A Council of Australian Governments Review

Final Report Part A

January 2001

National Competition Review of Drugs, Poisons and Controlled Substances Legislation

Final Report Part A*

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December 2000

*** Part B is bound separately**

ISBN 0 642 70510 0

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EXECUTIVE SUMMARY

The Review of Drugs, Poisons and Controlled Substances Legislation here presents its Final Report. Having conducted the research, consultation and analysis under Competition Principles, the Review is satisfied that most of the current controls provide a net benefit to the community as a whole in relation to the use of substances that have the potential to cause harm. The recommendations for change are in the areas of increasing national uniformity, improving efficiency, reducing the level of control where possible, and improving the net benefit to the community as a whole of those controls which rely on professional practice to be effectual.

Freedom from harm to the individual and the community as a whole is the key objective sought from the controls. The Review considered the range of harms the legislative controls were put in place to alleviate. It established that the use of certain poisonous substances, although of benefit to the community, can and do result in harm, and that this would be expected to worsen under unrestrained deregulation. Effort needs to be placed in reducing the current level of harm and the Review considered alternatives to regulation to minimise the restrictions on competition while achieving this, particularly mechanisms to improve the information available to consumers.

The harms from inappropriate use may lead to hospital, medical and social costs. The costs have an impact on government, individuals and the community as a whole. These harms include accidental and deliberate poisoning, medicinal misadventures and abuse. Because, drugs, poisons and controlled substances are widely used in the community, with most Australians using one or more every day, the Review concluded that the total potential for harm warrants acceptance of reduced competition and higher costs in some circumstances.

Used appropriately, these substances have considerable benefits for the community. For example, medicines play an important and, in some cases, a life-saving role in improving the health of humans and animals. Other substances improve the quality and quantity of food production or make household tasks, such as cleaning, easier. Maintenance of the relevant industries with the minimum regulation necessary and enhanced competition is also important.

The substances under review are included in human medicines,[1] veterinary products, garden pesticides, household cleaners and a variety of products used by farmers, horticulturists and various industries. For simplicity they can be referred to as medicines (covering human and animal) and poisons.

The controls under review

State and Territory governments have a range of medicines and poisons legislation that imposes restrictions on who can supply these substances, to whom they can be

[1] Medicines are defined to include prescription medicine, ‘over-the-counter’ and ‘complementary’ medicines.

supplied, how they can be supplied and in what circumstances. These restrictions are supported by a range of other controls.

Other legislation concerned with public health and safety in the use of substances includes the Commonwealth's *Therapeutic Goods Act 1989* and the *Agricultural and Veterinary Chemical Code Act 1994*, both of which control supply of products by a registration process. The Review was concerned with these controls in so far as they relate to, or overlap with, the State and Territory legislation. There are also links, for public health purposes, with occupational health and safety legislation concerned with substances in any form in the workplace, and food standards which restrict levels of pesticide residues, contaminants and food additives.

The other related legislation, which the Review identified as being particularly relevant to a review of medicines and poisons control, and on which the system of controls in part rely, is the State and Territory legislation regulating professional practice – in particular the medical, pharmacist and veterinarian professions.

The review process

The Review examined the legislation nominated for review and identified those provisions which impact on competition, the extent of that impact and their effect on the economy as well as a range of alternatives. The costs and benefits of the current controls and the alternatives, both legislative and non-legislative, were examined, as required by the Terms Reference. Also, as required by the Terms of Reference, the Review considered mechanisms to improve the overall efficiency of the system, including measures to minimise the compliance costs that flow from medicines and poisons legislation.

The independent Chair of the Review was Ms Rhonda Galbally, Managing Director of the Australian International Health Institute, aided by a Steering Committee comprising representatives of the Commonwealth and all States and Territories. In undertaking the Review, Ms Galbally consulted widely with a range of stakeholders in all jurisdictions. The information provided by stakeholders, both orally and in written submissions, together with research undertaken by the Review Secretariat was analysed to establish the costs and benefits of the current system, identify alternatives and assess the costs and benefits of those alternatives.

Stakeholder comments

No stakeholder proposed total deregulation and there was strong support for the objectives of the current legislation. In general, the current form and level of controls were considered effective in providing a net benefit to the community as a whole, 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 raised most often was a lack of uniformity across jurisdictions and the costs that this imposes on industry and, to a lesser extent, health professionals and government.

Clarification of objectives

The Review identified the objectives of the controls imposed by drugs, poisons and controlled substances legislation as to protect and promote public health by measures targeted at preventing poisoning, medicinal misadventure, and abuse of drugs. Most of the controls directly address the information asymmetry for consumers as purchasers of medicines and poisons, so that restrictions on access, requiring professional intervention and insisting that certain information be available are intended to improve the safe and efficacious use of potentially hazardous products.

Nature of the restrictions on competition

There are two broad classes of restriction on competition in medicines and poisons legislation: restrictions on WHO can supply, and restrictions on HOW these substances can be supplied. Licensing controls the entry of an operator into a business handling medicines or poisons, preventing or removing problem traders from the market. In conjunction with licensing, the *Schedules* provide the basis for the major legislative restrictions that control the manner in which medicines and poisons must be supplied. The restrictions attached to schedules in the respective State and Territory relevant Acts and Regulations specify who may sell, or supply, who may have access, and the amount and form of goods supplied. These controls are complemented by further specific controls that apply to matters such as advertising, supply of medical samples, labelling, packaging, storage, recording, reporting and disposal of unwanted medicines.

Effect of the restrictions on competition

The controls clearly restrict competition, particularly those which restrict market entry. By reducing competition from others, these restrictions may add to costs for industry, which are then passed to consumers through higher product prices.

Analysis of benefits and costs

It is not always possible to relate benefits to a particular control and in some cases it may well be a combination of factors, including several control measures that contribute to that benefit and impose the costs. The benefits of restricting access include lower hospital, medical and social costs through a reduction in accidental poisoning, deliberate poisoning, diversion to the illicit drug market and medicinal misadventure.

Consumers benefit from increased efficacy of medication with reduced medical costs and loss of income, as well as reduced pain and suffering. Farmers and pet owners experience similar benefits in caring for animals. Everyone benefits from more safe and effective use of chemicals in weed or insect control in an improved productivity and lifestyle. Governments benefit from reduced hospital and medical expenditure and cost-effective use of medical and pharmaceutical subsidies.

There are costs for industry, consumers, traders and government in maintaining restrictions on market entry and how medicines and poisons may be supplied.

However, a cost to one sector is sometimes a benefit to another. The Review considered a range of alternatives for each control.

With reduced competition in the industry, the sector's potential size and dynamism is likely to be reduced. This is predicted on the fact that general competition keeps costs and prices down and encourages innovation in service quality and products. Hence, under the current restrictions, the sector's contribution to the national economy may be smaller than otherwise. However, this cannot be confirmed because of the lack of good evidence of the effects of industry regulation on economic activity. Nonetheless the Review was able to reach some general conclusions on the effects of the controls on competition and the economy.

Generally, the Review considered that the level of regulation proposed under scheduling be in keeping with the hazards from inappropriate use, and the cost of the regulation is judged as being justified by the benefits from it.

Consider alternatives and make recommendations

The Review identified several areas where costs can be reduced. These are:

- removal of some controls, at least in some jurisdictions (e.g. requirement to hold a licence to supply clinical samples);
- less restrictive controls (e.g. storage requirements for *Schedule 2* medicines); and
- coregulation (e.g. a code of practice for supply of clinical samples).

With the objective of the controls centred on the need to address the information asymmetry, the Review also identified possibilities for improvement in ways to provide knowledge to the public and overcome the lack of skills of most consumers in the choice and use of medicines and poisons. Of particular interest to the Review in this regard was the effectiveness of labels, the availability of the Consumer Medicine Information leaflets, the use of advertising as information and education, and the availability and quality of counselling by doctors and pharmacists.

In addition, the Review believed it appropriate to make recommendations to improve the administrative efficiency of the legislation, particularly where this involves operation of the Schedule Committee, the National Coordinating Committee for Therapeutic Goods, inter-agency liaison, inter-government consistency and duplication of the safety assessments required for scheduling.

Conclusions

Based on its analysis, the Review determined that:

- there are sound reasons for Australia to have a comprehensive system of legislative controls that regulates drugs, poisons and controlled substances – notwithstanding the fact that many of these controls restrict competition;
- the level of regulation should be reduced in some areas and, in other areas, a coregulatory approach is appropriate;
- the efficiency of the regulatory system of controls and their administration across a significant number of areas should be improved by:

  - developing a uniform approach across jurisdictions to the legislation that regulates access to and use of drugs, poisons and controlled substances;
  - ensuring the interface between the various pieces of legislation is rational and avoids duplication and overlap, in order to achieve legislative alignment between specific drugs, poisons and controlled substances legislation and related legislation; and
  - ensuring the administrative processes associated with the legislation are efficient and do not impose any unnecessary costs on industry, government or consumers; and
- non-legislative measures should be used to complement legislative measures in meeting the underlying objectives of drugs, poisons and controlled substances legislation.

In brief, the Review recommends that:

- uniformity be improved by transferring the controls for advertising and product labels and packaging for medicines and agvet chemicals to Commonwealth legislation where;
  - the prohibition on advertising prescription medicines is retained, except that publication of the Consumer Medicine Information should be permitted as should advertisements which only provide information about the price of medicines or general information about disease states, in accordance with a code of practice underpinned by legislation to promote the informational nature of these advertisements; and
  - controls over labelling are amended to make them more outcomes focused;
- provisions relating to licences for *Schedule 5* and *6* substances be repealed in those jurisdictions that still have these provisions,
- mandatory requirements for recording the supply of *Schedule 3* substances be repealed in those jurisdictions that have such provisions;
- uniformity be improved by the development of model legislation that includes provisions for all matters related to the supply of medicines for therapeutic purposes and domestic supply of agricultural and veterinary and household chemicals, and incorporating:
  - clinical samples as a condition of licence for companies and a requirement that company representatives be permitted to supply the samples, provided they also comply with the code; and
  - consumer samples of *Schedule 5* and *6* poisons;
- licence requirements be outcomes focused and that, where appropriate, these be consistent with the requirements under Commonwealth legislation for the import, export and manufacture of controlled substances;
- the National Coordinating Committee on Therapeutic Goods be responsible for developing and maintaining this model legislation; and
- efficiency of the scheduling system be improved by:

- more closely linking the evaluation process for medicines and agvet products with the scheduling process; and
- establishing separate committees to make decisions about the scheduling of medicine and poisons.

RECOMMENDATIONS

Recommendation 1: Objectives of legislative framework

That all Commonwealth, State and Territory governments agree that:

a) There are net benefits to the Australian community as a whole in having a comprehensive legislative framework that regulates drugs, poisons and controlled substances, the principal objectives of the legislation being to promote and protect public health and safety by preventing:
   - accidental poisoning;
   - deliberate poisoning;
   - medicinal misadventures; and
   - diversion for abuse or manufacture of substances of abuse.

b) All relevant Commonwealth and State and Territory legislation needs explicitly to incorporate these objectives and be effective, transparent, equitable and the controls the minimum necessary to achieve these objectives.

Recommendation 2: On-going evaluation of the controls

Commonwealth, State and Territory governments allocate public health funding to ongoing research, including data collection to evaluate and monitor the effectiveness of the legislative controls in achieving the objectives of drugs, poisons and controlled substances legislation with a view to continually improving the cost effectiveness of those regulatory controls.

Recommendation 3: Objectives of scheduled medicine controls

That all Commonwealth, State and Territory governments agree that legislation covering the supply of scheduled medicines should explicitly set out its objectives. These objectives are to ensure that:

- in the case of prescription medicines, the conditions from which consumers are suffering are diagnosed correctly and the most appropriate treatment prescribed;
- the consumers of prescription medicines have adequate information and understanding necessary to enable them to use medicines safely and effectively;
- in the case of over-the-counter medicines, 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

- use of the medicines will not lead to dependence or the medicines will not be diverted for abuse purposes or for the illicit manufacture of drugs of abuse.

Recommendation 4: Adoption by jurisdictions of the SUSDP Schedules

That all Commonwealth, State and Territory governments agree that, in order to minimise unnecessary costs to industry and consumers, all States and Territories should adopt all the scheduling decisions covered in the SUSDP by reference and in accordance with timelines developed by the Schedule Committees.

Recommendation 5: Medicine schedules and associated professional support

That all Commonwealth, State and Territory governments agree:

a) That funds be allocated from the Pharmacy Development Program under the Third Community Pharmacy Agreement to commission:

   - independent research that provides baseline data and evaluation. Such research would demonstrate any improvements in health and other outcomes that can be attributed to the higher level and quality of pharmacy counselling flowing the new Quality of Care Standards, the implementation of which is being supported and funded under the Third Community Pharmacy Agreement. The outcomes of this research should be reported to the National Coordinating Committee on Therapeutic Goods by June 2004.
   - the development of comprehensive standards that facilitate a risk-based approach to professional intervention in the supply (including the distance supply) of scheduled products to individual consumers. The Pharmaceutical Society of Australia, should be responsible for developing these standards in consultation with Pharmacy Boards, the Pharmacy Guild of Australia, Pharmacists Branch of the Association of Professional Engineers, Scientists and Managers of Australia (APESMA), other relevant professional groups and consumer organisations and presenting those standards to the National Coordinating Committee on Therapeutic Goods by the end of June 2004.

b) That the National Coordinating Committee on Therapeutic Goods present the Australian Health Ministers Council with a report by the end of July 2004 on the results of the research and on the Standards proposed to be developed. This Report will enable Health Ministers to:

   - monitor the extent to which the restrictions on access to scheduled medicines, supported by improved counselling, deliver improved health and other outcomes;
   - determine whether there is an appropriate and cost effective control system for meeting the objectives of restricting access to over-the-counter medicines; and
   - review the implications of the expanded standard for the integrated operation of schedules and pharmacy practice.

c) That until the Australian Health Ministers have considered the report at the end of July 2004, *Schedule 2*, *3*, *4* and *8* and associated Appendixes be retained. If at that time there is no evidence to support the benefits of retaining *Schedules 2* and *3* they should be combined and new criteria developed.

Recommendation 6: Consumer information service on quality use of medicines

That the Commonwealth Department of Health and Aged Care fund a consumer information service to provide independent, comprehensive, quality advice in relation to the safe and effective use of medicines.

Recommendation 7: Administrative arrangements for scheduling

That all Commonwealth, State and Territory governments agree that:

a) The *Therapeutic Goods Act 1989* and relevant sections of State and Territory legislation be amended to:

- change the title of the *Standard for the Uniform Scheduling of Drugs and Poisons* to the *Standard for the Uniform Scheduling of Medicines and Poisons*; and
- disband the National Drugs and Poisons Schedule Committee and replace it with two separate committees – the Medicines Scheduling Committee, responsible for scheduling human medicines; and the Poisons Scheduling Committee, responsible for scheduling agricultural, veterinary and household chemicals – and that:
  - membership of the Committees include a mix of jurisdictional representatives, appropriate experts and representatives of relevant government and community sectors;
  - decisions of both the Medicines Scheduling Committee and the Poisons Scheduling Committee be decided by a majority vote of the members provided that majority also includes a majority of the jurisdictions; and
  - the decisions of both Committees be included in the *Standard for the Uniform Scheduling of Medicines and Poisons*.

b) The *Therapeutic Goods Act 1989* and the *Agricultural and Veterinary Chemicals Code Act 1994* and related subordinate legislation be amended, as necessary, to enable the Therapeutic Goods Administration, in the case of human medicines, and the National Registration Authority for Agricultural and Veterinary Products, in the case of agricultural and veterinary products, acting on the advice of the Commonwealth health portfolio in relation to public health matters to:

- make decisions about the labelling and packaging of medicines and agvet products during evaluation of those products;
- recommend the schedule in which a new substance should be included; and

- recommend changes to the schedule of a substance where, in evaluating new formulations, new presentations and new uses of substances currently included in the *Standard for the Uniform Scheduling of Medicines and Poisons*, a significant change in the risk profile of the substance is identified.

c) The *Therapeutic Goods Act 1989* be amended to enable the costs of operating the Medicines Scheduling Committee and the Poisons Scheduling Committee to be fully recovered by implementing a charge for re-scheduling applications by industry.

Recommendation 8: Vending machines

That Commonwealth, State and Territory governments agree that:

- provisions in State and Territory legislation which prohibit the supply of scheduled medicines from vending machines be repealed and replaced with uniform provisions in medicines and poisons legislation which prohibit the supply of scheduled medicines from vending machines;
- provisions in State and Territory legislation which prohibit the supply of unscheduled medicines from vending machines be repealed and replaced with provisions in medicines and poisons legislation that permit the supply of packs containing no more than two adult doses of unscheduled medicines from vending machines provided those machines are presented and located in a way that makes unsupervised access by children unlikely; and
- permission to operate such vending machines be subject to a requirement that the operators of such vending machines provide the National Coordinating Committee on Therapeutic Goods with an independent evaluation of the safe use and effectiveness of the quality control measures after two years of operation.

Recommendation 9: Controls over administration of medicines

The Commonwealth, State and Territory governments agree that the current level of controls over the administration of medicines be retained.

Recommendation 10: Authorisation to prescribe controlled substances

That the Health Insurance Commission consults with State and Territory health departments to develop procedures to reduce the administrative duplication that applies, in certain circumstances, to the prescribing of controlled substances and to clarify these procedures for health professionals and consumers.

Recommendation 11: Informational advertising of scheduled medicines [2]

That all Commonwealth, State and Territory governments agree that:

a) All provisions relating to advertising in State and Territory drugs, poisons and controlled substances legislation be repealed.

b) The current prohibition on advertising of *Schedule 3*, *4* and *8* medicines be retained in the *Therapeutic Goods Act 1989* except for certain, specifically permitted, advertisements.

c) The *Therapeutic Goods Act 1989* be amended to provide exemptions from the prohibition on advertising of *Schedule 3*, *4* and *8* medicines for the following advertisements:

- price, where such information may be solicited or unsolicited and may appear in a catalogue or other publication containing other permitted advertising for medicines but where such advertising is informational and not promotional;
- Consumer Medicine Information (CMI) where that information is presented in its entirety without embellishment and is not juxtapositioned with other informational material other than a press release;
- as at present, a one-off press release about the availability of a new medicine where that press release complies with the Australian Pharmaceutical Manufacturers Association Code of Conduct and the press release is accompanied by the Consumer Medicine Information for the product;
- where such advertisements comply with the Standard for Informational Price Advertising and Publication of Consumer Medicine Information (see d) below); and
- where Commonwealth, State and Territory governments decide to include information about specific products as part of a public health education initiative and have authorised the content, placement, timing and nature of such informational advertisements.

d) The National Coordinating Committee on Therapeutic Goods should develop a Standard for Informational Price Advertising and Publication of Consumer Medicine Information to be underpinned by the *Therapeutic Goods Act 1989*. This Standard should cover:

For price advertising:

- how permitted advertisements can be presented including:
  - the maximum print size;
  - must be part of a list of products from multiple product manufacturers;
  - must not be juxtapositioned with information, such as articles about the substance in the product; and

[2] This recommendation assumes that Recommendations 22 and 23 will be implemented. If not, then similar amendments will be required to State and Territory drugs, poisons and controlled substances legislation to deal with situations involving sole traders trading intrastate.

  - should not be accompanied by illustrations or pictures;
- the content of the advertisement (name, brand, strength, pack size and price);
- who can place the advertisements (i.e. may only be placed by suppliers and not manufacturers of products);
- the nature of the media where such an advertisement may be placed (e.g. not on television or radio); and

For Consumer Medicine Information, that the information:

- is presented in its entirety in the form required by *Schedule 12* and *13* of the Therapeutic Goods Regulations;
- is not embellished in any way or accompanied by pictures; and
- is not juxtapositioned with other information, such as articles about the substance in the product; and

Such other matters as the National Coordinating Committee on Therapeutic Goods considers necessary.

e) That the National Coordinating Committee on Therapeutic Goods, in consultation with industry, consumers and health professionals develop a Code of Practice to specifically cover consumer disease state advertisements and generic information directly or indirectly promoted by sponsors of *Schedule 3, 4* and *8* medicines and that this code be underpinned by the *Therapeutic Goods Act 1989*.

Recommendation 12: Supply of sample packs of medicine and poisons

That all Commonwealth, State and Territory jurisdictions agree that:

a) States and Territories repeal provisions relating to the prospective supply of products including samples of medicines and poisons within their drugs, poisons and controlled substances legislation. (With the exception of those relating to the prospective supply of *Schedule 7* products and *Schedule 8* substances, where the prohibition should be maintained).

b) The Australian Pharmaceutical Manufacturers Association, in consultation with government, consumers and health professional organisations, amend their Code of Conduct for the Supply of Clinical Samples. The Code should include standards for:

- the security of the stock;
- the quantities to be held, carried and supplied;
- quality issues, such as the temperature of storage;
- record keeping; and
- disposal.

c) State and Territory drugs and poisons legislation be amended to provide that:

- it be a condition of licence that manufacturers and wholesalers comply with the Australian Pharmaceutical Manufacturers Association Code of Conduct for the Supply of Clinical Samples; and
- authorised representatives of manufacturers and wholesalers be exempted from requirements in medicines and poisons legislation that would make it an offence for them to supply scheduled medicines provided they do so in compliance with the Australian Pharmaceutical Manufacturers Association Code of Conduct for the Supply of Clinical Samples.

d) A requirement be included in medicine and poisons legislation to ensure that those supplying medicines, including clinical samples, provide the consumer with adequate instructions, including labelling the samples with the directions for use, to enable the consumer to use the clinical sample safely and effectively.

e) The Australian Chemical Specialties Manufacturing Association, together with other chemical industry associations and in consultation with government, consumers and health professionals, develop a Code of Practice for the Supply of Consumer Samples of Poisons. The Code should include standards for:

- the substances which may be supplied as consumer samples;
- the way in which the consumer samples may be distributed;
- to whom they may be distributed;
- the size of the sample packs and the quantities which may be distributed to a consumer;
- the labelling and packaging requirements for the samples; and
- disposal.

f) State and Territory drugs and poisons legislation be amended to provide that, for consumer samples of *Schedule 5* and *6* poisons, distribution should be permitted provided such supply takes place in accordance with a Code of Conduct for the Supply of Consumer Samples of Poisons.

Recommendation 13: Schedule 5 and 6 licences

That Commonwealth, State and Territory governments agree that the provisions in State and Territory drugs and poisons legislation applying to licences for *Schedules 5* and *6* be repealed.

Recommendation 14: Licensed wholesalers

That Commonwealth, State and Territory governments agree that the provisions in State and Territory drugs, poisons and controlled substances legislation applying to wholesale licences for *Schedule 2*, *3*, *4*, *8* and *9* products and substances, be retained but, where they overlap with requirements for Commonwealth licences to import, export and manufacture controlled substances, amendments be made as necessary to:

- State and Territory drugs, poisons and controlled substances legislation; and
- the Customs (Prohibited Import) Regulations, Customs (Prohibited Export) Regulations and the *Narcotic Drugs Act 1975*;

to make the licence requirements uniform.

Recommendation 15: Licensed poisons sellers

That Commonwealth, State and Territory governments agree that State and Territory drugs and poisons legislation be amended to provide that *Schedule 2* poisons licence holders be permitted to sell all medicines containing *Schedule 2* substances, unless the Medicines Scheduling Committee has included that substance in an appendix to the *Standard for the Uniform Scheduling of Medicines and Poisons* to designate that the risk of diversion, poisoning or medicinal misadventure is such that the sale of that substance should only be from a pharmacy.

Recommendation 16: Recording and reporting

That all Commonwealth, State and Territory governments agree that provisions in State and Territory drugs, poisons and controlled substances legislation be amended to the effect that they:

- retain the requirements for recording of all wholesale and retail transactions of *Schedule 8* medicines and to specifically enable such records be kept electronically;
- continue the consistency of the recording requirements for *Schedule 8* medicines with the recording requirements relating to the supply of *Schedule 8* medicines at wholesale level under the *Narcotic Drugs Act 1975* and the Customs (Prohibited Import) Regulations;
- retain the requirements for recording wholesale supply of *Schedule 2, 3* and *4* medicines, except for those provisions that mandate the form in which those records are to be kept, which should be repealed;
- repeal the requirements for specific reporting of retail supply o*f Schedule 4* medicines (except those included in Appendix D of the *Standard for the Uniform Scheduling of Medicines and Poisons*);
- repeal mandatory recording of the retail supply *Schedule 3* medicines;
- repeal recording of *Schedule 5* and *6* poisons in those jurisdiction that have such provisions; and
- repeal recording of the supply of *Schedule 7* poisons at wholesale or retail level in those jurisdictions where there is other legislation within that jurisdiction that imposes requirements to meet the desired objectives.

Recommendation 17: Storage controls

That all Commonwealth, State and Territory governments agree that all provisions in drugs, poisons and controlled substances legislation related to storage and handling of:

- *Schedule* 8 substances and specified *Schedule 4* controlled substances at wholesale and retail level, and
- *Schedule 2, 3* and *4* substances at retail level,

be retained and amended to improve the transparency of the controls by identifying the intended outcomes of the controls for storage.

Recommendation 18: Handling controls

That all Commonwealth, State and Territory governments agree that the Therapeutic Goods Administration, in consultation with jurisdictions and industry, should amend the Code of Good Wholesaling Practice to include measures to ensure secure transport of controlled substances in a way that:

- prevents poisoning;
- reduces diversion of substances to the illicit market; and
- minimises the risks of supply which is not in accordance with the legislative objectives and requirements;

and that State and Territory drugs and poisons legislation be amended to make compliance with the Code of Good Wholesaling Practice a condition of licence for wholesalers.

Recommendation 19: Improving the effectiveness of labels

That Commonwealth, State and Territory governments:

- agree that labelling should be outcomes focused and be simplified;
- note that the Therapeutic Goods Administration is currently reviewing all the labelling requirements for medicines with a view to making labels more effective communication tools and reducing the complexity of the labelling requirements; and
- recommend to the National Registration Authority and the National Coordinating Committee on Therapeutic Goods that they consider the outcomes and recommendations of the Therapeutic Goods Administration Review of Labelling of Therapeutic Goods and, as appropriate, introduce similar requirements for labelling of agvet chemicals and household chemicals respectively to make the labels more effective communication tools.

Recommendation 20: Improving administrative efficiency of the controls

That Commonwealth, State and Territory governments agree that State and Territory drugs, poisons and controlled substances legislation be amended to provide for mutual recognition of administrative decisions in relation to exemptions from labelling and packaging controls.

Recommendation 21: Packaging

That Commonwealth, State and Territory governments agree that the current level of packaging controls be retained.

Recommendation 22: Commonwealth legislation

That the Commonwealth amend:

- the *Therapeutic Goods Act 1989* to include all controls on advertising, packaging and labelling (except signal headings) of human medicines; and

- the *Agricultural and Chemical Code Act 1994* to include all controls on advertising, labelling (except signal headings) and packaging for agvet products, provided this is consistent with the requirements for packaging of household chemicals included in the *Standard for the Uniform Scheduling of Medicines and Poisons*.

Recommendation 23: Complementary therapeutic goods legislation

That all Commonwealth, State and Territory jurisdictions agree that all States and Territories adopt the *Therapeutic Goods Act 1989* by reference into the relevant legislation.

Recommendation 24: Uniform national model legislation

That all Commonwealth, State and Territory governments agree that:

a) The Australian Health Ministers Advisory Committee expand the Terms of Reference of the National Coordinating Committee on Therapeutic Goods to give it responsibility for developing advice for the Australian Health Ministers Conference through the Australian Health Ministers' Advisory Committee on developing and maintaining model medicines and poisons legislation. The Terms of Reference should include responsibility for undertaking any necessary consultation to enable regulatory impact statements to be prepared and establishing supporting mechanisms which put in place an effective and efficient national system of controls.

b) The National Coordinating Committee on Therapeutic Goods develop model legislation that includes provisions for all matters relating to the supply of medicines for therapeutic purposes and to domestic supply of household chemicals:

   - setting out the objectives of the legislation;
   - specifying agreed outcomes for controls; and
   - identifying the specific levels of controls in the areas of:
     - licensing;
     - dispensing labels;
     - household chemical packaging;
     - storage and handling of drugs;
     - recording and reporting; and
     - supply of clinical samples.

c) State and Territory governments adopt the model legislation by reference.

Recommendation 25: Repeal of State and Territory legislation

That State and Territory governments repeal existing legislation relating to controls on labelling, packaging, advertising, access restrictions, licences, recording, reporting, storage, handling and supply of clinical samples of medicines.

Recommendation 26: Harmonising the labels of poisons and workplace chemicals

That the Commonwealth, State and Territory governments agree that the National Coordinating Committee on Therapeutic Goods and the National Occupational Health and Safety Commission work together to:

- Identify more clearly those products whose principal intended use is in the workplace and those intended primarily for domestic use and, therefore, when medicines and poisons legislation applies and when occupational health and safety legislation applies to the labelling of medicines and poisons. On the basis of this assessment, a judgement can then be made on the minimum requirements for a label under both legislative systems and the most appropriate legislation to control labelling and packaging.
- Examine the extent to which specific labelling requirements, such as signal headings and warnings, can be made consistent under drugs, poisons and controlled substances legislation and occupational health and safety legislation.
- Adopt labelling that is consistent with labelling agreed as part of the Globally Harmonised System for the Classification and Labelling of Chemicals in this area, provided such labels do not undermine the level of public health and safety protection for the Australian community afforded by the current labelling requirements.

Recommendation 27: Professional standards

That Commonwealth, State and Territory governments:

- note the importance of Professional Boards in exploring options to improve the level of compliance with professional standards, including measures to improve the timeliness, effectiveness and national consistency of the mechanisms to achieve compliance; and
- strengthen, as necessary, the capacity of Professional Boards to ensure compliance with the relevant practice standards.

CHAPTER 1 INTRODUCTION

1.1 Scope of the Review

Terms of reference addressed: General Issue 11.
Supporting detail for issues discussed in this Chapter are included in Attachment A3 and in Part B Section 1.2.

The National Competition Policy Review of Drugs, Poisons and Controlled Substances was announced in July 1999. The Council of Australian Governments asked the Review to examine State and Territory legislation that imposed controls in Australia on supply and use of drugs, poisons and controlled substances. This Review is one of a number of national reviews being undertaken under the National Competition Agreement to which all States and Territories and the Commonwealth are parties.

The Review was required to examine drugs, poisons and controlled substances legislation against the *Principles of National Competition Policy*. In particular, the Review needed to assess whether the **benefits** of the controls outweigh the **costs** that flow from the regulation so that they provide a net benefit to the community as a whole and that the objectives could only be achieved by restricting competition.

The Review's Terms of Reference also required it to address a number of more specific issues including the:

- relationship between the processes and arrangements for decisions on drugs and poisons scheduling and drugs and poisons regulation;
- national uniformity of regulation and administration of that regulation;
- 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;
- interfaces with related legislation to maximise efficiency in the administration of legislation regulating this area; and
- manner of supply by professionals of drugs, poisons and controlled substances.

Certain matters were excluded from the scope of the Review including legalisation of illicit drugs and harm minimisation strategies (e.g. needle exchange programs), professional prescribing rights, pharmacy ownership and the criteria for listing in the *Schedules*. The full terms of reference are listed in Attachment A1.

1.1.1 Conduct of the Review

The Review has been conducted by Ms Rhonda Galbally, Managing Director of the Australian International Health Institute, aided by a Steering Committee comprising representatives of the Commonwealth and all States and Territories. Consultation with stakeholders, including industry, health professionals, government and consumers has been undertaken, in three separate phases, before and after the release of an Options Paper in February 2000, and following the release of a draft report in September 2000.

Ms Galbally also met with stakeholders in all States and Territories. Details of those consulted are included in Attachment A2.

1.2 Issues considered by the Review

Consistent with its Terms of Reference, the Review considered not only the issues related to competition policy of the regulatory controls but also the efficiency of the regulatory controls.

1.2.1 Issues related to National Competition Policy

The Review considered the following questions:

- What are the objectives of the legislative controls? What is the nature and the magnitude of the health problems that the controls seek to address?
- Do the controls restrict competition? What is the likely effect of any restrictions on competition and on the economy in general?
- If yes, are there other non-regulatory ways to achieve the objectives of the legislation?
- What are, on balance, the costs and benefits and overall effects of drugs, poisons and controlled substances legislation and alternative less restrictive approaches?
- Is it possible to reduce the level of controls, without compromising achievement of the objectives and, in doing so, increase competition?

1.2.2 Efficiency of the regulatory controls

In considering the efficiency of the regulatory controls, the Review noted that costs are increased and competitiveness undermined by:

- variations in legislation across jurisdictions which adds to the complexity of the legislative requirements making compliance more difficult and costly;
- inefficiencies which arise at the interfaces with related legislation and which increase complexity and the costs of compliance; and
- administrative inefficiency.

The Review identified these issues as having the most significant impact on costs, particularly for industry. These costs are passed on to consumers and government (for subsidised medicine) and, at the margins, some businesses find that these costs undermine their viability and so do not enter the market.

Following on from this, the Review asked, in relation to those regulatory requirements that are considered essential: are there ways of improving the efficiency of their operation? If yes, do these ways involve:

- making changes to the relationship between the processes and arrangements for decisions on drugs and poisons scheduling and drugs and poisons regulations (General Issues and Specific Issue No. 1);

- developing national uniformity in the legislation and in administering the legislative controls; (General Issues and Specific Issue No. 2);
- revising the number and range of *Schedules* (Specific Issue No. 3);
- aligning the interface between specific drugs, poisons and controlled substances legislation with related legislation (General Issues and Specific Issue No. 4); and
- the manner of supply by professionals of drugs, poisons and controlled substances (Specific Issue No. 5).

1.3 Structure of the Report

Because there is considerable overlap between the issues covered by the Review's General and Specific Terms of Reference, the Report does not attempt to follow them in the sequence in which they appear. However, the Report indicates, as appropriate, which General and Specific Terms of Reference are covered under each issue discussed. For ease of reference, the General and Specific Review Issues have been numbered in Attachment A1 (Terms of Reference) and the numbers have been used throughout the Report to identify where these issues are addressed. In addition, a summary of where each of the General and Specific Terms of Reference are discussed in the Report is in Attachment A3.

