THE NATIONAL COMPETITION POLICY REVIEW OF DRUGS, POISONS AND CONTROLLED SUBSTANCES LEGISLATION

(THE GALBALLY REVIEW)

A Report to the Australian Health Ministers' Conference on Implementation of the Review Recommendations

(as endorsed by the Council of Australian Governments)

BY THE

NATIONAL CO-ORDINATING COMMITTEE ON

THERAPEUTIC GOODS

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GLOSSARY

AHMC	Australian Health Ministers' Conference
AHMAC	Australian Health Ministers' Advisory Council
APMA	Australian Pharmaceutical Manufacturers' Association (now Medicines Australia)
APVMA	Australian Pesticides and Veterinary Medicines Authority
ARMCANZ	Agriculture and Resource Management Council of Australia and New Zealand (now Primary Industries Ministerial Council)
ANZTPA	Australia and New Zealand Therapeutic Products Authority
ASMI	Australian Self-Medication Industry
CMI	Consumer Medicines Information
COAG	Council of Australian Governments
CSC	Chemicals Scheduling Committee (also known as the Poisons Scheduling Committee)
DAFF	Australian Department of Agriculture, Fisheries and Forestry
DoHA	Australian Department of Health and Ageing
GHS	Globally Harmonised System for Classifying and Labelling Chemicals
HIC	Health Insurance Commission
MSC	Medicines Scheduling Committee
NCP	National Competition Policy
NCC	National Competition Council
NCCTG	National Coordinating Committee on Therapeutic Goods
NDPSC	National Drugs and Poisons Schedule Committee
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NPHP	National Public Health Partnership
NRA	National Registration Authority for Agricultural and Veterinary Chemicals (now known as the Australian Pesticides and Veterinary Medicines Authority (APVMA))
OCS	Office of Chemical Safety
PIMC	Primary Industries Ministerial Council
SUSDP	Standard for the Uniform Scheduling of Drugs and Poisons
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons
TGA	Therapeutic Goods Administration

INTRODUCTION

The *Review of Drugs, Poisons and Controlled Substances Legislation* (the *'Galbally Review')* was one of a number of reviews undertaken under the National Competition Agreement to which all of the States and Territories and the Australian Government are parties. The Council of Australian Governments (COAG) asked the Review to examine State and Territory legislation that imposed controls in Australia on supply and use of drugs, poisons and controlled substances.

The independent Chair of the Review was Ms Rhonda Galbally, who at the time was the Managing Director of the Australian International Health Institute. Ms Galbally was assisted by Steering Committee comprising representatives of the Australian Government and State and Territory Governments.

The Review's final report was presented to the Australian Health Ministers' Conference (AHMC) in January 2001. A Working Party of the Australian Health Ministers' Advisory Council (AHMAC) was established in February 2001 to assist in the preparation of a response to Review Report and recommendations.

In preparing its response, the AHMAC Working Party took account of the comments of the Primary Industries Ministerial Council (PIMC), as some of the Review recommendations had implications for the regulation of veterinary medicines and ag/vet chemicals. The Working Party also took account of the proposal to establish the Australia New Zealand Therapeutic Products Authority (ANZTPA) (referred to at that time as the Trans Tasman Agency), and recommended that the Review recommendations be implemented in a trans-Tasman context.

In the last quarter of 2003, AHMC unanimously endorsed the AHMAC Working Party response to the Review out-of-session and agreed that the response and the Review Final Report should be forwarded to COAG for consideration. COAG endorsement of the Final Report of the Galbally Review and the AHMAC Working Party response was completed out-of-session in June 2005.

Most of the recommendations were accepted by the AHMAC Working Party, however recommendations 12 (e) and (f), that relate to the implementation of a Code of Practice for the Supply of Samples of Poisons, were rejected for reasons of practicality. The diverse nature of the particular poisons addressed by this Recommendation (which are included in Schedules 5 and 6 of the *Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP)*), the wide variety of retail outlets from which they are supplied, and the lack of industry association membership would make enforcement of a Code difficult.

A table of recommendations, which indicates those accepted by the AHMAC Working Party, and those with implications for National Competition Policy payments is at **Appendix 1**.

The key recommendations made by the Review relate to:

- changes to the levels of controls in some areas, including advertising of medicines and poisons,
- improved uniformity through moving controls on advertising, labelling and packaging to Australian Government legislation and model legislation to be adopted by reference in all States and Territories; and
- improved efficiency of administration by creating separate scheduling committees for medicines and poisons and closer links between evaluation and scheduling.

Implementation of the Review recommendations

At the time of the release of the Review's final report, the various options for addressing the exemption for therapeutic goods under the Trans Tasman Mutual Recognition Arrangement (TTMRA) were still being discussed. Hence, the Review did not consider these recommendations in the context of the Treaty which has been since been signed between the Australian and New Zealand Governments to establish a single regulatory agency for therapeutic products (the Australia New Zealand Therapeutic Products Authority – the Authority). The AHMAC Working Party response to the recommendations of the Review therefore proposed that the Review recommendations be progressed in a trans-Tasman environment.

The trans-Tasman Treaty required those Review recommendations with trans-Tasman implications to be progressed in a timely manner, in order for any relevant proposals to be included in the drafting instructions for the new legislation to support the Authority.

This report describes the action taken to implement the agreed Review recommendations which have been progressed in order to meet the 12 month timeline detailed in the AHMAC WP response, noting that the commencement of the trans-Tasman legislation has been deferred to the second half of 2007.

Regulation Impact Statements

A Regulation Impact Statement (RIS) was prepared on the Price Information Code of Practice (Recommendation 11). This RIS was released for targeted stakeholder consultation, along with the draft Code, in April 2004. Comments closed on the Code in June 2004 and all stakeholder comments were addressed by the NCCTG in implementation of Recommendation 11.

A Regulatory Impact Statement was also prepared for the Treaty underpinning the Authority.

RECOMMENDATION 1

Objectives of the 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.*

Summary

One of the terms of reference of the Review was to clarify the objectives of the legislation. The Review found that legislation that restricts access to and use of drugs and poisons may be seen as reflecting judgements being made by successive governments, at both the State and Commonwealth levels and that it was inappropriate to rely on a free market for these products. The Review confirmed that comprehensive legislation that regulates drugs and poisons is still required and that the principal objectives of the legislation were to promote and protect public health and safety by preventing accidental poisoning, deliberate poisoning, medical misadventures and diversion for abuse or manufacture of substances of abuse.

The Review recommended that State/Territory and Australian Government legislation needed to explicitly incorporate these objectives.

Action taken to implement

The draft Australia New Zealand Therapeutic Products Regulatory Scheme (Administration and Interpretation) Rule 2006, which sets out the future medicines scheduling processes, incorporates the principal objectives and allows for access restrictions to be placed on medicines in order to protect public health and safety.

