AUSTRALIAN HEALTH MINISTERS' ADVISORY COUNCIL
Working Party

response to

the Review of Drugs, Poisons and Controlled Substances

Legislation (the Galbally Review)

April 2003

GLOSSARY

ACSMA	Australian Chemical Specialties Manufacturers Association
AHMC	Australian Health Ministers Conference
AHMAC	Australian Health Ministers Advisory Council
ARMCANZ	Agriculture and Resource Management Council of Australia and New Zealand now renamed to Primary Industries Ministerial Council
AFFA	Department of Agriculture, Fisheries and Forestry, Commonwealth
AHMAC	Australian Health Ministers' Advisory Council
AMA	Australian Medical Association
APESMA	Association of Professional Engineers, Scientists and Managers in Australia
APMA	Australian Pharmaceutical Manufacturers Association (now Medicines Australia)
ASMI	Australian Self Medication Industry
CHC	Complementary Health Care Council
CMI	Consumer Medicines Information
COAG	Council of Australian Governments
DHA	Department of Health and Ageing, Commonwealth
DTC	Direct to Consumer
GHS	Globally Harmonised System for the Classification and Labelling of Chemicals
HIC	Health Insurance Commission
MSC	Medicines Scheduling Committee
NCP	National Competition Principles
NCC	National Competition Council
NCCTG	National Coordination Committee on Therapeutic Goods and Poisons
NDPSC	National Drugs and Poisons Scheduling Committee
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NPS	National Prescribing Service
NRA	National Registration Authority for Agricultural and Veterinary Chemicals (now known as Australian Pesticide and Veterinary Medicine Agency)
PGA	Pharmaceutical Guild of Australia
PHARM	Pharmaceutical Health and Rational Use of Medicines Committee
PIMC	Primary Industries Ministerial Council
PSA	Pharmaceutical Society of Australia
PSC	Poisons Scheduling Committee
SUSDP	Standard for the Uniform Scheduling of Drugs and Poisons
TGA	Therapeutic Goods Administration

Summary and Conclusions

The National Competition Policy Review of Drugs, Poisons and Controlled Substances Legislation Report was presented to AHMC in January 2001. AHMC is required by the Terms of Reference of the Review to forward the report to the Council of Australian Governments (COAG) with their comments. In preparing its comments AHMC is required to take account of the comments of the Primary Industries Ministerial Council (PIMC), formerly known as the Agriculture and Resource Management Council of Australia and New Zealand (ARMCANZ).

A Working Party of the Australian Health Ministers' Advisory Council (AHMAC) was established in February 2001 to assist the preparation of comments on the report for the COAG. The Working Party comprised the following members:

- Susan Alder - Principal Medical Adviser, TGA, Commonwealth Department of Health and Ageing to December 2001.
- Graham Peachey - Director, Trans Tasman Group from January 2002.
- John Lumby - Chief Pharmacist and Director Pharmaceutical Services, New South Wales Department of Health
- Murray Patterson - Chief Pharmacist Western Australia Department of Health

The Working Party sought comments from all State and Territory health and agriculture/veterinary departments in April 2001. Comments were received from all State and Territory Health Departments. Not all agriculture/veterinary Departments made submissions. Some chose to reserve their comments until the PIMC consultation. Comments were also sought in June 2001 from organisations or individuals that made submissions to the Review.

Working Party Recommendations

The Working Party is recommending adoption of all the recommendations with some minor amendments. The following table sets out the Working Party's recommendations

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

The Working Party has noted in the report where jurisdictions and stakeholders have not agreed with the recommendations.

Major Recommendations

Complementary legislation

Recommendation 23 recommends that the States and Territories adopt the *Therapeutic Goods Act 1989* by reference. Complementary legislation is required to be in place in order for some of the other recommendations to be effective eg Recommendation 11 (see advertising below). The current status of complementary legislation is outlined below:

NSW	agreed	completed 1996
Victoria	supported	currently have mirror legislation but review is underway
Queensland	supported	bill being drafted
South Australia	agreed	
West Australia	agreed	
Tasmania	agreed	completed Jan 2002
Northern Territory	supported	Bill being drafted
ACT	supported	Bill drafted, low category 3 priority

Model legislation

This recommendation provoked the strongest comments from the States and Territories. There was general support from all areas for uniform legislation across jurisdictions. However, the view was expressed that model legislation was only one approach that could be used to achieve this outcome and that there were other methods, which could also be used and were more likely to be implemented.