For ease of discussion and clarity, the Report has been presented in two parts. Part A brings together the broad analysis and recommendations under the following structure:

- ***Overview of the present legislative framework –*** describes the framework in which the legislation under review operates, including related legislation, associated bodies and other relevant matters.
- ***Nature and effect of the restriction –*** identifies the objectives of the legislative framework and discusses the key issues from a competition policy perspective.
- ***Schedules of drugs and poisons and related controls –*** discusses the drugs and poisons scheduling system that underpins the legislative controls as well as the scheduling processes and associated administrative issues.
- ***The appropriate level of regulatory controls*** – each area of control covered by the drugs, poisons and controlled substances legislation under review that affect competition have been examined against competition policy principles.
- ***Efficiency of the legislative framework –*** brings together the issues where improved efficiency could reduce costs and improve competitiveness. These areas are:
  - *Uniformity in the legislative framework* – identifies the problems caused by lack of uniformity between jurisdictions in their drugs, poisons and controlled substances legislation. This chapter also proposes options to reduce the costs caused by the present variations in legislative controls.
  - *Interface between specific and related legislation* – looks at various related legislation and examines the nature of that relationship and how efficiency can be improved by reducing duplication and overlap and by improved integration of the legislation.

- ***Administrative arrangements*** – proposes ways to improve administrative arrangements related to drugs, poisons and controlled substances legislation and, in doing so, reduce costs to industry and government.

The Appendixes to Part A include the Terms of Reference and details of all the individuals and groups consulted during the review together with a summary of their views.

Part B of the Report (published separately) provides supplementary information and a more detailed analysis to support the broad analysis in Part A. For ease of reference, the analysis in Part A identifies the relevant sections of Part B that expand on the issue. It should be noted that Section 2 of Part B provides general information on the harms the legislation is intended to prevent and so is applicable to all the issues addressed in both Part A and Part B.

More specifically, Part B provides:

- More detailed introductory material.
- Details of the harms the legislative controls seek to address.
- A general analysis of the implications for competition policy of the controls, including consideration of the broad range of possible alternatives.
- The rationale and evidence underpinning the analysis in Part A against the five steps of National Competition Policy for each control – the various alternatives discussed in Part A are considered in detail against each control. These analyses are based on the submissions received and research the Review undertook.
- The options for improving efficiency. These include a detailed examination of the possible alternatives for achieving uniformity and consideration of their appropriateness in the context of drugs, poisons and controlled substances legislation.
- Details of other matters the Review considered as a result of submissions received. In many cases, submissions raised matters that were outside the Review's Terms of Reference.

The Appendixes to Part B provide complementary information and an outline of the measures needed to implement the recommendations.

1.3.1 Terminology

Throughout the Report, the schedules and appendixes of the *Standard for the Uniform Scheduling of Drugs and Poisons* (**SUSDP**) have been used as a single point of reference. The schedule and appendix numbers in State and Territory legislation may be different to those in the SUSDP, or the controls may be implemented by a different mechanism. Where relevant to the discussion, the State or Territory schedule or appendix number, or implementation mechanism is explicitly mentioned.

When discussing **information** for consumers, consumer information or informed consumers, these terms are intended to include not only the availability of information necessary for the effective and safe use of medicines and poisons, but also the consumer's access to, and understanding of the information.

The terms **drugs**, **poisons** and **controlled substances** cause some confusion for stakeholders and are seen as inappropriate or misleading by others. Strictly all these substances can be poisonous, depending on the amount used. Drugs are often perceived to be illicit substances, such as heroin or marijuana. Consequently, the Review has preferred generally to use of the terms **medicines** and **poisons**, with controlled substances being a sub-set of medicines.

While the SUSDP lists **substances** the scheduling process recognises that the level of risk of a **product** containing that substance will vary, depending on a range of factors. These product differences are recognised in a generic way in the schedules and cover product characteristics such as strength, formulation, proposed use, packaging and labelling. These factors are also considered when medicines and agricultural chemicals are evaluated as required under the *Therapeutic Goods Act 1989* or the *Agricultural and Veterinary Chemicals Code Act 1994.*

Other terminology and abbreviations are listed in the Glossary.

CHAPTER 2 OVERVIEW OF THE PRESENT LEGISLATIVE FRAMEWORK

Terms of reference addressed: General Issue 5; Specific Issues 2 and 4.

2.1 Introduction

The legislation nominated for this Review operates in a complex framework of Commonwealth, State and Territory legislation that provides a suite of controls to provide for the safe and efficacious use of a range of potentially poisonous substances in the community.

The legislative controls contained in State and Territory drugs, poisons and controlled substances legislation operate to restrict supply: who may supply them, to whom they can be supplied and under what conditions. States and Territories also have professional practice legislation that imposes certain requirements on how health professionals deal with drugs, poisons and controlled substances. The effectiveness of drugs, poisons and controlled substances legislation is closely linked to the effectiveness of professional regulation.

The controls contained in State and Territory drugs, poisons and controlled substances legislation are linked to controls contained in Commonwealth legislation (the *Therapeutic Goods Act 1989* and the *Agricultural and Veterinary Chemicals Code Act 1994).* These Acts control which medicines and agvet[3] chemical products may be supplied in the Australian market and how they are to be supplied. The Review noted however, that there are no similar Commonwealth controls on the supply of household chemical products to the Australian market (see 2.4 below).

While the distinction in the focus of the controls imposed at Commonwealth level and those imposed at State and Territory level is not clear cut, for the purposes of this Report:

- the Commonwealth legislation can be characterised as imposing restrictions relating to the end-use safety, quality and efficacy of medicinal products (human and animal) and agvet chemical products permitted to be supplied in Australia; whereas
- State and Territory legislation can be seen to be more concerned with restrictions intended to prevent, or reduce unsafe or harmful use of medicines and agvet chemicals throughout the supply chain and use in the community, and with all aspects of the safety of household poisons.

Thus, the emphasis in Commonwealth controls is primarily on safety of the product, while at State and Territory level the emphasis is on substance-specific measures to ensure the safe use of the substances contained in products. The Commonwealth's power to impose control is limited by the Constitution. The relevant Commonwealth

[3] agvet refers broadly to all agricultural and veterinary products

powers relate to 'interstate trade', 'corporations', 'pharmaceutical benefits' and 'external affairs'.[4]

2.2 State and Territory drugs, poisons and controlled substances legislation

State and Territory drugs, poisons and controlled substances legislation imposes a number of controls on access, administration and business conduct. Generally these flow from the *Schedule* in which a substance is included. In addition to those regulatory controls that flow directly from the *Schedules* and the associated appendixes, each State and Territory has a series of other controls on drugs, poisons and controlled substances. These include such matters as administration of medicines, manufacture of medicines, and treatment of addiction (in controlled substances legislation).

The legislative instruments the jurisdictions use to give effect to regulatory controls, vary considerably as does the scope and detail of the particular controls.

2.3 Registration of medicines and agricultural and veterinary products

Products for human therapeutic use must be entered in the Australian Register of Therapeutic Goods (ARTG) before being supplied in Australia. The Commonwealth, under the *Therapeutic Goods Act 1989*, established the requirements for entry in the ARTG and the processes to be followed and the Act is administered by the Therapeutic Goods Administration (TGA). Also, the Commonwealth *Agricultural and Veterinary Chemical Code Act 1994* requires agricultural and veterinary products to be included on the National Chemical Register Information System before being supplied in Australia. The National Registration Authority for Agricultural and Veterinary Chemicals (NRA) is responsible for evaluating agricultural and veterinary chemical products under this Act.

2.4 The National Industrial Chemicals Notification and Assessment Scheme

New chemicals (i.e. those not currently used or in products in Australia) must be assessed for safety under the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and listed in the Australian Inventory of Chemical Substances before being supplied in Australia. The assessment is of the chemical used, not of the products in which it is contained. The National Industrial Chemicals Notification and Assessment Scheme also has a program for reviewing the safety of existing chemicals. These chemicals may be used in either industrial products or in household products. When used in household products the substance is subject to scheduling controls.

[4] Australian Constitution, sections 51(i), (xx), (xx iii A) and (xxix) respectively.

2.5 Scheduling of drugs, poisons and controlled substances

The scheduling of new substances (i.e. those not currently included in products on the Australian market or not already scheduled) takes place subsequent to the product's (medicines and agvet products) or the substance's (household chemicals) evaluation or assessment. The National Drugs and Poisons Schedule Committee (NDPSC) determines the classification, and thus the appropriate *Schedule*, of a substance[5] for inclusion in the SUSDP. In making its decision the NDPSC takes into account information referred to it by the evaluating agency. This process can delay a product coming to the market or, if it is marketed before the scheduling decision, may require changes to the labelling [6] and packaging shortly after entering the market or even, in some cases, restrictions on access.

In scheduling a substance, the intrinsic hazard (toxicity) is but one of the factors considered. Other criteria include the:

- purpose of use;
- potential for abuse;
- safety in use; and
- need for the substance.

The process for determining the SUSDP *Schedule* is set out in the Commonwealth *Therapeutic Goods Act 1989* and associated Regulations. Specific provision is made for consultation with stakeholders as part of the process.

NDPSC decisions require support of the majority of jurisdictions. NDPSC decisions generally have no effect and do not attract controls until they are included in State and Territory legislation. While jurisdictions generally adopt the SUSDP *Schedule*, some jurisdictions have chosen, in a few cases, not to do so.

The manner in which the NDPSC scheduling decisions are adopted into State and Territory laws also varies. In most jurisdictions they are adopted automatically by reference (unless action is taken not to accept a specific scheduling decision) while other jurisdictions require specific action, such as gazettal of the decisions, before they can come into force.

The *Schedules* may be adopted into drugs and poisons legislation (variously named by the jurisdictions) or controlled substances legislation (also variously named by the jurisdictions).[7] There is considerable variation in the extent to which the appendixes to the SUSDP are adopted and, while State and Territory legislation may include similar provisions, the extent to which these reflect the SUSDP control level is much more variable than for the *Schedules.*

[5] Generally, medicines are included in *Schedule 2*, *3*, *4* and *8* while other poisons are included in *Schedule 5*, *6* and *7*. *Schedule 9* covers prohibited substances.

[6] These labelling changes relate particularly to the Signal Heading which designates the Schedule of the product.

[7] See the list of legislation nominated to be reviewed under the Terms of Reference at Attachment A1.

The restrictions on the way household chemical products are supplied, which have no national registration scheme, are also determined by the *Schedule* in which they are included.

2.5.1 The Standard for the Uniform Scheduling of Drugs and Poisons

The *Standard for the Uniform Scheduling of Drugs and Poisons* (SUSDP) sets out the *Schedules* that the NDPSC has decided should apply to different substances. There are nine *Schedules*, although currently *Schedule 1* is not used. The SUSDP also includes a number of provisions (e.g. labelling, packaging and advertising) that relate to the level of control intended to apply to the *scheduled* substances. The SUSDP appendixes supplement the *Schedules* by setting out additional controls, and qualifications and exemptions that should apply to some substances. These controls relate primarily to point of sale and include:

- packaging;
- labelling (warnings, first aid instructions);
- to whom a product may be sold and under what conditions; and
- special controls for some substances, including prohibition on their supply.

The SUSDP covers controls on advertising in Part 3 and Appendix H.

The extent to which, and the way in which, jurisdictions adopt these additional provisions also varies considerably. For example, under paragraph 70 of the SUSDP, wholesalers and persons otherwise licensed or authorised are exempt from a requirement for prescribed professional qualifications. Under State and Territory drugs, poisons and controlled substances legislation, company representatives supplying samples to clinicians are required to be licensed in one jurisdiction, are restricted in the amount of each product they can carry and, in another, are prohibited from carrying any samples for prospective supply.[8]

2.5.2 Re-scheduling of drugs, poisons and controlled substances

Re-scheduling applications are handled by the NDPSC and do not involve the product registration process. These include references from State and Territory health authorities where a particular problem is identified, requests from industry marketing a product, or requests from professional organisations in response to an identified problem. They may also, on occasion, be initiated by the NDPSC where there is a perceived need to maintain consistency of scheduling of comparable substances. The evaluating agency (TGA or NRA) may refer questions of re-scheduling to the NDPSC where, in evaluating a product, the agency considers that the current scheduling should be reviewed. For example, the agency may consider such a review is required because of a significant change to the strength of the scheduled substance in a

[8] Prospective supply refers to the representative carrying stock of clinical samples, without having orders for those samples but with the expectation that the health professional will accept a supply of stock after discussion with the company representative.

product, the way in which a product is presented (e.g. different packaging), or the composition of the product (e.g. the scheduled substances is in combination with another substance which may increase or decrease the acute or chronic toxicity of the substance). If the matter is not referred to the NDPSC in such a case, the product sponsor may make a subsequent application for re-scheduling. This is most likely to occur where a sponsor of a product considers the risk profile of the substance has been lowered.

2.6 National Coordinating Committee on Therapeutic Goods

The Australian Health Ministers' Advisory Committee (AHMAC) established the National Coordinating Committee on Therapeutic Goods (NCCTG) to nationally coordinate regulation of therapeutic goods. Amendments to the Therapeutic Goods Act in 1998 provided for the NCCTG to have a policy-setting role in relation to operating the NDPSC. To accommodate this expanded role, AHMAC, of which NCCTG is a sub-committee, expanded its role to encompass poisons as well as therapeutic goods. To date, the Committee has concentrated its efforts, in relation to poisons, in coordinating administrative matters arising from the NDSPC and providing broad policy direction to the NDPSC on scheduling matters. For example, the NCCTG has issued guidelines for use by the NDPSC Working Party on Trans-Tasman Harmonisation. This working party has been considering, on a case-by-case basis, whether the scheduling of substances, which are currently scheduled differently in Australia and New Zealand, can be harmonised. Its recommendations are then considered by the NDPSC following its normal processes.

2.7 Professional practice legislation

As highlighted earlier, the other related legislation, which is particularly relevant in this area, is the State and Territory legislation relating to professional practice. The restrictions in drugs, poisons and controlled substances legislation are put in place on the assumption that health professionals will exercise their skills and knowledge to redress consumers' information deficit thereby enabling the consumer to use the products safely and effectively. If this professional input does not occur, the effectiveness of the controls is undermined. The standards that health professionals are expected to meet are managed through the legislation regulating professional practice (e.g. medical practitioner registration legislation, pharmacy acts, veterinarian registration legislation dental registration acts etc.) and the relevant professional practice boards established in each jurisdiction.

2.8 Occupational health and safety legislation

Occupational health and safety legislation in States and Territories also impacts on drugs, poisons and controlled substances legislation. In this case, lack of definitional clarity leads to overlap and uncertainty as to which legislative controls should be applied in relation to matters such as labelling requirements.

2.9 Other related legislation

Other legislation, such as that regulating the transport of dangerous goods and the activities of stock and station agents, is also related to the legislation under review and operates to regulate the behaviour of those involved in this activity. Such legislation also overlaps, 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).

General legislation, such as the Commonwealth *Trade Practices Act 1974* and State and Territory consumer protection legislation, is also relevant.

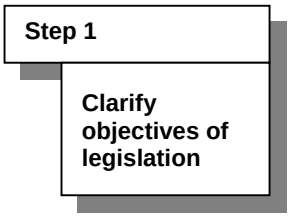
Other legislative controls, such as food acts, with their associated standards, must also be considered as they play a role in the framework of public health protection in this area. For example, the food standards set out the amount of a particular substance, such as selenium that can be included in a food product. Drugs poisons and controlled substances legislation sets out the level of access to products containing different amounts of a substance (e.g. selenium) or to be taken in different doses,

The Review also noted that a number of other legislative instruments rely on either the SUSDP or State and Territory drugs, poisons and controlled substances legislation to identify the scope of the requirements under those instruments (e.g. the provisions applying the goods and services tax to medicines). If the recommendations included in this Report are implemented, amendments may also be needed to these legislative instruments.

CHAPTER 3 THE NATURE AND EFFECTS OF THE RESTRICTIONS

3.1 Objectives of the controls

Terms of reference addressed: General Issue 1.
Supporting data and analysis for issues discussed in this Chapter are included in Part B Section 3.1.



The legislation that restricts access to and use of drugs, poisons and controlled substances may be seen as reflecting judgements being made by successive governments, at both the State and Territory and Commonwealth levels, that it was inappropriate to rely on a free market for these products. The controls may be seen as a response to perceived problems of:

- *information asymmetry* – where sellers have greater information and knowledge than buyers;
- *externalities* – where accidental or deliberate misuse of these substances could result in harm to individuals and the wider community; and
- *merit/demerit goods* – where individuals may not make judgements in their own best interest, e.g. on the use of narcotics.

Underlying the controls is an assumption that not only are consumers not fully informed about the consequences of their choices but that often it would be difficult for them to independently gain an adequate knowledge and understanding of:

- the substances and products needed to treat particular conditions;
- the risks associated with particular substances;
- the way in which products containing the substances need to be used safely and to achieve optimal health benefits;
- the potential interactions with other medicines or foods;
- contraindications with certain medical conditions; and
- poisonous substances that may be very dangerous if used inappropriately, whether intentionally or unintentionally.

Consumers' use of many substances covered by drugs, poisons and controlled substances legislation without the knowledge and understanding to enable safe and effective use could have serious and, in some cases, fatal consequences. Drugs, poisons and controlled substances legislation should contribute to the broader objectives of the overall framework aimed at protecting and promoting public health and safety by reducing:

- unintentional poisoning, of which most identified cases are acute poisonings in childhood;
- intentional poisoning, of which most cases are adult suicides or attempted suicides;

- medicinal misadventure (much of which is believed to be related to the misuse of prescription drugs, particularly in the elderly) and facilitating appropriate selection and effective use of medicines thereby contributing to the quality use of medicines; and
- dependence, abuse and diversion for abuse or manufacture of drugs of abuse.

1 ***Recommendation 1: Objectives of legislative framework***

That all Commonwealth, State and Territory governments agree that:

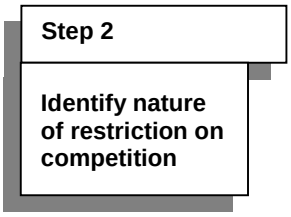
a) There are net benefits to the Australian community as a whole in having a comprehensive legislative framework that regulates drugs, poisons and controlled substances, the principal objectives of the legislation being to promote and protect public health and safety by preventing:

- accidental poisoning;
- deliberate poisoning;
- medicinal misadventures; and
- diversion for abuse or manufacture of substances of abuse.

b) All relevant Commonwealth and State and Territory legislation needs explicitly to incorporate these objectives and be effective, transparent, equitable and the controls the minimum necessary to achieve these objectives.

3.2 The nature of the controls

Terms of reference addressed: General Issues 2 and 7.
Supporting data and analysis for issues discussed in this Chapter are included in Part B Section 3.2 and 3.3.



Drugs, poisons and controlled substances legislation imposes controls in two broad areas: limitation on access to these products, and the way in which the products are marketed.

The *Schedules* provide the basis for the major legislative control on the level of access and the manner in which drugs and poisons must be supplied. These restrictions impact on both providers and consumers. The restrictions that are based on the *Schedule* in which a substance is included, generally specify who may sell or supply, who may have access (and in some cases possess or administer), and the amount and form of goods that can be supplied. Licensing schemes restrict access, at the manufacturing and wholesale levels, to those individuals who have demonstrated an adequate level of ability and security to deal with scheduled substances. Storage and handling controls are intended to complement and support the suite of controls on access to scheduled substances and, at the pre-retail level, are mainly directed at minimising diversion and assisting in quality assurance.

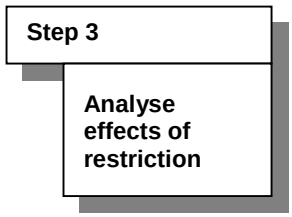
The controls that affect the way in which a product is marketed, support and complement the restrictions on access. Many of these controls are also based on the schedule in which a substance is included and include restrictions on:

- which products may be advertised, for what conditions and in what way;

- the labelling, packaging and manufacture of the products;
- the way in which products are supplied, stored, displayed and offered for supply; and
- the records which must be kept and reports provided on the supply of the products.

3.3 The effects of the controls on competition and the economy

Terms of reference addressed: General Issues 2 and 7.
Supporting data and analysis for issues discussed in this Chapter are included in Part B Section 3.2 and 3.3.



The Review found that Australia's drugs, poisons and controlled substances legislation imposes considerable barriers to competition both in terms of who can participate in the market (**market access**) and also the manner in which they can participate (**business conduct**).

3.3.1 Market access

The market access controls limit who can participate in the market by:

- restricting consumer access to certain substances, i.e. certain substances can only be obtained from a pharmacy. This access may be further restricted by the need to obtain a prescription from an authorised prescriber; and
- placing barriers on access to the market, i.e. only those who hold specified qualifications, possess certain attributes or meet appropriate standards of probity are permitted to operate.

For medicines, these restrictions prevent anyone, other than a pharmacist, doctor, veterinarian or a licensed poison seller, from entering the market. By reducing competition from others, these restrictions can be expected to add to costs. These costs are likely to be passed on to consumers through higher product prices. Further, they add to the consumer's costs of obtaining the product (i.e. through the need to attend a pharmacy and/or doctor) and to government costs where health practitioner visits are subsidised.

Schemes for licensing manufacturers, wholesalers and distributors provide an authority to operate a business and thus are used to control the entry of firms (and some individuals) into the market. While the licensing schemes do not provide any numerical restrictions on who can participate in the market, they do require operators to have specific knowledge, skills and character to deal with medicines and poisons safely and effectively. They aim to prevent traders, without these attributes, gaining access to the market or, in some cases, provide for removing 'problem traders' from the market.

3.3.2 Business conduct

Drugs, poisons and controlled substances legislation also imposes a number of controls on the business conduct of those who do enter the market. As described above, these controls cover such matters as advertising, labelling and packaging as well as manufacturing, storing and handling products. For some substances there are also requirements for recording and reporting.

At a retail level, the controls affect the level of access the public has to the products. These controls limit the options available to various parties in the supply chain, and so restrict the degree of competitive freedom that can be pursued. Some of the restrictions impose requirements that seek to redress the information asymmetry between suppliers and consumers, for example, requirements for labels to include warnings and first aid instructions. Other restrictions relate to physical requirements associated with particular substances. For example, certain products need to be packaged in child-resistant packaging in order to prevent accidental poisoning. There are also process requirements, such as the need to report supply of narcotic medicines, which are intended to prevent diversion for abuse.

It is difficult to ascertain the incremental burden of SUSDP-mandated labelling versus the other costs of labelling except where the SUSDP imposes relabelling costs (e.g. because a product is rescheduled or an additional warning is imposed). These costs impact on manufactures and importers. The restrictions are generally quite prescriptive (e.g. the size of the printing to be used on a label, where a product should be stored, the nature of the records to be kept and the height at which some products must be displayed for sale). Such costs may limit the market for these products, by increasing the price to consumers.

The restrictions on business conduct add to the costs for industry and may, especially for some smaller companies, be such as to prevent market entry to some where the cost of compliance makes it uneconomic for a firm to operate in that market.

The need for systematic data collection

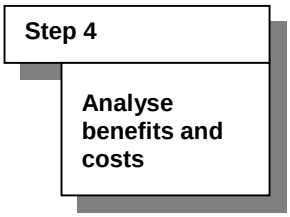
The task of the Review in establishing the cost-effectiveness of the individual controls in achieving the objectives of the legislation, would have been considerably easier if data had been systematically collected. The difficulty for the Review in assessing the available data was not only that it was often not readily accessible but that, in many cases, comparisons could not be drawn because of the various ways in which it was collected. Further, the lack of a comprehensive strategy for collecting data in this area meant that, in most cases, it was not possible to relate the effect of a particular control to changes in the costs and benefits of that control.

2 ***Recommendation 2: On-going evaluation of controls***

Commonwealth, State and Territory governments allocate public health funding to ongoing research, including data collection to evaluate and monitor the effectiveness of the legislative controls in achieving the objectives of drugs, poisons and controlled substances legislation with a view to continually improving the cost effectiveness of those regulatory controls.

3.4 Benefits of the controls

Terms of reference addressed: General Issue 3 and 9.
Supporting data and analysis for issues discussed in this Chapter are included in Part B Section 2 and 3.4.



The fact that the legislative controls are principally designed to avoid a range of negative events taking place, makes it very difficult to quantify the benefits of the controls – to do so would require a reliable basis for estimating the number of negative events that would have taken place in the absence of the legislative controls. As a consequence, the Review was unable to attach monetary values to the costs to the community that would be incurred if such negative events had taken place.

In terms of the threat to the health of individuals, or groups of individuals, the problems the controls are intended to redress include unintentional poisoning, intentional poisoning, medicinal misadventure, abuse and diversion for abuse. The costs resulting from these harms, even with the current level of control are significant. So, for example, the Review noted:

- the costs resulting from poisoning and medicinal misadventure are estimated at $600 million annually (Moller, 1998);
- it is estimated that as many as 40 000 hospital admissions annually that are related to medicinal misadventures are avoidable (Roughead, 1999); and
- the 1995 National Health Survey identified that over 3 per cent of those surveyed had recently used medicines for non-medical purposes (Australian Bureau of Statistics, 1997).

Data to link the effectiveness of particular controls to the benefits are generally not available and, in many cases, the Review considered that it is likely to be the combination of measures, rather than a single measure that provides the benefit. Nonetheless the Review has noted research that demonstrates that:

- requiring products to be packaged in child resistant packaging reduced the level of accidental poisoning (Routley et al., 1996);
- restricting the level of access reduced the level of deliberate poisoning (Whitlock 1975);
- reducing the level of access, by restricting their sale to pharmacies, or prescription only, of substances that were previously widely available significantly reduced the level of medicinal misadventure (Duggin, 1996; Gleeson, 1988; Nanra, 1993; Lee and Oldenburg, 1993);
- reducing access by limiting the pack size available from different suppliers reduced the level of poisoning (Prince et al., 2000; Turvil et al., 2000); and
- restrictions on the presentation of medicines makes the substances less attractive to children leading to fewer poisonings (anecdotal).

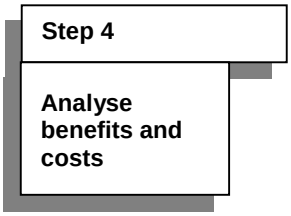
These reductions in harm benefit the community through reduced hospital and medical costs.

While the Review found the above research helpful, it was hampered in its attempts to quantify the costs and benefits of the controls on drugs, poisons and controlled substances by the lack of consistent or comparable databases which made assessment of the costs and benefits difficult. Despite the limitations on the available data, the Review considered that, without adequate controls, the costs to the community (increased poisoning, medicinal misadventure and abuse and associated hospital, medical and social costs) would be considerably higher than is currently the case. This view is supported by those with whom the Review consulted: all supported the need for control over access to the way in which drugs, poisons and controlled substances are supplied, although some questioned the net benefit to the community as a whole of some specific controls.

The Review considered it highly desirable that funds be committed to establish a database which would bring together the various and disparate data currently available, improve the quality of that data with a view to enabling analysis of the data in a way that better identified the effectiveness of particular controls and of other inititiaves to reduce the level of harm related to the use or misuse of drugs, poisons and controlled substances.

3.5 Cost of the controls

Terms of reference addressed: General Issue 7 and 9.
Supporting data and analysis for issues discussed in this Chapter are included in Part B Section 3.4.



As discussed above, the controls imposed by drugs, poisons and controlled substances legislation add to costs by restricting the way in which business can operate or restricting market access. In general, the costs flowing from the controls include:

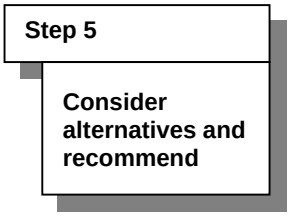
- costs to government in developing, administering and enforcing legislation;
- costs to industry due to the increased cost of market entry and business conduct;
- costs to consumers through denial of access to some products, and increased prices due to reduced competition; and
- costs to health professional through restrictions on business conduct.

There are several areas where the costs flowing from the regulation itself are going to significantly affect the cost of doing business. This may act as a deterrent to some, particularly small business. But even big business, e.g. supermarket chains, is blocked from entering some markets which may prevent the cost effectiveness being realised in the supply of products (see Chapter 5).

It has not been possible to definitively identify all the costs which flow from the controls, however, the Review has been provided with some detailed examples which serve to illustrate the nature and extent of the costs involved. While much of the data provided detail the costs arising from lack of uniformity, they also illustrate the costs of various levels of control.

3.6 Consideration of alternative approaches

Terms of reference addressed: General Issue 6.
Supporting data and analysis for issues discussed in this Chapter are included in Part B Section 3.5.



The Review considered the scope to remove the legislative controls that restrict access to drugs, poisons and controlled substances in Australia.

The Review formed the view that the potential for misuse and abuse of these products in a totally unregulated market was considerable and the resulting hospital, medical and social costs of such misuse and abuse too great for individuals and the community to bear. On this basis, the costs of having no regulation would significantly outweigh the potential benefits to individuals and industry.

By way of illustration, in considering packaging controls, the Review formed the view that market forces alone would be insufficient to ensure that these products were packaged and labelled in a way that would prevent poisoning, and facilitate safe and effective use. This could have serious or even fatal consequences, especially for children. Or, in the case of *Schedule 8* medicines, where the risk of dependence or abuse is very high, the Review considered that the benefits of the significant restrictions on access outweighed the costs.

The Review concluded that the costs of removing all regulation of the medicines and poisons market is such that it cannot be considered an appropriate alternative.

The Review also considered, as appropriate, a range of other alternatives against each control including:

- self-regulation;
- coregulation, including codes of practice;
- education and training;
- taxes;
- partial deregulation; and
- generic regulation, i.e. placing reliance on more general legislation such as consumer protection legislation.

After analysis, the Review found that in many instances these alternatives would not meet the objectives of the legislation. However, where the Review considered that the objectives of some areas of control could be achieved by less regulatory approaches, these have been recommended against those particular controls. As discussed above, the Review considered there was an urgent need for research that would enable better ongoing assessment of the cost effectiveness of particular controls.

CHAPTER 4 SCHEDULES OF DRUGS AND POISONS AND RELATED CONTROLS

Terms of reference addressed: General Issues 1, 2, 3, 5, 6, 7, 8, 9 and 10; Specific Issues 1, 2, 3, 4 and 5.
Supporting data and analysis for issues discussed in this chapter are included in Part B Sections 2 and 4.

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 Scheduling Committee (NDPSC). The controls described below on market access only come into operation when these NDPSC *Schedules* are adopted into State and Territory legislation.

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

For medicines

- *Schedule* 2 includes substances considered to be able to be used safely when available from a pharmacy where professional advice is available. These substances include analgesics (e.g. paracetamol) [10] and anti-fungals.
- *Schedule* 3 products require the supervision of a pharmacist in their supply to enable the product to be used safely and effectively. Substances covered 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 prescribing large quantities, prescribing for long-term treatment or in treating drug addiction. These substances include narcotics (e.g. morphine) and stimulants (e.g. methylphenidate).

The Review noted the recent Victorian legislation that provides for accreditation of traditional Chinese medicine practitioners and introduction of a *Schedule 1* to the Victorian *Drugs, Poisons and Controlled Substances Act 1981* and associated regulations, which designates the traditional Chinese medicines to which these accredited practitioners will have access. A similar approach may be appropriate for other herbal medicine modalities. The Review considered that, if an evaluation of the Victorian initiatives in relation to prescribing rights[11] for traditional Chinese medicine

[9] Some *Schedule 5* and *6* substances are also used in medicines.

[10] Small packs of analgesics are not restricted and may be purchased from supermarkets and other general outlets.

[11] Prescribing rights have specifically been excluded from consideration by this Review.

practitioners shows that this approach delivers a net benefit to the community as a whole, consideration should be given to similar systems for other complementary medicine modalities. Consideration should also be given to including an appropriate schedule in the SUSDP for adoption in all jurisdictions for traditional Chinese medicines and, as appropriate, for herbal and other complementary medicines.

Quality use of medicines

Implicit in the scheduling decisions related to medicines is an assumption that consumers alone cannot make informed judgements about what products to select and how to use the selected products safely and effectively. Interface with a suitably qualified professional is seen, on this basis, to be an essential prerequisite of the supply of the medicines covered by these *Schedules*.

Scheduling seeks to ensure, amongst other things, that use of these products is supported by adequate information to enable consumers to select, in the case of over-the-counter medicines, and use all medicines safely and effectively. Currently, this information can be 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).[12]

For poisons

- *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 or use. These poisons should be available only to specialised or authorised users who have the skills necessary to handle them safely. Special regulations restricting their availability, possession, storage or use may apply.

For *Schedule 5* and *6* substances, the major controls relate to the labelling and packaging for the substances. Apart from the signal heading, the labelling controls are largely substance or category-of-substance specific. For *Schedule 7*, restrictions to access apply in all jurisdictions.[13]

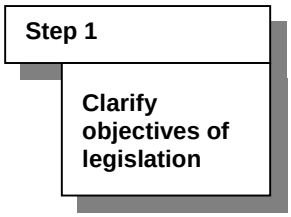
[12] The *Therapeutic Goods Act 1989* requires that CMIs be available for all *Schedule 4* and *8* medicines and some *Schedule 3* medicines.

[13] These controls may be included in drugs and poisons legislation or in agvet legislation.

The Appendixes

In addition to the *Schedules*, the SUSDP includes a number of Appendixes. These Appendixes fall into two broad categories: those imposing additional controls on supply of some scheduled substances (e.g. Appendixes E and F)[14] and those that are equivalent to the *Schedules* (e.g. Appendixes C and I).[15]

4.1 Objectives



The restrictions which flow from the scheduling, particularly those on access, are intended to reduce the level of poisoning, medicinal misadventure and diversion by:

- providing an appropriate level of expert intervention to redress the information asymmetry between industry and consumers which may lead to unsafe and ineffective use;
- providing supervision and processes to prevent diversion of substances for abuse or for the illicit manufacture of drugs of abuse; and
- other measures such as warning labels to redress the information asymmetry and packaging requirements to reduce the number and severity of poisonings.

Recommendation 3: Objectives of scheduled medicine controls

3

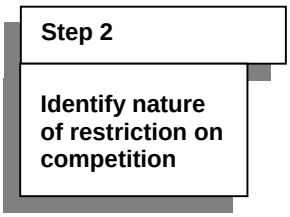
That all Commonwealth, State and Territory governments agree that legislation covering the supply of scheduled medicines should explicitly set out its objectives. These objectives are to ensure that:

- in the case of prescription medicines, the conditions from which consumers are suffering are diagnosed correctly and the most appropriate treatment prescribed;
- the consumers of prescription medicines have adequate information and understanding necessary to enable them to use medicines safely and effectively;
- in the case of over-the-counter medicines, 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
- use of the medicines will not lead to dependence or the medicines will not be diverted for abuse purposes or for the illicit manufacture of drugs of abuse.