In particular, the draft Rule sets out 'matters to be taken into account' in making scheduling decisions which are part of a risk management framework. This framework for the classification of therapeutic products provides the basis for a uniform system of access controls for therapeutic products in Australia and New Zealand which is designed to minimise the risks of accidental poisoning, deliberate poisoning, medicinal misadventures and diversion for abuse or manufacture of substances of abuse. In addressing these risks, the medicines scheduling

framework seeks to ensure that consumers have adequate information and understanding to use medicines safely and effectively and in the case of over-the-counter medicines to also enable consumers to select, with the assistance of a pharmacist where appropriate, the most appropriate medicines for their condition, taking into account their health status.

State/Territory drugs and poisons legislation is to be updated to incorporate the principal objectives of that legislation as the opportunity arises.

Work will shortly commence on the development of the Australian-only legislation to underpin the poisons scheduling model[1]. This legislation will also be developed to incorporate the objectives of this Recommendation.

[1] The proposed poisons scheduling model is currently under consideration by the Australian Health Ministers' Conference as part of a separate process.

RECOMMENDATION 2

Ongoing 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 drug, poisons and controlled substances legislation with a view to continually improving the cost effectiveness of those regulatory controls.

Summary

The terms of reference required the Review to identify to what extent legislation restricted competition. It found that drugs and poisons legislation imposed 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). However the Review also found that the lack of a comprehensive strategy for collecting data 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.

The Review therefore recommended that Commonwealth and State Governments allocate public health funding to ongoing research, including data collection to evaluate and monitor the effectiveness of the legislative controls in achieving the legislative objectives.

Implementation issues

In exploring options for funding of this type of research, assistance was sought from the National Public Health Partnership (NPHP) as the body responsible for identifying and developing strategic and integrated responses to public health priorities in Australia.

However, further to consideration of this recommendations at its meeting on 26 November 2004, the NPHP advised that the implications of Recommendation 2 were not entirely a matter for the NPHP as some issues such as data monitoring have a broader application than public health policy. The NPHP therefore suggested that the issue should be taken forward in a broader health context.

NCCTG considered that while this recommendation is unclear in that it does not put forward a succinct question to be addressed in terms of the commissioning a research project, there are likely to be benefits in considering how additional value could be leveraged from the existing disparate data being collected. It is therefore suggested that an initial scoping project be undertaken to better define existing data sources, any gaps in the data and the feasibility of consolidating this data in a meaningful way. Other activities are also currently underway that may assist in gathering data, including those being conducted by the pharmaceutical benefits scheme.

Action taken to implement

NCCTG recommends that in order to implement Recommendation 2, AHMC support a Commonwealth/State and Territory cost-shared study to identify data sources which may be used as relevant indicators of the effectiveness of drugs and poisons legislation including in areas such as: accidental and deliberate poisoning; diversion from existing regulatory controls; and dependence on scheduled and unscheduled medicines. One of the outcomes of this preliminary study should be to consider what further research would be necessary to review the data collected and how it could best be used to evaluate and monitor the effectiveness of legislative controls.

A NCCTG working party could oversight this project and report back to AHMC.

RECOMMENDATION 3

Objectives of scheduled medicines

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 and abuse.*

Summary

The Review found that the restrictions which flow from inclusion of substances in the *Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP)*, particularly those on access, are also intended to reduce the level of poisoning, medical misadventure and diversion. The Review specifically recommended that the objectives of the legislation be specified in the legislation to ensure that in the case of prescription medicines, the most appropriate treatment is prescribed and that consumers have adequate information to enable them to use the medicines safely and effectively. For over-the-counter medicines, it recommended that consumers have adequate information and understanding to enable them to select the most appropriate medicines. Furthermore, the objectives should ensure that the use of medicines will not lead to dependence and that the medicines will not be diverted for abuse purposes or for the illicit manufacture of drugs of abuse.

Implementation issues

In implementing this recommendation COAG accepted that the first and fourth dot points are outside the jurisdiction of State/Territory and Commonwealth drugs, poisons, controlled substances and therapeutic products legislation.

Action taken to implement

The scheduling-related provisions of the draft Australia New Zealand Therapeutic Products Regulatory Scheme (Administration and Interpretation) Rule 2006 incorporate the principal objectives stated in the second and third dot points and allow for access restrictions to be placed on medicines in order to protect public health and safety.

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.

Summary

The Review recommended, that in the interests of uniformity and in order to minimise unnecessary costs to industry and consumers, all States and Territories should adopt all of the scheduling decisions recommended by the National Drugs and Poisons Scheduling Committee (NDPSC) by reference and in accordance with the timelines developed by the Committee.

Action taken to implement

All States and Territories either adopt all of the scheduling decisions (including the date of effect of these decisions) covered in the SUSDP by reference into relevant State/Territory drugs / poisons legislation or are in the process of amending their legislation to provide for this. New South Wales, Queensland, Western Australia, Victoria, and Northern Territory adopt the SUSDP automatically by reference, including amendments. The Australian Capital Territory currently adopts much of the SUSDP and longer term arrangements are being put in place to implement the Galbally recommendations. South Australia currently adopts most schedules by reference and longer term arrangements are being put in place to also adopt Schedule 9 substances. Tasmania has drafted a Bill to revise the *Poisons Act 1971*, which will provide for adoption of the SUSDP by reference.

NCCTG members have agreed to the development of an electronic scheduling standard under the trans-Tasman arrangements, with access via the Australia and New Zealand Therapeutic Products Authority website, to further assist stakeholders' access to information on scheduled substances and minimise costs.

While each jurisdiction and New Zealand (in the case of therapeutic products) will be able to implement a different scheduling decision to that included in the scheduling standard, a decision to depart from the entry in the scheduling standard would not be taken lightly. NCCTG is committed to the principle of national uniformity and under the current arrangements there are only a minor number of entries in the SUSDP which have not been adopted on a nation-wide basis.

As particular access issues may arise in certain States/Territories as a result of particular scheduling recommendations it is appropriate that these jurisdictions are able to take a different decision where this is warranted. Additionally, any proposal to implement a different scheduling decision would require stakeholder consultation at

the jurisdictional level. It is also expected that NCCTG will play an active role in monitoring any increase in the number of different scheduling decisions implemented by the States/Territories.

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 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 the end of 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 or 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 Conference has considered the report at the end of July 2004, Schedule 2, 3, 4 and 8 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.*

Summary

One of the terms of reference of the Review was to examine the range and number of schedules in the SUSDP. The Review concluded that Schedules 2, 3, 4 and 8 be retained at present. However, it further recommended that both the over-the-counter Schedules (S2 and S3) be combined if there is no evidence by July 2004 that improvements in health and other outcomes can be attributed to the new Quality of

Care Standards. These standards are being funded under the Third Community Pharmacy Agreement between the Commonwealth Government and the Pharmacy Guild of Australia. The Review has therefore also recommended that funds be made available from the Pharmacy Development Program under the Third Agreement to commission independent research that provides baseline data and evaluation. Additionally, it recommends that funds be made available to develop comprehensive standards that facilitate a risk-based approach to professional intervention in the supply of scheduled products to individual consumers (that is an expansion of the existing Quality of Care Standards).