The comments expressed about model legislation were raised during the review process. When submitting the Report of the Review to AHMC the Chair, Rhonda Galbally wrote the following in the covering letter:

> *Despite differences in demographics across the States and Territories, Australia is increasingly becoming a single market and national uniformity is a recurring issue. In this report, I recommend the development and adoption by reference of model medicines and poisons legislation in order to achieve uniformity. I accept that this may not be supported by all jurisdictions, however, I think that one of the purposes of the Review is to set some benchmarks towards a nationally uniform system of regulation. I hope that you will give serious consideration to the adoption of model legislation, and alternatively, I challenge you to work towards national uniformity following another path.*

While noting that some States and Territories have not supported the use of model legislation as the preferred method of achieving uniform legislation, the Working Party has recommended the adoption of this recommendation but recognises that further consultation is required. It does note however, that those States and Territories (QLD, WA and NT) who did not support the use of model legislation to achieve uniform legislation have proposed alternative strategies to achieve the same outcome.

Advertising

In relation to advertising the Review recommended that:

- all State and Territory provisions on the advertising of medicines be repealed;
- the Therapeutic Goods Act's prohibition on the advertising of Schedule 3, 4 and 8 medicines for human use remain;
- the *Therapeutic Goods Act 1989* be amended to exempt the advertising of the price of these medicines in a catalogue, provided the advertising is informational and not promotional;

  - Recommendation 11(a), (b), (c)

- the Commonwealth amend the *Therapeutic Goods Act 1989* to include all controls on advertising for medicines for human use;
- the Commonwealth amend the *Agricultural and Veterinary Chemicals Code Act 1994* to include all controls on advertising for agvet products

  - Recommendation 22

- all States and Territories adopt the *Therapeutic Goods Act 1989* by reference

  - Recommendation 23

In recommendation 11(b), the Review recommends that the current prohibition on the advertising of prescription and some OTC medicines for human use in respect to

therapeutic claims should be retained. This has been opposed by some sectors of the industry and some sectors of Governments as anti-competitive. It is noted that all States and Territory Health Departments have supported this recommendation, and together with all the professionals' stakeholder groups oppose direct to consumer (DTC) advertising of prescription drugs.

Some sectors of the pharmacy profession are also opposed to the recommendation 11(c) to exempt price information for prescription medicines from the advertising prohibition. The objections raised with the Working Party were the same as were raised during the Review. The Working Party recommends the adoption of this recommendation.

However total control over all advertising cannot be achieved by amendment to the Commonwealth Therapeutic Goods Act alone. Section 6 limits the legislation's application to things done by natural persons in interstate trade or by corporations. The constitutional limitation of the Therapeutic Goods Act means that it does not cover advertising by sole traders, such as individual pharmacists, who trade only within State borders.

This means that all States and Territories will require complementary legislation to give enforcement to the Commonwealth Act to provide for control over all aspects of advertising of medicines for human use.

Only NSW, Tasmania and Victoria have complementary legislation. NSW and Tasmania, which adopt the Therapeutic Goods Act by reference, would not need to make any amendments. As Victoria has mirror legislation (its own provisions), and does not simply adopt by reference the Therapeutic Goods Act, it would need to prepare advertising amendments. ACT has drafted its legislation but it has low parliamentary business priority. The Northern Territory and Queensland are in the drafting phase. The remaining States support the concept of complementary legislation but are not yet at the stage of drafting.

Recommendation 11 and 22 are also relevant to the advertising of Schedule 4 veterinary medicines. As the *Therapeutic Goods Act* specifically excludes controls on advertising of medicines not for human use, controls on advertising of Schedule 4 medicines for veterinary use are currently implemented on a State by State basis. Any transfer of control to the Commonwealth would therefore require repealing of State/Territory legislation. While the PIMC comments support the need for uniform advertising controls, it has been suggested that further analysis on this specific issue and consultation with the States is required.