[14] Appendix D imposes additional controls on some *Schedule 4* and *8* substances while Appendix F sets out the warning statements that should be included on the label of some scheduled substances.

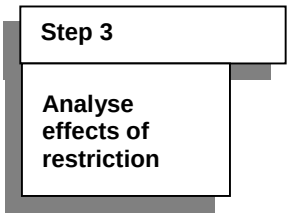
[15] Appendix C includes a list of substances that are totally prohibited but are not the illegal drugs associated with *Schedule 9*. Appendix I sets out the standards that apply to paints.

4.2 Nature of the current restrictions



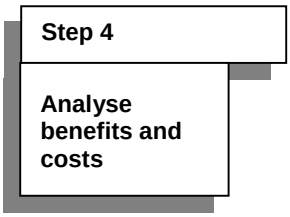
As discussed in Chapter 3, the major control which flows from the scheduling of a substance is the restriction on who may supply or administer the substance, to whom and under what circumstances. These restrictions are a significant impediment to competition. They also limit consumer access, making it more difficult and more costly (in time, convenience and money) for consumers to obtain products containing scheduled substances. Other restrictions, such as those applying to labelling, packaging storing and handling add to costs and may prevent some operators entering the market.

4.3 Effect of the current restrictions on competition and the economy



The controls on access flowing from the scheduling process place considerable restrictions on consumer choice. In addition, because only certain people can supply scheduled products, others are prevented from competing in the marketplace. Restrictions on market entry mean there is less competition, including in the area of price.

4.4 Costs and benefits of the restrictions



Terms of reference addressed: General Issues 2 and 7.
Supporting data and analysis for issues discussed in this Chapter are included in Part B Sections 2 and 4.2.

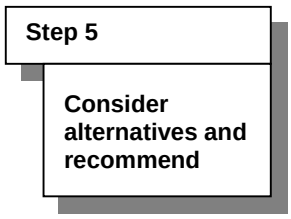
The Review noted that the controls which flow from the *Schedules* impose ***costs*** on INDUSTRY through reduced market entry and restrictions on business conduct. There are also ***costs*** for CONSUMERS because access is restricted and the restrictions on competition lead to higher prices. For GOVERNMENTS, in addition to the administrative costs which flow from the restrictions, there are also ***costs*** to subsidise doctor visits. Restrictions on business conduct also impose a ***cost*** on HEALTH PROFESSIONALS.

The key ***benefits*** for the COMMUNITY AS A WHOLE are that the costs arising from the harms from use or misuse are reduced because of the controls. These harms include accidental and deliberate poisoning, medicinal misadventure and abuse which lead to hospital, medical and social costs for governments and the consumer. The Review took the view that, without such restrictions there would be a significant level of serious and sometimes fatal consequences for the individual consumer and the community as a whole and that the level of diversion and abuse would increase considerably.

The Review noted that the extent to which the ***benefits*** to CONSUMERS of the restrictions on access to medicines are delivered relies heavily on the professional skills of those health professionals involved in supply to consumers.

In the case of *Schedule 7* poisons, there is a ***cost*** to INDUSTRY in that the supplier can only supply to those with the appropriate knowledge and training of the poisons seller. The ***benefit*** to the COMMUNITY is to restrict the use of these highly toxic substances to suitably trained persons who are trained to use them safely. A further benefit is to prevent the diversion of these substances for deliberate poisoning.

4.5 Alternatives to the current controls and their costs and benefits



The Review did consider whether removal of all regulation was an option, i.e. abandoning the scheduling system and its related controls. However, the Review considered that the scheduling of medicines and poisons plays such a critical role in avoiding problems of misuse and abuse of what are potentially very harmful substances that abandoning the scheduling controls would not deliver a net benefit to the community as a whole. The Review noted in this regard, that every comparable developed country has similar systems of controls. While not a reason to support retaining the controls the Review nonetheless felt this added weight to its view that there was a need for an appropriate system of controls.

The Review also considered a range of other, less regulatory, approaches including whether there was scope to remove the controls that mean consumers can only access scheduled products through contact with a suitably qualified professional. It would be possible, in theory, to provide sufficient information, e.g. through labelling and other product information to consumers so that would be able to select and use scheduled products safely and effectively.

The Review also considered whether it would be possible to reduce the level of control by reducing the number and range of schedules.[16] This issue is discussed in more detail below.

The Review concluded that, except for the lowest risk products, consumers could only acquire the information and understanding necessary to enable them to use the product safely and effectively through the intervention of an appropriate level of expertise and training. The health professionals, who control access to scheduled substances, are required to undergo years of specialised training in order to provide them with the necessary expertise to identify when the use of certain substances is appropriate and the way in which these substances can be most effectively and safely used.

The Review considered it unreasonable to expect consumers to acquire such expertise on the basis of general health information sources (e.g. books, Internet health pages and other media) or through more specific information sources such as product labelling, Consumer Medicine Information[17] or packaging inserts. This does not mean

[16] The Review is also required to consider the number and range of schedules under its Terms of Reference – Specific Issue 3.

[17] Consumer Medicine Information is required by the *Therapeutic Goods Act 1989* to be available for all *Schedule 4* and *Schedule 8* medicines and some *Schedule 3* medicines (See Chapter 5 for more detailed information).

that access to information to improve consumer understanding should be discouraged, rather it should be seen as supplementary to the information available from health professionals. However, the Review noted that information from some of these sources (especially the Internet and other media) is often inaccurate or incomplete and, as such, without professional advice, may pose a risk in itself by misleading the consumer. As noted previously, the toxicity of many of the scheduled substances is such that their improper use could have very serious, even fatal consequences thereby imposing hospital and medical ***costs*** on GOVERNMENTS and CONSUMERS.

The Review considered whether it would be possible to adopt a non-legislative approach to achieving the objectives of the scheduling system. For example, in theory, it would be possible to rely on a number of codes of practice to ensure access to particular substances was controlled and the associated conditions of supply (e.g. labelling and packaging) were put in place.

The Review did not consider, however, that such non-legislative approaches would be feasible in practice because of:

- the diverse number of organisations and individuals involved in the supply chain of drugs, poisons and controlled substances;
- the fact that the controls are essentially non-discretionary because of the serious problems that can occur as a result of inappropriate access to and use of these substances; and
- the lack of any appropriate body that could monitor and enforce compliance with a system of voluntary controls on drugs, poisons and controlled substances.

The Review concluded that, in general, there is a ***net benefit*** for the COMMUNITY AS A WHOLE in retaining many of the controls and in continuing the legislative basis of the controls. A legislative basis for the controls should ensure transparency and consistency in applying the controls.

The Review did consider whether the objectives could be achieved by reducing the number of schedules and this is discussed below.[18] However, in relation to some of the specific controls which flow from the schedules, the Review has recommended less regulatory approaches in those instances where no net benefit to the community as a whole could be demonstrated. These are discussed Chapter 5.

4.6 Adoption of the Schedules by jurisdictions

Terms of reference addressed: General Issue 4, Special Issue 2.
Supporting data and analysis for issues discussed in this Chapter are included in Part B Section 4 and 6.

As indicated previously, while jurisdictions largely adopt the SUSDP *Schedules* and there is a high level of consistency, there are some variations between jurisdictions that affect the controls that flow from the *Schedule* in which a particular substance appears in State and Territory legislation. These variations may impose ***costs*** to INDUSTRY. So, for example, a company may be required to label a product *Schedule 2*

[18] The Review is also required, by its Terms of Reference Specific Issue 3, to consider the number of schedules.

in one jurisdiction and *Schedule 3* in another. Quite apart from the cost of separate labels, there are also management costs in ensuring the correctly labelled product goes to the correct jurisdiction.

The Review also noted that the way in which the *Schedules* are adopted varies across jurisdictions. These variations impact on the ***costs*** to INDUSTRY where they result in differences in the time of adoption across jurisdictions with consequential impact on the ***costs*** to CONSUMERS where this results in delays in access to a product..

The Review could not identify any public health or other ***benefits*** to the COMMUNITY resulting from the variations in the extent to which, and the way in which, the *Schedules* are adopted by the different jurisdictions. The Review noted comments from stakeholders that the SUSDP was confusing and needs to be better indexed. The Review considered this a valuable comment which should be taken into account by those involved in preparing the scheduling documentation.

In order to minimise unnecessary costs to industry and consumers, the Review considered it highly desirable for the *Schedules* to be adopted uniformly by reference by all jurisdictions.

Recommendation 4: Adoption by jurisdictions of the SUSDP Schedules

4

That all Commonwealth, State and Territory governments agree that, in order to minimise unnecessary costs to industry and consumers, all States and Territories should adopt all the scheduling decisions covered in the SUSDP by reference and in accordance with timelines developed by the Schedule Committees.

4.7 The number of Schedules covering medicines

Terms of reference addressed: Special Issue 3.
Supporting data and analysis for issues discussed in this Chapter are included in Part B Section 4.3.

The Review is also required specifically by its Terms of Reference to consider the number and range of *Schedules*. In doing this, the Review considered whether the objectives of the legislation could be achieved by varying the number of schedules.

4.7.1 Prescription medicines (Schedules 4 and 8)

Both *Schedule 4* and *8* require a prescription before being supplied by a pharmacy. The objectives underlying this restriction are to ensure that:

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

The Review considered there would be ***benefits*** for the COMMUNITY AS WHOLE in making explicit reference, in relevant legislation, to the objectives underlying the controls on prescription medicines.

The restrictions on access for *Schedule 4* and *8* medicines significantly limit the opportunities for competition by restricting market entry. This, in turn, generally leads to increased ***costs*** for INDUSTRY, CONSUMERS and GOVERNMENT (for subsided medicine and medicines where a doctor's visit is required to obtain a prescription).

In the case of *Schedule 4* medicines, the conditions being treated with the substances in this *Schedule* are generally serious and require diagnosis by a qualified medical practitioner, veterinarian or other authorised health practitioner. These practitioners also have the expertise to determine the appropriate treatment for the diagnosed condition. Further, the substances in *Schedule 4* are likely to be toxic if used incorrectly and, in some cases may cause dependence or be abused.

The Review considered that the ***costs*** to INDUSTRY and CONSUMERS of maintaining the *Schedule 4* restriction on access is justified by the ***benefit*** to the individual CONSUMER and to the GOVERNMENT (reduced hospital and medical costs) when the significant information asymmetry between consumers and industry is redressed. The Review considered that this information asymmetry could only be redressed by the intervention of a suitably qualified health professional.

For *Schedule 8* substances, the risk of dependence and abuse are very high and the conditions being treated serious, and often life threatening. There are ***benefits*** to the COMMUNITY AS A WHOLE in maintaining *Schedule 8* and its associated controls, which are in addition to those provided for *Schedule 4* substances. While the restrictions do impose additional ***costs*** on INDUSTRY by limiting market access and on CONSUMERS by reducing their access to these products, there are additional ***benefits*** to the CONSUMER and the COMMUNITY because diversion for abuse and medically-induced dependency, with the associated medical hospital and social costs, are reduced. While the Review has identified some areas where the weight of the restrictions could be eased (e.g. reporting), or more efficient (e.g. duplication between jurisdictions and Commonwealth), the Review was not persuaded that there would be ***a net community benefit*** from any significant change to these controls.

Stakeholders do not question the need to provide this level of protection for certain medicines, nor do they regard the controls as anything but necessary. They see that the ***benefits*** to CONSUMER and GOVERNMENT (reduced hospital, medical and social costs) outweighs the ***costs*** to INDUSTRY (e.g. reduced market access), consumers (reduced access) and government (for subsidised doctor visits). The Review concurs with this view.

However, a less regulatory mechanism for some *Schedule 8* substances with special safety problems, could be provided by including these substances in both *Schedule 4* and Appendix D instead of using *Schedule 8*, with its fuller controls and restrictions. The Review noted that New South Wales in particular has used this approach (using *Schedule 4D*) for a number of substances, without evidence that the level of harm is greater (more dependence, abuse or diversion) than in jurisdictions with greater controls. It may be easier for the States and Territories to adopt Appendix D if the NDPSC reviewed the way in which it is structured.

4.7.2 Over-the-counter medicines (Schedules 2 and 3*)*

The task now for the Review is to determine whether there is a ***net benefit*** to the COMMUNITY AS A WHOLE in retaining one or both of the over-the-counter (OTC) schedules.

Schedule 2 covers substances are deemed to be able to be used safely when available from a pharmacy where professional advice is available. *Schedule 3* products are considered to require a pharmacist's intervention in their supply to enable the product to be used safely and effectively.

The underlying objectives of the controls on OTC medicines are:

- to ensure all consumers have adequate information and understanding to enable them to select and use 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.

The Review considered both these objectives to be sound.

It did note, however, that for both *Schedule 2* and *Schedule 3* medicines, access to a significant range of products is restricted in that only pharmacists are permitted to supply these products. Therefore, competition is reduced in that non-pharmacists cannot sell such products[19] which leads in turn, not only to higher prices, but also to an adverse impact on consumer choice and convenience.

Additional restrictions on the supply of *Schedule 3* medicines (the need for a pharmacist to be involved in the supply and, in some jurisdictions, the requirement that supply of some or all *Schedule 3* medicines be recorded) add further ***costs*** for CONSUMERS (more limited access and higher prices) and lead to additional constraints on competition for industry.

The Review also noted that the current restriction on supplying *Schedule 3* medicine is, in some cases, leading to further restrictions on competition. For example, it costs Internet or mail order pharmacies more to supply these medicines than it does for normal retail pharmacies. These additional ***costs*** arise because Internet and mail order suppliers generally require a prescription for these medicines so they can meet the requirement for pharmacist supervision for supply' as required by the *Schedule 3* medicine controls. This adds to CONSUMER ***costs*** to obtain a prescription and GOVERNMENT ***costs*** for subsidised doctor's visits.

The alternatives the Review considered were to:

- abolish OTC scheduling and rely on general legislation, such as consumer protection legislation, and the protection afforded by the common law duty of care. This option would see both *Schedule 2* and *3* abandoned and these medicines

[19] The exception to this restriction on who can supply these medicines is poisons licence holder which, in remote and rural areas, are permitted to sell some *Schedule 2* medicines. This is discussed further in Chapter 5.

available from a range of general outlets, including supermarkets and general stores;

- abolish *Schedule 2* in which case, the Review presumed, the criteria and level of professional intervention to redress the information asymmetry that currently applies to *Schedule 3* would not change;[20] and
- replace the current two *Schedules* with a single OTC *Schedule* in which case, criteria, including the level of professional intervention required for the new OTC *Schedule*, would need to be developed.

Abolishing both OTC schedules

Under this option, access to all products that are currently listed under *Schedule 2* and *3* would either become unrestricted or be included in *Schedule 4*.

For those products which were de-scheduled, the Review noted that harms occur in the use of OTC products in situations such as when:

- the product chosen is not suitable to treat the condition from which the person is suffering;
- a consumer does not fully appreciate the seriousness of potential side effects of the medicine (e.g. where the medicine may cause drowsiness);
- used in combination with other medicines – particularly prescription medicines;
- the person has a health condition that may make the use of the OTC medicine potentially harmful to his or her health;
- overuse of the product – in terms of the quantity taken or the duration of use, could lead to dependence or other health problems; and
- they are treated like ordinary domestic items leading to casual use and unsafe storage.

Many consumers would not have the knowledge and understanding to avoid these sorts of problems. There are ***benefits*** to CONSUMERS and the COMMUNITY AS A WHOLE in ensuring that the supply of OTC products is done under the supervision of a suitably qualified health professional. This professional supervision is built into the cost structure for the supply of these products.

In this context, the Review found it particularly relevant that a recently published United Kingdom study has demonstrated the benefits of restricting access to paracetamol in terms of reduced liver damage caused by overuse of this substance (Prince, 2000; Turvill, 2000). The United Kingdom had, until 1998, placed no restrictions on consumer access to paracetamol products – consumers could freely buy large packs of such products from supermarkets and a number of other outlets. In 1998, restrictions were introduced on pack sizes available on an unrestricted basis. These restrictions in turn led to a significant decrease in the number of hospital admissions associated with liver damage.

[20] The Review is precluded, by its Terms of Reference, from considering the criteria for scheduling.

The Review noted that in theory it would be possible for consumers to buy multiple small packs of products where only small packs were available from general outlets such as supermarkets. The Australian experience has been that this does not occur or at least not to any significant degree. The United Kingdom study demonstrated a similar outcome.

The Review also noted that having schedules or a schedule specifically covering products only available through pharmacies might in some cases actually reduce barriers to consumer access. For example, in the United States, where there is no equivalent to *Schedule 2* and *3,* consumers can only access certain medicines if they have a prescription from a medical practitioner. This increases costs for consumers in obtaining a prescription and would, in Australia, impose a cost on government to subsidise doctors visits. In Australia some of these same products can be purchased over the counter from a pharmacy thereby reducing costs for consumers and government.

One submission estimated the net benefit of retaining the two current OTC schedules and the associated advertising controls at between $78.4 million and $138.9 million per annum, however the Review noted that this was based on United States data and relied on a suite of assumptions on the correlation between the United States and Australian health systems.

OTC medicines are used to treat or relieve a range of conditions which, while less serious than those treated by *Schedule 4,* have the potential to cause serious health problems if used inappropriately which in turn lead to social, medical and hospital as well as lost productivity ***costs*** for CONSUMERS, GOVERNMENT and the COMMUNITY.

Notwithstanding the costs of restricting access to OTC medicines (restricted access for consumers and impediments to market entry for industry), the Review was persuaded there was a ***net benefit*** to the COMMUNITY AS A WHOLE in restricting access to a range of medicines to pharmacies as a result of the hospital, medical and social costs as well as other costs, such as lost productivity, which are avoided.

The further task for the Review was then to consider whether there was a net benefit to the community as a whole in retaining two OTC schedules.

Abolishing Schedule 2

The Review considered whether *Schedule 2* could be abolished. The Review noted that the bulk of the substances covered by the OTC schedules fall into *Schedule 2.*

Abandoning *Schedule 2* would provide a ***benefit*** to INDUSTRY through removing a barrier to competition for industry and could be expected to ***benefit*** CONSUMERS by leading to lower prices for these products through increased competition.

However, these substances are used to treat a variety of conditions and many have the potential to cause serious harm if misused, particularly if they are overused. For example, many simple analgesics are included in *Schedule 2.* Overuse of analgesics can irritate the stomach lining leading to bleeding which may in turn require hospitalisation to treat. As discussed in relation to paracetamol, overuse may lead to

serious liver damage, which in turn can lead to significant hospital and medical ***costs*** for GOVERNMENT and CONSUMERS.

Further, the Review concluded that there would be risks to the community in abolishing the current *Schedule 2*, as some of these products (e.g. pseudoephedrine) would be diverted to the illicit drug market if freely available.

For some other *Schedule 2* substances, the restrictions on access have also been shown to have an effect on the level of medicinal misadventure through side effects or interactions with other medication (e.g. aspirin and warfarin).

Consequently, the Review concluded that the objectives of the legislation would not be achieved by abandoning *Schedule 2.*

A single OTC schedule

The Review noted that the Industry Commission questioned the need for two OTC schedules and recommended that *Schedule 2* and *3* only be retained pending further research into the role of pharmacist counselling in ensuring improved health outcomes (Industry Commission, 1996). The Review was similarly hampered by lack of data, which would have enabled it to assess the net benefit to the community as a whole of retaining both OTC schedules.

While its Terms of Reference precluded the Review from examining the scheduling criteria, it considered the general rationale behind the basis for distinguishing between what substances should go into *Schedule 2* and what should go into *Schedule 3.*

It was noted in this regard that the use of two *Schedules* serves at present to elicit the pharmacist's behaviour according to the substance categorisation. The Review noted the development of the Pharmaceutical Society of Australia Schedule 2/3 Standards and that they provide powerful reinforcement of the underlying principles used to categorise substances into *Schedule 2* and *3*. The pharmacist is expected to exercise a greater degree of intervention for *Schedule 3* products than for *Schedule 2* products. Without appropriate professional intervention, substances in *Schedule 3* are considered to pose a greater risk of causing harm than those in *Schedule 2.*

As indicated previously, however, the most important factor to consider in using all OTC products is the interaction between the consumer and the product being used. The particular *Schedule* in which a product has been placed may not always be a good predictor of the potential harm it may cause if used inappropriately. Rather, the most critical factors may well be the underlying health conditions of the consumer using it, whether that person is taking other medications, and how that consumer uses the medication. Thus the Review considered that the triggers which should elicit pharmacist intervention should focus more on the particular consumer than on the substance.

Pharmacists have an important role in assessing whether use of a particular product poses any risks to individual consumers given their underlying health condition and/or their use of other medications.

The Review considered that reliance on pharmacists' expertise in determining the nature and extent of professional intervention necessary for the consumer's safe and effective use of a medicine would deliver a ***benefit*** to the COMMUNITY AS A WHOLE through preventing medicinal misadventure and diversion. The Review considered that a single OTC schedule would enable the pharmacists' professional judgement and expertise to be more validly used in establishing the level of risk associated with a consumer's use of a particular product than the present system of two OTC schedules. The current two-schedule system places the emphasis on the substance as the first criteria to establish the risks.

Under such a system, pharmacists' expertise and judgement would be the 'driver' behind the intervention rather than it being based on the chemical characteristics of a particular substance. The system would rely on a pharmacist's risk-based assessment of the nature and extent of the professional intervention needed to support the safe and effective use of medicines by particular consumers.

To perform this role, pharmacists would need to have in place procedures to identify 'at risk' consumers and standards to cover the advice that needs to be provided to consumers to enable them to select and use medicines safely and effectively. More specifically, procedures and associated standards would need to enable the pharmacist to:

- establish the therapeutic need for OTC medicine of the person for whom the product is being supplied and the quantity of the medicine required;
- establish whether there are any contra indications for the person who will be consuming the medicine, which would make it unsafe to supply the medicine to that person;
- ensure the person using or administering the medicine has the information and understanding necessary to use the product safely and effectively; and exercise a level of supervision over supply of these medicines such that medicines are not diverted for abuse or the illicit manufacture of drugs of abuse.

The Review noted in this regard that the Pharmacy Guild of Australia (the Guild) and the Pharmaceutical Society of Australia have developed and are progressively introducing new Standards related to the quality use of medicines and that these Standards are supported by Pharmacy Boards. As stated above, the Standards relating to OTC products are, however, predicated on maintaining the existing two *Schedules.*

For the reasons indicated above, the Review considered it would be desirable to move away from this 'two schedule approach' in which risk, in the first instance, is presumed based on substance characteristics. Instead, the Review considered that a single OTC schedule would reduce the level of regulation by providing an opportunity for increased self-regulation. This would require professional organisations to work towards developing 'customer at risk-based' standards that focus on the level of professional intervention needed to meet the individual needs of consumers in selecting and using OTC medicines.

The Review is precluded from examining the criteria for the schedules but considered that the criteria for a single OTC schedule should not simply be the criteria for either *Schedule 2* or *3* but should reflect the change in emphasis from substance risk to

consumer risk. The Review did not see this as necessarily leading to the de-scheduling of substances in *Schedule 2* but rather that, the substances included in both S*chedules 2* and *3* should be reassessed once the criteria and controls to apply to the revised schedule are decided.

Without pre-empting the outcome of the review of *Schedule 2* and *3*, the Review considered that the controls to be applied should reflect the increased reliance on coregulation through professional standards based on the expertise of the supervising pharmacist. This would reduce the current level of regulation associated with *Schedule 2* and *3* which, at present, is largely non-discretionary.

4.7.3 Schedule for complementary medicines

Some submissions to the Review expressed concerns about the restrictions on access to some herbal substances. In this regard, the Review noted that Victoria proposed to introduce a specific schedule to it legislation to cover substances to which accredited practitioners of traditional Chinese medicine will have access. The Review considered that this initiative could form a model for other jurisdictions, not just in relation to traditional Chinese medicine but for other complementary modalities. Therefore, the Review considered that States and Territories should review the outcomes of the Victorian legislation with a view to introducing a national system of controls which would provide appropriately qualified practitioners of traditional Chinese medicine and other complementary health care modalities with access to a wider range of medicines and medicinal substances, including herbal medicines.

4.7.4 Other matters

Evaluating the effectiveness of the controls and associated measures

Immediate steps need to be taken to establish baseline data so that any improvement in health outcomes from the higher level and quality of pharmacy counselling flowing from the Third Community Pharmacy Agreement can be assessed. This will enable evaluation and ongoing monitoring of the effectiveness of the controls and associated standards so that adjustments can be made to improve their effectiveness. The Review considered that part of the funding allocated to the Pharmacy Development Program under the Third Community Pharmacy Agreement should be allocated to collecting the baseline data and to undertaking the evaluation.

Enhancing professional standard for pharmacists

The extent to which the controls on access that flow from scheduling provide a benefit to the community is dependent to a large degree on the effective level of professional intervention. The Review noted the high level of hospital admissions which, it is claimed, are avoidable (Roughead, 1999). While the Review accepts that this may well be so, it recognised that the reasons for such adverse events are complex and there is no single solution to avoid them. Nonetheless, the Review considered that a key factor in avoiding such harms is the level of information and understanding that consumers have which will enable them to use medicines effectively and safely. In this context, the Review noted the team approach promoted by the Quality Use of Medicines program, where the consumer and all health professionals involved in that

consumer's health care have a role to play in ensuring the safe and effective use of the medicine.

Pharmacists have an important role to play in reducing the level of avoidable medicinal misadventures. They are often the first point of contact for consumers with health problems. For those presenting prescriptions, the pharmacist has an important role to play in reinforcing the prescriber's advice given, and addressing any concerns that may have arisen as a result of the visit to the prescriber.[21] The pharmacist should also provide any additional oral and written information necessary to enable the consumer to use a medicine safely and effectively. Communication experts advise that complex and important messages are more likely to be remembered and understood if they are repeated and presented in both oral and written forms

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 medicine 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 considered that urgent 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. In this regard, the Review noted the increased use of the Internet to source supplies of a variety of products, including medicines. Pharmacy Boards should be responsible for overseeing development of these standards by the Pharmaceutical Society of Australia, Pharmacists Branch of the APESMA, the Pharmacy Guild, Royal Australian College of General Practitioners and consumer organisations.

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.

Developing standards about the supply of medicines should be linked more generally with independent research to establish the extent to which health outcomes are

[21] These may arise for a number of reasons. For example, the consumer may have forgotten the advice given by the prescriber, or has subsequently thought of a question about 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.

improved by the initiatives in the Community Pharmacy Agreement to lift the level and quality of counselling services pharmacists provide in relation to all medicines. The Review appreciated the difficulty in measuring health outcomes and recognised that this may only be possible using secondary indicators, such as consumer and professional satisfaction with the standards and increased consumer knowledge.

The Review considered that it is vital to develop and implement these measures given that, with the ever-increasing numbers of products on the market, there is potential for significant harm because of interactions between products or because products may be contra-indicated in some consumers.

Improving consumer access to information about medicines

The Review noted a number of problems with the distribution of the Consumer Medicine Information required for all prescription medicines and some *Schedule 3* medicines under the *Therapeutic Goods Act 1989*. This matter is discussed further under Advertising in Chapter 5.

The Review also identified a number of other ways in which the information being provided to consumers could be improved, thereby redressing the information asymmetry between consumers and industry. These include establishing an independent source of information for consumers to support the quality use of medicines in the community. There could, for example, be a telephone counselling service and/or an interactive Internet site to complement medical practitioners' and pharmacists' advice. Such a service could be particularly useful in cases where face-to-face counselling is not available.

A consumer information service could also be seen to complement the very useful role played by the National Prescribing Service, which provides an independent source of advice on medicines to medical practitioners The Review believed that it is essential that such services be independent, readily accessible and of high quality.

5 ***Recommendation 5: Medicine schedules and associated professional support***

That all Commonwealth, State and Territory governments agree:

a) That funds be allocated from the Pharmacy Development Program under the Third Community Pharmacy Agreement to commission:

- independent research that provides baseline data and evaluation. Such research would to demonstrate any improvements in health and other outcomes that can be attributed to the higher level and quality of pharmacy counselling flowing the new Quality of Care Standards, the implementation of which is being supported and funded under the Third Community Pharmacy Agreement and that the outcomes of this research should be reported to the National Coordinating Committee on Therapeutic Goods by June 2004.

- the development of comprehensive standards that facilitate a risk-based approach to professional intervention in the supply (including the distance supply) of scheduled products to individual consumers. The Pharmaceutical Society of Australia, should be responsible for developing these standards in consultation with Pharmacy Boards, the Pharmacy Guild of Australia, Pharmacists Branch of the APESMA, other relevant professional groups and consumer organisations and presenting those standards to the National Coordinating Committee on Therapeutic Goods by the end of June 2004.

5 cont

b) That the National Coordinating Committee on Therapeutic Goods present the Australian Health Ministers Council with a report by the end of July 2004 on the results of the research and on the Standards proposed to be developed. This Report will enable Health Ministers to:

- monitor the extent to which the restrictions on access to scheduled medicines, supported by improved counselling, deliver improved health and other outcomes;
- determine whether there is an appropriate and cost effective control system for meeting the objectives of restricting access to over-the-counter medicines; and
- review the implications of the expanded standard for the integrated operation of schedules and pharmacy practice.

c) That until the Australian Health Ministers have considered the report at the end of July 2004, *Schedules 2*, *3*, *4* and *8* and associated Appendixes be retained. If at that time there is no evidence to support the benefits of retaining *Schedules 2* and *3* they should be combined and new criteria developed.

Recommendation 6: Consumer information service on quality use of medicines

6

That the Commonwealth Department of Health and Aged Care fund a consumer information service to provide independent, comprehensive, quality advice in relation to the safe and effective use of medicines.

4.8 Schedules and Appendixes covering prohibited substances and highly toxic substances

Schedule 9 and Appendix C contain highly toxic substances. The Review considered there were sound reasons, on public health grounds, to retain the restrictions associated with this *Schedule* and this Appendix. It was noted, however, that there was scope to reduce the complexity associated with the lack of uniformity in the ways in which jurisdictions deal with *Schedule 9* and Appendix C. Chapter 6 of this Report deals with this issue in more detail.

4.9 The number of Schedules covering poisons

Schedules 5, *6* and *7* largely cover poisons used in household products, agricultural and veterinary chemicals. The objectives of the controls are to prevent accidental and deliberate poisoning.

Schedule 5 and *6* controls relate not to access but rather to labelling and packaging requirements. The different levels of hazard are indicated by the signal headings – CAUTION for *Schedule 5* and POISON for *Schedule 6.* The Review was advised that use of the signal heading 'Poison' may act as a deterrent for some consumers thereby reducing the capacity of suppliers of these products to compete in the market and increasing ***costs*** to INDUSTRY. (Discussed further under Labelling in Chapter 5.) However, given the toxicity of the substances involved, the Review considered that there was a ***benefit*** to CONSUMERS in being alerted to the level of risk of using or misusing agvet and household chemicals. Consequently the Review considered that retaining *Schedules 5* and *6* was justified in that they provide a mechanism to discriminate between the relative toxicity of the substances contained in the two *Schedules.* Thus, by providing flexibility, the impact of the controls is appropriate to the level of risk so the ***benefits*** to the COMMUNITY AS A WHOLE outweigh the ***costs***.

Only *Schedule 7* involves controls on access[22] (substances in *Schedule 7* can only be supplied by licensed sellers). The Review considered that there were sound reasons for maintaining controls on access to *Schedule 7* products because of the very toxic nature and potentially fatal consequences of misuse of the substances covered by the *Schedule.* Thus, on balance, the Review considered that the ***costs*** of reduced market access for INDUSTRY and limitations on access for consumers to *Schedule 7* products were outweighed by the ***benefits*** to the COMMUNITY AS A WHOLE (reduced hospital and medical costs).

4.10 The Scheduling process

Terms of reference addressed: General Issue 8; Special Issue 1.
Supporting data and analysis for issues discussed in this Chapter are included in Part B Section 4.4.

As noted previously, the scheduling process is undertaken by the National Drugs and Poisons Schedule Committee (NDPSC), which is established under the *Therapeutic Goods Act 1989.*

Stakeholders have criticised the scheduling process as being inefficient: they say it adds to the costs of market entry because of the time taken for decisions to be made and then for them to be included in State and Territory legislation. The scheduling process is also said to interact inefficiently with other processes for assessing the safety of medicines and poisons. These impacts include delays to the marketing approval of agvet chemicals and, for household chemical products, delays in manufacturers being able to market their products or, where they are marketed ahead of the scheduling decision, the potential risk that they will have to be re-labelled.

Concerns were expressed to the Review about the NDPSC's administrative procedures including:

- the need to separate the scheduling of medicines and poisons;
- the membership of the NDPSC, particularly the lack of adequate representation from some sectors to deal with the subject matter being considered;

[22] In some jurisdictions these restrictions are imposed by drugs and poisons legislation while in others they are imposed by agvet legislation.

- the voting procedures – where jurisdictional members have the 'final vote'[23] on all scheduling decisions; and
- sequential rather than concurrent evaluation and scheduling decisions which impacts on the time taken to bring a product to market.

4.10.1 Separate medicines and poisons committees

The Review saw that the primary function of the NDPSC is to provide expert advice to jurisdictions on the scheduling of both medicines and poisons and to promote uniformity of those schedules. The issues associated with scheduling medicines are often quite different to those for scheduling poisons.

Scheduling of medicines requires a focus on the need to restrict access to ensure the safe and effective therapeutic use of these products. For poisons, the major concern is to ensure labelling and packaging controls are appropriate to prevent accidental or deliberate poisoning with that substance and to minimise the harm that may occur if such poisoning does occur.

During the course of the Review's consultations, stakeholders, from a wide range of areas, argued that there should be two separate committees – one to deal with scheduling human medicines and a second to deal with scheduling poisons (agvet and household chemicals). The Review noted that a number of previous reviews and inquiries have proposed separation of the scheduling of drugs and poisons.[24]

The Review also noted that Australia is unique in regulating drugs and poison under the same legislation. While this is not an argument for Australia to change its system of regulation, it does provide a model for re-examining the Australian controls. In re-examining this issue, the Review recognised the close relationship between drugs and poisons and that some of these substances may be used in both medicines and household products (e.g. antibiotics, steroids, eucalyptus oil).

