was laid with the *Arsenic Act 1851*, which progressed through a range of more comprehensive legislation to the current framework in which drugs, poisons and controlled substances plays an important role. See Options Paper Sections 1.5 and 1.6 for more detailed background discussion.

regulating the supply of drugs and poisons by developing a standard for uniform scheduling of drugs and poisons. In 1994 responsibility for the NDPSC was transferred from the National Health and Medical Research Council to the Australian Health Ministers' Advisory Committee. The Committee developed the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP). This has led to a high level of uniformity within the Schedules, but not necessarily in the Regulations that apply to them.

The Industry Commission report into the Pharmaceutical Industry (May 1996) commented on a lack of uniformity, which remains the same four years later. Industry continues to press the view that the process creates non-uniformity.

The NDPSC and the scheduling processes have been the subject of a number of reviews over the last decade (Bissett, 1992; KPMG, 1994). Following the 1996 Industry Commission report, a further review of the drugs and poisons scheduling arrangements was carried out later that year. It recommended, among other things, that the NDPSC and the SUSDP be given legal status under Commonwealth law.

In August 1997 all Health Ministers agreed to that proposal. Amendments to the *Therapeutic Goods Act 1989* were proclaimed on 1 April 1999 to give effect to this agreement.

The last 10 years in particular have seen the introduction of a number of other, mainly legislative, controls that address some of the specific risks associated with use of medicines, poisons and controlled substances. These serve to put in place a comprehensive national framework of controls to protect public health and safety.

Drugs, poisons and controlled substances legislation also provides a vehicle for implementing many of the requirements to meet Australia's obligations under the three United Nations drug treaties.

The broad framework of the current drugs, poisons and controlled substances legislation covers two levels of government – Commonwealth and State and Territory. Local government could be involved in areas such as storage and handling, but in practice, there is very little relevant regulation at this level.

Relevant Commonwealth legislative instruments include:

- *Therapeutic Goods Act 1989*;
- *Agricultural and Veterinary Chemicals Code Act 1994*;
- Customs (Prohibited Import) Regulations and Customs (Prohibited Export) Regulations;
- *Narcotic Drugs Act 1975*;
- *Australia New Zealand Food Authority Act 1991*;
- *Trans Tasman Mutual Recognition Act 1997*; and
- *Trade Practices Act 1974*.

The relevant State and Territory legislation relates to:

- drugs, poisons and controlled substances;
- the practice of health professionals;
- agricultural and veterinary chemicals;
- consumer protection; and
- occupational health and safety.

At the Commonwealth level, legislation was introduced in the last decade or so to manage the safety of medicines and agricultural and veterinary products supplied on the Australian market.<sup>107</sup> The Customs regulations and the *Narcotic Drugs Act 1975* are largely concerned with preventing diversion to the illicit market of substances which are likely to be abused. They give effect to Australia's obligations under the three United Nations drug treaties.<sup>108</sup> These, and the other legislation, are discussed in more detail below.

At the State and Territory level, controls associated with categorising or scheduling substances are applied under the power of relevant Acts. These Acts differ from State to State, and Territory, and the distribution of powers to cover all classes of poisons are variously made between different Acts depending on the State or Territory (e.g. Controlled Substances or Therapeutic Goods).

There are also several other legislative and quasi-legislative measures that influence the way these substances are supplied and used, and how the potential harms are managed. These include consumer protection legislation, dangerous goods legislation, stock medicine regulations, the Therapeutic Goods Advertising Code, the Quality Use of Medicines Policy and various industry codes of practice. These have been considered where appropriate in this review – not in terms of their own legislation, but as substitutes or complements in judging the effectiveness of the legislation directly referred for review here.

In examining related legislation, the Review has also considered other legislation and policies that influence the legislative framework, or may do so in the near future. For example, the move towards global harmonisation in several areas and the reduction of trade barriers between Australia and New Zealand are relevant in this regard.

As has been discussed elsewhere in this report, the key issue raised by almost all stakeholders was the lack of uniformity of the legislation.

Stakeholders, particularly industry, have argued that lack of uniformity increases the costs of compliance with the regulations. Health professionals commented that lack of uniformity created problems for those moving between jurisdictions in identifying the

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<sup>107</sup> *Therapeutic Goods Act 1989* and *Agricultural and Veterinary Chemicals Code Act 1994*.

<sup>108</sup> The Single Convention on Narcotic Drugs, 1961 and 1972 Protocol; the Psychotropic Substances Convention, 1971; and the Convention Against Illicit Trafficking in Narcotic Drugs and Psychotropic Substances, 1988.



requirements that apply in different jurisdictions. This was a particular problem for those practising in areas close to State borders.

Consumers also identified the lack of uniformity as confusing, particularly for those with chronic conditions when travelling interstate. They also commented on the variation in costs in different jurisdictions believed to be caused by different controls. For example, it was believed that there were additional costs passed on to consumers associated with recording the supply of *Schedule 3* products.

No submissions saw any benefit from lack of uniformity in legislation across jurisdictions, although some did see a need for special provision to be made for particular circumstances, e.g. rural and remote locations. The Review noted that most of these issues will be common to all jurisdictions, although in some instances, they may be of more significance to one or more jurisdictions.

A number of stakeholders supported improving the scheduling process by more closely integrating the process of making scheduling decisions with the evaluation processes for medicines and agvet chemical products. This issue was discussed in Section 4.

Examples were provided to the Review of the costs arising from lack of uniformity in the categories identified above.

## 6.2 Efficiency of the legislative framework

The Review has examined a number of controls included in drugs, poisons and controlled substances legislation against the Principles of National Competition Policy and considered when, and at what level, controls were justified on the basis of a **net benefit** to the COMMUNITY AS A WHOLE. As required by the Review's Terms of Reference, the further task was to consider practical mechanisms for improving the efficiency of the controls thereby minimising the costs to industry of complying with the necessary controls, to governments in administering the controls and to consumers in higher prices flowing from these costs.

Before considering how efficiency might be improved, the Review considered that it was essential to clarify the role of drugs, poisons and controlled substances legislation in relation to the controls imposed by related legislation, such as that listed above. Effective and appropriate settings in these regulatory areas are equally essential if drugs and poisons regulation itself is to be set at the right level of intervention. For example, effective professional practice can be substituted for more restrictive regulation under poisons and drugs regulations.

Occupational health and safety legislation in the States and Territories also impacts on drugs, poisons and controlled substances legislation. The Review noted, that a lack of definitional clarity leads to overlap and uncertainty as to what legislative controls should be applied in relation to such matters as labelling requirements. Quite apart from the need to define the boundaries between drugs and poisons legislation and occupational health and safety legislation, the Review also saw scope to improve the effectiveness of some controls: for example, greater consistency between the labelling required under both legislative systems.

Other legislation, such as that regulating the transport of dangerous goods and the activities of stock and station agents, are also related to the legislation under review and operate to regulate the behaviour of those involved in this activity. These pieces of legislation also overlap in some areas with the legislation under Review (e.g. the stock and station agent acts in some jurisdiction have restrictions on supplying steroids and on advertising veterinary medicines).

Other legislative controls, such as food acts, with their associated standards that cover, for example, the amount of a particular substance (e.g. selenium) that can be included in a food product, also play a role in the framework of public health protection in this area.

A number of administrative inefficiencies were also brought to the attention of the Review. In particular, a company wishing to market a product in all, or a number of jurisdictions, needs to approach authorities in all jurisdictions if it wishes to obtain an exemption from a particular restriction (e.g. the height of the print on the label). For other restrictions, such as recording and reporting, the process of monitoring interstate trade is not only inefficient, but in some cases may be ineffective in enabling the objectives of the legislation to be achieved (e.g. monitoring the interstate movement of steroids). These inefficiencies are discussed below.

After examining this legislation, the Review concluded that there is considerable scope to reduce costs for industry, professionals, government and consumers while still achieving the objectives of drugs, poisons and controlled substances legislation through:

- uniformity of the legislative requirements across jurisdictions;
- legislative alignment between drugs, poisons and controlled substances legislation and related legislation; and
- improved administrative efficiency operating the controls.

### **6.3 Uniformity**

As indicated previously, there are considerable variations in the ways in which different jurisdictions regulate drugs, poisons and controlled substances.

Even identifying which legislative instrument(s) applies can be difficult. For example, some jurisdictions include all, or most, controls related to controlled substances in special legislation (variously titled), while others include all matters related to the medical use of controlled substances in their drugs and poisons legislation and all other matters (e.g. treatment, criminal activity) in their controlled substances legislation.

In some jurisdictions the detail of the controls is in subordinate legislation such as Ministerial Orders or gazetted administrative decision. The differences in definitions within and across jurisdictions exacerbate the lack of uniformity and inefficiencies of the current controls. For example, the definition of ‘advertisement’ varies considerably, with one jurisdiction defining it as ‘any method of conveying information ...’, while another jurisdiction (and the Commonwealth) limit the

definition to ‘... any statement ... that is intended, directly or indirectly, to promote the use or supply ...’.