Issues Relevant to Implementation of the Recommendations

Timeframes

The Working Party believes that the timeframes for the implementation of the recommendations are very important in order to maintain the momentum of the reform process that has been initiated by the Review. Therefore it is recommending that the timeframe for implementation of each recommendation, unless otherwise specified in the recommendation should be 12 months from the time of COAG endorsement of the recommendation.

A significant amount of work has already been undertaken towards development of a Price Information Code (Recommendation 11). Recognising the importance of this Code, the Working Party has recommended that it be finalised prior to the response going to COAG, with the support of NCCTG, and a recommendation made that COAG note this decision.

National Competition Principles (NCP) Implications

National Competition Policy required the assessment of all legislative restrictions on competition and the removal of any unnecessary barrier to competition by 30 June 2002.

Legislative reforms were not completed by this date due to the need for extensive consultation and co-ordination of input from health and agriculture portfolios. The National Competition Council accepted that there had been a genuine attempt to meet the deadline, key areas for reform had been identified and the Government had endorsed these. Additionally, as stated earlier, the Working Party has recommended that the timeframe for implementation of each of the recommendations, unless otherwise stated, should be 12 months from the time of COAG endorsement of the recommendations. In their 2002 NCP Assessment, the NCC noted that "The Council will finalise its assessment of CPA compliance in the 2003 NCP assessment."

The Working Party has noted that many of the recommendations of the Review do not require a change to legislation but rather relate to administrative issues where there is no change in the level of control, for example Recommendation 7. The Working Party recognises that those recommendations requiring legislative reform do have NCP implications whereas it has deemed those relating to administrative matters do not. It has also deemed that recommended amendments to legislation that clarify the intent of the legislation only and that do not require a change to the level of control do not have NCP implications either (for example Recommendations 1 and 3). The report of the Working Party clearly identifies which of the recommendations of the Review have NCP implications for the states, based on the above criteria.

Trans Tasman Initiatives

In parallel to the Review process there have been a number of initiatives working towards exploring the possibility of a single joint agency for Therapeutic Goods between Australian and New Zealand. The final decision on this process is expected to be made in the first half of 2003. The Working Party can see that some recommendations (in particular Recommendation 7) will be impacted by a positive decision on a single joint agency. For this reason, the Working Party has recommended that a response to Recommendation 7 be finalised by AHMC after further consideration of the implications of the proposed establishment of the Joint Trans Tasman Agency in consultation with the States and the PIMC.

Consultations reviewed by the Working Party.

Responses from States and Territories

	Health Departments	Agriculture Departments
Queensland	x	
NSW	x	x
Victoria	x	x
Tasmania	x	x
ACT	x	
South Australia	x	
Western Australia	x	x
Northern Territory	x	
PIMC (incorporating AFFA and NRA)	x	
HIC	x	
DHA	x	

Organisation	Response/Recommendation No
APMA (now Medicines Australia)	11, 6, 12
ASMI	all
CHC	all
Peter MacCallum Cancer Institute	10
Pharmacy Board Tasmania	16
Queensland Nurses Union	1, 5, 9
Victoria Police	all
APESMA	all +15
Avcare	7
PSA (NSW)	2, 3, 4, 6, 10, 11, 12
PSA/PGA	All + 5, 7, 8, 11, 12
AMA	All + 8, 5, 7, 9, 27
Anonymous member of PHARM	8, 11
WorkCover Corporation	all
John Mathews	12(d)
National Pharmaceutical Services Assoc	16
MediKwik	7, 8
ACSMA	1,2,4,7,12,13,16-26.
Pharmaceutical Council of WA	4, 5, 8, 12, 15, 17
National Herbalists Assoc. of Aust	4

RECOMMENDATION 1

Objectives of Legislative Framework

That all Commonwealth, State and Territory Governments agree that:

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

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

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

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 recommends that State and Commonwealth legislation needs to explicitly incorporate these objectives.

Comments and Discussion

All submissions received were generally supportive. However, it is not clear to what extent this recommendation also applies to legislation controlling agricultural and veterinary products.

The PIMC response suggested that if this recommendation was intended to apply to agvet products, these objectives should co-exist with other legislative responsibilities within the agvet scheme.