Nonetheless, given the broad range of substances involved and the diversity and range of their uses, the Review considered that there would be merit in having separate, more specialised, committees to provide advice on the level of control which should apply to human medicines – the Medicines Scheduling Committee (MSC) – and that which should apply to agricultural, veterinary, and household chemicals – the Poisons Scheduling Committee (PSC). The Review considered that appropriate procedures could be put in place to ensure consistency of decisions. These measures might include TGA providing secretariat support for both committees[25] and requiring public health advice, in relation to scheduling agvet chemicals, to come from the Commonwealth health portfolio.[26]

[23] Currently a decision requires not only the majority vote of the committee as a whole but also that the decision be supported by a majority of the jurisdictional members.

[24] National Health and Medical Research Council, 1954; Industry Commission Report, 1996; Wall, 1996.

[25] Currently TGA provides the secretariat support for the NDPSC.

[26] The Review noted that the National Competition Policy Review of Agricultural and Veterinary Chemical Legislation recommended that the NRA seek competitive tenders for advice on public health and other matters, such as environmental protection.

While there may be some additional ***costs*** TO GOVERNMENT (additional meetings, more members) associated with having separate committees, these should not be significant.[27] Moreover, the Review considered that such additional costs are justified in terms of the ***benefits*** to the COMMUNITY AS A WHOLE from more appropriately constituted committees assessing the levels of control that should apply to particular substances (e.g. cost effective use of the relevant experts and a capacity to include a broader range of relevant experts in the committees).

The Review also considered that, given the new committee names, it would be appropriate to change the name of the *Standard for the Uniform Scheduling of Drugs and Poisons* to the *Standard for the Uniform Scheduling of Medicines and Poisons* to better reflect current understanding of the substances covered by the standard. This approach recognises the way in which the term 'drugs' is popularly used, i.e. as denoting an illegal substances. Further, while all substances can be considered to be a 'poison' when taken incorrectly, or in the wrong quantity, the Review considered the term 'medicine' would better reflect the purposes of the legislation for those substances used for therapeutic purposes.

4.10.2 Committee membership

A number of submissions to the Review argued that the current membership did not include expertise or representatives of all relevant sectors and that there should be further representation from particular sectors. The Review noted that the current Committee is quite large[28] and that to increase its membership further could make its deliberations more difficult and management of its processes less cost effective.

Further, the Review noted that the experience and expertise of some representatives and experts was primarily focused on either human medicines or agvet and household chemicals. As a result, involvement of all committee members in the full range of scheduling decisions was not the most cost-effective use of their time and expertise. The Review, therefore, considered that two committees would enable the membership of the committees to be more specifically focused.

The Review then considered a number of options for membership of each committee, including:

- an expert committee;
- a committee of jurisdictional representatives only; and
- a mix of jurisdictional representatives, experts and representatives of various community sectors (similar to the current NDPSC membership).

The Review considered that, while a committee composed solely of experts would provide governments with independent advice, such a committee may not adequately reflect or give due weight to State and Territory government responsibilities to protect public health and safety. Similarly, the decisions of a committee comprised solely of

[27] It is estimated that the additional costs would be less than $20 000 per annum.

[28] Currently the 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.

jurisdictional representatives would be less robust because they would be made without the benefit of input from and debate with a broad range of experts and representatives. 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 the scheduling of medicines and poisons.

The Review did not believe it was its role to make recommendations about the specific membership of the committees. However, the Review noted the comments on the appropriateness of the membership made in submissions to the Review. Consequently, in establishing the Medicines Scheduling Committee, the Review concluded that the Committee deliberations may benefit from the inclusion of a person representing practicing general practitioners and an expert in complementary medicine. For the Poisons Scheduling Committee, the Review considered that membership may benefit by the inclusion of a person to represent practicing veterinarians.

The Review also noted that, at the moment, under the single committee structure, both the industry and consumer representatives have an enormous task in representing the interests of their respective sectors across such a broad range of substances and uses. Establishing two committees will enable appointment of a representative of the medicine industry and the chemical industry and of consumers with particular expertise in the area of medicines and of chemicals to the relevant committees.

4.10.3 Voting procedures

The NDPSC voting procedure was one of the more contentious issues stakeholder representatives raised in the course of this Review. 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 decision requires the support of a majority of the jurisdictional members. This voting procedure was seen as devaluing the expertise other members brought to the committee in that some parties' votes, i.e. the votes of jurisdictional representatives, were seen as carrying more weight than those of other committee 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, responsibility for scheduling a substance 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.

The Review considered that, if all jurisdictions accepted the committee's decisions, the role of the jurisdictional representatives in the decision-making process, particularly the voting, becomes critical. 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, as set out in the *Therapeutic Goods Act 1989*, should be retained.

4.10.4 Evaluation and scheduling processes

The issues considered while, and the processes involved in, making scheduling decisions overlap with those involved in the product evaluation processes. As outlined above, all medicines and agvet products must undergo, at the product evaluation stage, an assessment that involves consideration of the safety of that product, the substances it contains, and the ways in which it is presented, labelled and packaged. Similarly, new chemicals used in household products must also be assessed for safety and included in the chemical register.[29] These matters are also taken into account during scheduling when assessing the level of professional intervention necessary for safe and effective use.

The Review considered that it would be possible to streamline the evaluation and scheduling processes without compromising public health and safety.

Specifically, the Review believed there would be ***cost savings*** to both INDUSTRY and GOVERNMENTS and ultimately to CONSUMERS if the scheduling recommendation for a new substance or the recommendations to re-schedule a substance are made during evaluation and referred, by the evaluator, to the Medicines Scheduling Committee or the Poisons Scheduling Committee. If this process is to proceed parallel with, rather than subsequent to, the registration process, the product sponsor will need to agree, when submitting an evaluation application, that notification of the scheduling recommendation can be published for consultation purposes before the product is entered on the ARTG or the National Chemical Register Information System.[30]

The guidelines for product evaluation by TGA or NRA may need to be expanded to include the scheduling criteria and guidelines, which incorporate a broad public health risk assessment. This approach should be more efficient in avoiding duplication of risk assessments, but still provide jurisdictions with the opportunity to consider all scheduling decisions based on their responsibilities under their own respective legislation. Regular applications for re-scheduling would be handled by the appropriate Scheduling Committee.

In incorporating the assessment for a scheduling decision into the product evaluation process, the agency, rather than the Scheduling Committee, would be in a position to take responsibility for the specific qualifications on the schedule classification of a substance – currently known as reverse scheduling. Thus medicine features, such as labelling and packaging, which reduce the risk associated with using a product, could be removed from the SUSDP and placed under direct administration of the TGA or the NRA since these features are very closely linked to the product evaluation.

However the Review noted concerns a number of stakeholders expressed that, in transferring responsibility for all labelling controls to the NRA, the level of public

[29] All chemicals used in domestic and industrial products in Australia must be in the Australian Inventory of Chemical Substances under the *Industrial Chemicals (Notification and Assessment) Act 1989*, however some of the chemicals, which have a long history of use in Australia, have not yet been fully assessed for safety.

[30] Currently, restrictions on disclosing 'commercial-in-confidence' information can delay the scheduling decision. In many cases, obtaining permission from the sponsor to proceed to scheduling before registration of a product adds to the administrative costs for the NDPSC.

health protection provided by labelling and packaging may be inconsistent with that for human medicines with consequential hospital and medical ***costs*** for the COMMUNITY from increased poisoning. The Review therefore considered that, in reaching a decision on the appropriate labelling and packing for particular products, the NRA should take into account advice from the Commonwealth health portfolio.[31] The ***benefits*** for INDUSTRY and GOVERNMENTS of improved efficiency from having labelling and packaging controls considered during the relevant evaluation process[32] are discussed in Chapter 6.

Final decisions of both the Medicines Scheduling Committee and the Poisons Scheduling Committee would then be included in the SUSMP for adoption by all jurisdictions.

4.10.5 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 very limited resources.

However, the Review believed that this transfer of some scheduling tasks to the TGA and NRA will be insufficient in addressing the issue of increased efficiency by the NDPSC in the timely assessment of applications for re-scheduling from industry.

Consequently, the Review considered that it would be appropriate that provisions be included in the *Therapeutic Goods Act 1989* to enable the costs of processing re-scheduling applications to be recovered. (Charges are already associated with new product evaluations and related scheduling decisions).

[31] The Review noted that the working group established as a result of the jurisdictions' response to the review of agvet legislation is currently considering whether there is scope for the NRA to use non-government providers for assessment services. However, the Review considered that, in relation to labelling and packaging, it was important there be a consistent level of protection for both human medicines and agvet products, particularly where they contain the same substance.

[32] The *Therapeutic Goods Act 1989* and the *Agricultural and Veterinary Chemicals Code Act 1994.*

7 *Recommendation 7: Administrative arrangements for scheduling*

That all Commonwealth, State and Territory governments agree that:

a) The *Therapeutic Goods Act 1989* and relevant sections of State and Territory legislation be amended to:
   - change the title of the *Standard for the Uniform Scheduling of Drugs and Poisons* (SUSDP) to the *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP); and
   - disband the National Drugs and Poisons Schedule Committee (NDPSC) and replace it with two separate committees – the Medicines Scheduling Committee (MSC), responsible for scheduling human medicines; and the Poisons Scheduling Committee (PSC), responsible for scheduling agricultural, veterinary and household chemicals – and that:
     - membership of the Committees include a mix of jurisdictional representatives, appropriate experts and representatives of relevant government and community sectors;
     - decisions of both the Medicines Scheduling Committee and the Poisons Scheduling Committee be decided by a majority vote of the members provided that majority also includes a majority of the jurisdictions; and
     - decisions of both Committees be included in the SUSMP.

b) The *Therapeutic Goods Act 1989* and the *Agricultural and Veterinary Chemicals Code Act 1994* and related subordinate legislation be amended, as necessary, to enable the Therapeutic Goods Administration, in the case of human medicines, and the National Registration Authority for Agricultural and Veterinary Products, in the case of agricultural and veterinary products, acting on the advice of the Commonwealth health portfolio in relation to public health matters to:
   - make decisions about labelling and packaging medicines and agvet products during evaluation of those products;
   - recommend the schedule in which a new substance should be included; and
   - recommend changes to the schedule of a substance where, in evaluating new formulations, new presentations and new uses of substances currently included in the SUSMP, a significant change in the risk profile of the substance is identified.

c) The *Therapeutic Goods Act 1989* be amended to enable the costs of operating the MSC and the Poisons Scheduling Committee to be fully recovered by implementing a charge for re-scheduling applications by industry.

4.11 Other matters

Terms of reference addressed: Special Issue 5.
Supporting data and analysis for issues discussed in this Chapter are included in Part B Sections 5.13.

4.11.1 Vending machines

A further issue raised with the Review was the supply of scheduled and unscheduled medicines from vending machines. Currently, such a manner of supply is prohibited

or requires special authority. The legislative instruments in which these prohibitions and restrictions are included vary across jurisdictions and, particularly in the case of unscheduled medicines, may be in legislation other than drugs, poisons and controlled substances legislation. The Review noted that, where these controls are included in drugs and poisons legislation, the controls may not apply to unscheduled medicines .

For scheduled medicines, the Review considered that the ***benefits*** to the CONSUMER and INDUSTRY of unrestricted access through vending machines would not outweigh the hospital and medical ***costs*** to the COMMUNITY as a result of medicinal misadventure or poisoning. In this context the Review noted the opportunity for product sponsors to seek de-scheduling of small packs (one or two doses), on a case-by-case basis.

For unscheduled medicines, the Review considered that, because of the potential for children to gain unsupervised access to vending machines, the risk of poisoning from unscheduled substances could be slightly higher than when the product is available from general retail outlets.

However, the Review considered that there is scope to ease the current level of control where these risks can be minimised, e.g. where vending machines only dispense limited doses and are located where access by unsupervised children is unlikely. Allowing unscheduled products, in small quantities to be available in situations where unsupervised access by children was unlikely, would provide benefits in terms of consumer access and convenience.

The Review noted the concerns a number of stakeholders expressed about the proposal to allow certain medications to be supplied through vending machines. These concerns related to overuse and to the undermining of the quality use of medicines. While the Review is not convinced that such overuse or misuse will occur if vending machines are permitted for unscheduled medicines, it does, nonetheless, consider it prudent to make it a condition of such permission, that an effective evaluation strategy be put in place.

The Review also considered that, in order to ensure uniformity, these measures be included in the medicines and poisons legislation in all jurisdictions.

Recommendation 8: Vending machines

8

That Commonwealth, State and Territory governments agree that:

- provisions in State and Territory legislation which prohibit the supply of scheduled medicines from vending machines be repealed and replaced with uniform provisions in medicines and poisons legislation which prohibit the supply of scheduled medicines from vending machines;
- provisions in State and Territory legislation which prohibit the supply of unscheduled medicines from vending machines be repealed and replaced with provisions in medicines and poisons legislation that permit the supply of packs containing no more than two adult doses of unscheduled medicines from vending machines provided those machines are presented and located in a way that makes unsupervised access by children unlikely; and

8 cont

- permission to operate such vending machines be subject to a requirement that the operators of such vending machines provide the NCCTG with an independent evaluation of the safe use and effectiveness of the quality control measures after two years of operation.

4.11.2 Administration of medicines

Administration of medicines was another issue raised with the Review. In particular, it was suggested that there needed to be additional restrictions placed on who could administer medicines in certain circumstances. For example, in an aged care facility where, it was argued, that medicines should only be administered by a qualified health professional.

Drugs, poisons and controlled substances legislation includes some restrictions on who can administer medicines and imposes restrictions, such as the need to record administration details, i.e. who administered the medicine, how much was administered and to whom. Similar requirements may be imposed by other legislation, such as the *Stock Medicines Act 1989* in New South Wales.[33]

While in some cases this issue is linked to a particular *Schedule* in which a substance appears, in many cases, it is also linked to prescribing rights, i.e. a person authorised to prescribe may also be authorised to administer a substance. Prescribing rights are excluded from this Review's Terms of Reference.

Restrictions on administration are sometimes used as a further restriction on access, particularly where the substance is likely to be diverted for abuse. Recording, storage and handling requirements (discussed in Chapter 5) also apply to those administering certain scheduled medicines, particularly controlled substances. The Review considered that the ***benefits*** to the COMMUNITY of these requirements (reduced diversion and fewer poisonings) outweigh the ***costs*** to HEALTH PROFESSIONALS (e.g. time to record) of these controls and CONSUMERS (where these recording requirements increase prices).

However, the Review could see no benefit in introducing additional legislative controls over administration in situations where medicines are administered by one person to another, after the medicine has been dispensed. These situations include:

- teachers in schools administering to children;
- nurses administering to patients in hospitals;
- nurses or carers administering to residents of nursing homes, aged care facilities or the patient's home; and
- parents administering to children.

In these circumstances, if controls are considered necessary, they should be dealt with by other mechanisms, such as standards for aged care facilities or codes of practice for teachers.

[33] Only veterinarians are permitted to administer anabolic steroids. This measure is intended to prevent diversion of veterinary steroids for illicit use by humans.

Recommendation 9: Controls over administration of medicines

9

The Commonwealth and State and Territory governments agree that the current level of controls over the administration of medicines be retained.

4.11.3 Duplication of prescribing requirements for controlled substances

The Review noted stakeholder comments about the complexity and apparent duplication of State and Territory requirements with those of the Health Insurance Commission concerning the additional authorisations needed to prescribe large quantities or long-term treatment of *Schedule 8* medicines. These procedures are confusing to health professionals and consumers alike and, for some elderly and chronically ill consumers, the process is distressing as they feel they are treated as drug addicts. At the State and Territory level, these requirements may be included in the primary legislation or in administrative or ministerial orders.

The Review recognised that the primary purpose of the Health Insurance Commission and the State and Territory health authorities in requiring such authorisations was different. For the Health Insurance Commission, the primary purpose is reducing costs by preventing 'doctor shopping' and unnecessary use of these medicines; while the primary purpose of State and Territory controls is to protect public health and safety by reducing abuse and diversion of these medicines. However, the Review considered that, as there was very little difference in the effect of the requirements, i.e. the right of health professionals to freely prescribe *Schedule 8* medicines is restricted, there should be scope to rationalise these requirements.

Recommendation 10: Authorisation to prescribe controlled substances

10

That the Health Insurance Commission consults with State and Territory health departments to develop procedures to reduce the administrative duplication that applies, in certain circumstances, to prescribing of controlled substances and to clarify these procedures for health professionals and consumers.

4.11.4 First-aid kits

Another scheduling issue raised with the Review included the different restrictions on what can be included in first aid kits in different jurisdictions particularly in relation to bronchodilators in *Schedule 3* and the problems of supplying scheduled medicines across jurisdictional borders. This issue highlights the need for uniform legislation and improved efficiency in administering the legislation. These matters are addressed in Chapter 6.

CHAPTER 5 THE APPROPRIATE LEVELS OF REGULATORY CONTROLS

Having concluded that there is a net benefit to the community as a whole in maintaining a comprehensive system of regulatory controls based on *Schedules* which allow a flexible system of control, the Review has considered the levels at which the controls should be set. (Issues of uniformity in the setting of levels of controls are discussed in Chapter 6.)

In considering the appropriate levels of control, the Review has been guided by the National Competition Policy Principles. These Principles, in effect, seek to ensure that regulatory controls are set at the lowest possible level, without compromising the public interest benefits that are the underlying objectives of the controls.

Reducing the levels of regulatory controls applying to particular aspects of using drugs, poisons and controlled substances is expected to result, in due course, in increased competition in some areas. Increased competition would lead to savings flowing to industry, health professionals, government and consumers.

The areas the Review considered had some scope to reduce the degree of regulation relate to the:

- information that can be provided to consumers through advertising;
- supply of clinical samples;
- licensing arrangements; and
- recording and reporting arrangements for certain drugs and poisons.

In considering these areas, the Review noted that, while each control imposed by drugs, poisons and controlled substances legislation contributes to the overall objectives of the legislation, it is possible to identify more specific objectives for each control.

5.1 Advertising

Terms of reference addressed: General Issues 1, 2, 3, 4, 6, 7, 9, and 10; Specific Issues 2 and 4.
Supporting data and analysis for issues discussed in this Chapter are included in Part B Section 5.1.

All jurisdictions include prohibitions in their drugs and poisons legislation on advertising, to the general community (known as 'direct to consumer' or DTC advertising), of *Schedule 4* and *8* products and some *Schedule 3* products. These restrictions apply to both medicines for human and for animal use.[34] Similar provisions are included in the *Therapeutic Goods Act 1989* in relation to human medicines.

[34] Controls on the advertising of agvet products is also included in other legislation in some jurisdictions such as the NSW *Stock Medicines Act 1989*.

Within the definition of advertising in jurisdictional legislation,[35] a range of situations such as price advertising, consumer medicine information and press releases can be advertising if used to promote use or supply of the products. Advertising covers all mediums – print and electronic.

State and Territory legislation also prohibits advertising of medicines for the treatment of certain disease conditions.[36] Similar prohibitions and restrictions are included in the Therapeutic Goods Advertising Code which is underpinned by the *Therapeutic Goods Act 1989.*

The disease conditions for which advertising is prohibited are generally serious and life threatening conditions that require professional expertise to diagnose and manage (e.g. cancer, infectious diseases such as HIV/AIDS and heart disease). Also, it needs to be recognised that *Schedules 4* and *8* medicines are likely to be more toxic than those in non-prescription products, and more likely to have significant side effects or be likely to cause dependence.

The underlying objectives of the restrictions on advertising relate to concerns that consumers – and particularly those in vulnerable positions because of serious health conditions – would not be in a position to assess the sort of claims that might be expected to appear in advertisements for many scheduled medicines. For veterinary products there are similar concerns about the asymmetry of knowledge of animal owners/managers and industry.

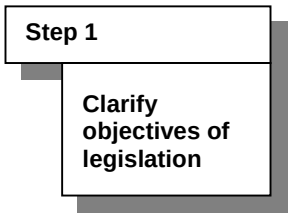
The Review noted that there are no legislative prohibitions or restrictions on marketing and advertising that can be directed at health professionals involved in supplying medicines. The assumption in this case is that such professionals will have the necessary training and expertise to allow them to critically evaluate the sort of claims that might be made about the merits of a particular product. While the Australian Pharmaceutical Manufacturers Association (APMA) code of conduct includes measures to prevent such behaviour, the Review noted reports that the methods some pharmaceutical companies used to induce doctors into prescribing particular products were excessive and outside the code. The Review considered that there was room to improve compliance with the APMA code of conduct in this area.

A number of stakeholders raised the issue of advertising via the Internet. The Review noted that the current advertising restrictions apply to all forms of advertising, including the Internet. However, the capacity of the Commonwealth, State and Territory governments to regulate Internet advertising originating from overseas sources is limited. This is an international problem and one, which the Commonwealth government and the governments of other countries are attempting to resolve. The Review was also concerned about the potential dangers facing consumers who purchase medicines from Internet suppliers.

[35] The scope of these definitions varies considerably although all cover a wide range of material.

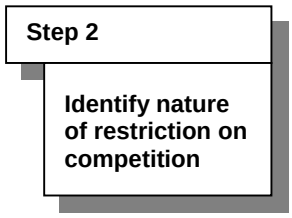
[36] The range of disease states varies across jurisdictions.

5.1.1 Objectives of the controls



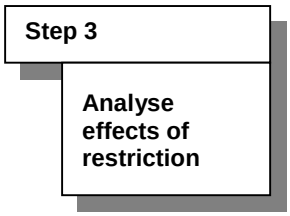
The primary objective of the restrictions on advertising is to redress the information asymmetry between industry and consumers by ensuring the information available to consumers is accurate, balanced and complete.

5.1.2 Nature of the controls



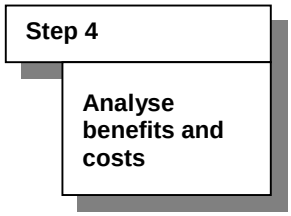
The controls prevent suppliers of *Schedule 4* and *8* and some *Schedule 3* medicines from advertising their products to the general public. Further, for those products which can be advertised, the controls limit the extent of that advertising by prohibiting sponsors advertising their products for certain conditions or diseases.

5.1.3 Effect of the controls on competition and the economy



The controls reduce the capacity of suppliers of medicines to compete fully in the market in that, as indicated above, they can only promote certain products to health professionals and not to the general community. By their nature the controls prevent firms from using advertising-based product differentiation as a freely available competitive tool for pursuit of market advantage, a situation otherwise permitted for most products (including many with significant propensity to harm, e.g. alcohol, cars). However, it should be recognised that the consumer (or animal owner/manager) cannot obtain these medicines without the intervention of an authorised health professional.

5.1.4 Costs and benefits of the controls



A judgement is needed as to whether there is a net public benefit in maintaining the present restrictions on advertising.

Companies are not prevented from advertising their products to the key decision makers, i.e. doctors, veterinarians and other authorised health professionals. Therefore the ***costs*** for INDUSTRY from reduced competition are less than would be the case if consumers were the ultimate decision makers on the purchase of these products. Against these costs, must be set the ***benefit*** to the COMMUNITY of preventing open advertising which:

- leads to inappropriate use of medicines where doctors succumb to patient pressure to prescribe a particular medicine;
- undermines the doctor–patient relationship where patients aggressively demand that a particular product be prescribed or leave the surgery dissatisfied because the product was not prescribed;
- results in confused or misinformed consumers because they have too little knowledge, and the information available to inform them is unbalanced;

- generates consumer anxiety through exaggerated promotion of disease risk particularly for those most vulnerable in society through lack of education or chronic or severe illness;
- leads to wide use of medicines in the community before a population risk profile is developed;
- results in increased harm, and possibly fatalities, with the combination of self-diagnosis and self-choice of medicine, particularly with use of the Internet, (especially where medical advice is bypassed or ignored);
- leads to acceptance of medicines as 'life solutions', to the detriment of better alternatives, such as diet and exercise (i.e. increased medicalisation of society, with an associated increase in risk of misadventure); and
- results in escalating costs to subsidise medicines and patient visits to doctors, particularly where consumers are 'doctor shopping' in an attempt to find a doctor prepared to prescribe a particular medicine.

There is, nevertheless, an alternative perspective to these concerns. Even in a fully deregulated market, some advertising will be informative and constructive. However, even where such advertising is informative, it will only provide very limited information in an area where the issues involved are complex and often highly technical. If the advertising is informative and constructive the knowledge of some consumers will be enhanced. And as a consequence of advertising prescription medicines:

- some prescribers will react constructively to consumer pressure;
- the doctor–patient relationship will, in some cases, be improved;
- earlier knowledge of treatment possibilities will, in some cases, ease anxiety about disease risk – those with limited education and severe illness may receive simple accessible information about potential therapy;
- medicines will be used to treat conditions earlier;
- in some cases, where professional advice would not otherwise be sought, preliminary diagnosis by patients will improve therapy by enhanced understanding and increased presentation to professionals;
- innovation for new medicines will, in some cases, be brought forward.

Clearly such propositions and counter-propositions each have varying degrees of merit. Resolution of their difference is ultimately an evidentiary issue: What are the relative costs and benefits? Which groups are most affected? Attaching weights to the effects established, via cost–benefit review, remains highly controversial in public health analysis.

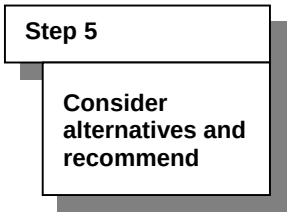
Research in the United States of America indicates that patient behaviour does alter in response to advertisements (Mintzes, 2000; Barents Group, 1999; Wilkes, 2000). People are going to doctors; discussing and requesting advertised medicines; and receiving prescriptions. There has not been sufficient research to determine whether, on balance, this activity in the United States of America corresponds to better health outcomes and not more harm. As new evidence accrues, the outcomes can be

revisited. While the United States of America situation serves as a useful 'case study', its outcomes may not necessarily be relevant to Australia.

For this Review, the factor to steer the arguments is the known potential for tragic risk given the nature of these particular products. The Review considered that, while there were undoubted ***costs*** to INDUSTRY in restricting a supplier's capacity to freely advertise their products, these costs were considerably less than would be expected if access to these products was not restricted.

The ***benefits*** for the COMMUNITY are that medical costs are not increased by unnecessary or longer doctor visits and medicinal misadventures and their associated hospital and medical costs are not increased. Therefore, the judgment of the Review is that the current advertising controls do offer a ***net benefit*** to the COMMUNITY AS A WHOLE.

5.1.5 Alternatives to the current controls and their costs and benefits



To remove all regulation of medicines and poisons would give rise to too many points of possible failure in the health system for the public interest to be served and significantly erode the benefits they provide. Each hazard point inherent in the risks of harm listed in the previous section can be shown to exist. The precise probabilities of each of them occurring are often unclear, but there are so many hazards that the overall likelihood of harm is high. A decision to restrict advertising can be drawn from the application of a precautionary approach, and can be drawn from National Competition Principles when consideration is given to the definite lack of benefit to the community while advertising tools are substantially promotional, not just informational.

The Review considered reliance on the other generic measures, such as trade practices or consumer protection legislation, to ensure the information is balanced and truthful. However, because this legislation is applied post-market, considerable anxiety or unfounded expectation can be created in vulnerable consumers before corrective action is taken. The Review was advised that the controls on advertising content in the United States of America are frequently breached and that action to correct these breaches is not timely. Consequently, these controls are far from effective in meeting their objectives. Consumers with serious diseases or conditions are the most vulnerable and it is these consumers who would pay the price for later intervention.

The Review considered that the present set of controls is not necessarily the best configuration of restrictions that can be adopted. Even if fully removing all regulation does not provide a net benefit there remained the task of examining alternatives. In doing this, the Review found it useful to distinguish the restrictions applying to advertising prescription medicines from those applying to advertising pharmacy-only medicines.

Advertising prescription medicines

The Review noted that the restriction on advertising prescription medicines only applies to advertisements aimed at the consumer. There is no restriction on advertising prescription medicines to health professionals. The advertisements for human medicines aimed at health professionals are regulated by the APMA Code of Conduct and the *Trade Practices Act 1974*. The Review further noted that doctors, veterinarians and other authorised health professionals are the ultimate decision makers about the supply of these substances. The Review considered that these health professionals, because of their training and experience, are in the best position to evaluate the content of the advertisement and to be able to weigh the risks and benefits of that product for treating a particular consumer.

The Review considered the possibility of allowing DTC advertising under various regulatory controls, including coregulation, provided the informational aspects could be enhanced and controlled.

In the United States, advertising prescription drugs is permitted provided certain requirements are met. Advertisements must:

- provide balanced information;
- include information about the adverse effects of the product (press advertisements are required to include details of the adverse reactions whereas electronic media need only make a general reference, such as 'This product may not be suitable for your condition'); and
- include a statement indicating that the doctor will decide if this is a suitable treatment.

The Review was told, however, that many advertisements do not comply with these criteria, or do so in a way which is misleading, thus doing little to redress consumers' information deficit. Further, where there is action to alter the advertisements, it is, inevitably, after the event, often some time after.

In New Zealand, where advertising has not been prohibited, examples are emerging of the subtly misleading way in which advertising can make truthful statements. Such statements are not permitted to be misleading under trade practices legislation, but it takes argument and regulatory effort, after the event, to prove they are misleading despite being truthful. For example, Xenical (weight reduction treatment) was said, in the advertisement, to be twice as effective as diet alone. This is misleading because diet alone, without exercise, is broadly ineffectual. Twice zero is still zero, but that is an oversimplified statement and the argument has to be explained in terms of the need to apply a better control, like other measures in combination with diet, compared with diet alone. The message of advantage is already in the public arena.

Of course, misleading or opportunistic advertising may be a focus 'at the border' and much constructive and ethical advertising of benefit may be proceeding without attracting attention. However, the Review did note that the amount of attention to questionable advertising is large. For example, much of the information on the Internet from overseas sources[37] is misleading, unbalanced and often untrue. Further,

[37] This cannot at present be controlled by Australian authorities.

media reports, stimulated by such advertising, exacerbate this position (Moynihan et al., 2000). If similar problems were to arise in Australia, this would undermine any benefits that could flow from allowing prescription medicines to be advertised.

The Review could not support a relaxation of the current prohibition that would result in a situation such as is occurring in the United States of America and New Zealand, which cannot be assessed as providing a net public benefit, despite reports of some individuals being helped.

Spending on DTC advertising of prescription drugs in the United States in 1999 was US$1.8 billion, of which 41 per cent was spent on advertising only 10 products (IMS Health, 2000). While these figures should be used with considerable caution, given the very different health systems in Australia and the United States, they cannot be entirely discounted when considering the possible effect on Australian consumers, and on the costs of subsidised medicine, were this prohibition to be relaxed.

The Review considered that, should DTC advertising of prescription medicines be permitted, the bulk of the advertising would be for a few new and generally high-priced products and for those used to treat some of the more common serious illnesses. In the United States of America, expenditures are increasing disproportionately for the conditions and medicines most heavily advertised to the public. Also associated with the explosion in advertising in the United States, is the measurement of a 15 per cent increase in sales of medicines for which there was only half that growth in sales in the top five European countries in the same period. These trends are occurring in a country which in the past has attained very poor therapeutic value for money (World Health Organization, 2000).

There is also a view that Australian manufacturers would be less likely to advertise older (possibly cheaper), but nonetheless, effective products to consumers, because it would be difficult to build the cost of such advertising into the price of the product, especially where the product is subsidised under the Pharmaceutical Benefits Scheme. Based on the United States of America experience the Review supports this view.

The Review is also concerned about a sudden relaxation, given the cultural context in Australia, where consumers have not been exposed to such advertising thus far. With the confidence Australians have in public health regulatory practices in this country, healthy scepticism and judgement of advertisements would require nurturing. This is consistent with Mintzes (2000) in her literature review of the impact of DTC on health. She warns that the public perceives advertisements as reliable just because the authorities allowed them, with the consequences being a greater expectation that the doctor will prescribe on request. Ideally, implementation of quality use of medicine procedure should overcome the information asymmetry between consumers and industry, but there is a long way to go before quality use of medicine measures are regularly and consistently applied.

Ideally, expectations that a doctor (or other health professional) will prescribe a requested medicine would only be fulfilled where the doctor assessed that the benefits associated with the advertised product outweighed the risks to the particular patient and that the product was the most effective treatment for that patient. Unfortunately, for a variety of reasons, this may not always be the case. Further, where the advertised product is not prescribed, because it is not the most appropriate treatment, the time

taken to discuss why it is not the most appropriate treatment can add to the length of a doctor's visit, thereby increasing ***costs*** for the CONSUMER and GOVERNMENTS (for subsidised doctor visits) or because the dissatisfied consumer may visit several doctors in an attempt to persuade one to prescribe the advertised medicine.

The current situation is seen as suffering from a lack of alternative information sources with which consumers may judge advertisements. This places reliance on the doctor or other health professional to redress the information asymmetry. As discussed, this may add to costs for consumers and government. The situation could be reviewed in three years if alternative sources of independent, credible information are readily available to all consumers.

Similarly, in balancing the costs and benefits discussed above in relation to human medicines, the Review considered that the ***costs*** to INDUSTRY (of restricted capacity to freely market their product) of the restriction on advertising *Schedule 4* and *8* veterinary medicines were outweighed by the ***benefits*** to ANIMAL OWNERS and the COMMUNITY. The benefits to the community arise where overuse and inappropriate use of products such as antibiotics, lead to the development of antibiotic resistant organisms. This can reduce the effectiveness of the available treatments for some serious and often life threatening infections (e.g. tuberculosis). In addition, the Review considered that to allow advertising of veterinary medicines, many of which are the same or similar to human medicines, could be confusing for consumers and may well lead to an increase in diversion of veterinary medicines for human use.[38]

Consequently, the Review considered that there would be no ***net benefit*** to the COMMUNITY AS A WHOLE in permitting advertising of veterinary medicines.

It is notable that DTC advertising of prescription products for Australia is not supported by organisations representing doctors, pharmacists or veterinarians, when one would expect that such advertising could increase their income. As professionals, they argued that market forces and coregulatory approaches were not able to deliver the benefits of the current controls. Of course, if advertising merely alters market share for competing products, and does not increase the total market, the foregone income argument has less substance in judging professional views, and the matter should be interpreted on its merits. Similarly, consumer organisations also argued strongly against allowing DTC advertising on the basis that such advertising, by its very nature, will not provide the balanced, independent and accurate information consumers need.

The Review also considered the intermediate alternative, between no regulation and the status quo, is self-regulation of prescription medicine advertising, possibly with legislative underpinning. However, the Review concluded that, in the light of the arguments discussed above, this approach was less likely to deliver a net benefit than more restrictive controls. Indeed, this view was strengthened by the complaints made to the Review about the effectiveness of the self-regulatory approach to press releases, generic disease state advertisements which seek to circumvent the prohibition on advertising prescription medicines and the promotional nature of *Schedule 3* advertising.