The Review identified variations in the level of control between the States and Territories in virtually every area in which they regulated drugs, poisons and controlled substances. Variations were particularly evident in the areas of:

- supplying clinical samples;
- licensing requirements;
- reporting requirements for controlled substances; and
- storing or displaying *Schedule 2* medicines in pharmacies.

The costs caused by lack of uniformity were identified as falling into two broad categories:

- Those associated with identifying and staying up to date with the requirements in each jurisdiction. The cost of doing this can be considerable. The Review was advised that, because of the complexity, companies and industry associations have found it necessary to engage legal experts to identify the requirements (e.g. in relation to sampling, storage); and
- Those associated with compliance with different levels of control and different controls across the jurisdictions. Companies need to have in place different procedures and different training programs for each jurisdiction in relation to the requirements associated, for example, with sampling, reporting and labelling.

Variations in requirements, duplication of requirements and overlap of controls make production, supply, training and administration more complex, raising costs for industry, government and consumers. In the case of industry, the costs make market entry more difficult for firms outside a particular jurisdiction. Also, if the Australian market faces high costs (even if evenly distributed) within Australia, it will be less competitive internationally.

The Review recognised that jurisdictional differences have arisen over time, largely because of the way in which separate drugs and poisons legislation has developed. The Review accepted that there may be some need for variation to deal with particular problems, such as those of rural and remote communities. However, it sees no justification, in a country with a relatively small population and an even smaller industry base, for the costs of maintaining individual State and Territory legislation. It is now time to consider how best the differences between jurisdictions can be minimised and the costs to industry, governments and consumers thereby reduced.

At the same time, it is important to recognise that the benefits of uniformity come only if the common standard is well chosen and if commonality itself does not inhibit regulatory innovation.

### 6.3.1 Options for achieving uniformity

The Review considered the following means of achieving uniformity:

- mutual recognition of products across the nation;
- the States and Territories vest powers in the Commonwealth totally;
- bring the controls under Commonwealth legislation where it is within the Commonwealth's Constitutional power to do so; or
- develop model legislation which jurisdictions either:
  - adopt by reference; or
  - adopt through mirror legislation.

#### Mutual recognition

Mutual recognition could be used in relation to some controls, such as labelling (to the extent that these relate to products traded interstate), packaging and advertising. The Review sees only limited application of mutual recognition in the area of drugs and poisons legislation because, as discussed in Section 5, many of the labelling, packaging and advertising requirements already come under Commonwealth legislation which ensures a uniform national approach. The Review did note however, that mutual recognition could be applied in relation to granting exemptions from the legislative requirements, e.g. in relation to labelling and packaging controls where controls in these areas remain under State and Territory legislation (e.g. household chemicals).

#### Vesting powers in the Commonwealth

Ceding of power, by referral to the Commonwealth, has been undertaken in some policy areas, e.g. transport and industrial relations. Hence it is, in principle, possible here too. However, no submission supported this approach, including State submissions. Further, such an approach may well prove impractical from an administrative perspective, as the Commonwealth does not have the resources in each jurisdiction for administering and enforcing the controls across the country. Indeed, in many cases it is more practical for the States and Territories to undertake day-to-day operational activities, such as warehouse inspections.

#### Uniformity through Commonwealth legislation

The Review noted that for medicines and agvet products labelling, packaging and advertising controls are imposed by both State and Territory drugs, poisons and controlled substances legislation and by Commonwealth legislation (*Therapeutic Goods Act 1989* for human medicines; *Agricultural and Veterinary Chemical Code Act 1994* for agvet products).

The current situation, where the controls are included in multiple legislative instruments (Commonwealth and State and Territory Acts, Regulations, Administrative Orders and Guidelines) is inefficient and adds considerably to compliance costs for industry.

There is difficulty for industry in establishing precisely the labelling, packaging and advertising requirements that apply and this adds to compliance **costs** for INDUSTRY. These **costs** are passed on to CONSUMERS and to GOVERNMENT (for subsidised medicines) in the form of higher prices.

In submissions to the Review, labelling, packaging and advertising controls were generally accepted as required. There was support in many submissions for all controls over labelling, and advertising of medicines to be transferred to the *Therapeutic Goods Act 1989* and in the case of agricultural and veterinary chemicals and packaging controls, to the *Agricultural and Veterinary Chemicals Code Act 1994*.

Some people were, however, concerned that separating the regulations relating to labelling human medicines from those for agvet products (and household chemicals) could result in different warnings for the same substances in different products, resulting in confusion for the consumer. These concerns were most strongly held by State and Territory officials.

Stakeholder concerns were based on the assumption that the type and level of risk is the same for the different types of product. While the Review appreciated these concerns, it considered that there were a number of other factors such as the way in which the product would be used that needed to be considered. Consequently, if the guidelines and processes used to assess the different products take due account of the public health risks in relation to that product, the Review considered that the objectives of the legislation should continue to be achieved.

Further, the Review noted that many of these controls have already been transferred to the Commonwealth. For example, the requirements for child-resistant packaging for medicines are regulated under the *Therapeutic Goods Act 1989*, and warning labels and first-aid instructions for agvet products have been effectively transferred for regulation under the *Agricultural and Veterinary Chemical Code Act 1994*, except in those jurisdictions which do not adopt SUSDP Appendixes E and F.<sup>109</sup>

### **Commonwealth powers**

The Commonwealth's powers are limited by the Constitution. While there are some areas that could be brought under Commonwealth control, there are still a number of areas in which the Commonwealth would not have the power to impose controls (e.g. access to medicines by consumer). The relevant Commonwealth powers, which are set out in Section 51 of the Constitution, are the inter-state trade power (s.51(i)), the corporations power (s. 51(xx)), the pharmaceutical benefits power (s. 51 (xxiiiA)) and the external affairs power (s.51 (xxix)).

The controls the Review has identified as being appropriate and which it considered can be managed more efficiently under Commonwealth legislation are those relating to labelling, packaging and advertising medicine and agvet products. The level of the controls that should apply in relation to these three areas is discussed in Section 5.

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<sup>109</sup> The SUSDP states that Appendixes E and F do not apply to products evaluated under the *Agricultural and Veterinary Chemical Code Act 1994*. All jurisdictions except the Australian Capital Territory and the Northern Territory adopt Appendixes E and F.

The Review noted that, apart from household chemicals, the labelling and packaging controls in relation to products could be incorporated in the processes required under Commonwealth legislation. Indeed, as already noted, in those jurisdictions which adopt SUSDP Appendixes E and F, most of the labelling controls for agvet chemicals in *Schedules 5, 6 and 7* have already been moved to the evaluation process under the *Agricultural and Veterinary Chemicals Code Act 1994*. Similarly, packaging controls for medicines are already regulated under the *Therapeutic Goods Act 1989*.

In the case of advertising controls, the controls in State and Territory drugs and poisons legislation largely duplicate the controls in the *Therapeutic Goods Act 1989*. The Review also noted that State and Territory advertising controls are rarely used.

Transfer of advertising, labelling, packaging, and advertising controls for medicines and agvet products to the Commonwealth under the *Therapeutic Goods Act 1989* and the *Agricultural and Veterinary Chemicals Code Act 1994*, respectively, would improve the efficiency of administering the controls and reduce the complexity caused by multiple regulations. The Review concluded that to do so would reduce the **costs** for INDUSTRY without diminishing the current level of **benefit** to the COMMUNITY AS A WHOLE.

It should be noted that, while transfer of controls in the above four areas will cover most situations, the Commonwealth's power does not extend to sole traders trading intrastate.

In this context the Review noted that after more than 10 years, during which only one State developed fully effective therapeutic goods legislation, the Commonwealth decided to bring in national legislation, which it did in 1989. However, given the limitations on its powers imposed by the Constitution, it cannot readily cover the field as sole traders trading intrastate are generally outside the Commonwealth's power.

When the *Therapeutic Goods Act 1989* was enacted, all Health Ministers agreed that, to ensure a truly national system of control over therapeutic goods, all States and Territories would enact complementary legislation to cover those situations which were outside Commonwealth powers. To date only two States have legislated to do so. Victoria chose to reproduce the legislation in full in its own statutes. However, the Review noted that the Victorian legislation has not been kept up-to-date with Commonwealth legislation and is now not uniform in a number of areas. New South Wales adopted the legislation by reference, with power to vary the amendments made to Commonwealth legislation if it wishes – but no variations have been made.

Adoption by the States and Territories of the *Therapeutic Goods Act 1989* would address the issues associated with sole traders trading intrastate in labelling, packaging and advertising of medicines.

### **Uniformity through model legislation**

The Review noted that by transferring controls to Commonwealth legislation the problem of uniformity in the areas transferred would be largely overcome. However, for those controls outside the Commonwealth's powers, development of model legislation covering all the necessary controls and which was adopted uniformly by all jurisdictions was considered the most cost-effective option.

Under this arrangement States and Territories would retain the capacity to reject amendments to the model legislation where there were particular jurisdictional reasons to deviate from the model legislation.