The ACSMA submission notes that “the objectives now aspire to “prevent” rather than “reduce” poisonings, etc. It is suggested that “this change does not reflect an appropriate risk management approach. There is nothing in the world that is totally free of risk.” Rather it is suggested that more appropriate wording would be to “mininise”.

NCP Implications for the States and Territories

Nil.

Recommendation to COAG

That Recommendation 1 of the Review be accepted for legislation applying to medicines for human use. The wording of the recommendation should be amended as include the word “minimise” rather than “preventing”.

Action to Implement

States/Territories and Commonwealth to amend the preamble to legislation as the opportunity arises.

For the Commonwealth it may be the preamble to the section relating to scheduling rather than the primary objective of the Therapeutic Goods Act.

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.

Comments and Discussion

No objections raised. PIMC noted the potential relevance of such monitoring to the agvet scheme.

NCP Implications for the States and Territories

Nil.

Recommendation to COAG

That Recommendation 2 of the Review be accepted.

Action to Implement

No legislative amendment is required. Implementation can be achieved through administrative arrangements through the Public Health Partnership. Commonwealth to approach the National Public Health Partnership.

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

This recommendation is an extension of recommendation 1. The Review has found that the restrictions which flow from inclusion of substances in the Poisons List, particularly those on access, are also intended to reduce the level of poisoning, medical misadventure and diversion. The Review specifically recommends 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 recommends 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.

Comments and Discussion

There was general agreement to the recommendation. However, much of the recommendation's intent is included in Recommendation 1. Other aspects to this recommendation are outside the scope of the Commonwealth Therapeutic Goods Act or State and Territory drugs and poisons legislation.

Dot points one and four relate to duty of care and standards of professional care. Some aspects of these issues are contained in State and Territory professional practice legislation. It is not appropriate for the objectives to be included in Therapeutic Goods or Drugs and Poisons legislation.

The Working Party supports the concept of all consumers having access to adequate information and understanding to make appropriate choices. The Commonwealth Therapeutic Goods Act does have some provisions relating to labelling, CMI

(Consumer Medicine Information), and advertising. State and Territory drugs and poisons legislation also include some provisions relating to labelling and packaging. These are not considered to be all inclusive of the total information available or necessary for consumers. Information for consumers comes from a range of sources including pharmaceutical companies, health professionals and increasingly others sources. The Working Party believes that it is very difficult to legislate what is "adequate information and understanding" necessary to ensure safe use.

The term “scheduled medicines’ is can also be interpreted as inclusive of veterinary medicines in Schedule 4 and some scheduled agricultural and veterinary substances in Schedules 5 and 6. The PIMC submission on this recommendation was generally supportive of the need for appropriate levels of evidence and other information being provided in support of the supply of any scheduled agvet substance.

NCP Implications for the States and Territories

Nil.

Recommendation to COAG

That Recommendation 3 of the Review be accepted, with the exception of dot points 1 and 4 which are outside the jurisdiction of the legislation.

Action to Implement

States/Territories and Commonwealth to amend the preamble to legislation as the opportunity arises.

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 has 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 by reference and in accordance with the timelines developed by the Committee.

Comments and Discussion

There was general agreement to this recommendation by States and Territories.

The central issue raised by industry is that adopting SUSDP by reference is needed to achieve the same timing in all jurisdictions. However, the States and Territories reserve the right to vary the schedules to take account of local circumstances. While supportive of the need for uniformity, PIMC emphasised the need to implement appropriate arrangements for the making of scheduling decisions as outlined in more detail at Recommendation 7.

NCP Implications for States and Territories

Yes, for some States and Territories.

Recommendation to COAG

That recommendation 4 of the Review be accepted.

Action to Implement

Some States and Territories will need to amend legislation.

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 have 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

A term of reference of the Review was to examine the range and number of schedules in the Poisons List. 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).

Comments and Discussion

There was general agreement to this recommendation.

Concerns were raised by some sections of the Pharmacy Professions (PGA/PSA) that the timeframe of this recommendation should be extended. The Working Party noted that this would delay part (c) of this recommendation. It is however, understood by the Working Party that this recommendation is already being actioned by the Department of Health and Ageing (DHA) and the PGA/PSA and therefore the Working Party does not support the extension of time.