[38] There is considerable evidence of veterinary medicines, particularly steroids, being diverted for abuse by humans.

Advertising pharmacist-only medicines

The advertising of *Schedule 3* medicines was reviewed consequentially to the review of the TGA in 1997. As a result, some advertising of *Schedule 3* products is now allowed on a case-by-case basis. The criterion used is the net benefit to the community as a whole of such advertising. The issues discussed above also apply to advertising of pharmacist-only medicines. In this case, it is the pharmacist's responsibility to ensure the consumer has a therapeutic need for the medicine and understands how to use the medicine safely and effectively.

A number of submissions expressed concern that the coregulatory approach, which has applied to the advertising of *Schedule 3* products since the prohibition on such advertising was relaxed in 1998, has not seen an improvement in the level of consumer knowledge and understanding about these products. Indeed, some submissions argued that additional consumption has had the effect of increasing the risk of drug interactions and adverse events. This is to be expected with increased consumption although appropriate pharmacist intervention should minimise these increases in harm.

Data to enable good quantitative analysis are limited. Despite the recommendations in the *Review of the Poisons Scheduling Process in Australia* (Wall, 1996) which led to the relaxation of the prohibition on *Schedule 3* advertising, namely that the effect of these changes should be monitored, no mechanism has been established to do so.

It is only in the last couple of years that advertising of *Schedule 3* products has been possible.[39] Therefore, it is difficult to estimate the effect of these changes with any degree of certainty. The Review was unable to identify any increased benefits that have arisen from the changes. Nor have any submissions pointed to any benefits, although in theory, there should be ***benefits*** for CONSUMERS and GOVERNMENTS (e.g. decreased hospital and medical costs as a result of fewer accidents involving machinery and fewer falls in the elderly with consequential injuries such as broken bones). However, several professional organisations and university researchers were of the opinion that the level of harm was increasing. Further information, including the ***benefits*** of increased sales for INDUSTRY of these products needs to be collected and evaluated to establish if there has been a ***net benefit*** to the COMMUNITY AS A WHOLE.

The Review considered that steps should be taken to put in place, as a matter of priority, mechanisms to collect data, which will enable the level of harm (poisonings, medicinal misadventure) to be monitored. The Review noted, as discussed above, that the level of harm is also dependent on the effectiveness of pharmacist's supervision and counselling when supplying these products. The level of harm determines the extent of the costs caused by the harms.

[39] NDPSC considers applications to permit advertising of *Schedule 3* substances on a case-by-case basis. Applicants must provide information to establish that such advertising is likely to have a public health benefit. These substances are then included in Appendix H of the SUSDP. Although all jurisdictions agreed to amend their legislation to adopt Appendix H and implement the consequential exemption of products containing these substances from the advertising prohibition, several jurisdictions have yet to do so.

Also, in considering advertising issues for *Schedule 3* medicines, it can be pointed out that the intrinsic dangers to health from inappropriate use of each drug are generally less than for prescription-only (*Schedule 4*) medications for which the medical practitioner acts as gatekeeper. However, the purpose of *Schedule 3* medicine classification is for the pharmacist to act as gatekeeper, particularly to reduce medication interaction problems and to restrict diversion and use for drug abuse.

Even where the pharmacist controls access to *Schedule 3* medicines, the Review considered that relaxation of the advertising controls would lead to an increase in the number of poisoning and medicinal misadventure incidents because of increased consumption. There will always be a proportion of poisonings and medicinal misadventures which are unpredictable. While the numbers of such adverse events could be expected to increase with increased consumption, the level of such adverse events when compared with the number of units consumed may not change. This would in turn lead to an increase in the associated costs for consumers and governments. Further, an increase in the number of problems would lead to pressure for 'up-scheduling' to occur – so increasing the degree of regulation (and public cost) for many medicines.

The Review noted that the United States of America is limited in the application of risk-based controls because of their lack of schedule categories. For example, Claratin is a heavily advertised prescription-only medicine in the United States of America, while in Australia it is a *Schedule 2* medicine. In this sense, the present multiple scheduling in Australia can provide a degree of flexibility and result in advertising being permitted where the risks are lower.

Consumers' need for information

On balance, the Review considered that the current prohibitions on DTC advertising must be maintained except where State and Territory health departments believe it can contribute to a ***net benefit*** to the COMMUNITY AS A WHOLE through information rather than promotion. Public benefits would include:

- more appropriate use of medicines through understanding of the need for compliance and when to report side-effects;
- encouragement of discussion and improved communication between doctors and patients within the context of quality use of medicine programs;
- better health outcomes from recognition of symptoms and treatment of under-treated conditions and increased opportunities for doctors to check for other problems;
- reduction of costs from the efficiency of earlier treatment; and
- consumer satisfaction that their 'right to know' has been met.

These benefits will not occur without also causing harm unless the informational aspects are emphasised. Promotional material, if used, should be part of a package to deliver information and education to the public, enabling these benefits to be realised. The package should also include attention to reliance on professional gatekeepers to redress the information asymmetry.

The Review considered however, that the current controls operate in some instances to prevent consumers having access to information to which they should have access. Consequently, it has proposed that a number of informational options, which, under the current legislation would fall within the definition of advertising (in all jurisdictions), should be permitted.

Inevitably this will lead to a need to interpret when these informational options become promotional. Consequently, to minimise confusion at this interface between informational and promotional advertising, the Review believes that the NCCTG should develop a strategy including standards, which clearly sets out the circumstances and conditions in which such advertising is permitted.

Consumer Medicine Information

The sponsor of all prescription medicines and *Schedule 3* medicines approved for registration after 4 July 1994 must, under Therapeutic Goods Regulation 9A (1A), provide Consumer Medicine Information (CMI) for these products. 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.[40] While industry is required to have CMIs available, there are no requirements for the product sponsor, or anyone else, to distribute CMIs. Consequently it is often difficult for consumers to access the CMI, or to even be aware of its existence. The Review considered that CMIs should be more readily accessible.

The Review also noted that CMIs may come within the definition of an advertisement if made widely available (e.g. if a sponsor places a CMI on its website or distributes it other than on direct consumer request for information). The Review considered that the restriction on advertising prescription medicines should be clarified to enable CMIs to be more widely distributed and more readily accessible to consumers especially those consumers using or prescribed a particular product. The first step in achieving this will be to clarify the definition of advertising to remove any barrier to distributing this information.

The Review understands that neither doctors or pharmacists distribute CMIs as a routine practice. The Review was told of problems because electronic copies were not available on the databases used in some pharmacies, and that pharmacists wished to be paid for supplying them. The recently concluded Third Community Pharmacy Agreement recognises the duty of pharmacists to supply consumers with information. The Review considered that, given their privileged position, doctors and pharmacists have an obligation to ensure consumers have access to accurate, comprehensive and balanced written information about the products they are taking, and that where they are mandated to be available for a product, doctors and pharmacists should ensure a consumer has been provided with a CMI.

The Review recognised that, in allowing wider use of CMIs, there is a potential for their use to be exploited for promotional purposes. The Review noted that distribution of CMIs and other educational material to the consumer is covered in the APMA

[40] *Schedules 12* and *13* of the Therapeutic Goods Regulations set out the requirements for these documents.

Code of Conduct. There was some criticism of the effectiveness of the Code in ensuring compliance. The Review considered that this could be overcome by providing legislative underpinning for these provisions of the Code and its complaint handling mechanisms under the *Therapeutic Goods Act 1989*. The NCCTG should investigate this when developing standards for distributing CMIs.

Press releases

Press releases can provide consumers with information about new products. The Review considered it appropriate that consumers have access to such information. While press releases may come within the definition of an advertisement, the prohibition has not generally applied to those which complied with the advertising code provisions of the APMA Code of Conduct. As mentioned above, there has been criticism that in many instances these press releases have not complied with the Code.[41]

The Review also noted that, where action has been taken about a press release that has breached the APMA Code of Conduct, it has been some time after the event and the inaccuracies and imbalances have been perpetuated by adoption into uncritical media reports. The Review was concerned to note that press releases might lead to unbalanced media reports. The poor quality of media reporting was highlighted by research showing the misleading and inaccurate nature of many media articles (Moynihan et al., 2000).

The Review considered that consumers have a right to be informed about new medicines, but this information should be balanced, setting out not only the indications, but the contra-indications and precautions to be taken in using that new product. The Review noted complaints that much of the media following release of a new product is inaccurate, misleading and unbalanced. One submission suggested that press releases should be required to be pre-cleared either by the Therapeutic Goods Administration or by the industry associations.

The Review considered that press releases should continue to be permitted as a means of informing consumers. While the Review did not consider that such press releases should be pre-cleared, it did consider that industry and governments should examine ways in which the current Code can be strengthened and enforcement made more timely and effective. These measures might include better publicity of the complaint procedures. Further, all sponsors should be obliged to accompany press releases with objective, balanced and complete technical information (e.g. CMI documentation) as is required under the APMA Code of Conduct. The Review considered that there could be benefit for the community and industry in providing legislative underpinning for the APMA Code of Conduct requirements in this area – this should be explored by the NCCTG.

The increased ***cost*** for INDUSTRY of providing CMIs with press releases should be minimal and the Review considered that these should be more than outweighed by the ***benefits*** to the CONSUMER of an improvement in the quality and balance of medical reports.

[41] The Review noted that not all companies are members of the APMA and this limits the effectiveness of the Code.

Generic or unbranded product advertising

The Review has considered the cost and benefits of permitting generic advertising (i.e. advertising that does not identify the brand name of a product but uses only the generic name of the ingredient or class of ingredient). However, the experience when such advertising of pharmacist-only medicines was permitted is that, where there is only one product in the market (and this will most generally be the case for the newer prescription medicines) this advertising can be quite aggressive and highly promotional.

The Review noted that when generic or unbranded advertising for a *Schedule 3* substances was permitted, it only occurred where there was a single branded product of a particular substance or class of substance. In essence, this amounted to brand advertising for that product. The Review considered that, except for new and expensive products, as discussed above, such advertising is unlikely to occur. Therefore allowing generic or unbranded advertising is equivalent to allowing brand advertising for a product.

For prescription medicines, the Review considered that such advertising would have many of the same problems as brand advertising of lack of overall balance, creating unreal expectations. While recognising that this imposed a ***cost*** on INDUSTRY in limiting the way in which a supplier can market its products the Review considered that there would be ***no net benefit*** to the COMMUNITY AS A WHOLE if it were to recommend any change in the current restrictions

Managing disease state advertising

The Review has been concerned to note a number of recent advertising campaigns focusing on disease states and lifestyle issues sponsored by drug manufacturers but which do not mention a product or identify the sponsor. In these cases, the advertisement provides information about a particular disease or condition (e.g. sexual dysfunction, obesity), advises consumers that treatment is now available and refers consumers to their medical practitioner. Because these advertisements do not mention a product or the company sponsoring the information, they do not come within the prohibition on advertising prescription medicines under drugs, poisons and controlled substances legislation. However, companies sponsoring such promotions clearly expect to benefit from the advertisements through increased sales of their products. In this context, the Review noted that the advertisements that have been run to date relate to products not subsidised by the Pharmaceutical Benefits Scheme.

The Review also noted the use of ‘advertorial’ promotions, i.e. where an article purporting to provide information is paid for by a sponsor or supplier of a product. The Review noted that under recent amendments to the Therapeutic Goods Regulations such promotional activity would come under the definition of ‘generic information’. Prior to these amendments to the Regulations, some sponsors of complementary medicines used this device as a dubious form of advertising to avoid the restrictions on the disease states for which a product could be advertised. The Regulations now require this generic information to comply with certain restrictions on how and where such information can be presented (e.g. it cannot identify the sponsor or the product being discussed).

Several stakeholders also raised the lack of equity of the prohibition on DTC advertising of prescription medicines compared to that of complementary medicines, where the efficacy of the products has not been established in the same rigorous fashion that is required of prescription medicines.

The case of St John's Wort – an unscheduled substance – is used to illustrate these contentions. St John's Wort contains 'hypericin', which has been reported to offer antidepressant and anti-anxiety activity equivalent to low doses of some *Schedule 4* medicines (Vorbach et al., 1994). The Review noted that, under the Therapeutic Goods Advertising Code, these products may be advertised for related conditions provided the sponsor holds the required level of evidence and they are only promoted through generic information for serious conditions, such as depression. However, the available evidence has not been evaluated. In comparison, sponsors of prescription medicines that have been through a comprehensive evaluation process are precluded from advertising their products. Further, sponsors of prescription medicines are required to provide a CMI whereas no such information is required for unscheduled products. The Review considered that the NCCTG should examine the equity of this situation.

Disease state advertisements or promotional material distributed direct to the consumer may be a breach of the Australian Pharmaceutical Manufacturers Association Code of Conduct.[42] A number of stakeholders expressed concern to the Review that the APMA Code of Conduct was ineffective in dealing with these situations. The APMA Code of Conduct relies on a complaints panel[43] to deal with breaches of the Code. However, the Review noted that the Code is a voluntary code which can only effectively be applied to members of the APMA. In some cases breaches of the Code may also lead to action under the *Trade Practices Act 1974.*

The Review noted that in some cases disease state advertisements would encourage consumers to seek medical advice. Where doctors undertake routine screenings (e.g. blood pressure), conditions which might otherwise have gone untreated, or where initiation of treatment would otherwise have been delayed, may be identified and treated.

On the other hand, disease state and lifestyle advertisements can lead to unnecessary doctor visits, inappropriate prescribing of these medicines and, where a doctor considers the treatment referred to in the advertisement inappropriate for a particular consumer, to doctor shopping.

The Review was also concerned about the lack of transparency of the current system in that there is nothing to alert the consumer to the fact that a drug company has sponsored and paid for the advertisements. While it would be possible to require the company to identify that they have paid for the advertisement, this could well lead consumers to conclude that a medicine was the solution to their problem which would lead to the same costs and benefits as discussed above in relation to DTC advertising of prescription medicines generally.

[42] Clause 9.4 of the Code deals with educational activities in relation to prescription medicines.

[43] The majority of the members of the complaints panel do not come from industry.

The dilemma for the Review is how to manage disease state promotions in a way that provides a ***net benefit*** for the COMMUNITY AS A WHOLE.

The Review considered that the current situation, where drug companies use disease state advertisements as mechanism to circumvent the prohibition on advertising prescription medicines, leads to unnecessary ***costs*** for GOVERNMENT (from subsidised doctor visits) and the CONSUMER. The Review was not convinced that these costs were outweighed by the ***benefit*** to CONSUMERS and the COMMUNITY AS WHOLE of preventing later hospital and medical costs. Equally however, the Review considered that to totally prohibit disease state promotions would not only impose ***costs*** on INDUSTRY by restricting their freedom to market their product, but would also impose a cost on GOVERNMENTS and CONSUMERS as a result of hospital and medical treatments which could have been avoided with earlier medical intervention.

Appropriate mechanisms to manage disease state promotions will be necessary if there is to be a ***net benefit*** to the COMMUNITY AS A WHOLE. The Review considered that a code of practice, with clear parameters for such disease state advertisements, as distinct from information, could, in some circumstances, provide a ***benefit*** to CONSUMERS by addressing their information deficit. There should be no impact on the ***costs*** for INDUSTRY and indeed, by removing uncertainty and providing more clarity, there may be a marginal reduction in costs for industry. Legislative underpinning for the code, through the *Therapeutic Goods Act 1989,* will ensure equity in the level of compliance.

In this context, the Review noted that the APMA has a Code of Conduct, which indirectly addresses disease state advertising. The Review considered that the NCCTG, in consultation with the industry, consumers and health professionals should develop a Code of Practice. To ensure compliance, the Code would need to be underpinned by legislation. In developing the Code, the NCCTG may wish to use the APMA Code of Conduct as a starting point. The Code of Practice should specifically identify the requirements for disease state advertisements.

The Review considered that this approach would provide a ***benefit*** to CONSUMERS and GOVERNMENT through improvements in identification and timely treatment of a range of diseases and conditions which are currently under-treated and the consequential reduction in hospital and medical costs. There would also be a reduction in ***cost*** for INDUSTRY in that they would have greater freedom to market their product.

Price advertising

The Review cannot see a public interest case in prohibiting information being provided on the price of prescription medicines and *Schedule 3* medicines for which advertising is prohibited. Such advertising should not promote use of the product, but be for information only. This will enable the consumer to choose a supplier on the basis of price as well as service.

These price advertisements should be able to be provided in publications such as catalogues with advertisements for other products. The Review sees no reason that such advertisements cannot be unsolicited. However, price advertisements placed in juxtaposition to an informational article, which refers to the product directly or indirectly, would be considered promotional. Similarly, large posters, single item

advertisements in large typeface or 'two for the price of one' type offers, would also be seen as promotional. Similarly, the Review considered that such advertisements on television or radio would, by the nature of the media, also be seen as promotional and should be regulated under the *Therapeutic Goods Act 1989* (see Chapter 6).

The Review appreciates that amending the legislation to allow the price of prescription medicines to be advertised may lead to some administrative problems in determining the precise borderlines of acceptable listing and portrayal. However, this 'border control' problem is a small inconvenience relative to the advantages of improved consumer knowledge of price and the competition between suppliers that this would enable.

A standard for informational price advertising, publication of CMI and disease state advertisements

The Review recommends that the NCCTG develop a Standard to cover what advertisements can be defined as coming within the category of permitted advertisements in relation to price advertising and CMIs. This Standard would clarify the border between informational and promotional advertisements.

The Standard, which should be underpinned by inclusion in the *Therapeutic Goods Act 1989*, should cover such matters as:

For CMIs the information:

- is to be presented in its entirety as required by *Schedules 12* and *13* of the Therapeutic Goods Regulations;
- is not to be embellished in any way or to be accompanied by pictures; and
- must not be juxtapositioned with information, such as articles about the substance in the product.

For disease state promotional material:

- the nature of the information such advertisements must include (e.g. the advertisement should discuss the range of possible treatment options); and
- where such advertisements can be placed (e.g. they must not be juxtapositioned with articles or other material that refers to a particular product or company).

For price advertising:

- how permitted price advertisements can be presented including:
  - the maximum print size;
  - must be part of a list of products from multiple product manufacturers;
  - must not be juxtapositioned with information, such as articles about the substance in the product; and
  - should not be accompanied by illustrations or pictures;
- price advertisements may only be placed by suppliers (i.e. not manufacturers of products);

- the content of the price advertisement (name, brand, strength, pack size and price); and
- the nature of the media where such an advertisement may be placed (e.g. not on television or radio).

The NCCTG should also be asked to advise jurisdictions on an appropriate mechanism for monitoring and policing compliance with the Standard and for resolving any disagreements about whether particular advertisements are permitted under the Standard. Whatever mechanism is developed for monitoring and ensuring compliance would need to be underpinned by appropriate provisions under the *Therapeutic Goods Act 1989*. The issue of the role of this *Act* in regulating advertising of medicines and poisons is discussed in Chapter 6 of this Report.

Public education campaigns

The Review was advised that, in some circumstance, the definition of advertising in the current legislation would prohibit governments from publishing information essential to the success of a public health education campaign. The Review can see some very limited occasions when, as part of a public health education campaign governments may wish to provide information about a particular product (e.g. a vaccine) either generically or by brand name, which may come within the definition of an advertisement. In these circumstances, the Review considered that where, as part of such a government information campaign, a Commonwealth, State or Territory health government decided that publishing such information is necessary for the success of the campaign, and has approved the content, placement and timing of such informational material, the legislation should not prohibit its publication.

Legal advice will be required to establish how the legislation should be amended to permit the informational advertising discussed above.

5.1.6 Conclusions

The Review considered that the prohibition on advertising prescription medicines should be modified to a limited extent to permit advertising that is in the public interest, as this will provide a benefit to the community as a whole. Thus, it is proposed that disease state and price advertising be permitted where they meet the required standards; that the CMI should be made more freely available; and that press releases, which comply with the APMA Code of Practice and are accompanied by a CMI, be permitted. It is also proposed that advertising that is incorporated in a government education campaign be permitted under strict criteria.

If implemented, the outcomes for the various community sectors can be summarised as:

- FOR INDUSTRY, information about new products would facilitate market entry at the point the product comes on to the market; and the situation, with regard to CMIs and disease state advertisements, would be clarified. The ability of companies to compete in the marketplace, while eased slightly, will remain much as at present.

- FOR CONSUMERS, there will be access to information that will help them select their supplier on the basis of price as well as service and convenience. Wider availability of the CMI will help reduce the information asymmetry between consumers and health professionals. The continuing use of press releases will alert consumers to new products as they enter the market.
- FOR PROFESSIONALS, doctors, veterinarians (or other authorised prescriber) will be able to provide balanced expert advice and prescribe rationally for the patient without undue pressure to prescribe a particular medicine. Pharmacists and veterinary suppliers will be able to advertise the price of the products.
- FOR GOVERNMENT, there could be benefits to the extent that public health campaigns are supported by appropriate advertising. Costs should not increase because the permitted forms of advertisement should not lead to inappropriate prescribing of medicines generated by consumer demand.

11 *Recommendation 11: Informational advertising of scheduled medicines* [44]

That all Commonwealth, State and Territory governments agree that:

a) All provisions relating to advertising in State and Territory drugs, poisons and controlled substances legislation be repealed.

b) The current prohibition on advertising of *Schedule 3*, *4* and *8* medicines be retained in the *Therapeutic Goods Act 1989* except for certain, specifically permitted advertisements.

c) The *Therapeutic Goods Act 1989* be amended to provide exemptions from the prohibition on advertising of *Schedules 3*, *4* and *8* medicines for the following advertisements:

- price, where such information may be solicited or unsolicited and may appear in a catalogue or other publications containing other permitted advertising for medicines, but where such advertising is informational and not promotional;
- Consumer Medicine Information (CMI) where that information is presented in its entirety without embellishment and is not juxtapositioned with other informational material other than a press release;
- as at present, a one-off press release about the availability of a new medicine where that press release complies with the APMA Code of Conduct and the press release is accompanied by the CMI for the product;
- where such advertisements comply with the Standard for Informational Price Advertising and Publication of CMIs (see d) below); and

[44] This recommendation assumes that Recommendations 22 and 23 will be implemented. If not, similar amendments will be required to State and Territory drugs, poisons and controlled substances legislation to deal with situations involving sole traders trading intrastate.

11 cont

- where Commonwealth, State and Territory governments decide to include information about specific products as part of a public health education initiative and have authorised the content, placement, timing and nature of such informational advertisements.

d) The NCCTG should develop a Standard for Informational Price Advertising and Publication of CMIs to be underpinned by the *Therapeutic Goods Act 1989*. This Standard should cover:

For price advertising:

- how permitted advertisements can be presented including:
  - the maximum print size;
  - must be part of a list of products from multiple product manufacturers;
  - must not be juxtapositioned with information such as articles about the substance in the product; and
  - should not be accompanied by illustrations or pictures;
- the content of the advertisement (name, brand, strength, pack size and price);
- who can place the advertisements (i.e. may only be placed by suppliers and not manufacturers of products);
- the nature of the media where such an advertisement may be placed (e.g. not on television or radio); and

For CMIs, that the information:

- is presented in its entirety in the form required by *Schedules 12* and *13* of the Therapeutic Goods Regulations;
- is not embellished in any way or accompanied by pictures; and
- is not juxtapositioned with other information, such as articles about the substance in the product; and

Such other matters as the NCCTG considers necessary.

e) That the NCCTG, in consultation with industry, consumers and health professionals develop a Code of Practice to specifically cover situations where and how consumer disease state advertisements and generic information directly or indirectly promoted by sponsors of *Schedules 3*, *4* and *8* medicines may be undertaken and that this code be underpinned by the *Therapeutic Goods Act 1989*.

5.2 Supply of product samples

Terms of reference addressed: General Issues 1, 2, 3, 4, 6, 7, 9 and 10; Specific Issue 2 and 5.
Supporting data and analysis for issues discussed in this Chapter are included in Part B Section 2 and 5.2.

Samples, in the context of drugs, poisons and controlled substances legislation, fall into two broad categories:

- **Clinical samples** which are packs of a medicinal product, often in smaller specially manufactured packs rather than the commercially available product, which are distributed by the manufacturer or wholesaler to a health professional,

free of charge. These samples are intended to be supplied by health professionals to consumers where the product is appropriate for treating the condition from which the consumer is suffering. The purpose of supplying the samples is to promote the product. Clinical samples are specifically addressed by the legislation in some jurisdictions, while in others, the controls that apply fall under more general provisions controlling supply of these products.

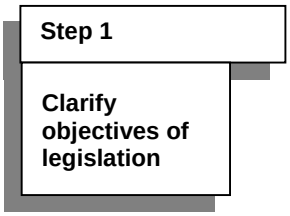
- **Consumer samples** are packs of products that are either unscheduled medicines or scheduled or unscheduled poisons. Only scheduled products come under the legislation under review, and then only in some jurisdictions; in other jurisdictions the controls are in other legislation. The controls that apply are imposed by provisions relating to supply of drugs and poisons by hawking or door-to-door distribution. The legislation does not specifically refer to consumer samples.

Drug company representatives distribute clinical samples as part of their marketing program, particularly for new products, when they visit health professionals (e.g. doctors, dentists, veterinarians pharmacists) to provide them with information about the company's products. During such visits, the representatives may provide health professionals with 'clinical samples' of the product(s) they are promoting. These clinical samples enable the health professional to supply the product to a patient as a trial, without cost to the patient.

All jurisdictions have controls on prospective supply of medicines and poisons such as the supply of clinical samples.

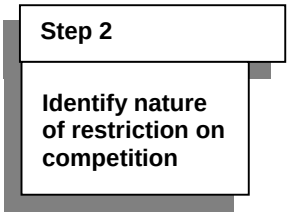
Similarly, distribution of consumer samples may be part of the promotional activities in relation to scheduled poisons and unscheduled medicines and poisons. These samples are generally unsolicited. While distribution of samples of unscheduled medicines and poisons is outside the scope of the legislation being reviewed, poisons legislation does prohibit distribution of consumer samples containing substances in *Schedules 5*, *6* and *7*.

5.2.1 Objectives of the controls



The underlying objectives of the controls on the supply of samples are to prevent harm to the community and individuals through poisoning, medicinal misadventure, diversion or deterioration in the quality of the products supplied.

5.2.2 Nature of the controls

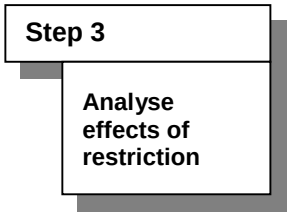


The nature of the controls vary considerably between jurisdictions. At the most restrictive end of the spectrum, two jurisdictions prohibits the prospective supply [45] of any samples of scheduled product. One jurisdiction requires both the company and its representatives to be licensed under drugs, poisons and controlled substances legislation, and another

[45] Prospective supply refers to the representatives carrying quantities of stock for which they have no orders or requests to supply.

jurisdiction requires only that certain records relating to the supply of clinical samples be kept. All jurisdictions prohibit the prospective supply of *Schedule 8* substances.

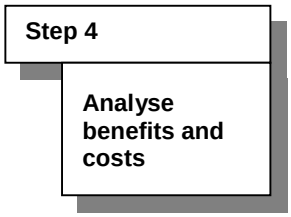
5.2.3 Effect of the controls on competition and the economy



The controls limit the way in which companies can market their products. The restrictions also impact on the extent to which companies can compete in the marketplace. The extent of that restriction depends on the jurisdiction. In some jurisdictions there are limits on the quantity of clinical samples a company representative can carry, who can supply the samples, to whom they can be supplied and, in one jurisdiction, clinical samples must be ordered. In relation to scheduled poisons, supply of samples to the consumer is generally prohibited, or significantly restricted by the provisions relating to hawking, door-to-door sales and supply in a public place.

5.2.4 Costs and benefits of the current controls

Clinical samples



The controls restrict competition and involve ***costs*** to INDUSTRY through the need to comply with the varied requirements of different jurisdictions. These variations include who can provide samples, what can be provided, how much can be supplied and indeed how and when they can be supplied. In addition to the ***costs*** for INDUSTRY arising from establishing the requirements in all jurisdictions in which a supplier wished to operate, the costs to industry varied considerably, depending on the jurisdiction. In one jurisdiction there was a cost to license company representatives; in another, prospective supply of samples by company representatives was prohibited, although orders could be taken. One company estimated that this prohibition on prospective supply of clinical samples added 5 per cent to the product costings for every new sample line.

Restrictions on supply of clinical samples was one of the issues industry raised to highlight the costs that arise from a lack of uniformity. The issue of uniformity is discussed in Chapter 6.

The ***benefits*** to the COMMUNITY derive from avoidance of harm caused through poisoning, diversion or deterioration in the quality of the products supplied. If these harms had occurred there would be associated hospital, medical and social costs.

The Review considered that there were risks of poisoning, diversion and misuse associated with clinical sampling and if unfettered, would result in increased ***costs*** for the COMMUNITY (hospital, medical and social costs). Removal of all regulation and elimination of all sample controls was not seen as a ***benefit*** to the COMMUNITY AS A WHOLE despite some potential improvements in competition for INDUSTRY. These were judged as more than offset by the risks of greater diversion and misuse of scheduled medicines without such controls.

For *Schedule 8* medicines, the risks of diversion and abuse are very high and the Review considered the ***benefits*** to the COMMUNITY AS A WHOLE outweighed the ***costs*** to INDUSTRY of restricting their capacity to market their products in this way. The Review considered that the prospective supply of clinical samples of *Schedule 8* medicines should continue to be prohibited and such samples only be supplied through an ordering process.

For consumer samples

The ***benefit*** of the controls that apply to supply of consumer samples for CONSUMERS and the COMMUNITY is a reduction in the level of poisonings, which might otherwise result from inappropriate sampling of *Schedule 5*, *6* and *7* poisons directly to consumers. 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 for samples of *Schedule* 7 products, the risk of harm was high so the ***benefits*** to the COMMUNITY of retaining the restrictions outweigh the ***costs*** to INDUSTRY. However, for samples of *Schedule 5* and *6* products the extent to which the controls provided a ***net benefit*** to the COMMUNITY AS A WHOLE was not so clear cut.

5.2.5 Alternatives to the current controls and their costs and benefits

Step 5

Consider alternatives and recommend

Clinical samples

While the Review considered the risks of supplying clinical samples as significant, it concluded that, in most cases, the risks could be appropriately managed, without compromising the public health objectives, through a code of practice. In this context the Review noted that the APMA Code of Conduct includes provisions relating to the supply of clinical samples. The Review considered this Code, if suitably underpinned by legislation, would ensure compliance and enable the objectives of the legislation to be met in a less regulatory manner than at present. The Code would however, need to be amended to cover matters such as record-keeping, quality control, quantities to be held and supplied and disposal arrangements.

For manufacturers and wholesalers, compliance with the Code should be a condition of the wholesaler's or distributor's licence. For company representatives, a reverse licence[46] should be adequate to achieve compliance. A reverse licence arrangement will reduce the ***cost*** for INDUSTRY of obtaining a licence in the jurisdiction that currently requires a licence and associated licence fee.

The extent to which this coregulatory approach, based on a the APMA Code of Conduct, would result in reduced levels of regulatory control would depend on the level of control on clinical sampling that currently applies in individual jurisdictions.

[46] A reverse licence is a general permission given under the legislation for a person to undertake an activity that would otherwise be prohibited. No paperwork is involved. Those who breach the requirements under the legislation would be deemed to be providing substances illegally.

This should result in a reduction in the level of control in nearly every jurisdiction and it is reasonable to assume there would be associated ***reductions in cost*** to BUSINESS and in turn to CONSUMERS.

The Review considered that the current controls in all jurisdictions should be repealed and replaced with a Code of Conduct suitably strengthened and appropriately underpinned by legislation. This will enable the objectives of the controls to continue to be met.

Labelling clinical samples

In supplying a clinical sample to a consumer, the health professional has an obligation to ensure the consumer understands how to use the medicine safely and effectively. Some jurisdictions impose specific labelling requirements in such circumstances. The Review considered that, to ensure their safe and effective use, clinical samples require the same labelling requirements as any other supply of a medicine.

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. The Review therefore considered that the current controls provided a ***net benefit*** to the COMMUNITY AS A WHOLE.

In the case of *Schedule 5* and *6* poisons, the ***benefits*** to the COMMUNITY AS A WHOLE of the current restrictions on distribution of consumer samples is less clear. However, the Review did consider that unrestricted distribution of samples would increase the risk of accidental poisoning 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 is not 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 the ***benefits*** for the COMMUNITY of preventing poisoning and diversion would be realised by self-regulation. The code of practice should cover such matters as:

- which substances are suitable for consumer samples;
- the requirements for packaging and labelling;
- how the samples are to be distributed (e.g. direct to adults, attached to other products, letter box drops); and
- where the samples can be distributed (e.g. shopping centres).

The Australian Chemical Specialties Manufacturing Association together with other chemical industry associations and in consultation with government, consumers and health professionals should be responsible for developing the code of practice.

12 *Recommendation 12: Supply of sample packs of medicine and poisons*

That all Commonwealth, State and Territory jurisdictions agree that:

a) States and Territories repeal provisions relating to the prospective supply of products including samples of medicines and poisons within their drugs, poisons and controlled substances legislation. (With the exception of those relating to the prospective supply of *Schedule 7* products and *Schedule 8* substances, where the prohibition should be maintained).

b) The Australian Pharmaceutical Manufacturers Association in consultation with government, consumers and health professional organisations, amend their Code of Conduct for the Supply of Clinical Samples. The Code should include standards for:

- the security of the stock;
- the quantities to be held, carried and supplied;
- quality issues, such as the temperature of storage;
- record keeping; and
- disposal.

c) State and Territory drugs and poisons legislation be amended to provide that:

- it be a condition of licence that manufacturers and wholesalers comply with the APMA Code of Conduct for the Supply of Clinical Samples; and
- authorised representatives of manufacturers and wholesalers be exempted from requirements in medicines and poisons legislation that would make it an offence for them to supply scheduled medicines provided they do so in compliance with the APMA Code of Conduct for the Supply of Clinical Samples.

d) A requirement be included in medicine and poisons legislation to ensure that those supplying medicines, including clinical samples, provide the consumer with adequate instructions, including labelling the samples with the directions for use, to enable the consumer to use the clinical sample safely and effectively.

e) The Australian Chemical Specialties Manufacturing Association together with other chemical industry associations and in consultation with government, consumers and health professionals develop a Code of Practice for the Supply of Consumer Samples of Poisons. The Code should include standards for:

- the substances which may be supplied as consumer samples;
- the way in which the consumer samples may be distributed;
- to whom they may be distributed;
- the size of the sample packs and the quantities which may be distributed to a consumer;
- the labelling and packaging requirements for the samples; and
- disposal.

f) State and Territory drugs and poisons legislation be amended to provide that, for consumer samples of *Schedule 5* and *6* poisons, distribution should be permitted provided that such supply take place in accordance with a Code of Conduct for the Supply of Consumer Samples of Poisons.