While in theory it would be possible for jurisdictions to adopt the legislation of one jurisdiction, the uniformity achieved would be eroded unless this was also accompanied by a mechanism which enabled all jurisdictions to participate in maintaining that legislation.

The Review noted advice from a number of jurisdictions that while they may be prepared to put in place nationally consistent legislation, adoption of model legislation by reference was unlikely to be acceptable. The Review considered that, unless jurisdictions were prepared to adopt model legislation by reference, many of the current costs would remain. Even where the legislation is consistent or the intended outcome is the same, the detail of the legislation will differ, thus requiring affected parties to identify the exact nature of the control that applies in all the jurisdictions where they intend to operate. Further, differences in language can lead to differences in interpretation. In addition, unless amendments to the legislation in all jurisdictions are made at the same time, these differences will increase, as amendments are made in some jurisdictions, but not in others.

While there may be an initial **cost** to GOVERNMENTS in developing the model legislation, adoption by reference of the model legislation would benefit governments by reducing costs of developing and amending their legislation. Model legislation adopted by reference by all jurisdictions would be of considerable **benefit** to INDUSTRY by reducing the costs of compliance and this in turn should **benefit** CONSUMERS through lower prices. Consequently the Review considered that adoption of model legislation by reference would lead to a significant **net benefit** for the COMMUNITY AS A WHOLE.

### **6.3.2 A mechanism to maintain uniformity of the controls for drugs, poisons and controlled substances**

**Terms of Reference addressed:** General Issue 10.

The Review noted that while the NDPSC was established almost 50 years ago to work towards a national system of uniform schedules. No such mechanism exists in relation to the controls, which apply to those schedules. The Review has identified model legislation as the most cost-effective mechanism to achieve uniformity for those controls which cannot be brought under Commonwealth control.

If such model legislation is to provide an effective and efficient framework to improve efficiency through an improved national uniform system of controls, it will be essential to have an effective mechanism to develop, implement and maintain that legislation. The model legislation must be appropriate to the needs of all jurisdictions, as well as provide industry, professionals and consumers with a transparent system of controls that are the minimum necessary to achieve the objectives.

To do this, the Review considered that a specific body or organisation needs to be charged with responsibility for maintaining the model legislation, a mechanism for

consulting all interested parties on amending the model legislation needs to be agreed and a process by which the changes are implemented established.

### **Body responsible for maintaining uniformity**

The Review noted that the National Coordination Committee on Therapeutic Goods was established in the 1970s to achieve uniformity of therapeutic goods legislation across all jurisdictions: it is a sub-committee of Australian Health Ministers' Advisory Committee.

The NCCTG coordinates a range of issues related to therapeutic goods and to drugs, poisons and controlled substances and provides a forum for discussion to resolve cross-border problems. The amendments to the *Therapeutic Goods Act 1989* proclaimed in April 1999 provide for the NCCTG to have a policy-setting role in relation to operating the NDPSC. The scope of its responsibilities has also been expanded to cover poisons as well as therapeutic goods. This has significantly broadened the role of the NCCTG.

Therefore the Review concluded that the NCCTG, which is already charged by Australian Health Ministers' Advisory Committee with responsibility for coordinating policy issues related to therapeutic goods and poisons, would therefore seem ideally placed to develop and maintain such model legislation.

NCCTG should take responsibility for establishing the consultation processes, which will enable the views of all interested parties to be considered when developing and maintaining the model legislation and subsequent amendments. This will require the Terms of Reference of the NCCTG to be amended to ensure that it has the authority to undertake the necessary consultation and to make recommendations on amendments to the model legislation (Appendix B3 sets out revised draft Terms of Reference for the NCCTG). The Review noted that the NCCTG Secretariat may require additional resources to support this increased function. However, the overall costs of developing and maintaining the legislation would be reduced as such consultation would need to be undertaken only once, ie in the developing or amending the model legislation..

### **Consultation mechanism**

It is important that all interested parties have an opportunity to comment on any proposed changes to the model legislation. The Review considered that a formal process whereby amendments to the model legislation proposed by the NCCTG should be published and public comment invited. A reasonable timeframe should be allowed for comments to be made. This process would facilitate adoption of the amendments by all jurisdictions. The NCCTG should be responsible for developing the detailed processes.

### **6.3.3 Conclusion**

The Review concluded that there would be **benefits** for INDUSTRY, GOVERNMENT and CONSUMERS if a much more consistent national uniform approach were taken to regulating drugs, poisons and controlled substances in Australia.



The Review also recognised that there would be **costs** for GOVERNMENTS in adopting model legislation by reference, these costs would be considerably less than if each jurisdiction developed and enacted separate legislation. These costs would include the administrative costs of developing and maintaining model legislation including the consultation process. Less tangible, in a monetary sense, but nonetheless significant, would be the costs that some jurisdictions perceive in the loss of sovereignty if the model legislation were to be adopted by reference. However, the Review believed that there would be no real loss of sovereignty if the model legislation provided for rejection of specific amendments in a jurisdiction when special circumstances within that jurisdiction warranted such action and resulted in a net benefit to the community.

The Review recognised that the strategies for achieving this national uniform approach would need to reflect the respective powers of the Commonwealth and the States and Territories under the Constitution.

On this basis, the Review considered that, where the Commonwealth has the Constitutional power to do so, it should enact legislation to ensure a uniform national approach to specific regulatory controls. These are in the areas of product labels, packaging for medicines and agvet products and advertising medicines.

In all other areas relating to regulation of drugs, poisons and controlled substances, where the Constitutional powers lies with the States and Territories, the Review considered that the States and Territories should adopt the model legislation by reference into the appropriate legislative instruments. The Review identified the NCCTG as the appropriate body to manage the process of developing and maintaining the model legislation.

## **6.4 Efficiency through closer alignment with related legislation**

The Review was asked to consider the interface between drugs, poisons and controlled substances legislation and other legislation, with a view to improving the efficiency of administering legislation in this area.

The Review has identified a number of legislative instruments related to drugs, poisons and controlled substances legislation at both the State and Territory level and the Commonwealth level where there is scope to improve the efficiency and effectiveness of this legislation through closer alignment.

### **6.4.1 Closer alignment with Commonwealth legislation**

**Terms of Reference addressed:** General Issues 5 and 8; Specific Issue 4.

#### **Drugs, poisons and controlled substances legislation and the Therapeutic Goods Act**

The *Therapeutic Goods Act 1989* is a Commonwealth Act, providing a substantially uniform national system of controls over therapeutic goods, facilitating trade between the States and Territories and benefiting both consumers and industry.

The objective of the Commonwealth Act is to provide a national framework for regulating the quality, safety, efficacy and timely availability of therapeutic goods in Australia. The Act sets out the legal requirements for importing, manufacturing and supplying medicines in Australia, and for export. With a few specific exceptions, all therapeutic goods, including medicines and disinfectants, must be included in the ARTG before being imported, supplied or exported. The Act details the requirements for including therapeutic goods in the ARTG, as well as many other aspects affecting supply such as requirements for advertising, labelling and packaging these products.

The Act applies to all corporations who supply or manufacture medicines for supply in Australia and unincorporated parties who supply or manufacture medicines for supply in Australia outside their own State or Territory, unless that jurisdiction has complementary legislation. The Act also applies to all parties who supply medicines under the Pharmaceutical Benefits Scheme and all parties who import or export medicines.

In the administration of the Act, the Therapeutic Goods Administration undertakes evaluations of each good to determine eligibility for entry into the ARTG. If the requirements for labelling and packaging are considered during the evaluation and assessment process for entry on the ARTG for human medicines, it will avoid duplication with the processes of poisons scheduling and streamline the marketing approval process for medicines.

As discussed above, the Review considered there would be a **net benefit** to the COMMUNITY AS A WHOLE if all aspects of certain controls of medicine properties, such as labelling, packaging and advertising, were to be regulated under this Act. The level of the controls is discussed in Section 5 of this Report.

### **Drugs, poisons and controlled substances legislation and the Agricultural and Veterinary Chemical Code Act**

The *Agricultural and Veterinary Chemicals Code Act 1994* establishes the NRA. The NRA administers the National Registration Scheme for Agricultural and Veterinary Chemicals as a statutory authority of the Commonwealth with agreement by the States and Territories to allow the NRA to administer certain powers on their behalf.

The NRA is responsible for regulating the manufacture, distribution and supply of agvet chemicals up to and including the point of retail sale.

All agvet chemicals have to be registered by the NRA before they can be manufactured, supplied or sold in Australia. The registration process involves an evaluation of each chemical's safety to humans and the environment as well as the safety for animals, its safety to non-target plants or animals, its efficacy and impact on trade.

The NRA works cooperatively with other Government agencies in meeting its legislative responsibilities. For example, the NRA obtains advice from the Commonwealth Department of Health and Aged Care on the human toxicology and public health matters, although it has no legal obligation to do so.

The products must also comply with State and Territory legislation, including drugs and poisons legislation. Consequently, before the Department of Health and Aged Care finalises its advice to the NRA, it refers the matter to the NDPSC for a scheduling decision, which is subsequently picked up in State and Territory legislation. Scheduled agvet products must carry labels compliant with drugs and poisons legislation.