Implementation Issues

Funding was provided under the Third Community Pharmacy Agreement for the Pharmacy Guild to commission an independent study to consider whether there are benefits in retaining the dual S2/S3 non-prescription scheduling framework in Australia in 2001. The final research report was submitted to the NCCTG for consideration in mid April 2005.

Action taken to implement

The NCCTG presented AHMC with a report on the results of the research and the Quality of Care Standards in November 2005. Further to this report, Health Ministers have decided to:

- retain the pharmacy (schedule 2) and pharmacist-only (schedule 3) schedules for non-prescription medicines for an interim period of 5 years;
- request that the Quality Care Pharmacy Program (QCPP) submit the summarised results of the mystery shopper program to the NCCTG on a yearly basis for the next 5 years in order for the NCCTG to monitor any improvement in compliance with the voluntary S2/S3 standards;
- at the end of the 5 year period, the restrictions on access to over-the-counter medicines be reassessed in Australia and New Zealand to determine if the objectives of these restrictions are being met, taking into account relevant data, including the data gathered from the mystery shopper program and an analysis of pharmacies which are not QCPP accredited;
- reassess the restrictions on access to over-the-counter medicines to determine if the objectives of these restrictions are being met at the end of the 5 year period, taking into account relevant data, including the data gathered from the mystery shopper program and an analysis of pharmacies which are not QCCP accredited; and
- request that the QCPP review of the S2/S3 pharmacy standards give due consideration to integrating into those standards the identification of risks to consumers making a product based request and appropriate action to address those risks.

At the end of the 5 year review period, NCCTG will submit a final report to AHMC to include recommendations regarding the future scheduling arrangements for over-the-counter medicines.

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.

Summary

Consumer Medicine Information (CMI) is required to be made available by product sponsors for products registered with the Therapeutic Goods Administration (TGA) after July 1994. However, while sponsors of therapeutic products are required to have CMI available, there is no requirement for the product sponsor, or anyone else (medical practitioners or pharmacists) to distribute CMI at point of retail sale. The Review considered that the public should have ready access to such information that could come from a consumer information service.

Action taken to implement

Recommendation 6 has been implemented through a number of activities, listed below.

- Medicines Information to Consumers (MIC) program

The MIC program was first implemented in December 2002 under the Third Community Pharmacy Agreement between the Commonwealth and the Pharmacy Guild of Australia. Under the Fourth Community Pharmacy Agreement that commenced on 1 December 2005, the MIC program continues to provide an incentive payment to encourage pharmacists to promote the quality use of medicines and assist consumers to make informed decisions.

Eligible pharmacists now receive incentive payments for providing consumer medicine information at the rate of 10 cents per subsidised paid prescription. From 1 December 2005 the Pharmaceutical Benefits Scheme (PBS) and Repatriation Pharmaceutical Benefits Scheme (RPBS) dispensing fees have included these payments.

From 1 December 2005, there has been no requirement to register as a MIC program participant and no requirement to provide certification statements for claim periods. There are now no separate lump sum payments for MIC allowance claims for prescriptions supplied as existed under the Third Community Pharmacy Agreement scheme.

Community pharmacists are required to provide CMI to consumers in accordance with the pharmacy professional standards and guidelines published by the Pharmaceutical Society of Australia in their Professional Practice Standards. These standards are called (*Patient Counselling. PSA Professional Practice Standards,*

Version 2 (2002), pp 22-25). They specify that all counselling on dispensed medicines must be conducted by a pharmacist and provide five examples of when CMI should generally be provided, for example when a medicine is first provided to a consumer.

The Pharmacy Guild of Australia provides further information on MIC on its website.

• The Community QUM Program

On-going and enhanced funding was provided to the National Prescribing Service (NPS) Limited under the 2005-06 Budget *Quality Use of Medicines Package* measure to continue the Community Quality Use of Medicines (CQUM) Program which began in 2003.

The NPS' Mission is to create an awareness, culture and environment that will support Quality Use of Medicines among all stakeholders. The NPS programs and services provide accurate, balanced, evidence-based information and services to health professionals and the community on Quality Use of Medicines (QUM).

This program offers the community a range of consumer-friendly medicines activities, resources and services. The aim is to promote better health by building awareness, knowledge and skills in the community that will lead to QUM. National media awareness campaigns and community based programs for specific population groups are part of the ongoing program for consumers.

National strategies
The national advertising campaign '*medicine without the mix-ups*' ran twice during 2004. The primary campaign message was 'You need good information about medicines and other treatment options which are essential to the safe and effective use of medicines'.

During the past two years, a number of resources have been developed for consumers to improve communication of key program messages, increase awareness, skills and knowledge of QUM. Medimate was the first such resource and 1.43 million copies have been distributed (as at June 2005).

A national consumer campaign *'Common colds needs common sense'* was implemented for its fifth consecutive winter in 2005.

• *NPS Medicines Line: 1300 888 763*

This service has been operating since 2002 and provides consumers with a convenient, confidential and independent source of information about their prescription, over-the-counter, natural and complementary medicines.

More than 1500 people call Medicines Line each month asking questions about side effects, drug interactions, therapeutic choices and medicines use in pregnancy or when breastfeeding.

Medicines Talk

MedicinesTalk is a quarterly publication written by consumers, which aims to inform consumer groups about QUM and to encourage groups to become involved in QUM activities. *MedicinesTalk* has approximately 2,360 subscribers. Community groups may reproduce in part or whole material form *MedicinesTalk* providing the source is acknowledged.

Targeted population strategies

Interventions targeted to specific populations in conjunction with program partners, include initiatives with seniors, culturally and linguistically diverse communities, Aboriginal communities and rural communities.

Seniors Program

The Seniors Program has 290 trained peer educators, who have delivered 1300 education sessions to seniors in the general community and 60 education sessions to seniors from multicultural communities. In total some 30,000 seniors have been involved.

Multicultural Program

Activities under the Multicultural Community Program have included delivery of community education sessions to approximately 7,000 people from a multicultural background, bilingual Medimates developed in Vietnamese, Chinese, Greek and Italian, a community awareness campaign on SBS Radio and the development of QUM teaching materials for the national Adult Migrant Education program curriculum.

Indigenous Program

The implementation of a train-the-trainer strategy to three pilot sites is underway for the Indigenous Program, in conjunction with the National Aboriginal Community Controlled Health Organisation. Four modules are being developed on general QUM, diabetes, hypertension and asthma as part of the strategy to train Aboriginal Health Workers.