As noted by PIMC, this recommendation does not specifically exclude scheduled veterinary medicines and should new standards be proposed which will impact on veterinary medicines, PIMC, veterinarians and suppliers of veterinary products should also be engaged in the process of review and evaluation.

NCP Implications for States and Territories

Not immediately but may following the results of the research.

Recommendation to COAG

That Recommendation 5 of the Review be accepted with clarification that it is applicable only to scheduled medicines for human use.

Action to Implement

No legislative amendment is required. Implementation can be achieved through administrative arrangements between the Commonwealth and the Pharmacy Guild. Commonwealth to negotiate with the Pharmacy Guild.

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 after July 1994. However while industry is required to have CMI's available, there is no requirement for the product sponsor, or anyone else (medical practitioners or pharmacists) to distribute CMI's. The Review considered that the public should have ready access to such information that could come from a consumer information service.

Comments and Discussion

All States are supportive of this recommendation except Victoria who question if the service is necessary or desirable. Comment was received from the Commonwealth Department of Health and Ageing that this was already being actioned through the PHARM Committee and the National Prescribing Service (NPS).

NCP Implications for States and Territories

Nil.

Recommendation to COAG

That Recommendation 6 of the Review be accepted.

Action to Implement

Being implemented by DHA.

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 agvet products during evaluation of those products;*
- *recommend the schedule in which a new substance should be included; and*
- *recommend changes to the schedule of the substance where, in evaluation new formulations, new presentations and new substances currently included in the Standard of the Uniform Scheduling of Medicines 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 has recommended that the National Drugs and Poisons Scheduling Committee (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 Poisons

Scheduling Committee - PSC). Currently the NDPSC deals with all classes of substances. The Review has 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 has also recommended recovery of the costs of operating the committees for re-scheduling applications made by industry.

Comments and Discussion

All States and Territories agreed to the splitting of the committee. The PIMC submission strongly endorsed the proposed approach "to separate the scheduling processed into two separate but parallel streams under an overarching policy framework". Concerns were raised by some regarding costs of travel but this can be addressed in the administrative arrangements of the two committees. South Australia noted its concern that human health issues must remain a consideration in the scheduling of poisons.

All industries commented on the power of States and Territories to have control of the voting in the committees but the Review has recommended no change in the voting arrangements. The real concern of industry appears to be related to national uniformity rather than any objection to the voting power of the States and Territories.

Other industry stakeholders including ASMI, APMA (now Medicines Australia), and ACSMA raised issues on this recommendation but their comments to the Working Party were the same as those supplied to the Review. The recommendations in the Review were made in the full knowledge of these stakeholders concerns.

The Working Party noted the lack of understanding of many of the professional groups to the structure and procedures of the NDPSC and suggests that the TGA undertake more work in the area of communication with these groups to improve their knowledge and understanding of the process of drug evaluation, approval and scheduling.

The Review recommended a change to the procedures for the initial scheduling of new products. This change is to allow the initial decision about scheduling to be made by the TGA and the NRA (and the Working Party assumes NICNAS in the case of new industrial chemicals) within criteria set by the scheduling committees and the decision to be ratified by the MSC or PSC at a later date. This is in line with current practice in that the initial decision on the scheduling of new substances is made as part of the initial approval of products. This initial decision is rarely controversial and to provide for the MSC and PSC to ratify the recommendation of the relevant regulatory group would greatly speed the introduction of new substances to the market.

All rescheduling decisions would remain with the MSC and the PSC with full public consultation before and after the decision is made. In order to ensure the appropriate consistency and role of the MSC and PSC the committees would provide to the regulators the criteria for the initial scheduling decisions.

The PIMC submission proposed a more policy-focussed role for the two scheduling committees which was also supported by Avcare Ltd as the National Association for Crop Production and Animal Health.