5.3 Licensing

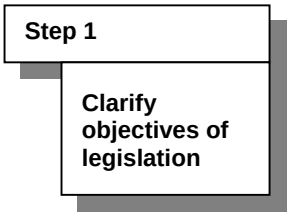
Terms of reference addressed: General Issues 1, 2, 3, 4, 5, 6, 7, 8, 9 and 10; Specific Issues 2 and 4.
Supporting data and analysis for issues discussed in this Chapter are included in Part B Section 5.3.

State and Territory legislation includes a variety of licensing requirements. These include licences for individuals (see Supply of Clinical Samples above), licences for manufacturers of therapeutic goods, retail licences (see Scheduling above) and wholesale licences. Commonwealth legislation also imposes licensing requirements, some of which overlap with the requirements of State and Territory licences. In particular, the requirements for licences to import, export and manufacture controlled substances that are imposed under the Customs (Prohibited Import) Regulations, Customs (Prohibited Export) Regulations and the *Narcotic Drugs Act 1975*.

There are considerable variations between jurisdictions as to the particular products that can be sold by licensed poisons sellers: in one jurisdiction they can sell all *Schedule 2* products, while other jurisdictions place various limitations on which *Schedule* 2 substances can be sold by the licence holders.

The Review noted that, in some jurisdictions, suppliers of agvet products might, under certain circumstances, be authorised to supply scheduled medicines (other than *Schedule 8*).

5.3.1 Objectives of the controls

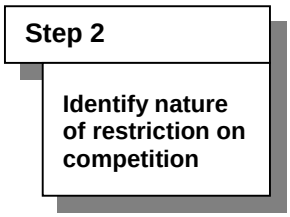


The objective of the licensing requirements is generally to ensure that only those who have demonstrated the necessary competencies in dealing with poisons, who meet other requirements such as secure storage, and who supply these substances in accordance with relevant controls are given a legal right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

For *Schedule 2* poisons licences, the objective is to provide access to medium to low risk products to those who would otherwise not be able to access these products or for whom it would be difficult to do so.

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

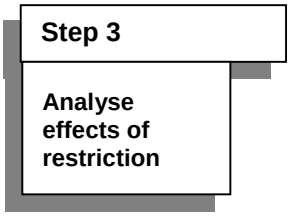
5.3.2 Nature of the controls



At the wholesale level, the licensing controls operate to support the restrictions on access provided by the scheduling arrangements. However, the *Schedule 2* licences at retail level operate to permit access to those who would otherwise not have ready access to such medicines. As indicated previously, normally *Schedule 2* substances can only be provided from a pharmacy; *Schedule 2* licences permit people, such as general store owners and garage proprietors, to sell *Schedule 2* substances in rural and remote

communities. Where such a licence is granted, the person is described as a 'licensed poison seller'. Conditions generally apply to these licences (e.g. cannot be sold from premises housing animals, the quantities to be held) which are intended to protect the quality of the medicines and limit the opportunities for misuse or diversion.

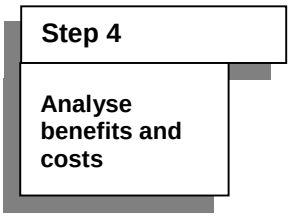
5.3.3 Effects of the controls on competition and the economy



The consequence of licensing for competition policy is that legal entry to the market to supply medicines and poisons is restricted to those who hold the requisite licences, in areas where such licensing applies. Not everyone who might want to operate in this market can enter the market to compete.

Entry restrictions and increased costs mean reduced competitive supply and some degree of price increase.

5.3.4 Costs and benefits of the current controls



The ***costs*** for INDUSTRY of meeting the entry requirements and of the licensing process may act as a deterrent to some entering the market. For persons or firms who meet the licensing standards, costs will have been raised by the costs of investment in gaining the necessary qualification and training and having these verified and approved. These costs are multiplied where different legislative requirements apply in different jurisdictions, or under different legislation. In addition there will be the cost of the licence fee.

The ***benefits*** for CONSUMERS and GOVERNMENT that arise from the licensing controls are that they minimise the risk of persons diverting scheduled substances for illegal supply. The risks of many scheduled substances being diverted for profit are high. It is therefore considered to be a benefit to the COMMUNITY AS A WHOLE to ensure that people handling these substances in the course of their jobs meet appropriate standards of probity.

For *Schedule 2* retail licences, the ***benefits*** are that CONSUMERS in remote and rural areas have access to some scheduled medicines which may otherwise be denied them or where such access might be difficult and costly. However, it has been pointed out to the Review that in such cases consumers do not have access to the pharmacist's advice to meet any information needs they may have. The need for of Consumer Medicine Information services as an alternative to face-to-face counselling by a pharmacist is discussed in Chapter 4 and in section 5.1 (Part A). The Review also sees merit in developing a standard to apply to such supply. In addition to matters such as the amount of stock which should be held and the way in which it should be stored the standard could include a requirement to direct consumers to where independent information about these products can be obtained. The NCCTG should be responsible for developing such a standard.

5.3.5 Alternatives to the current controls and their costs and benefits

Step 5

Consider alternatives and recommend

The Review considered the range of licensing requirements under drugs, poisons and controlled substances legislation, and examined whether the objectives of the controls could be achieved by alternative means.

In a few low risk areas, the Review considered that the ***costs*** of the licensing provisions for INDUSTRY (in obtaining the licence and meeting the criteria for a licence) and GOVERNMENT (in administering the licensing system) were not justified by the low level of risk. These low risk areas were Sch*edule 5* and *6* licences. Consequentially, the Review believed that there would be ***benefits*** to the COMMUNITY in repealing the licensing provisions for *Schedule 5* and *6* substances in those jurisdictions that still have these provisions. As discussed previously, the Review also considered that a reverse licence provided an appropriate level of control for company representatives distributing clinical samples.

Other alternatives the Review considered included self-regulation, partial self-regulation and reverse licences. However, the Review concluded that these options would not achieve the objectives set out above, would make it difficult to ensure compliance and would lead to high costs to the community, particularly social costs if these substances were diverted for abuse.

The Review considered that, while it might be possible to exempt a limited number of substances or forms of substance within *Schedules 2, 3* and *4* from the licencing requirements, this would add to ***costs*** for INDUSTRY in identifying those substances and for GOVERNMENT in administering such a complex set of controls. The Review found that, in general, the system of licensing provided a cost effective mechanism to achieve the objectives of the legislation and that the alternatives to licences would not achieve these objectives.

The Review considered that *Schedule 2, 3* and *4* licences, at wholesale level, should be retained, but that it would be more efficient:

- if the licence requirements were uniform across jurisdictions; and
- in the area of controlled substances, where there is duplication, if requirements for Commonwealth import, export and manufacture licences for these substances and the requirements for licences under drugs, poisons and controlled substances legislation were more closely aligned. These issues are discussed further in Chapter 6.

The Review also considered that, in general, the ***benefits*** to CONSUMERS of permitting most *Schedule 2* substances to be supplied by licensed poisons sellers outweighed the potential risks (increased poisonings and medicinal misadventures). However, where the Medicines Scheduling Committee identifies a particular risk associated with a *Schedule 2* substance, the substance should be included in an Appendix to the SUSMP and State and Territory legislation should prohibit its supply by licensed poisons sellers.

13 Recommendation 13: Schedule 5 and 6 licences

That Commonwealth, State and Territory governments agree that the provisions in State and Territory drugs and poisons legislation applying to licences for *Schedules 5* and *6* be repealed.

14 Recommendation 14: Licensed wholesalers

That Commonwealth, State and Territory governments agree that provisions in State and Territory drugs, poisons and controlled substances legislation applying to wholesale licences for *Schedules 2*, *3*, *4*, *8* and *9* products and substances, be retained but, where they overlap with requirements for Commonwealth licences to import, export and manufacture controlled substances, amendments be made as necessary to:

- State and Territory drugs, poisons and controlled substances legislation; and
- the Customs (Prohibited Import) Regulations, Customs (Prohibited Export) Regulations and the *Narcotic Drugs Act 1975*;

to make the licence requirements uniform.

15 Recommendation 15: Licensed poisons sellers

That Commonwealth, State and Territory governments agree that State and Territory drugs and poisons legislation be amended to provide that *Schedule 2* poisons licence holders be permitted to sell all medicines containing *Schedule* 2 substances, unless the Medicines Scheduling Committee has included that substance in an appendix to the SUSMP to designate that the risk of diversion, poisoning or medicinal misadventure is such that the sale of that substance should only be from a pharmacy.

5.4 Recording and reporting

Terms of reference addressed: General Issues 1, 2, 3, 4, 5, 6, 7, 8 and 9; Specific Issues 2, 4 and 5.
Supporting data and analysis for issues discussed in this Chapter are included in Part B Section 5.4.

Drugs, poisons and controlled substances legislation includes a number of provisions relating to recording and reporting transactions of scheduled medicine and poisons. These requirements apply at both the wholesale and the retail levels. For controlled substances there are also recording and reporting requirements under the *Narcotic Drugs Act 1975*, the Customs (Prohibited Import) Regulations and the Customs' (Prohibited Export) Regulations The requirements under these Regulations enable Australia to fulfil its obligations under the three United Nations drug treaties.[47]

5.4.1 Objectives of the controls

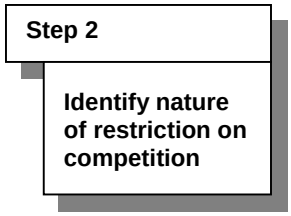
Step 1

Clarify objectives of legislation

The objectives of the controls are primarily to prevent diversion, especially of controlled substances, and to facilitate the quality use of medicines.

[47] The Single Convention on Narcotic Drugs 1961, the Psychotropic Substances Convention 1971 and the Convention Against Illicit Trafficking in Narcotic Drugs and Psychotropic Substances 1988.

5.4.2 Nature of the controls



All the legislative instruments set out the way in which records of controlled substances are to be kept and the way in which reports are to be made. The Review noted that the requirements in State and Territory legislation and Commonwealth legislation are generally consistent in the area of recording and reporting the wholesale supply of controlled substances.

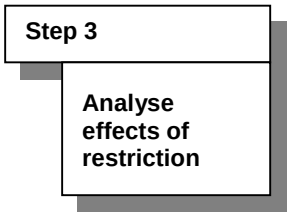
At the retail level, all jurisdictions require that records be kept of all *Schedule 4* supplies. In some jurisdictions there is also a requirement to report on the supply of some *Schedule 4* medicines. Some jurisdictions also require records to be kept of the supply of some or all *Schedule 3* medicines.

In a number of jurisdictions supply of *Schedule 7* substances is controlled under legislation other than drugs and poisons legislation (e.g. agricultural and veterinary legislation). The level and extent to which recording and reporting is required varies.

In most, but not all, jurisdictions there are no requirements at either the wholesale or retail level for records to be kept of the supply of *Schedule 5* and *6* substances.

5.4.3 Effect of the controls on competition and the economy

Medicines



The provisions requiring wholesale records to be kept and reports made on the supply of *Schedule 8* and Appendix D[48] medicines impose ***costs*** on INDUSTRY. Similarly, the recording requirements at retail level impose a cost on health professionals. Some jurisdictions also impose a reporting requirement at retail level for *Schedule 8* medicines and some *Schedule 4* medicines.

Recording requirements at wholesale level for other scheduled medicines are generally much less prescriptive. The requirements are unlikely to impose any significant burden on industry, as the sort of information that needs to be maintained is very much in line with good business practice. Only in companies whose business practices did not ensure adequate record-keeping, would the regulatory recording controls require any additional effort.

The legislative basis for the recording requirements is considered important for those companies whose business practices are less than optimal.

The requirements in all jurisdictions that records be kept of all *Schedule 4* supplies and, some jurisdictions of *Schedule 3* supplies, impose ***costs*** on PHARMACISTS that may be passed on to consumers. In those jurisdictions that require reporting on the supply of some *Schedule 4* substances there will be further costs to pharmacists in meeting this requirement.

[48] In some jurisdictions a separate schedule operates which reflects the additional restrictions imposed by Appendix D on *Schedule 4* substances.

Poisons

Jurisdictions that require records to be kept at either the wholesale or retail level relating to supply of *Schedule 5, 6* or *7* substances, would impose ***costs*** on WHOLESALERS OR RETAILERS.

5.4.4 Costs and benefits of the current controls

Step 4

Analyse benefits and costs

Medicines

The ***costs*** for INDUSTRY of maintaining records of the supply of *Schedule 8* medicines can be significant although where such records are maintained electronically this cost can be considerably reduced, once the initial costs of establishing a database have been met. Similarly the cost of reporting can be reduced where such reporting can be done electronically. Recording and reporting, as required by Commonwealth legislation,[49] at wholesale level is largely handled electronically.

The Review formed the view that the ***benefits*** to the COMMUNITY AS A WHOLE of reduced diversion of these substances for abuse outweighed the costs of wholesale recording and reporting.

While there is a ***cost*** to PHARMACISTS, DOCTORS and OTHER AUTHORISED SUPPLIERS in keeping records at the retail level supply of *Schedule 8* substances the Review considered these were outweighed by the ***benefits*** to the COMMUNITY through reduced abuse and diversion. The Review considered there could be benefits in reduced costs if an effective electronic system were to be implemented. This would not affect the requirements that paper copies of prescriptions be retained for evidentiary purposes.[50] However, the Review had concerns about the effectiveness of the way in which reporting is being handled at present. At the retail level, the effectiveness of the controls requiring reporting to prevent diversion of controlled substances, is undermined because:

- of the delays between the supply taking place and the regulator being in a position to monitor that supply, check it against any permission given to prescribe and establish whether a consumer is obtaining unauthorised supplies from multiple sources; and
- the reporting does not include supplies received from interstate. Currently, there is no formal arrangement to enable such information to be exchanged between jurisdictions.

Possible ways of addressing these problems are discussed below.

[49] *Narcotic Drugs Act 1975* the Customs (Prohibited Import) Regulations and the Customs (Prohibited Export) Regulations.

[50] The Review noted moves to introduce electronic prescribing and noted that any such system would need to address the status of such prescription where legal action relating to those prescriptions is taken.

The Review also considered that the provisions requiring supply of *Schedule 4* medicines to be recorded at retail level contribute to the ***benefits*** to CONSUMERS that the restrictions on access to these substances provide.

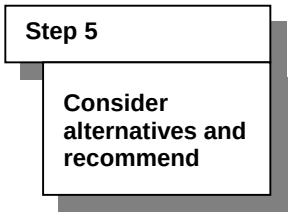
However, the Review was not convinced that the ***benefits*** (less medicinal misadventure) to CONSUMERS, of the mandatory requirement that supply of *Schedule 3* medicines be recorded, outweighed the ***costs*** to the PROFESSION (to make such records) and CONSUMERS (in the additional cost of the medicine) of the restrictions.

Poisons

The Review recognised that the requirement for recording of *Schedule 7* transactions did impose a ***cost*** on INDUSTRY and RETAIL SUPPLIERS. However, the Review considered that, because of the highly toxic nature of the substances involved, recording of supply enabled checks to be made to ensure that those using these substances were qualified to use them safely and that the products are not deliberately misused. The Review considered that the costs of keeping such records and the limitation on market access that these controls impose was outweighed by the ***benefits*** to the COMMUNITY AS A WHOLE of reduced poisonings.

The Review did not believe there were any benefits in maintaining records for *Schedule 5* and *6* transactions.

5.4.5 Alternatives to the current controls and their costs and benefits



The Review considered that total removal of the requirements for recording and reporting could lead to a significant ***loss of benefit*** to the COMMUNITY as the level of diversion for abuse and the level of poisoning would be likely to increase considerably, given the nature of the substances involved.

The Review considered whether record keeping and reporting could be managed by codes of practice or coregulation. However, it concluded that these alternatives would not provide the level of certainty, transparency and accuracy necessary to consistently support the restrictions on access thereby reducing the level of benefit (i.e. through an increased level of poisoning, medicinal misadventure and diversion and their associated hospital, medical and social costs) of those controls. Therefore the Review concluded that the current controls were a cost-effective means of tracking access to, and use of, a range of toxic substances. A legislative basis ensures a consistent and transparent approach is taken to recording and reporting requirements.

Medicines

The Review examined the extent to which it was necessary to mandate the form of the records for medicines and decided that, apart from *Schedule* 8 substances, where the risk of diversion or poisoning is high, this should not be required.

The Review also considered whether there were non-regulatory mechanisms for managing recording and reporting of *Schedule* 8 substances. However the Review considered that options, such as codes of practice and self regulation, would not lead to the high standards of record keeping or the timely reporting the Review saw as central to the underlying objective of reporting, i.e. preventing diversion of substances for abuse and illegal use.

The Review strongly urges jurisdictions to develop electronic reporting systems that will enable swift identification of diversion of substances of abuse. Mechanisms should also be put in place to enable interstate transactions to be monitored in a timely manner. Further, the Review noted that, in a number of cases, the reporting requirements for controlled substances at the retail level had only limited benefits in preventing diversion or abuse, because of the time lapse before records could be accessed for monitoring and because such records were State and Territory specific and did not include supplies from other jurisdictions. The Review could, however, see merit in such monitoring, if the timeliness of the reporting could be considerably improved (probably through adoption of an electronic system) and procedures were put in place to enable interstate transactions to be monitored in a timely manner.

The Review could see no particular benefit in a mandatory requirement to record the retail supply of *Schedule 3* medicines that would not be achieved by a voluntary system. Such a voluntary system would be based on a partnership arrangement between the consumer and the pharmacist that such a record be kept to help improve the quality use of medicines for that patient.

Poisons

Given the highly toxic nature of the substances included in *Schedule 7*, the Review considered that the requirements for recording of the supply of these substances was the most cost effective mechanism for achieving the objectives of the legislation. However where these requirements are included in legislation other than drugs and poisons legislation (e.g. agvet legislation), the Review would see no reason to retain these requirements in drug and poisons legislation.

16

Recommendation 16: Recording and reporting

That all Commonwealth, State and Territory governments agree that provisions in State and Territory drugs, poisons and controlled substances legislation be amended to the effect that they:

- retain the requirements for recording of all wholesale and retail transactions of *Schedule 8* medicines and specifically enable such records be kept electronically;
- continue the consistency of the recording requirements for *Schedule 8* medicines with the recording requirements relating to supply of *Schedule 8* medicines at wholesale level under the *Narcotic Drugs Act 1975* and the Customs (Prohibited Import) Regulations;
- retain the requirements for recording wholesale supply of *Schedule 2, 3* and *4* medicines, except for those provisions that mandate the form in which those records are to be kept, which should be repealed;

16 cont

- repeal the requirements for specific reporting of retail supply o*f Schedule 4* medicines (except those included in Appendix D of the SUSMP);
- repeal mandatory recording of the retail supply *Schedule 3* medicines;
- repeal recording of *Schedule 5* and *6* poisons in those jurisdiction that have such provisions; and
- repeal recording of supply of *Schedule 7* poisons at wholesale or retail level in those jurisdictions where there is other legislation within that jurisdiction that imposes requirements to meet the desired objectives.

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.
Supporting data and analysis for issues discussed in this Chapter are included in Part B Section 5.5.

Storage controls relate to how a substance or product is stored or displayed on the premises from which it is supplied. Handling requirements relate to how substances or products are transported between the premises of different suppliers.

Requirements relating to storage and handling of medicines and poisons at the wholesale and retail levels are included in drugs, poisons and controlled substances legislation in all States and Territories.

5.5.1 Objectives of the controls

Step 1

Clarify objectives of legislation

Storage and handling controls are intended to form part of, and so complement and support, a suite of controls on access to medicines and poisons provided by the scheduling arrangements. The controls seek to address multiple objectives including:

- avoiding poisoning incidents (e.g. loss during transport, easy access by children to substances from suppliers);
- preventing diversion for abuse, misuse or illicit manufacture; and
- maintaining the quality of the product.

5.5.2 Nature of the controls

Step 2

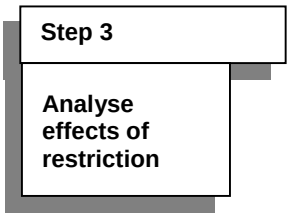
Identify nature of restriction on competition

Storage and handling controls relate to the level of security that must be exercised over the way goods, particularly controlled substances, are stored at wholesale and retail level. These controls impose restrictions on how they are to be stored (e.g. in a safe or wire cage); the nature of security arrangements; and the way in which the goods are to be transported and/or handled; and, at retail level, where the goods may be displayed in a store.

For medicines, there are controls in drugs and poisons legislation at the wholesale level that seek to ensure the quality of the products is maintained during storage and handling. There are similar controls relating to quality under the *Therapeutic Goods Act 1989.*

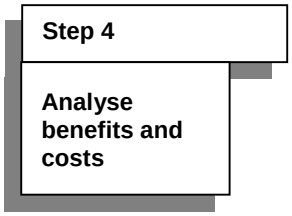
For poisons at the wholesale level, the State and Territory controls may duplicate or overlap controls imposed under occupational health and safety legislation.

5.5.3 Effect of the controls on competition and the economy



Storage and handling controls limit the options available to the various parties in the supply chain in the way in which they can store, handle and transport products. This restricts the degrees of competitive freedom that can be pursued.

5.5.4 Costs and benefits of the current controls

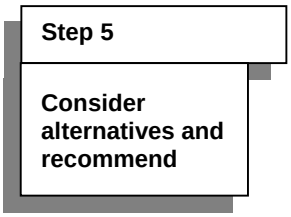


The current legislative restrictions on storage and handling may limit the number of players in the market to the extent that the ***costs*** for INDUSTRY flowing from the restrictions, inhibit market entry

Additional ***costs*** are incurred by GOVERNMENTS from the diversion of resources to the tasks of ensuring regulatory compliance. Some costs also flow from the controls associated with disposing of these products, although many of these costs flow from environmental protection legislation rather than drugs, poisons and controlled substances legislation.

The ***benefits*** for the COMMUNITY are seen to be that of obliging safer and more secure handling and storage than would be adopted in a free market with resultant reductions in poisoning and diversion of these products for abuse.

5.5.5 Alternatives to the current controls and their costs and benefits



The Review examined a number of possible alternatives to the controls including voluntary standards and information and education strategies.

The Review considered that, while general laws relating to consumer protection and duty of care also operate in this area to reduce the incidence of harmful events, these were not adequate to manage the risk in most cases. This is because such controls operate largely after the event and do not adequately address the weak points in the supply chain.

The Review considered that, with the support of the recording and reporting controls discussed above, handling controls could be effectively managed at the wholesale level by expanding the Code of Good Wholesaling Practice to cover matters related to security during transport. To ensure compliance, this Code should be underpinned by the drugs, poisons and controlled substances legislation.

However, the Review considered, in the case of storage controls, such approaches provided only general guidance and would be unlikely to provide sufficient protection from the harms except in cases where the risk being managed was low.

Poisons

For *Schedule 5*, *6* and *7* poisons at a wholesale level, where occupational health and safety legislation also imposes controls, the Review considered that there was no need to include provisions in drugs and poisons legislation. For *Schedule 5* and *6* poisons, the Review was not convinced there would be a ***net benefit*** to the COMMUNITY by requiring specific controls on where and how these substances are displayed at the retail level, especially where they are packaged in child resistant packaging. The Review considered that the risks could be managed adequately by the general law and retailer education.

For *Schedule 7* poisons at the retail level the Review considered that, because of the highly toxic nature of these substances and the risks of diversion or use for deliberate poisoning, the controls imposed on their storage and handling are appropriate. However, in those jurisdictions where these controls are included in legislation other than drugs and poisons legislation, the Review considered that any provisions in drugs and poisons legislation should be repealed.

Medicines

In the case of medicines that contain controlled substances, the Review considered that the risks of diversion at both the wholesale and retail levels, are such that there is a need to maintain regulations covering the storage and handling of these products.

Given the range of products handled and the different circumstances in which they are stored the Review considered it desirable for there to be as much flexibility as possible in the regulations while ensuring the public health objectives of the legislation continue to be met.

The Review noted that the legislation in some jurisdictions was very prescriptive in terms of specifying storage requirements (e.g. safe sizes are stipulated) while in other States, minimum standards are set out with provision for more rigorous standards to be applied administratively. The Review considered that it would be more transparent and provide greater flexibility if the legislation was more outcomes focused.

The States and Territories also have legislative requirements relating to storage and handling of other scheduled medicines at wholesale level. Again, there are differences between jurisdictions as to the degree to which these controls are prescriptive or outcomes based.

The risks of diversion of medicines not containing controlled substances is relatively low. However, the Review considered that having legislation seeking to prevent unauthorised access to them was still justified. Such legislation would support the restrictions on access which are aimed at reducing the risk of medicinal misadventure and the consequential hospital and medical ***costs*** for CONSUMERS and **governments**.

The Review considered that this support could best be provided by legislation that sets out the desired outcomes (i.e. that these substances are only supplied to persons authorised to deal in the substances and should not be able to be accessed directly by consumers). However, these outcomes should be clear and precise, particularly where the risks of diversion or poisoning are high.

The Review considered that the effective operation of such outcomes based legislation would be enhanced by expanding the Code of Good Wholesaling Practice.[51] This Code should be underpinned by the legislation, making compliance with the Code a condition of licence. This will ensure the objectives of the legislation are met consistently by all those involved in supplying these products.

Restrictions on storage and handling of *Schedule 2, 3* and *4* medicines at retail level complement the restrictions on access and the level of intervention required by the pharmacist to ensure safe and effective use of these products.

The Review examined whether professional standards alone were adequate to manage the risk associated with storing and handling these medicines but considered that the failure of even a few pharmacists to comply with such standards, would pose an unacceptable level of risk.

Consequently, the Review concluded that drugs and poisons legislation should include controls on the appropriate storage and handling of these substances. The Review, however, considered that, rather than prescriptive requirements, particularly for the storage and handling of *Schedule 2* and *3* medicines, the legislation should set out the outcomes the restrictions are intended to achieve.

The Review also identified costs for industry associated with the differing requirements across the jurisdictions. These are discussed in Chapter 6.

17

Recommendation 17: Storage controls

That all Commonwealth, State and Territory governments agree that all provisions in drugs, poisons and controlled substances legislation related to storage and handling of:

- *Schedule* 8 substances and specified *Schedule 4* controlled substances at wholesale and retail level; and
- *Schedule 2, 3,* and *4* substances at retail level;

be retained and amended to improve the transparency of the controls by identifying the intended outcomes of the controls for storage.

[51] The Code of Good Wholesaling Practice is established by the Therapeutic Goods Administration in consultation with the National Pharmaceutical Distributors Association.

Recommendation 18: Handling controls

18

That all Commonwealth, State and Territory governments agree that the Therapeutic Goods Administration, in consultation with jurisdictions and industry, should amend the Code of Good Wholesaling Practice to include measures to ensure secure transport of controlled substances in a way that:

- prevents poisoning;
- reduces diversion of substances to the illicit market; and
- minimises the risks of supply which is not in accordance with the legislative objectives and requirements;

and that State and Territory drugs and poisons legislation be amended to make compliance with the Code of Good Wholesaling Practice a condition of licence for wholesalers.

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.
Supporting data and analysis for issues discussed in this Chapter are included in Part B Section 5.6.

The controls fall into two broad categories: product labels (i.e. those affixed by the manufacturer of the product); and dispensing labels (those affixed by the pharmacist or other authorised person at the time the medicine is dispensed).

Product labelling is covered by requirements in State and Territory drugs, poisons and controlled substances legislation, as well as Commonwealth legislation (the *Therapeutic Goods Act 1989* and the *Agricultural and Veterinary Chemical Code Act 1994* and associated instruments). The requirements for dispensing labels are covered by State and Territory drugs, poisons and controlled substances legislation. Many of the product labelling requirements are set out in the SUSDP and these are adopted in varying degrees by States, Territories and the Commonwealth. First aid instructions and warning statements for agvet products are set out in the TGA First Aid Instructions and Safety Directions Handbook.

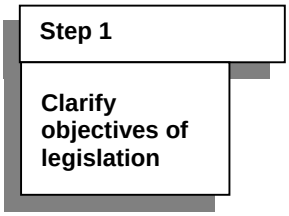
The SUSDP also sets out some requirements for dispensing labels including some specific warning statements for certain highly toxic medicinal substances (e.g. thalidomide) if not already included by the sponsor of the goods and sedation warnings for substances listed in Appendix K. These are adopted by all jurisdictions.

In some cases, labelling requirements may also be imposed by occupational health and safety legislation.

Labelling controls mandate the information for inclusion on the label of the primary pack and sometimes other labels. Labelling provides the consumer with information to assist in its safe use and provides the handlers, professional workers and consumers with guidance for compliance with the appropriate controls, such as on access and storage. Some submission commented that the signal heading required for *Schedule 6* products was inappropriate in some circumstances (e.g. on veterinary medicines) and may also deter some consumers from purchasing *Schedule 6* products.

There is considerable variation in product label requirements across and within jurisdictions and under the different legislative instruments. This is confusing for industry and adds considerably to the cost of establishing the requirements. For example, a sponsor wishing to market an inhalation product containing eucalyptus would need to check the requirements under the *Therapeutic Goods Act 1989* and its associated instruments,[52] the SUSDP, State and Territory drugs and poisons legislation and State and Territory occupational health and safety legislation. Where there is conflict or uncertainty there are costs for the product sponsor in resolving the requirements that apply. Further, if the sponsor wishes to seek an exemption from one of the requirements (e.g. the letter height to be used) the sponsor would need to approach Commonwealth officials[53] and officials in all the jurisdictions in which they intended to market the product. This issue is discussed further in Chapter 6.

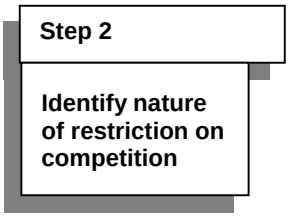
5.6.1 Objective of the controls



The objective of the labelling controls is to provide consumers with information to help them select (in the case of OTC medicines) and use the products safely and effectively. The labels also provide information to the person dispensing or administering the product (e.g. pharmacist, nurse) to enable them to select the correct product.

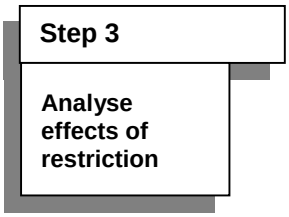
The Review noted where the NDPSC has considered that labels can adequately address the information asymmetry between consumers and industry, medicines may be unscheduled or may be included in a lower schedule than would otherwise have been the case. Thus, Vitamin A products without the required warnings, are prescription only. However, with the warnings, and depending on the recommended daily dose, they may be supplied by a pharmacy or, for lower doses, a supermarket (i.e. the product is unscheduled).

5.6.2 Nature of the controls



The controls specify the nature of the information to be included on the label (e.g. ingredients, signal headings, warnings) and how it is to be presented (print size and font, position). The controls apply to product and dispensing labels.

5.6.3 Effect of the controls on competition and the economy

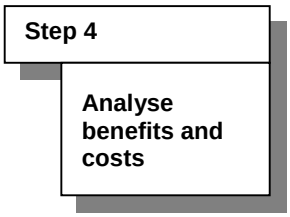


Labelling controls impose costs on industry – both product manufacturers and pharmacies. These costs are passed on to consumers and government (for subsidised medicines). These controls restrict competition to the extent to which they limit the ability of companies to distinguish their products from those of other companies in the market.

[52] Therapeutic Goods Regulations and the Therapeutic Goods Orders related to labelling.

[53] Therapeutic Goods Administration or National Registration Authority.

5.6.4 Costs and benefits of the current controls

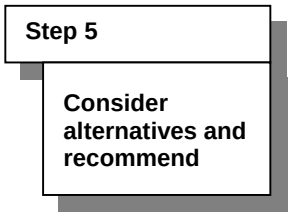


The labelling restrictions add to ***costs*** for INDUSTRY by reducing the freedom for suppliers to choose, without constraint, how they wish to market, and present their product in the drugs, poisons and controlled substances arena. In turn, CONSUMERS are restricted in the extent to which they may make product choices on the basis of the product labelling presentation.

The Review noted that the major costs for industry appear to be associated with the complexity and confusion of the product labelling requirements – particularly for small business. Product sponsors need to identify, and then comply with, the requirements imposed by a number of different legislative instruments at the State and Territory and Commonwealth levels. There are also costs where a company wishes to seek an exemption from a labelling restriction (e.g. the size of the print) as such an exemption needs to be sought from all jurisdictions. (This issue is discussed further in Chapter 6)

The ***benefits*** for the COMMUNITY AS A WHOLE from the labelling controls are that consumers are provided, in the case of OTC medicines and poisons, with information to help them select the most appropriate product to meet their needs and to use these products in a way that minimises the risk of harm being caused through improper product use. As discussed previously, improper use of medicines and poisons can lead to medical, hospital and social costs.

5.6.5 Alternatives to the current controls and their costs and benefits



The Review concluded that removal of the labelling controls will 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, dispenser and administrators to select and use medicines safely and effectively. Removing the controls on labelling could lead to some products being inadequately labelled and, as a consequence, it may become necessary moved substances to a higher *Schedule* to redress the resulting information asymmetry. This in turn would lead to additional costs for consumers (to purchase the medicine) and governments (in subsidising doctors visits if the substance is moved to *Schedule 4*).

The Review did however, see scope to improve the effectiveness of labels as communication tools and noted the medicine labelling project the TGA is undertaking. The TGA is preparing a proposal to introduce a performance-based labelling scheme which emphasises the desired performance outcomes in using the label as a communication tool for consumers and other users. In this scheme, performance would be tested by the sponsor according to guidelines and the results would be submitted in the usual evaluation process. Guidelines will also include recommended requirements (such as currently mandated in a Labelling Order) to be used by those sponsors not wishing to individually test performance. With this scheme sponsors will have greater flexibility and incentive to design labels with the

consumer in mind, rather than simply adhering to a list of requirements, i.e. to be more effective. The Review considered that the outcome of this project would provide a valuable basis upon which to consider the appropriate labelling requirements that should be included in relevant legislation.