Rural Program

The Rural Community QUM Program through its 16 Rural Project Schemes and Community Engagements has conducted 157 community QUM events around Australia, involving over 5,100 consumers.

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 committee 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 ag/vet products during evaluation of those products;*
   - *recommend the schedule in which a new substance should be included; and*
   - *recommend changes to the schedule of the substance where, in evaluating new formulations, new presentations and new substances currently included in the Standard of the Uniform Scheduling of Drugs and Poisons, a significant change in the risk profile of the substances 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 rescheduling applications by industry.*

Summary

The Review recommended that the NDPSC be disbanded and replaced with two separate committees, one responsible for medicines (the Medicines Scheduling Committee - MSC) and the other responsible for agricultural, veterinary and

household chemicals (the Chemicals Scheduling Committee - CSC). Currently the NDPSC deals with all classes of substances. The Review also recommended concurrent rather than sequential evaluation and scheduling decisions. Industry has criticised the current process as it substantially delays the entry of new products into the market place. The Review also recommended recovery of the costs of operating the committees for re-scheduling applications made by industry.

Implementation Issues

At the time of the release of the Review's final report, the various options for addressing the exemption for therapeutic goods under the Trans Tasman Mutual Recognition Arrangement (TTMRA) were still being discussed. Hence, the Review did not consider these recommendations in the context of the Treaty which was signed by the Australian and New Zealand Governments to establish the Authority. The AHMAC Working Party response to the recommendations of the Review therefore proposed that this recommendation be progressed in a trans-Tasman environment.

The Treaty provides for the Authority to develop and maintain a scheduling framework for medicines which will apply in Australia and New Zealand. COAG endorsed the proposal by Health Ministers that work proceed on the development of drafting instructions for the new legislation that would underpin the scheduling model for medicines.

Action taken to implement

A harmonised model for the scheduling of medicines was developed by the NCCTG for Australia and New Zealand. (The model developed by the NCCTG, in consultation with the Australian Department of Agriculture, Fisheries and Forestry (DAFF) and the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), for the scheduling of poisons applies only to Australia. However, both scheduling models have been aligned wherever possible and take account of all of the Review recommendations.)

Stakeholder consultation on the proposed models and a draft Scheduling Policy Framework was undertaken in August – September 2005, following endorsement of the Galbally Review final report and the AHMAC Working Party Response by COAG. Consideration of stakeholder comments by the NCCTG resulted in some refinements to the proposed scheduling models and the introduction of further administrative processes to support the models.

<u>Development of new scheduling arrangements for medicines</u>
All stakeholder comments received in the 2005 consultation process were taken into account by the NCCTG in the development of the final medicines scheduling model which received policy approval from the Australian Health Ministers' Conference (AHMC) at its meeting on 7 April 2006.

The new model for the scheduling of medicines incorporates the key elements of this recommendation including:

- the Authority to make decisions on the scheduling of medicines with each

Australian State/Territory and New Zealand expected to automatically adopt these decisions with the provision for jurisdictional departures in exceptional circumstances, subject to ongoing review (which will allow for greater alignment of decisions on product licensing and scheduling);

- establishing a medicines scheduling committee as an expert advisory committee to advise the Authority with members selected from relevant experts in Australia and New Zealand with each committee member having equal voting rights;
- The Minister for Health in each Australian State/Territory to nominate an expert member for appointment on the committee;
- The Therapeutic Products Ministerial Council to appoint other experts to the committee (where gaps in required expertise have been identified).

The final model formed the basis for the scheduling-related provisions of the draft Australia New Zealand Therapeutic Products Regulatory Scheme (Administration and Interpretation) Rule 2006[2].

It is anticipated that the draft Rule will be made available for stakeholder consideration in October 2006. A joint consultation process will be undertaken with stakeholder meetings to be held in Australia and New Zealand.

It is anticipated that the revised draft Scheduling Policy Framework will be made available for stakeholder consultation, along with the draft Standard for the Uniform Scheduling of Medicines and Poisons, in early 2007.

Action has also been taken to remove packaging and labelling requirements (other than the signal heading) from the SUSDP and transfer these requirements into the draft Managing Director Orders for labelling and packaging of medicines (as part of the new package of ANZTPA legislation). Once this new legislation is in effect, any future decisions on labelling and packaging of therapeutic products will be made by the Authority as part of the evaluation process. However, it is expected that the MSC (as the expert advisory committee on the scheduling of medicines) may provide advice to the Authority on labelling and packaging in relation to scheduling proposals.

Development of new scheduling arrangements for poisons

The comments received in the 2005 consultation process were also taken into account by the NCCTG in the development of the final poisons scheduling model. As the scheduling of poisons will apply only to Australia, new Commonwealth legislation is expected to be developed to replace related provisions that are currently in the *Therapeutic Goods Act 1989* and *Therapeutic Goods Regulations 1990.*

Drafting instructions for the new legislation are underway. Policy approval from the Australian Health Ministers' Conference (AHMC) is currently being sought out-of-session for the proposed poisons scheduling arrangements, in order to proceed with development of this new legislation.

Similarly, the Primary Industries Ministerial Council agreed at its meeting on 20 April 2006 to the transfer of controls on labelling, packaging and advertising of agricultural and veterinary chemicals to relevant Commonwealth legislation. When the relevant

[2] Subject to change following stakeholder consultation process to be undertaken in October 2006.

legislative amendments take effect, any future decisions on labelling and packaging of agricultural and veterinary chemicals will be made by the Australian Pesticides and Veterinary Medicines Authority (APVMA) as part of the evaluation process. The Chemicals Scheduling Committee (as the expert advisory committee on the scheduling of poisons) may provide advice to the APVMA (through the Office of Chemical Safety) on labelling and packaging in relation to scheduling proposals.

(See also Recommendation 22)

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 machine 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.*

Summary

The Review recommended that the prohibition on the supply of scheduled medicines by vending machines should be located in drugs and poisons legislation. It also recommended that the sale of unscheduled medicines (that is medicines currently available in supermarkets) be made available through vending machines subject to certain restrictions (limit on pack size and location of the machines). Additionally, it recommended that owners of vending machines provide the NCCTG with an independent evaluation of the safe use and effectiveness of the quality control measures after two years.

Action taken to implement

State/Territory legislation has been amended (where necessary) to prohibit the supply of scheduled medicines from vending machines and to restrict the supply of unscheduled medicines from vending machines subject to limits on pack sizes and access by children.

AHMC provisions that apply in respect of un-scheduled medicines supplied via vending machines in each jurisdiction are used by some jurisdictions as the basis for granting exemptions to the prohibition on sale of such medicines. The AHMC provisions are expected to be reviewed by the NCCTG in 2007.

RECOMMENDATION 9

Controls over administration of medicines

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

Summary

The Review recommended that the current level of controls over the administration of medicines be retained.