The output of the chemical registration process is a label, which provides user directions designed to minimise impacts on health and the environment for the proposed use of the chemical and which are based on good agricultural practice.

The Review considered that matters relating to labelling and packaging could be more cost-effectively dealt with during the evaluation process and therefore responsibility for the controls on all labelling of agvet products should be transferred to the Commonwealth agvet Act.

The SUSDP Appendixes providing first aid and safety directions (E and F) no longer apply to agvet chemicals. The warnings and first aid instructions for agvet chemicals are now published in a separate handbook<sup>110</sup>. The only label requirements that continue to be controlled under drugs and poisons legislation are those in Part 2 and 3 of the SUSDP. These include the Signal Heading (designating the risk attached to the schedule in which the substance is included) and some general warning statements (e.g. KEEP OUT OF THE REACH OF CHILDREN).

The levels of controls are discussed in Section 5.

### **Australian Food Standards Code**

The *Australia New Zealand Food Authority Act 1999*, particularly the *Australian Food Standards Code*<sup>111</sup>, and drugs, poisons and controlled substances legislation are only related in so far as some substances regulated as poisons may also appear in foods. Drugs, poisons and controlled Substances legislation does not apply to foods except food additives before incorporation into a food or when used as a means of administering a poison for therapeutic use.<sup>112</sup>

The public may be exposed to poisons through foods, either because of naturally occurring minerals, or agricultural practices such as use of pesticides, or from toxins from biological contamination. The Australian and New Zealand Food Standards make provision to limit consumers' exposure to these substances.

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<sup>110</sup> The First Aid and Safety Direction Handbook is developed by the Therapeutic Goods Administration which provides advice on public health matters to the National Registration Authority for Agricultural and Veterinary Chemicals.

<sup>111</sup> The Review noted that there has recently been a COAG review of food regulation in Australia under the program of National Competition Reviews. The recommendations of that Review do not preclude the opportunities for developing greater consistency in the controls over food standards and scheduling controls.

<sup>112</sup> See SUSDP Appendix A. The precise detail of this exemption varies across jurisdictions.

Also, certain substances may be used both as a food additive in food products and as an ingredient of a medicine, e.g. selenium. In the case of selenium, the amount that can be added to a food product may be considerably more than the amount permitted in an unscheduled medicine. It may not be immediately obvious why the quantitative limits differ between foods and medicines particularly where the intake of a food may be unrestricted but a medicine will have a dosage regimen. There may be sound scientific reasons for this variation, but it may also simply reflect a lack of consistency in the ways in which foods and medicines are regulated.

The Review noted that the overall objective of both regulatory systems is to prevent harm from exposure to potentially poisonous substances and considered it desirable that, wherever possible, there be consistency in how substances are assessed in terms of risk to public health. It is also desirable to avoid unnecessary duplication of administration between the two regulatory systems.

Food standards limiting substance amounts (e.g. contaminants and food additives) are based on scientific information about the total exposure through the diet, the intake from particular food sources and the availability of the substances to the body when eaten in foods. Food standards are developed through a process open to stakeholders and mostly with two rounds of consultation. They are finalised at Ministerial Council level by a majority vote. There is thus no need to apply poisons regulation to foods.

The technical nature of the risk assessment processes is beyond this Review's Terms of Reference. However, the Review considered that there was scope for improved consistency within the technical decision-making processes for both food and medicines and poisons. The Review noted that both mechanisms include public consultation but it appears that there is no formal mechanism to exchange information, particularly in relation to technical data. The Review saw scope for more formal liaison in this area to resolve any apparent anomalies.

### **Trans-Tasman Mutual Recognition Act**

The *Trans-Tasman Mutual Recognition Act 1997* provides a temporary exemption for therapeutic goods and some chemicals. Agvet chemicals have a permanent exemption.

The NDPSC has established a working party to work towards greater harmonisation of scheduling between Australia and New Zealand. In New Zealand, medicines and poisons are regulated separately and by different agencies. Controlled substances are also regulated by a separate agency although both agencies are located within the Ministry of Health.

Significant change in the Australian regulatory framework may have implications for the Trans-Tasman Mutual Recognition Arrangements. Preliminary discussions with New Zealand officials indicate that separate drugs and poisons legislation in Australia may facilitate harmonisation.

The Review noted that until regulations to give effect to the recently enacted New Zealand Hazardous Substances and New Organisms Act have been introduced, it is difficult to assess if the level of public health protection afforded by the new legislation will provide an acceptable level of public health protection in Australia,

particularly in relation to labelling and packaging of the substances covered by the legislation.

The Review noted that the New Zealand Hazardous Substances and New Organisms Act might further change the processes and emphasis of drugs and poisons regulation. These potential changes in the New Zealand framework make it difficult to establish the exact implications of any changes which might arise as a result of the recommendations of this Review.

New Zealand is also considering proposals to change the Controlled Substances Act. This could have implications for harmonisation of the scheduling between Australia and New Zealand in relation to products containing these substances.

### Other legislation

The Review has also identified overlap in the area of licences and reporting, with provisions in the *Narcotic Drugs Act 1975*, the Customs (Prohibited Import) Regulations and the Customs (Prohibited Export) Regulations. This is discussed in Section 5.

## 6.4.2 Closer alignment with State and Territory legislation

### Legislation regulating professional practice

The Review has previously highlighted the importance of the relationship between drugs, poisons and controlled substances legislation and the legislation regulating professional practice.

As discussed in Section 4, the **benefits** to the COMMUNITY of the controls imposed under drugs, poisons and controlled substances legislation depend, in large measure, on the effectiveness of the professional practice standards and the level of compliance with those standards. The Review has discussed the effects of the failure of health professionals to meet the expected standards, such as increased diversion and medicinal misadventure, and noted that this in turn has led, in some instances, to products being re-scheduled to a higher schedule. Such re-scheduling adds to the **costs** of INDUSTRY and CONSUMERS (also potentially for government, where a product is re-scheduled from an OTC schedule to *Schedule 4*).

While it is not the role of this Review to examine the legislation regulating professional practice, or recommend how compliance with professional standards should be managed, professional registration boards are urged to consider options for improving the effectiveness of this legislation in achieving compliance.

The Review noted that if professional practice regulation worked effectively, some of the drugs, poisons and controlled substances controls could be relaxed. However, where regulation of professional practice is ineffective in achieving its objectives, this can lead to an increase in the level of control. For example, the NDPSC recently rescheduled large packs of pseudoephedrine to a higher schedule (*Schedule 2* to *Schedule 4*) because some pharmacists, despite frequent reminders from Pharmacy Boards, failed to adequately exercise their professional obligations to supervise supply of these products.

Improved compliance with professional standards would reduce the use of re-scheduling as a mechanism to deal with the failure of some health professionals to comply with the relevant professional standards. The Review supported the recommendations made by the National Competition Policy Review of Pharmacy that the pharmacy Acts and delegate legislation clearly set out the complaints and disciplinary processes and the grounds for incompetence and professional misconduct.<sup>113</sup> The Review would see failure to comply with drugs, poisons and controlled substances legislation as being grounds for such disciplinary action.

The Review also noted that the National Competition Policy Review of Pharmacy recommended that registration of pharmacy premises be removed from State and Territory legislation and that community pharmacies adopt legislation and agreements which require appropriate quality assurance and professional practice standards for delivering pharmacy and health services.<sup>114</sup> The Review also noted, and supported, the recommendation that States and Territories move to replace the qualifications-based criteria for registration and re-registration of pharmacists with registration requirements that are solely competency-based.<sup>115</sup>

The Review also noted that several medical boards have recently moved to improve the effectiveness of their compliance measures by introducing procedures to deal with minor breaches as well as more serious lapses.

## Household Chemicals

As there is no national registration system for household chemicals, labelling and packaging requirements for household chemicals will need to remain in the SUSDP and State and Territory legislation. To the maximum extent possible, these requirements should be consistent with requirements under occupational health and safety legislation. This would **benefit** INDUSTRY in some cases by simplifying the labelling requirements. There may also be some **benefits** for CONSUMERS through more comprehensive information to help them use the products safely.<sup>116</sup>

### Labelling of household chemicals

The Review noted the overlap and confusion at the interface with occupational health and safety legislation requirements for signal headings and warnings. The Review recognised that the exact nature of the signal heading and other required label text under drugs and poisons legislation is a technical issue. However, the Review nonetheless considered that there may well be scope to improve the effectiveness of the labelling requirements by making the signal heading more useful in conveying the level of risk and the nature of the risk (e.g. corrosive, damaging to the eyes). In this context, the Review noted research that found that the *Schedule 5* signal heading CAUTION failed to convey the intended message to consumers (Ley, 1995)

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<sup>113</sup> Recommendation 19, National Competition Policy Review of Pharmacy, 2000

<sup>114</sup> Recommendations 7 and 8, National Competition Policy Review of Pharmacy, 2000.