Furthermore, the Review identified considerable scope to reduce the costs of the controls by increased uniformity and clarification of overlap. This is discussed in Chapter 6.

5.6.6 Measures to improve efficiency related to multi-jurisdictional product supply

Administrative inefficiencies also occur where companies are required to deal with multiple jurisdictional administrators. For example, a sponsor seeking an exemption from a particular requirement (such as print size of a label) would need to approach nine jurisdictional administrations to obtain such an exemption to allow that sponsor to market the product in all jurisdictions. This is a considerable and unnecessary ***cost*** to both INDUSTRY and **government**.

It is noted in this regard that even if all jurisdictions were to adopt uniform labelling requirements, as has been recommended later in this report, this would not overcome the need, on occasions, for companies to seek exemption from these labelling requirements from all jurisdictions

Similarly, while the Review has made recommendations concerning reporting the supply of controlled substances, it has also noted that the effectiveness of these measures will be undermined if mechanisms for exchanging reports of supply across State and Territory borders are not also developed.

It should reduce administrative ***costs*** for INDUSTRY and GOVERNMENT and improve efficiency, if these matters can be handled by one jurisdiction. Where the matter is brought under the Commonwealth's jurisdiction (e.g. product labelling for medicines), this will automatically occur. However, for other controls, State and Territory legislation needs to provide for recognition of an exemption granted in another jurisdiction (e.g. for labels of household chemicals). A mechanism also needs to be found to ensure that reports of supply across jurisdictional borders can be exchanged in a timely manner.

The Review considered whether it would be possible to apply the *Mutual Recognition Act 1992* to overcome these problems. The Review noted that it may be appropriate to rely upon this Act providing there was uniformity across jurisdictions in their adoption of the *Schedules* (see Recommendation 2).

Recommendation 19: Improving the effectiveness of labels

19

That Commonwealth State and Territory governments:

- agree that labelling should be outcomes focused and be simplified;
- note that the Therapeutic Goods Administration is currently reviewing all the labelling requirements for medicines with a view to making labels more effective communication tools and reducing the complexity of the labelling requirements; and
- recommend to the National Registration Authority and the National Coordinating Committee on Therapeutic Goods consider the outcomes and recommendations of the Therapeutic Goods Administration review of labelling of therapeutic goods and, as appropriate, introduce similar requirements for labelling of agvet chemicals and household chemicals respectively to make them more effective communication tools.

Recommendation 20: Improving administrative efficiency of the controls

20

That Commonwealth, State and Territory governments agree that State and Territory drugs, poisons and controlled substances legislation be amended to provide for mutual recognition of administrative decisions in relation to exemptions from labelling and packaging controls.

5.7 Packaging

Terms of reference addressed: General Issues 1, 2, 3, 4, 5, 6, 8, 9 and 10; Specific Issues 2 and 4.
Supporting data and analysis for issues discussed in this Chapter are included in Part B Section 5.7.

Drugs and poisons packaging controls refer to requirements imposed in relation to the primary pack[54] covering such matters as its closure, the immediate container and the wrapper. Scheduling decisions are sometimes based on how a product will be packaged (e.g. where child resistant packaging is considered to reduce the risk of accidental poisoning a product may be included in a lower schedule).

For medicines for human use, packaging controls are imposed under the *Therapeutic Goods Act 1989.* All other controls relating to the packaging of household chemicals and agvet products are in State and Territory drugs and poisons legislation.

5.7.1 Objectives of the controls

Step 1

Clarify objectives of legislation

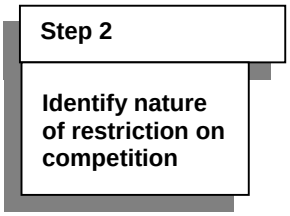
Packaging controls are part of the suite of controls intended to ensure safe and effective use in the community The objectives of the packaging controls are to:

- reduce the risk of abuse, overuse, dependence and illicit use;

[54] 'Primary pack' means the pack in which the product, or the product and its container, is presented for sale or supply to consumers.

- reduce accidental poisoning by medicines and poisons; and
- minimise the risk of medicines being used in intentional overdose.

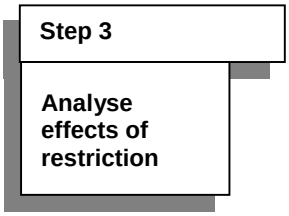
5.7.2 Nature of the controls



Packaging controls require certain products to be packaged in a particular way. For some products a child-resistant closure is required. For other products different forms of child-resistant packaging, such as blister packs, are required.

For many poisons the requirements are quite prescriptive, e.g. the container to be embossed with the word POISON. There may also be limitations on the size of the container.

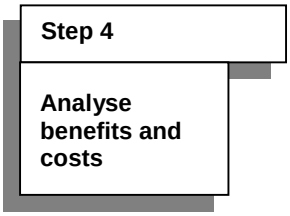
5.7.3 Effect of the controls on competition and the economy



These restrictions limit the opportunities for competitors to use this form of product differentiation as flexibly as they would wish in the absence of such controls. While product differentiation is not direct price competition, it is very much a vehicle for competition between firms using non-price mechanisms, especially in markets with many competitors.

A consequence of the existing requirement to restrict the pack sizes that are available in some outlets (e.g. supermarkets) limits the achievement of full-scale economies in such outlets, so reducing availability of some product configurations and raising prices for those that are available. While, in theory, it would be possible for consumers to purchase multiple small packs from the supermarket, this does not appear, in practice, to happen.[55]

5.7.4 Costs and benefits of the current controls



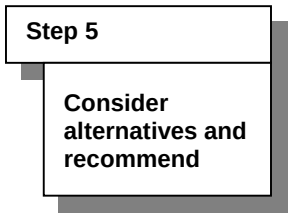
The ***cost*** to INDUSTRY of the requirement for specific packaging (such as child resistant packaging) adds to the cost of a product. These costs are ultimately passed on to the CONSUMER or GOVERNMENT (for subsidised medicines) the Review was concerned that, without specific mandatory requirements, some businesses may choose not to use such packaging without fully appreciating the impact it can have on the likelihood of poisoning, especially in children.

The Review considered that the packaging controls, working in concert with other controls, such as access restrictions and labelling requirements, contributed to minimising the risk of accidental and deliberate misuse of drugs and poisons. Real ***benefits*** to the COMMUNITY flow in terms of reduced hospital, medical and social costs.

[55] This view is supported by the recent UK experience in relation to small packs of paracetamol [Prince et al, 2000]

The Review noted that controls on pack size does, in some cases, limit the achievement of full-scale economies, reduce the availability of some product configurations and increase prices. These restrictions have been shown to reduce the level of poisoning and its associated hospital, medical and social costs. While, in theory, it would be possible for a person to purchase multiple small packs, the reality is that, while this may occur in a few instances, this has not been the experience where such restrictions have been put in place. Without such a control, the alternative would be to restrict access to all pack sizes of a product. This would reduce both consumer access and market access for companies. Consequently the Review considered that there is a net benefit to the community as a whole in retaining controls on pack size.

5.7.5 Alternatives to the current controls and their costs and benefits



The Review considered a range of non-legislative approaches for ensuring adequate packaging of medicines and poisons to achieve the objectives of the controls. Possible approaches considered included codes of practice, taxes or subsidies and information and education strategies for the community and suppliers.

However, for several reasons, including:

- the range of persons involved in supplying these products (e.g. multinational companies, sole traders),
- that many suppliers do not belong to industry associations, and
- the high risk of harm with some products if they are packaged inappropriately,

the Review concluded that these options would not be practical or would not achieve the objectives of the controls.

However, the Review considered that there was scope to improve the efficiency of the packaging controls for agvet products[56] by bringing them under Commonwealth control and for household poisons, if the controls were made uniform by bringing them under model legislation. These issues are discussed further in Chapter 6.

Conclusion

The Review concluded that there was a ***net benefit*** to the COMMUNITY AS WHOLE in retaining the current controls but that there was room to improve the efficiency of the packaging controls for agvet products and household chemicals.

Recommendation 21: Packaging

21

That Commonwealth State and Territory governments agree that the current level of packaging controls be retained.

[56] The packaging controls for medicines are already under the *Therapeutic Goods Act 1989* except for packaging by sole traders trading intrastate where most jurisdictions have only limited controls.

5.7.6 Dose administration aids

Another packaging issue that was raised with the Review was the filling of Dose Administration Aids (DAAs).

These devices are intended to aid compliance with medication regimens. The DAAs may be packaged by a pharmacist, nurse, or other health professional or by family or carers. The DAAs packaged by pharmacists are generally blister packs that contain each dose in a blister with the time at which it is to be taken. The controls which apply generally (e.g. labelling and packaging) to dispensing of medicines, together with the appropriate professional standards would also apply to the dispensing of medicines in DAAs.

The Review noted the concerns that have been expressed about safety issues associated with using blister packs. The Review acknowledges that some concerns about safety may be legitimate but considered that, in general, this is an issue of professional practice which is beyond the scope of this Review. Nor is it reasonable or practical to set out requirements for family and other carers who may fill DAAs.

Conclusion

Many of the controls on administration relate to professional practice or to situations where it is not practical or even useful to legislate. However, in those circumstances where the administration of medicine falls under drugs and poisons legislation, the Review considered that, in general, the current controls are matters for professional practice.

CHAPTER 6 EFFICIENCY OF THE LEGISLATIVE FRAMEWORK

Terms of reference addressed: General Issues 4, 7, 8 and 10; Specific Issue 2.
Supporting data and analysis for issues discussed in this Chapter are included in Part B Section 6.

The most significant costs the Review identified arose from the complexity of the legislative controls. These costs were particularly evident where the controls were not uniform across jurisdictions and where there was duplication or overlap of the requirements in drugs, poisons and controlled substances legislation with requirements in other legislation. The Terms of Reference require the Review to examine ways of increasing overall efficiency by reducing compliance costs.

The Review considered that there is considerable scope to reduce costs while still achieving the objectives of the legislation through:

- uniform legislation;
- legislative alignment between drugs, poisons and controlled substances legislation and related legislation; and
- improved administrative efficiency in the operation of the controls.

This Report has recommended a number of ways to improve the administrative efficiency of processes associated with particular legislative controls. For example, recommendations relating to improved efficiency in the scheduling process are in Chapter 3 and a recommendation on ways to improve administrative decision making in relation to labelling requirements is in Chapter 5.

Uniformity and the legislative alignment of drugs, poisons and controlled substances legislation with related legislation is discussed below.

6.1 Uniformity

Terms of reference addressed: General Issues 4, 7, 8 and 10; Specific Issue 2.
Supporting data and analysis for issues discussed in this Chapter are included in Part B Sections 6.3 and 6.4.

As indicated throughout the Report, 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 substance in special legislation (variously titled), while others include all matters related to the medical use of controlled substances in their drugs and poisons legislation with all other matters dealt with in their controlled substances legislation. For 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.

The Review identified variations between the States and Territories in virtually every area in which they regulate drugs, poisons and controlled substances. Variations were particularly evident in the areas of:

- supply of clinical samples;
- licensing requirements;
- reporting requirements for controlled substances; and
- storage or display of *Schedule 2* medicines in pharmacies.

Lack of uniformity was identified as a major ***cost*** for INDUSTRY and, in turn for CONSUMERS, to the extent that industry passes on costs to consumers.

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; and
- those where there is a need to comply with different controls imposed by different jurisdictions, such as different labelling requirements.

Variations in requirements make production, supply, training, and administration more complex, raising direct costs for industry, government and consumers and making market entry more difficult for firms outside a particular jurisdiction. Also, if the Australian market faces high (even if evenly distributed) costs within Australia, it will be less competitive internationally.

While the Review accepted that there may be some need for variation to deal with particular problems, such as those of rural and remote communities, it sees no justification, in a country with a relatively small population and an even smaller industry base, for the costs resulting from maintaining individual State and Territory legislation. The Review recognised that these jurisdictional differences have arisen over time, largely because of the way in which separate drugs and poisons legislation have developed. However, it is now time to consider how best these differences can be resolved.

The difficulties caused by lack of uniformity are compounded by similar difficulties arising through the interface between specific drugs, poisons and controlled substances with related legislation, such as occupational health and safety legislation, within each jurisdiction. The Review considered that development of model legislation for medicines and poisons that provided clear definitions and clarified the interface with related legislation would address these problems.

The Review considered a number of options for achieving uniformity including mutual recognition and the States and Territories transferring their powers to the Commonwealth. However, the Review concluded that these options would not lead to the objectives of the various legislative controls being met in the most efficient and effective manner.

6.1.1 Options for achieving uniformity

The Review considered the following means of achieving uniformity:

- mutual recognition of products across the nation;
- States and Territories cede their powers to the Commonwealth;

- bring the controls under Commonwealth legislation where it is within the Commonwealth's Constitutional power; and
- develop model legislation which jurisdictions either:
  - adopt by reference; or
  - adopt through mirror legislation.

Mutual recognition

The Review considered whether the exemption applying to therapeutic goods under the *Mutual Recognition Act 1992* should be lifted. If this occurred, it would apply to labelling and packaging controls. If labelling and packaging controls for medicine and agvet products are transferred to the Commonwealth under the *Therapeutic Goods Act 1989* and the A*gricultural and Veterinary Chemical Code Act 1994*, the *Mutual Recognition Act 1992* would be relevant to and could be applied to labels of household chemicals. If this did not occur, the costs of obtaining exemptions from labelling restriction from all jurisdictions would continue unless some alternative mechanism to recognise an exemption granted by one jurisdiction is implemented. The Review considered that the current exemption for medicines and poisons in the *Mutual Recognition Act 1992* should be repealed.

States and Territories ceding their power

The Review considered that it was unlikely and, to some extent, undesirable for the States and Territories to vest their power in the Commonwealth as it is more practical, in many cases, for the States and Territories to undertake day-to-day operational activities, such as warehouse inspections.

Uniformity through specific Commonwealth legislation

The Commonwealth's powers are limited by the Constitution. Consequently only some of the controls could be brought under Commonwealth legislative control. Therefore, the Review concluded that those controls that relate to the process of bringing a product to market, or activities which are difficult to confine within jurisdictional boundaries (e.g. advertising), should be brought under specific Commonwealth law, where appropriate specific legislation exists.[57] As well, the controls on labelling, packaging and advertising products, and manufacturing licences relating to product quality should be brought under Commonwealth control. The signal heading identifying the *Schedule* in which the product is placed for distribution control would remain in State and Territory legislation. The level of the controls that should apply to these three areas was discussed in Chapter 5.

It should be noted that, while transfer of controls in these three areas will cover most situations, the Commonwealth's power does not extend to sole traders trading intrastate. Therefore, the States and Territories will need to amend their legislation to

[57] Therapeutic goods (human medicines and disinfectants) are covered by the *Therapeutic Goods Act 1989* and agricultural and veterinary chemicals by the *Agricultural and Veterinary Chemicals Code Act 1994.* There is no Commonwealth legislation covering the controls on household chemicals.

ensure these situations are covered. State and Territory adoption of the *Therapeutic Goods Act 1989* would largely overcome this problem in relation to medicines.

Uniformity through model legislation

In areas where the Commonwealth does not have Constitutional power, uniformity could most appropriately be achieved through the States and Territories adopting, within their legislation, the provisions of model uniform legislation.

The Review considered that, unless jurisdictions are prepared to adopt model legislation by reference, many of the current costs would remain. Even where 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 in which they intend to operate. Further, over time, these differences will increase, as amendments are made in some jurisdictions, but not others.

The Review recognised that if jurisdictions are to adopt model, it will be essential to have an effective mechanism to develop, implement and maintain that legislation. The NCCTG, which is already charged by AHMAC with responsibility for coordinating policy issues relating to therapeutic goods and poisons, would seem ideally placed to develop and maintain such model legislation by providing advice to the Australian Health Ministers' Conference through AHMAC.

6.1.2 Conclusion

The Review concluded that there would be considerable ***savings*** to INDUSTRY, GOVERNMENT and CONSUMERS if there were a more consistent and uniform national approach taken to regulating drugs, poisons and controlled substances in Australia. The Review recognised that the strategies for achieving this approach would need to reflect the respective powers of the Commonwealth and the States and Territories under the Constitution.

On this basis, the Review has recommended that, where the Commonwealth has the Constitutional power to do so, it should enact Commonwealth legislation to ensure a uniform national approach to specific regulatory controls – these are in the areas of product labels, packaging and advertising. The Review noted that, with respect to labels, the signal heading on the label will remain a matter for States and Territories as these reflect the State and Territory responsibilities, particularly where these controls indicate the level of access to apply to a particular product. In all other areas relating to regulating drugs, poisons and controlled substances, where Constitutional powers lies with the States and Territories, it is recommended that the States and Territories adopt the model legislation the appropriate legislative instruments.

The Review concluded that, to ensure a uniform national approach to regulating drugs, poisons and controlled substances, all Commonwealth, State and Territory governments should agree to:

- transfer some controls over product registration to the Commonwealth;
- develop complementary legislation to pick up the Commonwealth *Therapeutic Goods Act 1989* by reference; and

- for the controls to remain with the States and Territories repeal of the existing State and Territory legislative controls and develop model legislation to be adopted by reference.

Recommendation 22: Commonwealth legislation 22

That the Commonwealth amend:

- the *Therapeutic Goods Act 1989* to include all controls on advertising, packaging and labelling (except signal headings) of human medicines; and
- the *Agricultural and Chemical Code Act 1994* to include all controls on advertising, labelling (except signal headings) and packaging for agvet products provided this is consistent with the requirements for packaging of household chemicals included in the SUSMP.

Recommendation 23: Complementary therapeutic goods legislation 23

That all Commonwealth, State and Territory jurisdictions agree that all States and Territories adopt the *Therapeutic Goods Act 1989* by reference into the relevant legislation.

Recommendation 24: Uniform national model legislation 24

That all Commonwealth, State and Territory governments agree that:

a) The Australian Health Ministers Advisory Committee expand the Terms of Reference of the National Coordinating Committee on Therapeutic Goods to give it responsibility for preparing advice for the Australian Health Ministers Conference through AHMAC on developing and maintaining model medicines and poisons legislation. The Committee's Terms of Reference should include responsibility for undertaking any necessary consultation to enable regulatory impact statements to be prepared and establishing supporting mechanisms which put in place an effective and efficient national system of controls.

b) The National Coordinating Committee on Therapeutic Goods develop model legislation that includes provisions for all matters relating to supply of medicines for therapeutic purposes and to domestic supply of agricultural and veterinary and household chemicals:

- setting out the objectives of the legislation;
- specifying agreed outcomes for controls; and
- identifying the specific levels of controls* in the areas of:
  - licensing;
  - dispensing labels;
  - household chemical packaging;
  - storage and handling of drugs;
  - recording and reporting; and
  - supply of clinical samples.

* Discussed in Chapter 5.

c) State and Territory governments adopt the model legislation by reference.

25 *Recommendation 25: Repeal of State and Territory legislation*

That State and Territory governments repeal existing legislation relating to controls on labelling, packaging, advertising, access restrictions, licences, recording, reporting, storage, handling and supply of clinical samples.

6.2 Improved alignment between drugs, poisons and controlled substances legislation and related legislation

Terms of reference addressed: General Issue 8; Specific Issue 4.
Supporting data and analysis for issues discussed in this Chapter are included in Part B Section 6.5, 6.6 and 6.7.

The Review was asked to consider the interface between drugs, poisons and controlled substances legislation and related legislation to maximise efficient administration of legislation regulating this area. In particular, the Review was asked to consider:

- whether the exemptions under the *Mutual Recognition Act 1992* and the Trans-Tasman Mutual Recognition Agreement could be lifted;
- whether the advertising restrictions, imposed by the *Therapeutic Goods Act 1989* and drugs, poisons and controlled substances legislation, could be rationalised; and
- the relationship between drugs and poisons legislation and regulation of foods under the *Australia New Zealand Food Authority Act 1991*.

The Review also sought to identify opportunities to improve the efficient administration of legislation in this area by clarifying the respective roles of drugs, poisons and controlled substances legislation and occupational health and safety legislation, particularly in relation to labelling. In this context the Review has also noted developments towards a globally-harmonised system of chemical classification and labelling.

While not specifically identified within the Review's Terms of Reference, the Review considered that the most significant legislative interface issue is probably that between the legislation under review and the legislation regulating professional practice. Other legislation of which the Review has taken note is the *Trans-Tasman Mutual Recognition Act 1997*.

Policies such as the Quality Use of Medicines, and Australia's obligations under the three United Nations drug treaties have also been taken into account in making recommendations.

6.2.1 Mutual Recognition Act

The Review considered whether it was possible to use the *Mutual Recognition Act 1992* to manage controls over matters such as labelling and packaging but concluded

that this would not achieve the objectives of the drugs, poisons and controlled substances legislation. These controls are included in different legislative instruments, some outside the Terms of Reference for this Review. Also, bringing these controls under this Act would lead to the lowest level of control being adopted which may not always achieve the objectives the legislative controls are intended to address.

6.2.2 Therapeutic Goods Act and Agricultural and Veterinary Chemicals Code Act

The Review has recommended that the Commonwealth assume all responsibility for advertising, labelling and packaging of medicinal products under the *Therapeutic Goods Act 1989* and for labelling and packaging of agvet products under the *Agricultural and Veterinary Chemicals Code Act 1994*.

6.2.3 Australia New Zealand Food Authority Act

The Review considered the relationship between drugs, poisons and controlled substances legislation and the *Australia New Zealand Food Authority Act 1991*. The Review noted that the SUSDP Appendix A excludes foods from the scheduling controls, although Appendix A is not adopted by all jurisdictions.

The Australia New Zealand Food Standards restrict the amount of certain substances which can be added to food or which foods may contain. Many of these substances are also included in the *Schedules (*e.g. selenium, vitamin A*).*

The Review has heard of a number of apparent anomalies between the amounts of a substance permitted in food and the amounts that may be included in an unscheduled medicine. The Review sees these anomalies as largely technical issues, which it is not appropriate for this Review to address. However, the Review considered that these should be addressed by closer liaison between the scheduling process and the process for setting food standards. The Review considered that there is room for closer liaison between the Medicines Scheduling Committee and the Australia New Zealand Food Authority.

6.2.4 Occupational health and safety legislation

The Review identified a level of overlap and confusion at the interface between medicines and poisons legislation and occupational health and safety legislation 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. The Review also noted the comments from industry and professionals questioning the appropriateness of the POISON signal heading, particularly when used on veterinary medicines.

The Review recognised that there may be legitimate reasons for labelling and packaging requirements in a work setting to differ from those in a domestic setting. For example, there are generally no children in the workplace and the quantities used for household purposes are usually much smaller than those used in the workplace.

The Review considered, however, that there may be scope in some cases to bring the labelling requirements closer together and reduce the level of complexity for industry without undermining public health and safety.

An important first step in this simplification process would be to identify more clearly those products that are to be used in the workplace and those intended primarily for domestic use. There should also be agreement on the minimum requirements for labels required under either system.

In this context, it is noted that the National Occupational Health and Safety Commission has been consulting with the TGA (and others) to revise the Model Labelling Regulations for occupational health and safety legislation.

The Review also noted comments that the signal headings for poisons are not always appropriate (e.g the use of POISON on veterinary medicines) or meaningful. For example, the signal heading CAUTION[58] was found to have little meaning for consumers. In contrast, the Review noted that the signal heading required under occupational health and safety legislation require the specific hazard to be identified, e.g. irritating to the eyes, causes burns, were generally more informative.

The Review also noted that Australia has been participating in international initiatives to harmonise chemical classification and labelling. This program is known as the Globally Harmonised System for the Classification and Labelling of Chemicals.

26 *Recommendation 26: Harmonising the labels of poisons and workplace chemicals*

That the Commonwealth, State and Territory governments agree that the National Coordinating Committee on Therapeutic Goods and the National Occupational Health and Safety Commission work together to:

- Identify more clearly those products whose principal intended use is in the workplace and those intended primarily for domestic use and therefore when medicines and poisons legislation applies and when occupational health and safety legislation applies to the labelling of medicines and poisons. On the basis of this assessment, a judgement can then be made on the minimum requirements for a label under both legislative systems and the most appropriate legislation to control labelling and packaging.
- Examine the extent to which specific labelling requirements, such as signal headings and warnings, can be made consistent under drugs, poisons and controlled substances legislation and occupational health and safety legislation.
- Adopt labelling that is consistent with labelling agreed as part of Globally Harmonised System for the Classification and Labelling of Chemicals in this area, provided such labels do not undermine the level of public health and safety protection for the Australian community afforded by the current labelling requirements.

[58] CAUTION is the required heading for all *Schedule 5* poisons.

6.2.5 Legislation regulating professional practice

The Review identified the importance of the relationship between drugs, poisons and controlled substances legislation and the legislation regulating professional practice. As discussed previously, the benefits of the controls imposed under drugs, poisons and controlled substances legislation depend, in large measure, on the effectiveness of the professional practice legislation and its enforcement. 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*** to INDUSTRY and CONSUMERS (and potentially for government) where a product is re-scheduled from an OTC schedule to *Schedule 4).*

It is not the role of this Review to examine the legislation regulating professional practice or to recommend how compliance with professional standards should be managed under that legislation. However, it would strongly urge professional registration boards to consider options for improving the effectiveness of this legislation and its mechanisms to achieve compliance and avoid the need to use rescheduling to deal with the failure of some health professionals to comply with relevant professional standards. The Review considered that, in some cases, it might be appropriate for professional practice legislation to identify breaches of drugs, poisons and controlled substances legislation as breaches of the required professional standards.

The Review supports the National Competition Policy Review of Pharmacy recommendations that the pharmacy acts and delegated legislation clearly set out the complaints and disciplinary processes and the grounds for incompetency and professional misconduct.[59] 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 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. The Review noted that the National Competition Policy Review of Pharmacy recommended that registration of pharmacy premises be removed from State and Territory legislation and that legislation and agreements for delivering pharmacy and health services require community pharmacies to adopt appropriate quality assurance and professional practice standards.[60] The Review noted, and supports, 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.[61]

[59] Recommendation 19, National Competition Policy Review of Pharmacy, 2000.

[60] Recommendations 7 and 8, National Competition Policy Review of Pharmacy, 2000.

[61] Recommendations 16(g), 17 and 18, National Competition Policy Review of Pharmacy, 2000.

27 ***Recommendation 27: Professional standards***

That Commonwealth, State and Territory governments:

- note the importance of Professional Boards in exploring options to improve the level of compliance with professional standards, including measures to improve the timeliness, effectiveness and national consistency of the mechanisms to achieve compliance; and
- strengthen, as necessary, the capacity of Professional Boards to ensure compliance with the relevant practice standards.

6.2.6 Trans-Tasman Mutual Recognition Act

The Review noted the exemption provided for therapeutic goods and chemicals under the *Trans-Tasman Mutual Recognition Act 1997*. Under this Act, where there were significant reasons to maintain different controls that would prevent the product being traded freely across the Tasman, a permanent exemption was included in the legislation. In other areas, where it was considered that there may be scope to resolve the differences in the controls, a temporary exemption was granted. In these areas, there is a commitment for Australian and New Zealand officials to work towards identifying where, and to what extent, mutual recognition may be possible or whether there are other ways to meet the objectives of the legislation.

A permanent exemption was granted to agvet products, while hazardous chemicals and therapeutic goods were granted temporary exemptions. The exemptions for both hazardous chemicals and therapeutic goods involve controls under a range of legislative mechanisms in addition to those imposed under drugs, poisons and controlled substances legislation. These legislative instruments include the *Therapeutic Goods Act 1989*, occupational health and safety legislation and dangerous goods legislation.

The Review noted that the NDPSC has established a working party to examine the scheduling of drugs and poisons. Work has already been completed on harmonising a significant proportion of the substances in *Schedules 2*, *3* and *4*. Work is progressing, on harmonising the scheduling of the remaining substances. More generally, the working party is also exploring options for overcoming differences in the scheduling processes between Australia and New Zealand so that, in future, decisions made on both sides of the Tasman are consistent.

The Review considered that the recommendations it has made for changes to the current scheduling system are broadly consistent with the objectives of the *Trans-Tasman Mutual Recognition Act 1997*.

Attachment A1 Terms of reference

In April 1995 State, Territory and Commonwealth Governments agreed to a wide-ranging program of microeconomic reform under National Competition Policy. The aim of National Competition Policy is to increase economic growth and the wellbeing of the community as a whole through increased competition across the Australian economy. The scope for increased competition will vary from sector to sector depending on the extent to which other policy objectives of government can be achieved in conjunction with increased competition.

In accordance with obligations under National Competition Policy and the Competition Principles Agreement, the State, Territory and Commonwealth Governments commissioned a review to examine legislation and regulation pertaining to drugs, poisons and controlled substances.

The review will identify and assess restrictions contained in legislation against criteria outlined in clause 5(1) of the Competition Principles Agreement. When assessing restrictions on competition against clause 5(1) the review may also have regard to a range of other policy considerations outlined in clause 3 of the Agreement. After receiving the review report governments will develop a response.

Legislation to be reviewed

The review will examine the case for reform of legislative restrictions on competition contained in the legislation and regulations governing drugs, poisons and controlled substances. The Acts and Regulations to be reviewed are listed at the end of this Appendix.

The review will have regard to the relevant sections of the Competition Principles Agreement, the Council of Australian Governments (COAG) *Guidelines and Principles for Standard Setting and Regulatory Action*, and make use of material contained in guidelines published by government on regulatory impact statements and on conducting National Competition Policy legislation reviews. The review should have regard to the Mutual Recognition Agreement, particularly when considering issues relating to packaging and labelling. The review should also have regard to public health considerations and the need for consumers to make an informed choice from a safe range of products.

There has already been significant work done in the areas of drugs, poisons and controlled substances and the review should have regard to previous reviews including, but not limited to the:

- 1996 report of the Industry Commission into the Pharmaceutical Industry;
- Review of the Poisons Scheduling Process in Australia (Brian Wall, 1996);
- Review of the Brand Advertising of Schedule 3 (Pharmacists Only) Medicines (Brian Wall, October 1997); and
- Review of the Mutual Recognition Agreement (COAG Committee for Regulatory Reform).

Exclusions

The review **will not** address the issues of:

- 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; or
- criteria for listing in Schedules.

General issues

The Chair will report on the appropriate arrangements for regulation, if any, and in particular will:

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.

Note: numbers have been added and are consistent with references within the report.

Specific review issues

Having regard to the general issues above, the review should specifically address the following main issues:

1. The relationship between the processes and arrangements for decisions on drugs and poisons scheduling and drugs and poisons regulation.

There is currently a national process for Scheduling drugs and poisons but there is not a national process for developing regulations and legislation that applies to those Schedules. Consideration should be given to developing a coherent process/connection between Scheduling and regulation. For example, consideration could be given to whether the Scheduling committee should make recommendations to another body which considers issues of legislation policy.

2. National uniformity of regulation and administration of that regulation.

Inconsistencies in regulation that could be addressed by the review include:

- *licensing manufacturers, wholesalers and retail suppliers of drugs and poisons.*

For example, licensing currently occurs in some areas at both Commonwealth and State levels for the same establishments. Options could include rationalising current licensing arrangements and analysing the effectiveness of current codes of practice. An assessment could be made of the potential for further development of codes of practice and other appropriate regulatory options.

- *packaging and labelling standards.*

In the case of most goods, the cost imposed on business of different labelling standards between States has been significantly reduced by the Mutual Recognition Agreement. An exception to the mutual recognition principle applies to requirements relating to the 'manner of sale' because of the link between packaging and labelling requirements. Without limiting its consideration of packaging and labelling standards, the review should consider options for reducing costs imposed on businesses through greater uniformity of packaging and labelling requirements between jurisdictions. Alternatively, the review might consider the impact of applying the Mutual Recognition Agreement to drugs and poisons packaging and labelling as a means of addressing non-uniformity issues or to underpin any proposals for uniform arrangements.

- *advertising restrictions.*

- *storage and handling requirements.*

Some jurisdictions require medicines, labelled TO BE KEPT OUT OF THE REACH OF CHILDREN when displayed for sale, to be kept above a certain height. Other jurisdictions have no particular requirements for retailers on this issue.

- *any additional requirements, such as recording of sale.*

It is known that there are variations in the requirements for the lists of substances in *Schedule 3* (Pharmacists Only). While substances included in *Schedule 3* are identical, each State and Territory makes its own decisions about how this *Schedule* is applied. Similarly, substances may be put into a more restrictive *Schedule* to address specific public health concerns related to misuse or abuse within a particular jurisdiction.

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.**

4. **Interfaces with related legislation to maximise efficiency in the administration of legislation regulating this area.**

   For example, an analysis of the potential effects of lifting the exemptions applying to therapeutic products currently under the *Mutual Recognition Act 1992* and the Trans-Tasman Mutual Recognition Agreement.

   Advertising restrictions may be imposed by both the *Therapeutic Goods Act 1989* and drugs, poisons and controlled substances legislation. The increasing importance of the drug–food interface needs to be addressed through analysis of the relationship between the *Australia New Zealand Food Authority Act 1991* and State and Territory drugs, poisons and controlled substances legislation.

5. **Manner of supply by professionals of drugs, poisons and controlled substances.**

   Whilst the issue of prescribing rights is to be excluded from the review, the manner of supply, including the way prescriptions are written, handled and processed, should be considered having regard to consistency across professions and across jurisdictions.

   For example, regardless of profession, when a medicine is supplied, a label detailing safe use may be required.

Review arrangements

The Review will be conducted by an independent Chair who will be supported by a Secretariat. The Chair will be advised by a Steering Committee specifically established for that purpose.

The Chair will be appointed by the heads of government at the time the terms of reference are approved. The Chair will be selected from a nominee or nominees provided by the Chair of the National Public Health Partnership (NPHP) in consultation with the Chair of the COAG Committee on Regulatory Reform.

The NPHP will nominate membership of the Steering Committee and ensure that each jurisdiction is represented. Jurisdictions which are not members of the NPHP will provide a representative on the Committee. The Committee should aim for consensus decisions but where a vote is required, each member of the Committee will have one vote. In addition, there will be other officers nominated by the COAG Committee on

Regulatory Reform. There should also be expertise in health risk analysis and public health law available to the Chair. The Chair may co-opt people as deemed necessary. The Chair will consult with jurisdictions regarding obtaining wider expertise to ensure others affected by the legislation are consulted. For example, those responsible for administering agricultural and veterinary chemicals and industrial chemicals. The Steering Committee will meet as often as is deemed necessary by the Chair.