Action taken to implement

No action was required of either State/Territory or Australian governments as the Review recommended that the current level of controls of 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.

Summary

The Review recommended that Medicare Australia (previously known as the Health Insurance Commission (HIC)) consult with State and Territory Health Departments to develop procedures to reduce the administrative duplication that applies, in certain circumstances, to the prescribing of narcotic drugs.

Implementation issues

State and Territory drugs, poisons and controlled substances legislation requires prescribers to obtain authority to prescribe controlled medicines[3] for a continuous period of more than 2 months and to drug dependent patients.[4]

A written application (in the form of the authority prescription form) is required to seek a Medicare Australia authority to prescribe controlled medicines listed on the PBS for a continuous period exceeding 1 month, for a period up to 3 months.[5]

Thus the apparent duplication occurs in the specific situation where a prescriber seeking an authority from the relevant State/Territory Health Authority to prescribe a PBS listed controlled medicine for a period of more than two months must also seek a required authority from Medicare Australia to prescribe that controlled medicine, for the same period, in order for the patient to receive the medicine at the PBS subsidised cost. In some jurisdictions, further exemptions apply where the patient is being treated in a hospital or require only a notification (rather than a need for an application for a permit) for the treatment of certain medical conditions with opioid analgesics.

Discussions between the Pharmaceutical Benefits Branch of the Department of Health and Ageing, the NCCTG and Medicare Australia identified that there is actually very little duplication other than in the very specific circumstances outlined above. The requirements are quite different, albeit essential, and that while the subsequent administrative processes may appear to be related (in that they relate to the prescription of controlled medicines) they are not unnecessarily duplicated as they

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[3] All States and Territories have controls on prescribing S8 medicines, some jurisdictions also apply these controls to certain S4 medicines and S7 poisons.

[4] Exemptions to these provisions may apply if the medicine is prescribed for chronic pain as a result of cancer or if the life expectancy of the patient is less than 12 months.

[5] Telephone authority can be sought to prescribe a controlled medicine for a period of 1 month, based on compliance with relevant PBS subsidy requirements.

have quite different purposes. State and Territory legislation requires compliance with certain provisions for the prescription of controlled medicines for long term treatment, as distinct from Medicare Australia requirements of compliance with PBS subsidy criteria in providing the PBS benefit for controlled medicines for long term treatment.

Action taken to implement

While it was not accepted that there is unnecessary administrative duplication, State and Territory Health Authorities and Medicare Australia agree that cooperation has improved between them in the administration of the respective requirements for these medicines. NCCTG members also agreed that they would work with Medicare Australia to educate medical practitioners and consumers on the perceived duplication of processes, as opportunities arise.

RECOMMENDATION 11

Informational advertising of scheduled medicines

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*
     - *should not be accompanied by illustrations or pictures;*
   - *the content of the advertisement (name, brand, strength, pack size and price);*
   - *who can place the advertisement (ie may only be placed by suppliers and not manufacturers of products);*

- *the nature of the media where such an advertisement may be placed. (eg 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 or 13 of the Therapeutic Goods Regulations;*
- *is not embellished 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.*

Summary

The Review recommended that in the interests of uniformity, all provisions relating to advertising in State and Territory drugs and poisons legislation be repealed and that the Commonwealth Therapeutic Goods Act be the principal legislation that controls advertising of medicines for human use. It also recommended that the Commonwealth Act be amended in respect of the restrictions that apply to the advertising to the public of medicines in Schedules 3, 4 or 8 to allow for price information to be provided, to allow for Consumer Medicine Information to be published in its entirety without embellishment and to allow for a one-off press release about the availability of a new medicine, all such exceptions being subject to strict conditions.

Implementation issues

Direct-to-consumer advertising of human and veterinary prescription medicines and some non-prescription medicines is prohibited in Australia. These prohibitions are included in State and Territory drugs, poisons and controlled substances legislation. Similar prohibitions are included in the *Therapeutic Goods Act 1989*. While the definition of advertising in State and Territory drugs and poisons legislation and the Commonwealth *Therapeutic Goods Act* varies across all jurisdictions, all definitions cover a wide range of material and behaviours.

As a result of these definitions, price lists for medicines from a supplier, CMI (in some circumstances), press releases and some information contained on the label of products come within the scope of the controls of advertising.

Similarly, the provision of price information of prescription and some Schedule 3 medicines is also prohibited. The Review recommended that the prohibition on the publication of CMI, price information and disease state advertising be lifted, and recognised that standards for provision of this information should be developed to avoid inappropriate promotional advertising.

Action taken to implement

All provisions relating to advertising of medicines in State and Territory drugs, poisons and controlled substances legislation are to be repealed as legislative timetables for each jurisdiction permit. The only reference to advertising in the new draft scheduling standard is the prohibition on the advertising of Schedule 9 substances. The current prohibition on advertising of Schedule 3 (other than those substances which have been granted permission to be advertised), 4 and 8 medicines direct to consumers is be transferred into the Australian-only Regulations of the new therapeutic products legislation which is to be administered by the Authority.

A Price Information Code of Practice (the Price Code) was developed in consultation with stakeholders which will permit information on the price of Schedule 3, 4 and 8 to be published by pharmacists without being considered to be advertising. Aspects of the Price Code that are of particular note are:

- price information will only be able to be provided by suppliers of products (that is, pharmacists, agents acting on behalf of pharmacists, and dispensing doctors);
- product manufacturers, distributors or sponsors will not be able to provide price information, other than pharmacy marketing groups who sponsor their own brand products;
- price information will be able to be provided by any method except television, radio and 'outdoor advertising' eg on billboards and buses;
- provision will be made for the exclusion of controlled substances prone to misuse/abuse, on public health and safety grounds; and
- price information will be defined as information about the cost to consumers "at the pharmacy till", that is, after subsidies and any applicable premiums and concessions have been applied.

As proposed by the Review, the Price Code applies to products listed on the Pharmaceutical Benefits Scheme (PBS), although there can be little price variation between these products. The Regulation Impact Statement prepared on the draft Price Code was provided to stakeholders and published on the TGA internet site during 2004. Fifteen written responses were received to the draft Regulation Impact Statement across the therapeutic products industry, healthcare professionals and State/Territory governments. Of the responses received, six stakeholders expressly confirmed their support for the Price Code. None of the other respondents raised any objection.

NCCTG considered the stakeholder comments received and agreed to endorse the Price Code. It is anticipated that the Price Code will become an Order under the Australian-only legislation and will take full effect at the time the joint regulatory scheme commences. The Price Code is expected to be implemented on a voluntary basis later in 2006.

Disease state advertising and generic information are specific types of advertising which are covered by the draft Australia New Zealand Therapeutic Products Advertising Code. Any complaints received on disease state advertising or generic

information or Consumer Medicine Information will be handled through the usual complaints mechanisms for the advertising of therapeutic products.