<sup>115</sup> Recommendations 16 (g), 17 and 18, National Competition Policy Review of Pharmacy, 2000.

<sup>116</sup> In some instances occupational health and safety legislation requires specific warnings about the exact nature of the hazards of the products, e.g. IRRITATES THE EYES, MAY BURN THE SKIN.

The Review also noted the concerns expressed by some industry representatives that the labelling requirements under drugs and poisons legislation may be different to those required under occupational health and safety legislation. These differences may result in additional costs to industry, both in terms of compliance and in terms of the lack of flexibility through not being able to freely distribute their products in different markets unless they are re-labelled.

While the Review considered that greater integration between hazardous chemicals requirements under industrial chemical health and safety legislation and drugs and poisons legislation was clearly a desirable aim, it recognised that this would not be a simple process. Chemicals such as ammonia and chlorine have requirements under industrial hazardous substances legislation which could be easily picked up, but other important consumer chemicals that are poisonous, for example eucalyptus oil, are not mentioned in the NOHSC designated hazardous substances list because of the different purpose of that list. This difference means the integration must be approached cautiously rather than simply assuming what is suitable for one is suitable for the other. The Review recognised that in many cases there would need to be differences in the label information to address the differing uses of the products and the understanding of users.

### **Occupational health and safety legislation**

Occupational health and safety legislation operates at the State and Territory level to protect the health and safety of workers in the workplace. The legislation relating to industrial chemicals is based on, but is not identical to, model legislation developed by the National Occupational Health and Safety Commission.

The model legislation for industrial chemicals includes model regulations for labelling chemicals in the workplace, and provision of other information, such as material safety data sheets.

The Review has identified a level of overlap and confusion at the interface of medicines and poisons legislation and occupational health and safety legislation particularly in relation to labelling. The difficulty for industry in establishing the requirements that apply and in complying with those requirements adds to the costs of marketing the product.

In order to simplify labelling requirements for industry, those jurisdictions that do not currently do so, should adopt the SUSDP Appendixes E and F by reference. This will facilitate compliance for suppliers marketing products that may fall under both sets of legislation and cross-jurisdictional boundaries.

### **National Occupational Health and Safety Commission review of model labelling regulations**

The Review noted that the NOHSC is currently reviewing model labelling regulations for industrial chemicals and that the problems of definition at the interface with drugs and poisons legislation are being examined with a view to clarifying that interface. These efforts should also facilitate progress towards harmonisation of labelling with New Zealand, which may improve the trading of products across the Tasman as part of the Trans-Tasman Mutual Recognition Arrangements. Moreover, the Trans-

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Tasman arrangements themselves provide an important impetus for seeking to adopt a uniform labelling approach to products in this area.

In conducting this review the Commission has been consulting with the TGA (and others) to revise the Model Labelling Code for occupational health and safety legislation.

### **Model legislation**

Earlier in this Section, it was proposed that model legislation be developed to regulate household chemical labelling, among other things. Development of model legislation for medicines and poisons, which provides clear definitions and clarifies the interface with the model occupational health and safety legislation, would considerably reduce the problems outlined above, thereby reducing costs for industry. There could also be benefits for consumers and workers in ensuring that label information enabled the product to be used safely in both the domestic setting and the workplace.

### **Other options for closer integration with occupational health and safety legislation**

The Review considered that the NCCTG, as a matter of policy, should examine other ways of bringing labelling of poisons and that of industrial chemical closer together and to consider how the complexity of the current presentation of requirements could be simplified. One submission suggested that the CAS number<sup>117</sup> should be used to identify the substances being scheduled to facilitate identification of the substances and make links with occupational health and safety controls easier. The Review saw this a technical issue and merely raises it as matter for consideration by the NCCTG.

## **6.5 Other matters to be considered**

### **6.5.1 International treaties**

Australia is a party to the United Nations Treaty on Drugs – The Single Convention on Narcotic Drugs 1961, The Convention on Psychotropic Substances 1972 and The Convention on Illicit Trafficking of Narcotic Drugs and Psychotropic Substances 1988.

These treaties impose certain obligations on Australia including the need to restrict access, record and monitor use and control manufacture of narcotic drugs and other controlled substances.

These controls are exercised through Commonwealth laws (e.g. the Narcotic Drugs Act and the Customs (Prohibited Import) Regulations) and through State and Territory drugs, poisons and controlled substances legislation. Any amendments to medicines and poisons legislation need to ensure Australia continues to meet its treaty obligations.

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<sup>117</sup> All chemicals are assigned a Chemical Abstracts Service (CAS) number, which is used internationally, across all sectors, to identify a given substance.



## 6.5.2 International cooperation

The Review also noted that Australia has been participating in international initiatives to harmonise the classification and labelling of chemicals. This program is known as the Globally Harmonised System for the Classification and Labelling of Chemicals.

The Review was advised that reform of the model labelling regulations, which NOHSC is currently undertaking, is taking account of the Globally Harmonised System for the Classification and Labelling of Chemicals.

If labels can be harmonised with international standards without compromising the level of protection afforded to Australian consumers, it should facilitate international trade in these products.

The Review also understood that the Globally Harmonised System for the Classification and Labelling of Chemicals is seen as an important element in the reform of hazardous chemical legislation in New Zealand.

## 6.6 Administrative efficiency

### 6.6.1 Labelling and packaging exemptions

The Review also noted the need to reduce the administrative cost of obtaining exemptions from labelling and packaging requirements. Currently a sponsor seeking an exemption needs to apply in all States and Territories. For industry, nationally uniform requirements for product labels would reduce costs by reducing the complexity of the regulations and providing a one-stop-shop for administration and enforcement. The Review considered that the current arrangements impose an unnecessary **cost** on INDUSTRY and that provision should be made for all jurisdictions to recognise an exemption given in one jurisdiction. For example, the costs for industry of complying with labelling requirements for each State and Territory are illustrated by Case study 7.

All human medicines and agvet chemicals (with few exceptions)<sup>118</sup> are required to be included in the appropriate register (ARTG, National Chemical Registration Information System (NCRIS), respectively) before being supplied in Australia. Prior to being registered, products are evaluated or assessed for compliance with certain standards including labelling and packaging. The products must continue to comply with those standards for as long as they are marketed in Australia.<sup>119</sup> The Review's proposal to transfer labelling and packaging responsibility to the Commonwealth for human medicines and agvet products will overcome this problem for those products.

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<sup>118</sup> e.g. clinical trials, special access where the condition may be life threatening etc.

<sup>119</sup> Currently the standards imposed under the *Therapeutic Goods Act 1989* and the *Agricultural and Veterinary Chemicals Code Act 1994* rely, in part, on labelling and packaging requirements set out in the SUSDP. This means a manufacturer or sponsor of products must establish what the standards are by reference to both the SUSDP and the other specific standards imposed by these legislative instruments, not only upon registration, but throughout the life of the product.

However, the problem remains for household chemical products. The Review considered that the NCCTG should establish an appropriate mechanism that would enable all jurisdictions to mutually recognise exemptions granted by one jurisdiction. As noted previously, the Review has suggested that mutual recognition should be applied in such circumstances. Alternatively the NCCTG could establish different mechanism which would enable sponsors to apply to a single point for national exemptions.

#### **CASE STUDY 7 Labelling requirements**

As a result of the Trans-Tasman Harmonization, a particular product was in extremely short supply, due to production problems at the registered manufacturing site and the company was unable to meet its orders for the Australian market. The product is used in the treatment of a life threatening illness.

In order to maintain supply of the product in Australia, the company approached the TGA for a 'single batch' labelling exemption that would allow them to import the product from an unregistered manufacturer with labelling that did not comply with either the Commonwealth or State and Territory legislation. The TGA approved the importation of the product as a single batch and was satisfied that the proposed labelling, whilst not compliant with current Australian requirements, would not result in an unacceptable risk.

The company was prevented from supplying the product immediately in Australia until separate exemption from the requirement for a signal heading was obtained from all States and Territories. This was obtained from all States. Although the company did not directly incur any additional monetary outlays for application to TGA or the States, considerable time was spent by company personnel to negotiate the exemption in each State, including personnel time costs of interstate telephone calls and follow-up faxes. Similar costs were incurred by government departments in each jurisdiction.

**Source:** Australian Pharmaceutical Manufacturers Association Inc (APMA).

### **6.6.2 Interstate monitoring mechanisms**

The Review has also identified the need for a mechanism to enable the movement of controlled substances and other substances of concern (e.g. anabolic steroids) across State and Territory borders where such monitoring has been identified as necessary to prevent diversion. This may require legislative amendments to provide the power for such information to be transferred between jurisdictions.

The Review considered that the NCCTG also needs to develop administrative processes to ensure this occurs in a timely and cost effective manner.

### **6.6.3 Improving the efficiency of the scheduling process**

Measures to improve the efficiency of the scheduling process have been discussed in Section 4. These include linking the scheduling decision-making process more closely with the product evaluation process. The Review has also proposed replacing the NDPSC with two, more focused, committees – the Medicines Scheduling Committee and the Poisons Scheduling Committee (see Appendix B2 for these Committees' proposed functions).