Work may be done, from time to time, by consultants as the Chair, in consultation with the Steering Committee, deems necessary.

The Chair is to be supported by a Secretariat . The cost of the review, including the Secretariat, the Chair's fees and recurrent costs, will be shared proportionately according to the population of each State and Territory. The Commonwealth will fund half the cost of the review. Where considered appropriate by the Chair, a jurisdiction may second an officer to the Review Secretariat, as part or all of its contribution to the cost of the review. Each jurisdiction will cover their steering committee participation costs.

The Chair will report her findings to the Australian Health Ministers Conference. Upon consideration of the report and receipt of comments from jurisdictions the report and recommendations will be made to COAG.

Review process

The Chair will establish a process for national consultation with key interest groups and affected parties and publish a report. The review will use the structure of the National Public Health Partnership for establishing links with all jurisdictions and for administration.

Key dates

The review will commence on the date on which the Steering Committee is established. The review will report within 12 months of establishing the Steering Committee.

Secretariat

The Secretariat will be based at the Therapeutic Goods Administration in Canberra. The Secretariat will report to the Chair and work as directed by the Chair. The Secretariat will consist of officers with expertise in the review of legislation under National Competition Policy, an understanding of the structure and workings of the National Public Health Partnership and an understanding of public health law, drugs and poisons administration and microeconomics.

The Secretariat will take responsibility for all administrative arrangements relating to the review and work as directed by the Chair.

Legislation nominated for review

New South Wales	*Poisons and Therapeutic Goods Act 1966* (updated 14 July 1998)
	Poisons and Therapeutic Goods Regulations 1994 (reprinted as at 30 Jan 1997)
	Drugs Misuse and Trafficking Act 1985 (updated 7 Aug 1998)
Queensland	*Health Act 1937* (reprinted as in force as at 6 Jan 1999)
	Health (Drugs and Poisons) Regulation 1966 (reprinted as in force as at 19 Oct 1998)
South Australia	*Controlled Substances Act 1984* (obtained from Internet 1 Feb 1999)
	Controlled Substances (Declared Drugs of Dependence) Regulations 1993 (reprinted as at 19 Dec 1997)
	Drugs of Dependence (General) Regulations 1985 (obtained from Internet 1 Feb 1999)
	Controlled Substances Act (Exemptions) Regulations 1989 (obtained from Internet 1 Feb 1999)
	Controlled Substances (Poisons) Regulations 1996 (incorporating all amendments at 3 Dec 1998)
	Controlled Substances (Volatile Solvents) Regulations 1996 (obtained from Internet 1 Feb 1999)
Tasmania	*Poisons Act 1971* (consolidated at 1 Feb 1999)
	Poisons Regulations 1975 (no date – supplied by Tasmania)
	Alcohol and Drug Dependency Act 1968 (consolidated at 1 Feb 1999)
	Pharmacy Act 1908 (consolidated at 1 Feb 1999)
	Criminal Code Act 1924 (consolidated as at 10 Mar 1999 – Tax. Govt. Internet site)
Victoria	*Drugs, Poisons and Controlled Substances Act 1981* (incorporating amendments at 5 May 1997)
	Drugs, Poisons and Controlled Substances Regulations 1995 (reprinted as at 12 Feb 1998)
Western Australia	*Poisons Act 1964* (produced 30 April 1998)
	Poisons Regulations 1965 (produced 30 April 1998)
	Division 5 [Drugs], Division 6 [Medicines and disinfectants] and Division 7 [Manufacture of therapeutic substances] of Part VIIA of the *Health Act 1911* (as at 30 April 1998)
	Drugs of Addiction Notification Regulations 1980
	Health (Drugs and Allied Substances) Regulations
Australian Capital Territory	*Drugs of Dependence Act 1989* (obtained from Internet 22 Feb 1999)
	Drugs of Dependence Regulations 14/1993
	Drugs of Dependence Regulations 26/1995
	Drugs of Dependence Regulations 29/1995
	Poisons Act 1933 (updated as at 9 Dec 1998)
	Poisons Regulations 1933
	Poisons and Drugs Act 1978 (updated as at 9 Dec 1998)
	Poisons and Drugs Regulations 1933
	Public Health (Sale of Food and Drugs) Regulations
Northern Territory	*Poisons and Dangerous Drugs Act* (in force as at 10 Dec 1997)
	Poisons and Dangerous Drugs Regulations (in force as at 17 March 1986)
	Therapeutic Goods and Cosmetics Act (in force as at 10 Dec 1997)
	Pharmacy Act (in force as at 10 Dec 1997)

Attachment A2 Consultation with stakeholders

In August 1999, advertisements were placed in national newspapers calling for submissions from interested parties against the Terms of Reference. Fifty-nine written submissions were received. In addition, the Chair undertook extensive consultation with a broad range of stakeholders, including meetings with the Executive Officers of the health departments of all the States and Territories. Following release of the Options Paper in February 2000, a further 72 written submissions were received and additional meetings were held with key stakeholders. A draft final report was released for final consultation in September, leading to further written submissions and discussions.

The following table lists the stakeholders that made contributions to the Review and this is followed by brief summaries of the issues raised. The summaries are not intended to be comprehensive. Copies of the written submissions can be obtained from the Review Secretariat.

Organisation	Written submissions			Face-to-face
	Initial	Second	Final	
ACT Health and Community Care				✔
ACT Vet Surgeons Board				✔
Aerosol Association of Australia Inc		✔		
Andrew Podger, Secretary, Department of Health and Aged Care				✔
Association of Professional Engineers, Scientists and Managers Australia	✔	✔	✔	
Australia New Zealand Food Authority	✔			
Australian Chemical Specialties Manufacturers Association	✔	✔	✔	✔
Australian College of Midwives		✔		
Australian College of Pharmacy Practice	✔	✔		
Australian College of Podiatric Surgeons	✔			
Australian Competition and Consumer Commission		✔		
Australian Consumers Association		✔		✔
Australian Dental Association Inc	✔	✔	✔	✔
Australian International Health Institute				✔
Australian Medical Association		✔		
Australian Medical Association (ACT)			✔	
Australian Medical Association (Victoria)		✔	✔	
Australian Nursing Federation	✔	✔		
Australian Pharmaceutical Advisory Committee (APAC)		✔		✔
Australian Pharmaceutical Manufacturers Association	✔	✔	✔	✔
Association of Pharmacy Registering Authorities			✔	✔
Australian Podiatry Association of Victoria		✔		
Australian Supermarket Institute		✔		✔
Australian Veterinary Association - ACT Division				✔
Australian Veterinary Association Ltd	✔	✔		
Avcare – National Association for Crop Protection and Health	✔	✔		
Bristol-Myers Squibb			✔	
Brian Foster		✔		
Chronic Illness Alliance	✔			
Coles Myer Pty Ltd		✔		
Combined Pensioners and Superannuants Association of		✔		

Organisation	Written submissions			Face-to-face
	Initial	Second	Final	
New South Wales Committee on Regulatory Review				✔
Community Services and Health Industry Training Board	✔			
Complementary Healthcare Council of Australia	✔	✔	✔	✔
Consumers' Health Forum	✔	✔	✔	✔
Curtis Jones and Brown Advertising Pty Ltd	✔			
Darwin Holistic Health Centre Inc		✔		
Department of Agriculture, Victoria				✔
Department of Health and Aged Care	✔			
Department of Health and Human Services Tasmania - Pharmaceutical Services Branch	✔			
Department of Human Services SA		✔		
Department of Natural Resources and Environment	✔			
Department of Primary Industries and Resources SA		✔		✔
Dr NA Buckley		✔		
Faulding HealthCare Pty Ltd		✔	✔	
Glaxo Wellcome Pty Ltd				✔
Haztech Environmental	✔	✔		
Kidsafe				✔
Legislation Reform Working Group		✔		
Mater Medication Helpline				✔
Medi Kwik		✔	✔	
Medical Practitioners Board of Victoria		✔		✔
Mr Joe Friend		✔		
Mr John Matthews				
Mr Paul Cracknell		✔		
Mr Roger Napthine, Nurse Consultant	✔			
Ms Janet Forster, Physiotherapist	✔			
Ms Tracey Bessell		✔		
National Aboriginal Community Controlled Health Organisation	✔			
National Association of People Living with HIV/Aids		✔	✔	
National Drugs and Poisons Schedule Committee (NDPSC)	✔		✔	
National Herbalists Association of Australia	✔	✔		
National Industrial Chemicals Notification and Assessment Scheme	✔	✔	✔	✔
National Injury Surveillance Unit		✔		✔
National Registration Authority	✔	✔		✔
National Therapeutics Committee	✔			
Naturopaths and Herbalists of the NT (Darwin)		✔		
NSW Department of Agriculture	✔	✔		
NSW Farmers Association		✔		
NSW Workcover Authority - Chemical Safety Unit				✔
NT Department of Primary Industry				✔
NT Health Services				✔
NT NRA Representative				✔
NT Police (Drug Enforcement Unit and Drug Liaison)				✔
Nursing Federation				✔
NYNAS (Australia), Brisbane	✔			
Peter MacCallum Cancer Institute	✔	✔	✔	
Pharmaceutical Society of Australia (ACT Branch)				✔
Pharmaceutical Benefits Scheme				✔
Pharmaceutical Council of Western Australia	✔	✔	✔	

Organisation	Written submissions			Face-to-face
	Initial	Second	Final	
Pharmaceutical Education Program Study	✔			
Pharmaceutical Health and Rational Use of Medicines Committee (PHARM)	✔		✔	
Pharmaceutical Society of Australia		✔	✔	✔
Pharmaceutical Society of Australia - Queensland Branch	✔			
Pharmaceutical Society of Australia - SA Branch		✔		
Pharmaceutical Society of Australia - Tasmanian Branch, Pharmacy Board of Tasmania and Pharmacy Guild of Australia				✔
Pharmaceutical Society of Australia - Victorian Branch	✔			✔
Pharmaceutical Society of Australia (NSW Branch)	✔			✔
Pharmacy Board of New South Wales	✔	✔		✔
Pharmacy Board of South Australia	✔	✔	✔	✔
Pharmacy Board of the ACT	✔		✔	
Pharmacy Board of the Northern Territory	✔			
Pharmacy Board of Victoria	✔	✔	✔	
Pharmacy Direct				✔
Pharmacy Guild of Australia	✔	✔	✔	✔
Pharmacy Guild of Australia - ACT Branch	✔			✔
Pharmacy Guild WA				✔
Pharmacy Practice and Quality Use of Medicines Research Group				✔
Pharmacy Society SA				✔
Primary Industries and Resources South Australia				✔
Plastics and Chemical Industries Association (PACIA)				✔
Podiatrists Registration Board of Victoria		✔		
Poisons Information Centre				✔
Poppy Advisory and Control Board				✔
Population Health, DHAC				✔
Productivity Commission	✔			
Australian Self Medication Industry (Proprietary Medicines Association of Australia Inc.)	✔	✔	✔	✔
Queensland Health	✔	✔		✔
Queensland Nurses Union	✔			
Queensland Treasury Department				✔
Royal Australian College of General Practitioners - Therapeutic Committee			✔	✔
Royal Australian College of General Practitioners, Victoria				✔
Royal Hobart Hospital				✔
SA Public and Environmental Health				✔
Schering Pty Ltd		✔		
Senator Tambling				✔
Sigma Pharmacy Service Division	✔			
Society of Hospital Pharmacists of Australia		✔	✔	
Society of Hospital Pharmacists of Australia, Queensland		✔		
South Australia Health				✔
South Australian Police	✔			✔
Tas Health				✔
Tasmania Police				✔
Tasmanian Alkaloids Pty Ltd	✔			✔
Tasmanian Resource Planning and Development Commission	✔			
The Pharmacy Guild of Australia	✔	✔		✔
The Remote and Isolated Pharmacists Association of	✔			

Organisation	Written submissions			Face-to-face
	Initial	Second	Final	
Australia Inc. Therapeutic Goods Administration				✔
University of Queensland, School of Pharmacy		✔		
University of South Australia, School of Pharmacy and Medical Sciences	✔	✔		✔
Veterinary Practitioners Registration Board of Victoria	✔	✔		
Veterinary Surgeons Board				✔
Victoria Health				✔
Victoria Police	✔	✔	✔	✔
Victorian Association of Health and Extended Care	✔			
Victorian Herbalists Association	✔			
Ms Janet Veilands			✔	
WA Agriculture		✔		✔
WA Health				✔
WA Pharmacy Council				✔
Workcover Corporation	✔			✔

Pharmaceutical industry

Identified costs were associated with the current lack of national uniformity in controls and the timeframes for NDPSC scheduling decisions and subsequent adoption by the States and Territories. Areas of non-uniformity included scheduling (e.g. pseudoephedrine is S3 in Victoria but S2 elsewhere), sampling (e.g. representatives providing samples in Queensland must be licensed, and in Victoria samples cannot be carried by the representative but must be ordered), labelling, and advertising. Other costs associated with non-uniformity were also raised, such as the cost of monitoring the different pieces of legislation and the costs of negotiating with all of the States and Territories on non-routine matters such as exemptions. The development and adoption by reference of model legislation was strongly recommended in order to achieve uniformity. It was noted that the adoption of consistent complementary legislation, instead of model legislation, would not reduce the costs associated with monitoring changes to the different legislation, nor would it simplify the process of dealing with multiple agencies. It was also noted that consistent complementary legislation in the States and Territories may change over time and lead to inconsistency.

Concern was raised over possible contradictions between the new Therapeutic Goods Advertising Code and jurisdictional legislation. Only a couple of submissions supported deregulation of advertising of medicines, but there was general support for a relaxation of the current restrictions (e.g. allow CMIs on Internet sites, information on new medicines or new medical findings, and wider advertising of S3). All submissions from this industry supported a partnership approach to advertising and transfer of the controls to the Therapeutic Goods Act.

In order to reduce timeframes for scheduling recommendations for new therapeutic goods, it was argued that scheduling considerations be either coordinated with

evaluation or be included in the evaluation process, and that scheduling decisions be made under the *Therapeutic Goods Act 1989*. Separation of the scheduling of medicines from agvet and other poisons was suggested by some, as was the separation of the controls and legislation for licit and illicit drugs.

It was recommended that all matters relating to product labelling be moved to the *Therapeutic Goods Act 1989*, but dispensing labels remain under State and Territory legislation. Risk based counselling by pharmacists was supported and one submission expressed confidence in an ongoing improvement in pharmacy practice nationally. One submission supported the availability of medicine for chronic care from a pharmacy. The benefit of mandatory recording of S3 products at the pharmacy level was questioned.

Complementary health care

Broadly, the two issues raised by the complementary health care industry and health care practitioners were prescribing rights and the perceived marginalisation of the sector. Specifically, concern was expressed that representation on national committees, such as NDPSC and NCCTG, are biased towards conventional medicine, so that decisions on complementary medicines are made without representation and without input from appropriate complementary health care practitioners. Counselling of consumers by pharmacists on the use of complementary medicines was seen as another area of marginalisation of this sector and concern was raised over the training of pharmacists to provide appropriate counselling in this area. It was suggested that another schedule be added to the SUSDP for complementary medicines that pose a risk, but are suitable for prescription from a complementary health care practitioner. There was strong support for national uniformity and Trans-Tasman Mutual Recognition Arrangements. Significant costs due to protracted scheduling processes were reported and there was a call for a merits appeal mechanism against NDPSC scheduling recommendations.

Nurses organisations

The principal concerns were the regulations covering administration of medicine by nurses and carers and the increasing use of DAAs in aged care. There is apparently significant non-uniformity in the rights to administer medicine, however this is outside the Terms of Reference of this Review. The value of DAAs to assist in self medication was noted, however there was concern over the growing practice of using DAAs by carers and/or non-nursing staff to administer medicine to the aged. National regulation of DAAs was recommended to minimise the practice of re-packaging medicines and to restrict the use of DAAs to patients who have been assessed by their doctor as benefiting from a DAA for the purpose of self-medication. There was strong support for national uniformity generally, and specifically for regulations relevant to nursing because of the mobile nursing workforce.

Physicians

National uniformity in general was supported and in particular the establishment of a national register was recommended to overcome problems with interstate supply of

some medicines and to ensure that doctors deregistered in one jurisdiction cannot practice in another. (Registration of practitioners is outside of the Terms of Reference for this review.)

It was felt that Competition Policy should not be applied to controlled substances and maintenance, or strengthening, of the current controls on controlled substances was recommended. Drug dependence of patients with chronic pain, and also of a small number of doctors, was discussed. Some felt the barriers to prescribing controlled substances were useful in preventing abuse, while many felt these barriers were too severe when the patient was genuinely in need of long-term S8 medicines (e.g. cancer patients). Increased use of electronic surveillance of prescribing and dispensing controlled substances, linked to Medicare and Health Insurance Commission databases was suggested for more effective monitoring.

Most supported the use of electronic prescribing and opposed prescribing by pharmacists for chronic illnesses or long-term medication. Concern was expressed over potential interactions between prescription medicines and S2 and S3 medicines, over which the doctor had no control. Most viewed the role of pharmacists as important in assisting patients with the management of their medicines.

Relaxation of the restrictions on advertising was strongly opposed, especially for prescription medicines. Direct to consumer advertising of prescription medicines was expected to undermine the doctor–patient relationship and influence the prescribing practices of many doctors. There was general concern over Internet information on medicine and also on international Internet medicine supply.

Strict regulation of complementary medicines, to the level of conventional medicines, was recommended. Specialists also raised issues related to prescribing rights, which is outside the Terms of Reference of this Review.

Dentists

The role of community pharmacy was strongly supported. The inclusion of some dental materials on the Pharmaceutical Benefits Scheme was suggested, as well as other matters related to prescribing rights, both of which are outside the Terms of Reference of this Review.

Pharmacy boards and organisations

It was expressed in one submission, and supported by others, that scheduled medicines are not items of commerce and *caveat emptor* (let the buyer beware) does not apply. Thus there was strong support for the current level of controls. There was also support for national uniformity, but many submissions felt there were instances where uniformity would not benefit public health, such as access issues or prescribing rights in remote locations. One submission suggested that human medicines should be separated from agvet and other poisons in scheduling, while another was concerned about consistency where there was overlap.

There was nearly unanimous support for maintaining the current schedules for medicines, with some possible redefinition of access to include wider prescribing

rights for pharmacists. Relaxation of controls on access for S2 and/or S3 were expected to result in many medicines being up-scheduled to maintain the current restrictions and were not predicted to have a beneficial effect on public health. Movement of S2 to open sale was strongly discouraged because of the resultant lack of counselling and supervision (with respect to diversion to the illicit market). One submission thought the fee for recording S3 products was excessive, but overall there was little support for maintaining this requirement because there was no perceived benefit.

Notification of changes to the SUSDP to pharmacists was reported to be ineffective (by company representatives, journals or professional organisations) and the complexity of the SUSDP was raised. It was recommended that the SUSDP be reformatted for simplicity and be available on the Internet.

Some acknowledged that counselling and advice are not always provided, however all agreed on the value of appropriate pharmacist–patient interaction. The value of other pharmacist obligations were also pointed out, such as ensuring supply and the provision of quality medicines. Drug and poisons legislation was not seen as the appropriate means of enforcing pharmacy practices, but support was expressed for Government–Guild Agreement, and a strong case was made for maintaining *Schedules 2* and *3* during the term of the agreement. There was some support for pharmacists prescribing medicines for patients with chronic conditions or prescribing long-term use medicines such as contraceptives, however several felt that research into the benefits of such prescribing practice should first be undertaken.

Advertising of S4 and S8 medicines was strongly opposed because of biased information, possible overuse, and damage to the doctor–patient relationship. Views on advertising of other medicines were mixed, but national uniformity in advertising controls was supported. One submission suggested the development of an advertising code of practice with some elements of self-regulation.

There were concerns that mail order pharmacies could not adequately provide counselling to consumers and also that they threatened the viability of small rural pharmacies. There were strong concerns about the Internet as a source of information on medicines and also with respect to international supply. The Internet was seen as a way of avoiding compliance with access and advertising controls and there was strong support for national regulation.

Several submissions recommended that physician's samples should be accompanied by the Proprietary Information and/or CMI. Concerns were expressed that Trans-Tasman Mutual Recognition Arrangements will lead to a reduction in Australian public health and safety. The requirement that S8 medicines must be supplied in the same jurisdiction as the registered prescriber was viewed as anti-competitive by one stakeholder, while most felt that competition principles should not be applied to controlled substances. Concerns were raised over the possible movement of the complete regulation of agvet products to the NRA and the use of Codes of Practice for household chemicals, both of which were expected to cause a reduction in public health protection.

Consumers and injury prevention agencies

There was strong overall support for maintaining the current level of control on medicines and poisons. The relatively low rate of poisoning in Australia was seen to reflect the effectiveness of the restrictions and there was concern that a reduction in the controls might increase the incidence of poisoning. There was a call for an education campaign on the regulatory process for medicines so consumers would have a clearer understanding of the expected quality of various medicines during self-selection. (Note that product quality is covered by the *Therapeutic Goods Act 1989*, and is not an objective of medicines and poisons legislation.) It was noted that many consumers do not distinguish between S2 and S3 medicines, but maintaining both *Schedules* was supported if counselling services were improved.

Concerns were raised over the information on labels, some of which is seen to be advertisements, and the interpretation of such information by those with low literacy skills. The use of consistent dosing formats was recommended (e.g. for children by weight or age). 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. Several thought CMIs should be mandatory for OTC medicines.

There was consensus that child-resistant closures have reduced the incidence of poisoning in children, but information on the proper use of such packaging was also felt necessary. Concerns were raised that formulation information for some products was not available to Poisons Information Centres and it was suggested that obsolete or highly toxic products be removed from the market where there are less toxic equivalents available. Movement of the regulation of labelling and packaging to the *Therapeutic Goods Act 1989* was supported for uniformity.

It was considered important for the chronically ill to have access to price information for medicines (including S4 and S8) and some expressed appreciation for the lower prices available from mail order pharmacies. Correspondingly, advertising of picture and price were considered acceptable, but most felt that promotional advertising was not informative (including press releases) and there was a call for transparency in advertorials. Some expressed appreciation for pharmacy assistance in the management of their medications (advice and financial aspects), while others had not developed a positive relationship with their local pharmacist. Several relayed that the processes of authorisation and counselling (by general practitioner and pharmacist) was daunting and often confusing for patients needing long-term treatment with antibiotics or S8 medicines. The down-scheduling from S4 to S3 was not viewed as increasing access since this often removes the Pharmaceutical Benefits Scheme subsidy.

Poppy industry and police departments

These submissions were principally concerned with controlled substances and the controls that are in place to prevent abuse and diversion. All of the submissions agreed that the level of restrictions that are currently placed on these drugs should not be reduced, however most recommended national uniformity in both the controls and the substances that are controlled. Most felt that competition principles should not apply to controlled substances. Police departments expressed concern over access to

precursors of illicit drugs (e.g. pseudoephedrine) and commented on the support from pharmacists in preventing such diversion. They also expressed a need for flexibility in dealing with substances of abuse and their precursors, because drug recipes on the Internet changed according to the availability of precursors and also because of local problems.

Comments and recommendations on specific controls were generally mixed. The need to obtain authority for prescribing controlled substances was considered useful in preventing abuse. Some felt that electronic prescribing could lead to an increase in fraudulent prescriptions, while others recommended the use of electronic prescribing, monitoring and recording to facilitate a national effort to reduce abuse and diversion. Benefits were expected from a national system with improved cross-border cooperation in enforcement and this was seen as an important area for reform.

The international significance of the Australian poppy industry was noted and any changes to the current controls on licensing (farm/manufacture) were strongly opposed.

Veterinary organisations and boards

Some felt that the scheduling/regulation of agvet chemicals should be separated from human medicines and household chemicals, while others did not because of the significant overlap and concerns for public health and safety. It was pointed out that restrictions recommended for the use of antibiotics by the Joint Evaluation and Technical Advisory Committee on Antibiotic Resistance were more restrictive than the controls imposed by the drugs and poisons legislation. Consolidation of scheduling and evaluation/registration of products was recommended.

Non-uniformity in scheduling and the controls applied to the schedules was said to cause confusion and add costs to veterinarians operating in multiple jurisdictions and there was a call for uniformity. Retention of S4 and the inclusion of all antibiotics in this schedule was supported. Costs associated with the secure storage of S4 products, especially when dealing with large herds and /or flocks were raised. The creation of a veterinarian only schedule (analogous to S3) was suggested, although some felt research into the practicality of such a schedule was first required. A loophole in the current regulatory system was noted, where non-veterinarians could import veterinary medicines that are not scheduled in Australia, but would be S4 if they were.

Several concerns were raised about the related legislation covering professional practice for agvet wholesalers and veterinarians. The related legislation was viewed by many as not fully effective and educational campaigns and changes to the related legislation to strengthen enforcement were recommended. Mandatory reporting by peer groups was suggested as a method of increasing enforcement.

Agricultural bodies

The NRA submission was supported, as was movement of all regulation of agvet products to the NRA. The NRA was viewed as efficient and effective and adequate in the protection of public health. The added cost of veterinary medicines was considered worth the benefit of advice and correct selection, and retention of S4

veterinary medicines was supported. Advertisement of S4 veterinary medicines was opposed because of unbalanced information and pressure to prescribe more medicines than necessary.

Retail outlets (non-pharmacy)

An argument was made for the movement of S2 medicines (and possibly some S3) to open sale. Substantially reduced prices and increased access were cited benefits. The lack of evidence demonstrating increased consumption following movement to open sale, the availability of S2 products from mail order or Internet pharmacies where counselling is not given, and the fact that most medicinal misadventures involve prescription drugs supported the argument. It was also claimed that Australian retailers have not behaved in an irresponsible or profligate way with respect to the sale of medicines that are currently open sale and are not likely to do so with respect to S2 or S3 medicines. One submission specifically called for the movement of a wider range of analgesics in a variety of pack sizes and nicotine replacement therapies to open sale.

There was support for maintaining the current controls on S5 and S6 household chemicals. The costs of child-resistant closure and tactile packaging was felt commensurate with the benefits of decreased poisoning. One submission expressed strong support for strict regulation of herbal remedies for safety and efficacy by the TGA, as for other medicines.

Chemical industry (non-pharmaceutical)

There was strong support for national uniformity generally, and specifically in the areas of licensing, labelling, packaging, storage, advertising and sampling. There was some concern over direct-to-consumer sampling of cosmetics, personal care products and cleaning products, and development of a national code of practice was recommended.

Most supported the transfer of regulation of agvet products to the NRA and many commented on the NRA's strength in public health protection. There was some support for co-regulation of S5 and S6, while others pointed out the burden that this would place on small business.

Dissatisfaction with the processes of the NDPSC in scheduling substances was unanimously expressed. The process was considered too slow by most, while one suggested longer lead times for business to comply with changes to the SUSDP. It was recommended that:

(i) all chemicals should be considered by the NDPSC within chemical families (salts, esters etc) and not in isolation;

(ii) the CAS[62] number be included in the SUSDP for consistency with Material Safety Data Sheets;

[62] All chemicals have been assigned a Chemical Abstracts Service (CAS) number, which is used internationally, across all sectors, to identify a given substance.

(iii) that scheduling of non-medicinal poisons be considered by a specialised sub-committee of the NDPSC (although one was concerned about overlap of medicines and poisons); and

(iv) that scheduling be linked to evaluation.

The label warnings required in the SUSDP were considered to be often deficient or inappropriate and several felt that the National Occupational Health and Safety Commission hazardous substances approach, which includes health criteria, is more effective and appropriate for non-medicinal poisons. One submission suggested using the hazardous substances legislation (with additional safety warnings) for all chemicals that are not routinely used in household products. It was felt that presentation of the SUSDP could be improved and that it should be available on the Internet.

The appropriate use of child-resistant closures was supported and their role in preventing poisoning was recognised, however the mandatory use of child-resistant closures for all scheduled poisons was not supported and a risk management approach was recommended. The availability of contents information for Poisons Information Centres was a recognised problem, especially when there is parallel importation of products with different formulations to the Australian products. Provision of Material Safety Data Sheets to Poisons Information Centres was recommended.

State and Territory departments

Across all of the States and Territories, it was strongly felt that the current level of control is effective in minimising harm and provides health benefits to governments, communities and individuals. While it was recognised by most that some improvements could be made in efficiency and transparency, concerns were raised that changes to the current legislative system would lead to a reduction in the level of control and thus perhaps a reduction in public health benefits. All States and Territories expressed the need for flexibility to address particular needs of their jurisdiction. Nearly all opposed moving all of the controls on agvet products to the NRA because of concerns for public health and also because of implications for State departments with respect to enforcement issues.

Commonwealth departments

The complexity of the issues covered by this review was noted and there was support for greater national consistency and efficiency. It was emphasised that public health protection and safety should remain a high priority and that proposed changes should not diminish the level of protection provided by the present legislative system. The objectives were supported, but broader statements that are proactive rather than simply reactive were suggested.

It was recommended that, in the spirit of uniformity and to facilitate amendment, it would be preferable that the jurisdictions consider inclusion of the descriptors for scheduling classifications in their subordinate legislation, rather than in the Acts.

The costs and benefits of combining S2 and S3 into a single schedule (with S2 criteria) was predicted to lead to reduced overall costs, however the movement of

some current S3 medicines to S4, and the resultant reduction in accessibility, was raised. The range of control on access afforded by the current medicine schedules was considered valuable in providing accessibility while minimising harms. The combination of S2 and S3, with new schedule criteria, was not supported because of public health concerns and the impending Government–Guild Agreement.

Movement of all regulations for agvet products to the NRA was supported in general, however while some departments felt that the NRA commitment to public health protection was adequate, other departments thought that the *Agricultural and Veterinary Chemicals Code Act 1994* required amendment to strengthen this commitment.

There was support for nationally uniform restrictions on public access to and labelling for hazardous chemicals. Concerns were raised that there is no mechanism for placing restrictions on substances that are not scheduled and that some substances may fall outside of the scope of the NDPSC (i.e. those giving rise to hazardous substances when used). Concern was also expressed that the jurisdiction for controlling hazardous chemicals in cosmetics was unclear.

Direct-to-consumer advertising of prescription medicines was considered not in the interest of public health, and therefore was opposed. The role of the Trade Practices Act in advertising of medicines was pointed out. In particular, Sections 52 (general prohibition on misleading or deceptive conduct) and 53 (false or misleading representations).

ATTACHMENT A3 Summary of where the terms of reference are addressed

	in Part A of Report	in Part B of Report
General Issue 1:	Chapter 4 and Chapter sections 3.1, 5.1, 5.2, 5.4,.5.5, 5.6 and 5.7	Sections 3.1, 4.2.1, 4.6.2, 4.7.2, 4.8.2, 4.9.2, 4.10.2, 4.11.2, and 4.12.2
General Issue 2:	Chapter 4 and Chapter sections 3.2, 3.3, 5.1, 5.2, 5.3, 5.4, 5.5, 5.6 and 5.7	Sections 3.2, 4.1.3, 4.1.4, 4.2.2, 4.6.3, 4.7.3, 4.8.3, 4.9.3, 4.10.3, 4.11.3, and 4.12.3
General Issue 3:	Chapter 4 and Chapter sections 3.4, 5.1, 5.2, 5.3, 5.4, 5.6 and 5.7	Section 2 and Sections 4.2.5, 4.3.5, 4.4.5, 4.5.5, 4.6.5, 4.7.5, 4.8.5, 4.9.5, 4.10.5, 4.11.5, and 4.12.5
General Issue 4:	Chapter 6 and Chapter sections 4.6, 5.1, 5.2, 5.3, 5.4, 5.5, 5.6, and 5.7	Sections 3.6, 4.11.4. and 4.12.4
General Issue 5:	Chapters 2 and 4 and Chapter sections 5.3, 5.4, 5.5, 5.6, and 5.7	Sections 4.24.11, 4.12, and 5.5
General Issue 6:	Chapter 4 and Chapter sections 3.6, 5.1, 5.2, 5.3, 5.4, 5.5, 5.6, and 5.7	Sections 3.5, 4.2.5, 4.6.6, 4.7.6, 4.8.6, 4.9.6, 4.10.6, 4.11.6, and 4.12.6
General Issue 7:	Chapters 4 and 6 and Chapter sections 3.2, 3.3, 3.5, 5.1, 5.2, 5.3, 5.4, 5.5, and 5.6	Sections 3.3, 4.2.3, 4.3.3., 4.4.3, 4.5.3, 4.6.3, 4.7.3, 4.8.3, 4.9.3, 4.10.3, 4.11.3, and 4.12.3

General Issue 8:	Chapters 4 and 6 and Chapter sections 4.10, 5.3, 5.4, 5.5, 5.6, and 5.7	Sections 5.3, 5.5, 5.6, and 5.8
General Issue 9:	Chapter 4 and Chapter sections 3.4, 3.5, 5.1, 5.2, 5.3, 5.4, 5.5, 5.6, and 5.7	Sections 3.4, 4.2.4, 4.3.4, 4.4.4, 4.5.4, 4.6.4, 4.7.4, 4.8.4, 4.9.4 4.10.4, 4.11.4, and 4.12.4
General Issue 10:	Chapters 4 and 6 and Chapter sections 5.1, 5.2, 5.3, 5.6, and 5.7	Section 5.4
General Issue 11:	Chapter section 1.1 and Attachment A2	Section 1.2.3
Specific Issue 1:	Chapter 4 and Chapter sections 5.5 and 5.6	Sections 4.4 and 5.8.3
Specific Issue 2:	Chapters 2 and 4 and Chapter sections 5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7 and 6.1	Section 5.3
Specific Issue 3:	Chapter 4	Section 4.3
Specific Issue 4:	Chapters 2 and 4 and Chapter sections 5.1, 5.3, 5.4, 5.5, 5.6, 5.7 and 6.2	Sections 5.5 and 5.6
Specific Issue 5:	Chapter 4 and Chapter sections 5.2, 5.4 and 5.5	Section 4.13

Acronyms

AHMAC	Australian Health Ministers' Advisory Council
APESMA	Association of Professional Engineers, Scientists and Managers of Australia
APMA	Australian Pharmaceutical Manufacturers Association
ARTG	Australian Register of Therapeutic Goods
CMI	Consumer Medicine Information
COAG	Council of Australian Governments
DAA	dose administration aid
DTC	direct to customer
MSC	Medicines Scheduling Committee
NCCTG	National Coordinating Committee on Therapeutic Goods
NDPSC	National Drugs and Poisons Schedule Committee
NPHP	National Public Health Partnership
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
TGA	Therapeutic Goods Administration

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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