The Primary Industries Ministerial Council agreed at its meeting on 20 April 2006 to the transfer of controls on labelling, packaging and advertising of agricultural and veterinary chemicals to relevant Commonwealth legislation. These legislative amendments will enable the Australian Pesticides and Veterinary Medicines Authority (APVMA) to regulate the advertising of prescription veterinary medicines.

(See also Recommendation 22)

RECOMMENDATION 12

(as accepted)

Supply of sample packs of medicines 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 or 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 the 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 Pharmaceuticals 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 samples safely and effectively.*

Summary

The recommendation concerns both the supply of samples of medicines to health professionals (and subsequent supply to patients) and the supply of certain poisons to the general public.

The Report has recommended that State and Territory legislation with controls over the supply of clinical samples (that is licensing of medical representatives) be repealed. It has also recommended that an industry code of conduct be developed covering the supply of clinical samples and that State legislation be amended to make compliance with the code mandatory. In addition, when clinical samples are provided to patients they should be fully labelled with directions for use.

Action taken to implement

Medicines Australia (formerly known as the Australian Pharmaceutical Manufacturers Association) has developed a Code of Practice for the Supply of S4 Starter packs to Healthcare Professionals. This Code has been endorsed by the NCCTG and the States/Territory members have agreed that (as legislative timetables permit where necessary) any specific provisions relating to the supply of starter packs will be repealed and replaced with the general requirement that compliance with the Code is a condition of licensing for manufacturers and wholesalers.

Starter pack labels will be required to comply with the requirements of the new labelling standard which is being developed as a Managing Director Order for Australia and New Zealand (as part of the new package of ANZTPA legislation).

NCCTG also noted that the Galbally Review considered that the term 'clinical samples' included S2/S3 starter packs and that there is currently some variation between jurisdictions on controls for these products. In order to support national uniformity, those States and Territories which have specific requirements for S2/S3 starter packs are to repeal the relevant legislative provisions and make compliance with the Code of Good Wholesaling Practice (which includes certain provisions for starter packs) a licence condition for wholesalers.

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.

Summary

The Review recommended that drugs and poisons legislation that requires licences by wholesalers and retailers to sell substances in Schedules 5 and 6 be repealed.

Action taken to implement

New South Wales and Queensland do not require a manufacturer or retailer or wholesale supplier of a Schedule 5 or 6 poison to be licensed. Victoria has repealed the provisions which required wholesale licences to sell substances in Schedules 5 and 6 in November 2004. Jurisdictions which currently require a manufacturer or retailer or wholesale supplier of Schedule 5 or 6 poisons to be licensed are to repeal relevant sections of legislation as timetables permit.

While Tasmanian legislation still requires a manufacturer or wholesaler of a schedule 5 or 6 poison to be licensed, these provisions are to be rescinded when the T*asmanian Poisons Act 1971* is revised later in 2006. The Australian Capital Territory, Western Australia, Northern Territory and South Australia also require wholesale licences to sell substances in Schedule 5 and/or Schedule 6 but will be reviewing these requirements in the context of the implementation of other Review recommendations.

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 wholesaler 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 1967;*

to make the licence requirements uniform.

Summary

The Review recommended the retention of all current requirements in both Commonwealth and State legislation applying to wholesale licences for products in Schedules 2, 3, 4 and 8.

The Review also recommended that there should be uniform requirements across the States and Territories legislation, the Customs (Prohibited Imports and Prohibited exports) Regulations and the *Narcotic Drugs Act 1967*.

Implementation issues

State and Territory drugs, poisons and controlled substances legislation is to retain the provisions which relate to wholesaler licences for Schedule 2, 3, 4, 8 and 9 products and substances. In reviewing any possible overlap with requirements for these wholesaler licences and Australian Government licences to import, export or manufacture controlled substances, NCCTG concluded that there was very little, if any, overlap of requirements.

Action taken to implement

Taking into consideration that there is no overlap of requirements, no action was taken to implement this recommendation.

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.

Summary

The Review recommended that persons holding Poisons Licences which permit the retail sale of Schedule 2 products in remote areas where there is no pharmacy be allowed to sell the full range of products in Schedule 2 unless risk of diversion, poisoning or medical misadventure is such that the sale of that product should only be from a pharmacy. It was recommended that the MSC define those products which licensed poison sellers are not allowed to sell by inclusion in an appropriate Appendix to the scheduling standard.

Action taken to implement

The draft of the new Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) includes Appendix L as a list of Schedule 2 substances that may not be sold by licensed poisons sellers. It is expected that the States and Territories will adopt this Appendix through their respective legislation once the joint regulatory scheme commences (which will establish the SUSMP) and as State/Territory legislative timetables permit.

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 to 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 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 of 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 jurisdictions 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.*

Summary

The Review recommended that the current recording of the sales of narcotic drugs be retained. It also recommended the retention of the recording of wholesale sales of products in Schedules 2, 3 and 4. In the latter case it recommended that the form of recording should not be mandated so as to allow for electronic recording. Additionally it recommended the repeal of legislation that requires the recording of retail sales of substances in Schedules 3, 5 and 6.

Action taken to implement

Jurisdictions are to repeal the requirements for specific reporting of retail supply of Schedule 4 medicines (except those included in Appendix D of the *Standard for the Uniform Scheduling of Medicines and Poisons*).

Any general provisions for the mandatory recording of the retail supply of Schedule 3 medicines are to be repealed (as legislative timetables permit) and instead each jurisdiction is to adopt by reference the mandatory recording of any substance in Appendix H of the new SUSMP (as a list of substances which have been shown to pose a significant risk of diversion to the illicit market and the public health benefits of recording the supply of these substances has been established).

States and Territories are to consult with the professional registration boards to ensure that where they may impose additional controls over medicines, they do so with recognition of the commitment to national uniformity and minimum regulatory barriers to access, consistent with appropriate public health concerns.

The recording of Schedule 5 and 6 poisons is to be repealed in those jurisdictions that have such provisions.

The recording of the supply of Schedule 7 poisons at wholesale or retail level is to be repealed 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 specific 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.

Summary

The Review recommended that the existing provisions relating to the storage of Schedule 8 products at both wholesale and retail level be retained. Similarly it recommended that the existing provisions for the storage of Schedule 2, 3 and 4 products at retail level be retained. It also recommended that the legislation be framed to identify the intended outcome of the storage requirements.

Action taken to implement

The intended outcomes of controls on storage are to be clarified in State/Territory legislation as legislative timetables permit.

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 transparency 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.

Summary

The Review recommended that the Code of Good Wholesaling Practice, agreed to by government and industry, be strengthened to ensure the risk of poisoning and diversion of substances to the illicit market is minimised during transport. It also recommended that the legislation be amended to make compliance with the Code mandatory.