## **Appendix B1: Summary of legislative amendments and other action resulting from recommendations**

### **A. STATE AND TERRITORY LEGISLATION**

This Appendix briefly outlines the actions and the nature of the legislative changes that would be required if the Review's recommendations are accepted.

#### **MODEL MEDICINES AND POISONS LEGISLATION**

The report recommends the adoption of model legislation by reference. The broad nature of the controls to be included in the model legislation are set out in the recommendations against each general area of control. The model legislation would also need to include other related matters such as those related to the scheduling process, definitions and enforcement mechanisms. Where relevant to illustrate the nature of the control, reference is made to the controls set out in the SUSDP.

#### **Objectives**

The legislation would set out the objectives of the legislation.

#### **Definitions**

The model legislation should include clear definitions to define the scope of the legislation. These could be based on the definitions in Part 1 and in Appendix A of the SUSDP and be consistent with definitions in the Standard for Uniform Scheduling of Medicines and Poisons (SUSMP).

#### **Outcomes**

The legislation should identify the required outcomes for the controls included in the legislation.

It should also define the relationship of medicines and poisons legislation to the legislation regulating professional practice.

#### **Scheduling decisions**

The legislation will recognise the Medicines Scheduling Committee (MSC) and the Poisons Scheduling Committee (PSC) established under the *Therapeutic Goods Act 1989*.

The decisions of the Medicines Scheduling Committee and the Poisons Scheduling Committee, as recorded in the SUSMP, and given legal status under the *Therapeutic Goods Act 1989*, will be adopted into the legislation by reference to underpin the levels of access and related controls.

## Access controls

The model legislation would specify the levels of access and in some instances possession (e.g. as in para 41 (3) SUSDP). These will be related to the schedules for medicines and to one of the poisons schedules. For medicines there will be three levels of access:

- those restricted to supply from a pharmacy (the OTC schedule), or licensed poisons seller where an SUSMP Appendix would be used to designate which of the OTC schedule substances should not be available from a licensed poisons seller (combining. SUSDP *Schedules 2 and 3*);
- those restricted to supply from a pharmacy on the prescription of a doctor, veterinarian, dentist or other authorised health professional (SUSDP *Schedule 4*); and
- those restricted to supply from a pharmacy on the prescription of a doctor, veterinarian or other authorised health professional and on which additional restrictions may be placed, such as the practitioner requiring special authorisation to prescribe these substances in some circumstances (e.g. large quantities, long periods of treatment), and other controls such as requirements to record or report supply or store the product in a particular way (SUSDP *Schedule 8*).

The legislation will deal with other matters relating to supply of medicines for therapeutic use. This would include supply of single dose packs of unscheduled substances from vending machines, where the machine meets certain specifications to reduce the risk of children accessing the products, and ensure the quality of the product is maintained.

For poisons there would be one schedule to which limitations on access would apply (SUSDP *Schedule 7* and SUSDP Part 3, para. 41).

In addition to the above schedules and restrictions on access there would also be a schedule which would designate those substances where supply, other than for limited scientific purposes, is prohibited (SUSDP *Schedule 9* and Appendix C).

The model legislation should expand the scope of SUSDP Appendix D to provide an flexibility in the extent of the controls to be applied to some controlled substances.

The model legislation should include restrictions on access as set out in the SUSDP Appendixes I and J and allow for exemption from the restrictions on access for low risk dilute preparations (SUSDP Appendix G).

## Licences

The legislation would include requirements for wholesale licences for those manufacturing or distributing all medicines. The requirements for the licences, which would be linked to the schedules, would include storage, handling, recording, and reporting. For some schedules there would also be requirements to meet certain standards of probity, security and expertise. Where they overlap, these requirements should be the same in this legislation and the requirements for customs import and export licences under the Customs (Prohibited Import) Regulations and the Customs

(Prohibited Export) Regulations and for licences to manufacture narcotic drugs under the *Narcotic Drugs Act 1975*.

Poisons licences for retail supply of some OTC medicines would also be included. This should be based on para 35 of the SUSDP and would be linked to an SUSMP Appendix to designate any OTC substances, which such a licence holder cannot supply.

The legislation would include provisions for licences for the most toxic poisons (*Schedule 7*) but it is intended that this provision would only be adopted in those States and Territories where there are no provisions in other legislation (e.g. agvet legislation) which met the objectives of the model medicines and poisons legislation.

### **Labels**

The legislation would include provisions for labelling:

- dispensed medicines, - for example, the information to be included by the dispenser on the label (name of the substances, identifying number, name of the supplier, directions for use, and warnings, etc.) and on how it should be presented (in English, font size etc.) These would be similar to those currently included in State and Territory drugs, poisons and controlled substance legislation and include those matters in the SUSDP, para. 45 and SUSDP Appendix K; and
- household poisons, where these would include the requirements as currently set out in SUSDP Part 2 and 3 and Appendixes E and F. Exemptions would be made for agvet chemicals labelling in accordance with the First Aid and Safety Instructions Handbook prepared by the TGA Chemicals Unit.

### **Packaging**

The SUSMP would include provisions for packaging of household poisons similar to those currently in SUSDP Part 2.

### **Supply of clinical samples**

The legislation would prohibit the prospective supply of samples of controlled substances (*Schedule 8*). It would be a condition of licence that those distributing clinical samples of other scheduled products must comply with the a Code of Practice for the Supply of Clinical Samples. Authorised company representatives would be given a reverse licence to supply clinical samples of all medicines other than controlled substances to health professionals provided they comply with the Code of Practice for the Supply of Clinical Samples.

### **Supply of consumer samples of poisons**

The legislation would authorise the supply of samples of scheduled poisons to consumers provided such supply complies with is the code of practice developed by the chemical industry in consultation with governments and consumers.

## Recording

The legislation will provide for the recording of all controlled substances (*Schedule 8*) by wholesalers, distributors, pharmacists, doctors and all others who supply or administer these substances. The detail required in these records will be specified but will provide flexibility to enable such records to be kept electronically.

Wholesalers will be required to keep records of all transactions of other medicines and poisons. The way in which these records are to be kept will not be specified but the desired outcome, i.e. that the supply can be tracked efficiently and in a timely manner, for recall or other purposes, if that is necessary, would be specified.

Pharmacists will be required to keep a record of all prescriptions. Records of transactions of other scheduled medicines will not be required.

Licence holders for toxic poisons (*Schedule 7*) would be required to keep records that included specified information.

## Reporting

Reports of wholesale narcotic drug transactions (*Schedule 8*) are required under Commonwealth legislation. The model legislation should include provision for reporting of certain other wholesale and retail transactions to be declared to be necessary (e.g. by inclusion in a schedule to the legislation or an SUSMP Appendix) where that substances has been identified as one that requires timely and on-going monitoring to reduce the level of abuse or diversion and where the monitoring can be achieved in a way that enables timely enforcement action to be taken.

## Storage

The legislation will make provision for storage of controlled substances (*Schedule 8*) at both wholesale and retail level.

At the wholesale level, storage restrictions may also be imposed on substances other than those in *Schedule 8* where there is a significant risk of abuse or diversion for use in the illicit manufacture of drugs. These requirements should be consistent with any such requirements under the Customs (Prohibited Import) Regulations and the Customs (Prohibited Export) Regulations. The legislation will set out the desired outcomes of the controls as well as general provisions for achieving those outcomes.

The legislation will include requirements that pharmacists store:

- prescription medicines in a part of the premise to which the public does not have access; and
- OTC medicines in such a way as to support the pharmacist meeting the expected professional standards in supplying these medicines, i.e. that he or she is in a position to help the consumer select the appropriate medicine and use it safely and effectively.

Provisions will also be made for storage and display of medicines by persons licensed to sell *Schedule 2* medicines.

Licensed sellers of toxic (*Schedule 7*) poisons will be required to comply with specified storage provisions to ensure only those authorised to use these poisons have access.

The model legislation will include the desired outcome for retailers displaying *Schedule 5* and *6* poisons for sale together with general requirements to achieve those outcomes.

### **Handling**

Requirements for the safe and secure handling of controlled substances (*Schedule 8*) medicines and toxic poisons (*Schedule 7*) will be included in the legislation. Provisions for controlled substances should be consistent with any requirements under the Customs (Prohibited Import) Regulations and the Customs (Prohibited Export) Regulations and other legislative requirements such as dangerous goods legislation and postal regulations. The legislation will set out the desired outcomes of the controls as well as general provisions for meeting those outcomes.

To address handling controls, where they apply to maintaining the quality of the products during handling, e.g. storage temperature during transport, the legislation will underpin the Code of Good Wholesaling Practice.

## **DRUGS, POISONS AND CONTROLLED SUBSTANCES LEGISLATION**

Given the considerable variation in the scope of the various legislative instruments under review, it is not possible to identify, other than generically, the requirements that apply. In some instances these requirements may fall outside the legislation under review for some jurisdictions (e.g. in some jurisdictions *Schedule 7* licences are included in agvet legislation and not in drugs and poisons legislation). Further, variations in the definitions used in the different legislative instruments make direct comparisons difficult if not impossible.