The PIMC has suggested that the following refinements be recommended to Health Ministers:

- The Secretariat for both committees reside within the Department of Health and Ageing and the overarching policy for scheduling is a matter for the Department of Health and Ageing to maintain.
- The role of the PSC and MSC be one of ensuring appropriate implementation of the policy, once a policy has been established.
- The PSC and MSC should have the responsibility to ensure that the agencies operate in accordance with the policy and/or implementation issues, which would require additional/alternative guidance for the regulators to be developed.
- The NRA under the overarching policy guidance would provide recommendations to the Department of Health and Ageing for inclusion of agricultural and veterinary substances into the relevant schedules.
- The PSC and the MSC have the capacity to review any particular listing or group of listings on a "reasonable cause" basis and to require a review of an earlier decision by the agencies. Rescheduling would be the responsibility of the MSC or PSC provided it was on a systemic basis.
- Where a substance could be listed both as a medicine for human use and veterinary use, both regulatory agencies would consult and provide a joint recommendation to the two committees.

The key difference between Recommendation 7 and the PIMC proposal is the role of the committees in reviewing every initial scheduling decision and having a "power of veto". The Working Party does not object to the regulatory agencies making an initial scheduling decision to be later ratified by the scheduling committees. However, based on further consultation with the States and Territories through the NCCTG, the key objections to the PIMC refinements are centred on the inability of the committees to routinely review initial decisions and overturn an initial decision by the regulatory agency. Considerable concern was expressed that the power of the committee to overturn an initial decision underpins the jurisdictions' role in being operationally responsible for legislation dealing with controls over and access to scheduled medicines and poisons.

This recommendation is also relevant to the proposal for a single joint agency to regulate therapeutic goods with New Zealand. Pending a final decision to create a new agency for the regulation of therapeutic goods, an exposure draft of new legislation is being prepared in mid 2003, which is expected to incorporate some of these recommendations such as the creation of a Medicines Scheduling Committee and a Poisons Scheduling Committee. The Therapeutic Goods Act and Regulations will need to be repealed before the commencement of the proposed joint agency in mid 2005 under this new legislation.

As the Galbally review took place in 2000, it did not need to take into consideration how scheduling decisions on medicines for human use should be made after the commencement of the proposed Trans Tasman Joint Agency, which is to be equally applicable to two sovereign countries. The Working Party is of the opinion that

further deliberation is required on whether these impending changes now warrant a slightly different model for the Medicines Scheduling Committee. In addition, as the PIMC refinements go considerably beyond the recommendations of the Galbally Review and are unlikely to be supported by the States at this time, further consultation is required.

NCP Implications for States and Territories

Nil. There may be a need for some States and Territories to amend legislation to recognise the name change of the committees but there is no change to the level of control of the legislation.

Recommendation to COAG

That Recommendation 7 not be accepted at this time, but COAG agree that a response to Recommendation 7 be finalised by AHMC after further consideration of the additional PIMC refinements and the implications of the proposed establishment of the Joint Trans Tasman Agency. This consideration should include whether it is possible to implement the new scheduling arrangements at the one time under the proposed Trans Tasman Joint Agency legislation

Action to Implement

TGA to consult with the States, NICNAS and PIMC on the PIMC submission and implications of the Joint Trans Tasman Agency.

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 that two adult doses of unscheduled medicines from vending machines provided those machine are presented and located in away 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 has recommended that the prohibition on the supply of scheduled medicines by vending machines should be located in drugs and poisons legislation. It has 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 has been recommended that owners of vending machines provide the National Coordinating Committee on Therapeutic Goods (NCCTG) with an independent evaluation of the safe use and effectiveness of the quality control measures after two years.

Comments and Discussion

The Working Party endorses the recommendation to allow the sale of goods from vending machines but emphasises that the Review's recommendations relate to unscheduled medicines for human use only. However it does not support the requirement for an evaluation after 2 years.

Some States and Territories may exercise controls over unscheduled medicines in legislation other than poisons legislation. To give effect to the intent of the amended recommendation, some states will need to either broaden the scope of existing drugs and poisons legislation to allow for controls to be placed on unscheduled medicines or amend other State and Territory legislation. It should be noted that the NCCTG has already developed guidelines for a uniform national approach for the supply of unscheduled medicines through vending machines.

Approvals to supply unscheduled medicines through vending machines have previously been granted by NSW and Victoria and are subject to compliance with the NCCTG guidelines. Monitoring of compliance with these guidelines can be implemented at a State level.