Implementation issues

The Primary Industries Ministerial Council noted in their submission to the Review that the Code of Good Wholesaling Practice applies only to human medicines and that there is no commensurate Code which could be amended to provide a national standard for the secure transport of controlled substances for agricultural or veterinary use.

Action taken to implement

A review of the Code of Good Wholesaling Practice (GWP) was undertaken by the Therapeutic Goods Committee in 2005-2006. The Review took into account (amongst other matters) Recommendation 18 of the Galbally Review. The revised Code of GWP (which is to be adopted by each State/Territory) includes measures to ensure the secure transport of controlled substances.

Taking into consideration that the wholesaling requirements included in the WA Ag/vet Code are based on those included in the Code of GWP for human medicines, the NCCTG will be formally recommending to the APVMA that it adopts the WA Ag/vet Code (after the Ag/vet Code has been updated to reflect the principles of the revised Code of GWP).

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 Coordination 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 ag/vet chemicals and household chemicals respectively to make the labels more effective communication tools.*

Summary

The Review recommended that labelling should be outcomes focussed and simplified. It noted that the Therapeutic Goods Administration was at the time of the Review undertaking a review of the labels for medicines with the objective of making them more effective communication tools. It recommended that when the labelling review was finalised, the NCCTG consider the report and if appropriate, approach the APVMA, with a view to applying the principles to ag/vet and household chemicals as well.

Action taken to implement

The NCCTG forwarded a copy of the outcomes and recommendations of the labelling review of medicines to the APVMA (through the Department of Agriculture, Fisheries and Forestry) in December 2004 and suggested that the APVMA consider these outcomes and recommendations in terms of their potential application to the labelling of agricultural and veterinary chemicals.

RECOMMENDATION 20

Improving administrative efficiency of the controls

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

Summary

The Review recommended that Commonwealth, State and Territory legislation be amended to provide for mutual recognition of administrative decisions in relation to exemptions from labelling and packaging. Exemptions usually relate to products that have been reclassified in the scheduling standard or to products that are imported but only on a small scale as a service line. Under current arrangements a company is required to approach the Commonwealth and /or each state individually.

Action taken to implement

Criteria have been developed by NCCTG to allow mutual recognition of labelling exemptions granted by other jurisdictions. These criteria have been included in Part 2 – Labelling and Container Requirements - of the draft of the *Standard for the Uniform Scheduling of Medicines and Poisons* as follows:

2.05 Exemptions for signal heading for medicines

(1) The labelling requirements for signal headings do not apply to a specified medicine which has been granted a special exemption from the need for product licensing under the joint agency legislation (*specific details to be inserted*) or where an appropriate authority has granted a labelling exemption for a specified medicine based on the following criteria:

(a) whether the lack of availability of the medicine would be likely to have a negative impact on public health;

(b) whether the medicine is a Schedule 2 medicine reclassified to Schedule 3, or the reverse;

(c) whether the medicine is a Schedule 4 medicine reclassified to schedule 3;

(d) whether the medicine is subject to a decision taken by the Authority to allow a variation to a schedule which is not yet effective;

(e) whether the medicine is a Schedule 2 medicine reclassified to open sale and the medicine will continue to be supplied from pharmacies only;

(f) the likely impact on the distribution chain of incorrect labelling and the steps the applicant proposes to take to minimise that impact; and

(g) the practicability of re-labelling the medicine to comply with the signal heading requirements.

(2) the labelling exemption from an appropriate authority referred to in subsection (1) must be limited to no more than 12 months from the effective date of the scheduling decision for retail supply of the specified medicine and not be granted solely on the basis that a signal heading or specific warning statement is incorrect or missing due to printing errors.

It is expected that the States/Territories will adopt this part of the new scheduling standard by reference, once the standard is established in the new ANZTPA legislation.

RECOMMENDATION 21

Packaging

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

Summary

The Review recommended that the current packaging controls be retained.

Action taken to implement

No action was required of either State/Territory or Australian governments as the Review recommended that the current 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 ag/vet products, provided this is consistent with the requirements of household chemicals included in the Standard for the Uniform Schedule of Medicines and Poisons.*

Summary

The Review recommended that Commonwealth legislation be the primary legislation responsible for all controls on advertising, packaging and labelling (except signal headings) of human medicines. It proposed a similar system for ag/vet and household chemicals.

Action taken to implement

(See also Recommendations 7 and 11.)

Controls on labelling, packaging and advertising of therapeutic goods (excluding signal headings) are to be transferred from the SUSDP to the new therapeutic products legislation. Draft Managing Director Orders are currently being developed which will reflect this transfer of controls. Building on this recommendation, the NCCTG has also recommended that all packaging and labelling controls on therapeutic products in Schedule 5 and 6 are transferred into Managing Director Orders in the Australia New Zealand Therapeutic Products Authority. Substances in Schedules 5 and 6 in the new scheduling standard will therefore not include substances which are specifically used for human therapeutic use.

The Primary Industries Ministerial Council agreed at its meeting on 20 April 2006 to the transfer of controls on labelling, packaging and advertising of agricultural and veterinary chemicals to relevant Commonwealth legislation. The Department of Agriculture, Fisheries and Forestry (DAFF) has advised that it is anticipated that this transfer of controls will be achieved through:

- amendment of the *Agricultural and Veterinary Chemicals Code Act 1994* to include restrictions on advertising of Schedule 4 and Schedule 8 veterinary chemicals; and
- amendment to the *Agricultural and Veterinary Chemicals Code Regulations 1995* to include Ministerial Orders on labelling and packaging of agricultural and veterinary chemicals.

Controls on the labelling and packaging of household chemicals will be retained in the new scheduling standard as (unlike therapeutic goods and ag/vet chemicals) there

is no national product registration scheme for household chemicals.

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.

Summary

The Review recommended that, in the interests of uniformity, all states adopt the Commonwealth Therapeutic Goods Act by reference.

Implementation issues

It will be unnecessary for the States and Territories to adopt the new therapeutic products legislation to be administered by the Authority as the Australian Government will be able to regulate all individuals who supply (and/or manufacture for supply) therapeutic products only within a State or Territory (sole traders), through the use of the external affairs powers of the Treaty between Australia and New Zealand when that Treaty enters into force.

Action taken to implement

No action required to implement.

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 Committee on developing and maintaining model medicines and poisons legislation. The Terms of Reference should include responsibility for undertaking any 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 of 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.

Summary

The Review recommended, in the interests of uniformity, that for the controls that remain a State/Territory responsibility, model legislation should be developed and adopted by reference by the States and Territories. Existing legislation should then be repealed.

Implementation issues

As anticipated in the report of the Galbally Review, NCCTG members agreed that due to the number of linkages currently in place between medicines and poisons legislation and other State/Territory legislation, model medicines and poisons legislation could not be implemented without significant legislative amendments to a number of various State/Territory Acts and Regulations. Implementing the required amendments would also be likely to be a cumbersome process due to the local legislative drafting process.