Consequently, the amendments required to the legislation are described in general terms. Further, the amendments described may not be necessary in all jurisdictions because that jurisdiction has already adopted the *Therapeutic Goods Act 1989*, although even here, there will be variations depending on whether it is adopted by reference or as mirror legislation.

### **General**

Those States and Territories, which have not already done so, will need to amend the relevant legislation, or enact new legislation to adopt the *Therapeutic Goods Act 1989* by reference. This will ensure full national coverage of all labelling, packaging and advertising of human medicines.

All States and Territories should adopt the model medicines and poisons legislation described above, by reference, and repeal all provisions within their legislation which are covered by the provisions of that model legislation. The general areas of control which will need to be repealed are outlined below.

## **Definitions**

The definitions in the legislation determine the scope of the controls included in the legislation. Jurisdictions should repeal all relevant definitions wherever they appear including any reference to Part 1 or Appendix A of the SUSDP and adopt the definition included in the model legislation.

## **Labels**

All requirements for product labels for human medicines and agvet products will be included under Commonwealth legislation – the *Therapeutic Goods Act 1989* and the *Agvet Chemical Code Act 1994*.

States and Territories should repeal all provisions related to labelling of agvet products, including in those jurisdictions which adopt them, Appendixes E and F of the SUSDP.

States and Territories should repeal the current labelling requirements that apply to household chemicals and adopt the labelling requirements in the model legislation.

## **Packaging**

States and Territories should repeal all requirements in their current legislation that apply to product packaging and adopt the packaging requirements in the model legislation

## **Advertising**

State and Territory restrictions on advertising medicines (human and animal) duplicate and overlap Commonwealth restrictions on advertising *Schedule 4* and *8* and some *Schedule 3* medicines and the restrictions on advertising certain disease conditions. Variations in the definition of ‘advertising’ in all jurisdictions lead to additional differences in the scope of the controls across jurisdictions.

States and Territories should repeal all provisions relating to advertising medicines.

## **Licences**

States and Territories should repeal all requirements that apply to licences and adopt the licensing requirements in the model medicines and poisons legislation.

## **Supply of clinical samples consumer samples of poisons, storage, handling, recording, reporting and other restrictions on business conduct**

States and Territories should repeal all provisions relating to these matters and adopt the requirements in the model legislation.

## **Scheduling decisions**

States and Territories should repeal all reference to the National Drugs and Poisons Schedule Committee (NDPSC) and the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) and adopt the model legislation references to the Medicines



Scheduling Committee (MSC) and the Poisons Scheduling Committee (PSC), and the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).

### **The Schedules – levels of access**

States and Territories should repeal all references to the SUSDP *Schedules 2, 3, 4, 5, 6, 7, 8 and 9* and the SUSDP Appendixes A, C, D, E, F, G, H, I, J, K and associated controls. In those jurisdictions, which did not adopt these, repeal all equivalent provisions. States and Territories should adopt the schedules, appendixes and associated controls included in the model legislation.

Those jurisdictions with restrictions on supply of unscheduled medicines by vending machine should repeal those provisions and adopt the provision in the model legislation. Note: In some jurisdictions these provisions are in legislation other than drugs and poisons legislation.

## **PROFESSIONAL PRACTICE LEGISLATION**

Amendments may be required to professional practice legislation to provide more flexible mechanisms for ensuring compliance with professional standards and to clarify the relationship with medicines and poisons legislation e.g. to explicitly identify that a breach of the model medicines and poisons legislation is *prima facie* a breach of professional standards.

## **B. COMMONWEALTH LEGISLATION**

### **THERAPEUTIC GOODS ACT 1989**

#### **Product labels for medicines**

A number of aspects of labelling of medicinal products are already controlled under this Act. State and Territory legislative requirements impose additional requirements and, in some cases, duplicate the Commonwealth requirements.

The Act, and related subordinate legislation (Regulations, Orders, Standards) be amended to add all controls relating to product labels for human medicines currently included in State and Territory legislation, including required warnings, cautionary statements, first-aid instructions.

#### **Packaging**

Packaging of medicinal products is already controlled under this Act except for those products manufactured and supplied within jurisdictional boundaries

There may however be a need to change subordinate Therapeutic Goods legislation (e.g. Orders) to accommodate some of these packaging controls now attached to specific substances in the schedules (e.g. essential oils in containers of 15 mL or less fitted with restricted flow inserts).

## **Advertising**

The legislation will need to be amended to clarify that the prohibition on advertising prescription medicines applies to animal medicines as well as to human medicines.

## **Scheduling committee**

Currently the National Drugs and Poisons Schedule Committee is established and its procedures and processes set out in the Act and subordinate legislation (Regulations and Standard).

Amendments will be needed to repeal the current legislation and replace it with legislation to establish the Medicines Scheduling Committee (MSC) and the Poisons Scheduling Committee (PSC) and set out the functions and processes for these committees.

## **Schedules and Appendixes**

All references to the SUSDP should be repealed and replaced with the SUSMP. The Schedules and Appendixes will be included in the SUSMP. This standard, which should distinguish between the medicines and the poisons schedules by grouping them separately would include three schedules relating to supplying medicines for therapeutic purposes – one OTC schedule, one general PRESCRIPTION ONLY schedule and a schedule for controlled substances. There would also be three poisons schedules. There would be a further schedule of prohibited substances.

It may also be appropriate to consider establishing a special schedule for herbal substances.

## **THE AGRICULTURAL AND VETERINARY CHEMICAL CODE ACT 1994**

### **Packaging**

Amendments will be needed to the Act or subordinate legislation to impose packaging controls that are consistent with those for the same substance in the SUSMP and for the associated administrative arrangements (e.g. granting of exemptions from the standard).

## **CUSTOMS (PROHIBITED IMPORT) REGULATIONS CUSTOMS (PROHIBITED EXPORT) REGULATIONS AND NARCOTIC DRUGS ACT 1975**

### **Licences**

The purpose of some licences requirements (security, probity of the persons involved etc.) for import, export and manufacture of narcotic drugs and other controlled substances are similar, but not always the same, as those required for licences under State and Territory law.

Amendments may be needed to ensure consistency between requirements under this legislation and those under State and Territory medicines and poisons legislation to

provide that a State or Territory licence is prima facie evidence of compliance with those requirements.

Reporting of all transactions of narcotic drugs (*Schedule 8*) should continue to be required.

## **OTHER REQUIRED ACTION**

### **National Coordinating Committee on Therapeutic Goods**

To develop model medicines and poisons legislation for adoption by all jurisdictions and establish on-going mechanisms to maintain that legislation. This will require the NCCTG to develop mechanisms for consultation on the proposed legislation, amendments and for advising the Australian Health Ministers Conference and for implementing the agreed changes.

To develop mechanisms to enable the timely exchange of information on the interstate movement of controlled substances or other designated substances such as precursor chemicals.

In consultation with the pharmaceutical industry, consumers and health professionals to develop a code of practice for the supply of clinical samples

In consultation with the chemical industry and consumers to develop a code of practice for the supply of consumer samples of scheduled poisons.

In consultation with industry, health professionals and consumers, to develop the Standard for Informational Price Advertising and Publication of CMI for prescription medicines.

## Appendix B2: Proposed Medicines Scheduling Committee and Poisons Scheduling Committee – Functions

The following changes to the *Therapeutic Goods Act 1989* and the Therapeutic Goods Regulations 1990 have been identified as necessary for restructuring the National Drugs and Poisons Schedule Committee into the Medicines Scheduling Committee (MSC) and the Poisons Scheduling Committee (PSC).

### THERAPEUTIC GOODS ACT 1989

Amend Section 52C - Functions of the Committee

The proposed functions of the **Medicines Scheduling Committee** are:

- (a) to make decisions in relation to the classification and scheduling of medicinal substances; and
- (b) to provide technical advice to governments in relation to the legislative restrictions, including restrictions as to accessibility and availability to be imposed in respect of particular medicinal substances; and
- (c) to maintain the schedules for medicinal substances in the current Poisons Schedule<sup>120</sup>; and
- (d) to facilitate the harmonisation between Australia and New Zealand of the legislative provisions relating to the classification and scheduling of medicinal substances; and
- (e) to undertake public consultation with respect to matters relating to the classification and scheduling of medicinal substances that are of public health interest or significance; and
- (f) to consider any matters referred to it by:
  - (i) the Minister or Secretary; or
  - (ii) the subcommittee of the Australian Health Ministers' Advisory Council known as the National Coordinating Committee on Therapeutic Goods;and report to the Minister, Secretary or subcommittee the results of its consideration; and
- (g) any other functions that are prescribed by the regulations.

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<sup>120</sup> Note: the 'Poisons Standard' is currently defined in the *Therapeutic Goods Act, 1989* as referring to the Standard for the Uniform Scheduling of Drugs and Poisons. This definition will need to be amended to refer to the Standard for the Uniform Scheduling of Medicines and Poisons..