To the extent that the term "scheduled medicines" encompasses scheduled veterinary medicines, PIMC noted that the supply of agricultural and veterinary products from vending machines is not currently permitted under the agvet scheme. Consequently, the supply of these medicines from vending machines could not be supported without an analysis of the risk of this form of supply, as per the requirements of the agvet scheme.

NCP Implications for States and Territories

Yes – for some States and Territories only.

Recommendation to COAG

That recommendation 8 of the Review be accepted, with clarification that this Recommendation applies to medicines for human use only.

Action to Implement

Some States and Territories will need to amend legislation to implement this recommendation.

NCCTG to consider further the evaluation after two years. The implications for existing operators of vending machines will need to be reviewed if the NCCTG guidelines are amended.

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

Comments and Discussion

General agreement although two submissions make reference to issues surrounding residential aged care facilities. These are outside the Terms of Reference of the Review as they relate to the qualifications to dispense and are controlled by professional conduct legislation. PIMC agreed that the current levels of control over veterinary medicines is adequate in terms of the overlap with medicines for human use.

NCP Implications for States and Territories

Nil

Recommendation to COAG

That Recommendation 9 of the Review be accepted

Action to Implement

None required.

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 has recommended that 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.

Comments and Discussion

Accepted by all States and Territories. Supportive comments from Peter MacCallum Hospital. The HIC responded that "the HIC can consult with State and Territory departments to develop and clarify procedures for health professionals and consumers". To the extent that veterinarians use controlled substances, PIMC supported the reduction of administrative duplication, provided that appropriate agvet authorities and veterinarians are consulted in any changes to be made.

The recommendation has been agreed by the appropriate parties. Discussion between HIC and States/Territories to follow, including agvet authorities, as required.

NCP Implications for States and Territories

Nil

Recommendation to COAG

That recommendation 10 of the Review be accepted.

Action to Implement

No legislative amendments are required. This can be achieved by administrative arrangements. Some changes to administrative procedures may be required by States and Territories and HIC.

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 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 has 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 has 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.

Comments and Discussion

All States and Territories agree to the intent of the recommendation in relation to medicines for human use.

In recommendation 11(b) the Review recommends that the current prohibition on the advertising of prescription and some OTC medicines in respect of therapeutic claims should be retained. This has been opposed by some sectors of the industry and some sectors of Governments as anti-competitive. It is noted that all States and Territory Health Departments, and together with all the professionals' stakeholder groups oppose direct to consumer (DTC) advertising of prescription drugs. The Working Party supports this latter view.

Some sectors of the pharmacy profession are also opposed to recommendation 11(c) to allow price information for prescription medicines. The objections raised to the Working Party were the same as were raised during the Review. The Working Party recommends the adoption of this recommendation and given the significance of this Code and the work which has already been undertaken, that finalisation and implementation of a Price Information Code is facilitated as a priority.

The Working Party also supports the amendment of the advertising provisions of the *Commonwealth Therapeutic Goods Act 1989* (Therapeutic Goods Act*)* to permit the publication of CMI in its entirety without embellishment and the development of the Code that will give effect to the recommendation. The Working Party notes that in the Medicines Australia, *Code of Conduct*, edition 14, it is actually a requirement for a media release to be accompanied by a copy of the product's CMI.

Similarly the Working Party supports amendments to the Therapeutic Goods Act to permit the one-off press release informing the public on the availability of a new medicine where the press release complies with Medicines Australia Code of Conduct and the press release is accompanied by the CMI for the product. Some stakeholders questioned the need for the press release to be accompanied by the CMI. However, the Working Party considers that those who opposed this did not appear to understand that the intent of the Review recommendation was that the provision of CMI is intended to provide a balance to promotional claims included in press releases. The provision of CMI is intended to better inform the journalists receiving press releases.

However, total control over all advertising to give effect to the Review's recommendations cannot be achieved by amendment to the Commonwealth Therapeutic Goods Act alone. The constitutional limitation of the Commonwealth Therapeutic Goods Act means that it does not cover advertising by sole traders, such as individual pharmacists, who trade only within State borders. Section 6 of the Therapeutic Goods Act limits the legislation's application to things done by natural persons in interstate trade or by corporations.