While not supporting the mechanism for achieving national uniformity in these areas, NCCTG agreed that this objective should be worked towards through other means, as described below.

Action taken to implement

Licensing:
The implementation of recommendations 13, 14 and 15 will result in greater uniformity of controls on licensing.

An appendix to the scheduling standard has been developed which includes those S2 substances which can only be sold from a pharmacy.

Dispensing labels:
An agreed set of labelling requirements for dispensing labels has been developed as a new appendix to the new scheduling standard.

Household chemical packaging:
An agreed set of requirements for containers has been developed as part of the new scheduling standard

Storage and handling of drugs:
Greater uniformity is to be achieved through each jurisdiction requiring compliance with the Code of Good Wholesaling Practice as a condition of licence for wholesalers.

Recording and reporting:
National requirements for recording of S3 medicines are to be adopted through an Appendix to the new scheduling standard

Supply of clinical samples:
Greater uniformity for prescription medicines is to be achieved through each jurisdiction repealing specific legislation for supply of S4 starter packs and replacing these provisions with compliance with the Medicines Australia Code of Practice for Supply of Clinical Samples as a condition of licence for wholesalers.

State/Territory legislation which imposes specific requirements for the supply of S2/S3 starter packs is to be repealed.

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.

Summary

The Review has recommended, in the interests of uniformity, that for the controls that remain a State/Territory responsibility, model legislation should be developed and adopted by reference by States and Territories. Existing legislation should then be repealed.

Implementation issues

Adopting model legislation would require substantial change to drugs and poisons legislation of every jurisdiction, as the controls that remain a State/Territory responsibility (ie access restrictions, licences, recording, reporting, storage, handling and supply of clinical samples of medicines) are generally integrated into State/Territory legislation and referenced in different ways. Given the time and cost of completely rewriting these various Acts and Regulations, the NCCTG is of the view that it is more efficient to consider alternative mechanisms that could be implemented to work towards enhancing national uniformity in these areas.

Action taken to implement

(See recommendations 4, 22 and 24.)

In transferring controls on labelling, packaging and advertising (excluding signal headings) on therapeutic goods and ag/vet chemicals from the *Standard for the Uniform Scheduling of Drugs and Poisons* (SUSDP) to Managing Director Orders in the new ANZTPA legislation and the Ag/vet Code (respectively), State and Territory legislation will be amended automatically through amendment of the SUSDP, or (as legislative timetables permit) to remove these references accordingly.

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 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.*

Summary

The Review recommended that products be more clearly identified to distinguish between those with a principal intended use in the workplace and those with a principal intended use in domestic circumstances. Product labelling requires this distinction as safety requirements differ for each intended use. Workplace products are subject to Occupational Health and Safety requirements whereas domestic products are subject to Drugs and Poisons requirements. The Review also recommended that where possible, the labelling requirements be harmonised.

Action taken to implement

Global Harmonisation Scheme

The Office of Chemical Safety (OCS) is undertaking a situational analysis, for the National Drugs and Poisons Scheduling Committee (NDPSC), of the implementation of the Globally Harmonised System for Classifying and Labelling Chemicals (GHS) within the scheduling of domestic poisons. A proposal for the consideration of NDPSC is expected to be provided for its October 2006 meeting. NICNAS and OCS are already assessing all industrial and ag/vet chemicals for workplace classification in accordance with the GHS criteria. To date over 400 chemicals have been assessed against the GHS criteria. These data are being used to examine the impact of the GHS on national chemicals regulation and have been made available to the Department of Employment and Workplace Relations (DEWR) and NDPSC to assist in impact analysis.

DEWR are currently working to develop a new Australian Workplace Chemicals' Framework which will include a single new standard covering the safe use of chemicals. The current *National Model Regulations for Workplace Hazardous Substances* and the *National Standard for Storage and Handling of Dangerous Goods* will be merged for this exercise. The new single standard will employ GHS as a classification tool and will include a review of labelling including the use of harmonised wording from the GHS system.

These two implementation activities provide the platform to fully implement Recommendation 26.

Notably, the *Report of the Taskforce on Reducing Regulatory Burdens on Business (the Banks Report)* recommended (4.58) that COAG establish a taskforce to develop integrated, national chemicals policy that would also (among other issues) take into account the development and implementation of arrangements for the GHS, and consider the ramifications of GHS for classifying and labelling domestic agricultural/veterinary products. The government's response to the Banks Report supported this recommendation and has referred the issues to the ministerial taskforce being set up under COAG to develop measures to achieve a streamlined and harmonised system of national chemicals and plastics regulation. This taskforce is to report on progress to COAG by mid-2006.

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.*

Summary

The Review recognised the importance of the close relationship between drugs and poisons legislation and legislation regulating professional practice. The Review urged professional registration boards to consider options for improving the effectiveness of their legislation 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. It recommended that, in some cases, it might be appropriate for professional practice legislation to deem certain breaches of drugs and poisons legislation to be professional misconduct.

Action taken to implement

Advice was requested from each State/Territory medical, dental and veterinary registration boards, and the Council of Pharmacy Registering Authorities (COPRA) on whether these organisations had considered this recommendation and if so, whether there is any intent to make amendments to the relevant professional practice legislation.

The professional boards and representative councils acknowledged that it is appropriate to link breaches of drugs and poisons legislation to issues of professional misconduct. The responses from the relevant boards and councils generally affirmed that their current professional practice legislation allowed them the capacity to consider as professional misconduct breaches of drugs and poisons legislation. Some of the boards indicated that their professional practice legislation was due to be changed and that compliance with drugs and poisons legislation would be considered in this context.

The NCCTG considered the responses of the boards and councils at their meeting on the 26 and 27 April 2005 and noted 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. The NCCTG noted that existing State and Territory professional practice legislation allowed the relevant professional boards the capacity to ensure compliance with the applicable practice standards.

APPENDIX 1

Review Recommendation	Working Party recommendation to COAG	NCP Implications
1	Accept with minor amendment to wording - to include word "minimise" rather than "preventing"	Nil
2	Accept	Nil
3	Accept except for dot points 1 and 4	Nil
4	Accept	Yes
5	Accept	Nil
6	Accept	Nil
7	Not accepted	Nil
8	Accept	Yes
9	Accept	Nil
10	Accept	Nil
11	Accept but further analysis required on advertising of S4 veterinary medicines	Yes
12	Accept a) to d), reject e) and f)	Yes
13	Accept	Yes
14	Accept	Nil
15	Accept	Yes
16	Accept	Yes
17	Accept	Not immediately
18	Accept	Yes
19	Accept	Nil
20	Accept	Yes
21	Accept	Nil
22	Accept but further analysis required on advertising of S4 veterinary medicines	Nil
23	Accept	Yes
24	Accept but recognises that further consultation is required	Yes
25	Accept	Yes
26	Accept	Nil
27	Accept	Nil