The proposed functions of the **Poisons Scheduling Committee** are:

- (a) to make decisions in relation to the classification and scheduling of poisonous substances, excluding medicinal substances; and
- (b) to provide technical advice to governments in relation to:
  - (i) the legislative restrictions, including restrictions as to accessibility and availability to be imposed in respect of particular poisonous substances; and
  - (ii) the policies to be adopted with respect to labelling, packaging and advertising of poisons; and
- (c) to maintain the schedules for poisonous substances in the current Poisons Schedule; and
- (d) to facilitate the harmonisation between Australia and New Zealand of the legislative provisions relating to the classification and scheduling of poisonous substances; and
- (e) to undertake public consultation with respect to matters relating to the classification and scheduling of poisonous substances that are of public health interest or significance; and
- (f) to consider any matters referred to it by:
  - (i) the Minister or Secretary; or
  - (ii) the subcommittee of the Australian Health Ministers' Advisory Council known as the National Coordinating Committee on Therapeutic Goods;and report to the Minister, Secretary or subcommittee the results of its consideration; and
- (g) any other functions that are prescribed by the regulations.

Amend Section 52E - Matters to be taken into account in exercising powers

Matters to be taken into account will be the same for each committee and the same as currently for NDPSC.

## **THERAPEUTIC GOODS REGULATIONS 1990**

### **Regulation 42ZCD Committee members**

#### **Proposed Membership of the Committee (Medicines Scheduling Committee)**

The Committee comprises each jurisdictional member and other persons appointed by the Minister under this regulation.

The Minister may appoint as a member an expert or a representative.

Each of the following persons is a **representative**:

- a) a person nominated by the Therapeutic Goods Administration,

- b) a person nominated by an agency of the New Zealand government responsible for regulation of medicines for human use,
- c) a person whom the Minister is satisfied represents the pharmaceutical industry,
- d) a person whom the Minister is satisfied represents consumers,
- e) a person whom the Minister is satisfied represents practicing pharmacists, and
- f) a person whom the Minister is satisfied represents practicing complementary medicine practitioners.

Each of the following persons is an **expert**:

- a) a medical practitioner expert in clinical pharmacology,
- b) an expert in veterinary medicine or pathology,
- c) a toxicologist, and
- d) an epidemiologist

#### Proposed Membership of the Committee (**Poisons Scheduling Committee**)

The Committee comprises each jurisdictional member and other persons appointed by the Minister under this regulation.

The Minister may appoint the following experts or representatives.

Each of the following persons is a **representative**:

- a) a person nominated by the National Registration Authority,
- b) a person nominated by an agency of the New Zealand government responsible for the regulation of agricultural and household chemicals,
- c) a person whom the Minister is satisfied represents the chemical industry, and
- d) a person whom the Minister is satisfied represents consumers.

Each of the following persons is an **expert**:

- a) an expert in occupational health,
- b) a toxicologist,
- c) an epidemiologist, and
- d) an expert in public health (poisonings)



## Appendix B3: National Coordinating Committee on Therapeutic Goods – Terms of Reference

### Current Terms of Reference

The functions of the Committee are to take action necessary to bring about coordination of legislative and administrative controls on therapeutic goods and poisons and to make recommendations to the Australian Health Ministers' Advisory Council as necessary.

### Role as defined in the Therapeutic Goods Act

The role of the NCCTG in providing policy direction to the NDPSC is designated by the *Therapeutic Goods Act 1989* as:

#### Section 52C: Functions of Committee

- (f) to consider any matters referred to it by:
  - (i) the Minister or Secretary; or
  - (ii) the subcommittee of the Australian Health Ministers' Advisory Council known as the National Coordinating Committee on Therapeutic Goods;and report to the Minister, Secretary or subcommittee the results of its consideration; and

#### Section 52E: Matters to be taken into account in exercising powers

- (2) In taking into account the matters referred to in subsection (1), the Committee must comply with any guidelines of the Australian Health Ministers' Advisory Council or the subcommittee of the Council known as the National Coordinating Committee on Therapeutic Goods, notified to the Committee for the purposes of this section.

### Recommendations of this Review

The foremost principle underlying the recommendations of this review is national uniformity and, as discussed in Section 6, the NCCTG is considered the most appropriate body to direct its implementation. Accordingly, the Australian Health Ministers Advisory Committee (AHMAC) should be requested to strengthen the NCCTG Terms of Reference in relation to coordination of national policies on medicines and poisons including giving the NCCTG responsibility for providing advice to Health Ministers, through AHMAC, on the development and maintenance of model medicines and poisons legislation. It is also expected that provision of policy direction to the NDPSC will increase in importance as changes to the scheduling process and committee structure are put into practice, and this aspect of the NCCTG should also be included in its Terms of Reference.



## Revised Terms of Reference

The functions of the Committee are

- to advise Ministers of agreed key principles and desired outcomes of medicines and poisons legislation;
- to develop model legislation as the basis for uniform legislation across jurisdictions;
  - to undertake public consultation and prepare a regulatory impact statement for the legislation and any amendments.
- to provide a coordination mechanism to facilitate:
  - interstate trade of medicines and poisons;
  - prevention of cross border diversion; and
  - cooperation in the area of enforcement;
- to provide policy direction to the Medicines Scheduling Committee and the Poisons Scheduling Committee in the form of guidelines that:
  - recognise the Competition Principles;
  - include effective, efficient, transparent and timely consultation processes; and
  - are based on an agreed risk strategy for protecting public health and safety; and
- to make recommendations to ministers, TGA and the Australian Health Ministers' Advisory Council as necessary.

## Acronyms

AHMAC	Australian Health Ministers Advisory Committee
APMA	Australian Pharmaceutical Manufacturers Association
ARTG	Australian Register of Therapeutic Goods
CMI	Consumer Medicine Information
DAA	dose administration aid
DRUMS	Drug Reporting Utilisation Monitoring System
DTC	direct to customer
JETACAR	Joint Evaluation Technical Advisory Committee on Antibiotic Resistance
MSC	Medicines Scheduling Committee
NCCTG	National Coordinating Committee on Therapeutic Goods
NCRIS	National Chemical Registration Information System
NDPSC	National Drugs and Poisons Schedule Committee
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NOHSC	National Occupational Health and Safety Commission
NRA	National Registration Authority for Agricultural and Veterinary Chemicals
OTC	over-the-counter
PSC	Poisons Scheduling Committee
SUSDP	Standard for the Uniform Scheduling of Drugs and Poisons
SUSMP	Standard for Uniform Scheduling of Medicines and Poisons
TGA	Therapeutic Goods Administration
TGAC	Therapeutic Goods Advisory Committee

## Glossary

**Agvet** chemicals or products are agricultural and veterinary substances or products which are covered by the *Agricultural and Veterinary Chemicals Code Act 1994*.

**Asymmetric information** refers to a systematic difference in information between buyers and sellers.

**Benefit** refers to a benefit conferred on individuals, groups or government (or in the case of a veterinary medicine, an animal) by a regulatory control. The benefit may involve directly improving health, or indirectly by reducing the risk of harms such as poisoning, abuse or diversion.

**Cost** refers to the adverse impact on individuals, groups (e.g. industry) or government as a result of a regulatory control. These costs may be direct or may be borne by another party, e.g. the cost to government of a hospitalisation of a child that is

poisoned. It also includes non-monetary costs, such as emotional trauma to individuals and communities, resulting from tragic harms.

**Cost–benefit analysis** is the systematic documentation of relevant benefits and costs over time; quantified in monetary terms where possible or qualitatively assessed in the absence of quantitative data.

**Externalities** means effects beyond those contracted for by parties in a market transaction, often on third parties.

**Handling** refers to transport and distribution up to the point of retail sale, e.g. from manufacturer to distributor to retailer. See also **Manner of supply**.

**Health risk** means the probability of an adverse health outcome associated with using a substance.

**Household chemicals** as used in this paper does not include agvet products when intended for use in the household. Nor does it include chemicals used in the workplace.

**Manner of supply** refers to issues relating to handling at or after retail sale.

**Market failure** is the failure of a free market to fully and efficiently meet community needs in the area of that good or service.

**Market** refers to an area of close actual or potential competition between buyers and sellers.

**Poisoning** includes immediate harmful internal ingestion, chronic effects because the substance accumulates in the system, corrosive effects (e.g. on the skin or eyes), teratogenic, mutagenic and carcinogenic effects or any other harm to the individual related to that substance.

**Schedule 2, 3, 4, 5, 6, 7, 8, 9** refers to Schedules in the *Standard for the Uniform Scheduling of Drugs and Poisons* (SUSDP). Some of these may be identified differently in State and Territory legislation.

**Storage** refers to the storage of medicines and poisons when regulated by the drugs and poisons or controlled substances legislation. There are several other legislative controls which impact on storage, including dangerous goods legislation, environmental protection legislation and the *Agricultural and Veterinary Chemicals Code Act 1994*.

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