The Review recognised this limitation. To cover this gap it will be necessary for all States to introduce complementary legislation (as per recommendation 23) preferably by adopting the Commonwealth Therapeutic Goods Act by reference. State and Territory law would then render a sole trader subject to Commonwealth Therapeutic Goods Act sanctions for breaching the advertising restrictions.

Recommendation 11a is also relevant to the advertising of Schedule 4 veterinary chemicals which is currently controlled through State/Territory legislation. PIMC suggests that uniform controls should be imposed on advertising of all Schedule 4 substances under the Therapeutic Goods Act. Advertising of schedule 4 medicines for human medicines to the public is a breach of the Therapeutic Goods Act and penalties may be imposed. However, the Working Party is not convinced that it is appropriate for advertising controls on Schedule 4 veterinary medicines to be regulated by the TGA.

While the Working Party agrees with the PIMC on the need for adequate and uniform advertising controls on medicines for veterinary use, this is a complicated issue which may require further consideration as to whether the NRA has the appropriate technical capacity to take on responsibility for advertising compliance. Additionally, PIMC advise that (in relation to amending the *Agricultural and Chemicals Code Act 1994*): "*Any changes would require agreement from the States and would also extend the scope of the NRA with regard to advertising.*"

The Working Party acknowledges that while this activity is not currently performed by the NRA, it is within the scope of the *Agricultural and Veterinary Chemicals Code Act 1994*. One of the objectives of this Act is to control the supply of veterinary chemical products, with the term "supply" defined as including "expose for sale", which could reasonably be taken to cover advertising.

The objective of a uniform approach to advertising of scheduled veterinary medicines remains supported by both PIMC and the Working Party. The Working Party

considers that it would be premature at this time to advise the States and Territories Governments to relinquish their controls on such advertising until further consideration and consultation by PIMC on necessary legislative changes.

NCP Implications for States and Territories

Yes, for some States and Territories.

Recommendation to COAG

That Recommendation 11 of the Review be accepted, with:

- deferral of 11a as it applies to Schedule 4 medicines for veterinary use until further analysis by PIMC in consultation with the States; and
- the development of a Code of Conduct for the Publication of CMI and advertising of disease states and generic information related to Schedule 3, 4 and 8 medicines taken up under the advertising review of the proposed Joint Agency.

In relation to Recommendation 11(d):

- that the AHMC note the significant work which has already been undertaken to develop the Code for Provision of Price Information.; and
- that the AHMC agree that as the Code relates only to therapeutic products for human use (ie it has implications only for health portfolios) work can commence immediately to implement the Code and related regulatory arrangements; and
- that the final Code need only be endorsed by NCCTG, as a subcommittee of AHMAC, without the need for further referral to AHMC.

Action to Implement

States and Territories to introduce complementary legislation by adopting the Commonwealth Therapeutic Goods Act by reference.

The Code of Conduct for the Provision of Price Information to the consumer to be drafted with consultation with industry, professional groups and consumers. The Commonwealth to amend the Therapeutic Goods Regulations definition of an advertisement to exclude price information when provided in accordance with the Code.

A Code of Conduct for the Publication of CMI to be considered as part of the review of the advertising arrangements under the proposed Trans Tasman Joint Agency.

A Code of Practice covering consumer disease state advertisements and generic information directly or indirectly promoted by sponsors of Schedule 3, 4 and 8 medicines to be considered as part of the review of advertising arrangements under the proposed Trans Tasman Joint Agency.

PIMC to undertake further analysis and consultation specifically on legislative changes required to the *Agricultural and Veterinary Chemicals Code Act 1994* to impose advertising controls on Schedule 4 veterinary chemicals.

RECOMMENDATION 12

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.

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

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

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

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.

In respect of the supply of samples to the general public the Report has recommended that legislation be amended to allow the sampling of poisons in Schedules 5 and 6 and that an industry code be developed which is underpinned by legislation.

Comments and Discussion

Parts (a) to (d) of this recommendation relate to the supply of clinical samples of medicines to health professionals and subsequent supply to patients. The APMA (now Medicines Australia) has given a commitment to consult with stakeholders in relation to amending its Code of Conduct for Medical representatives to include the principles described in the Review in relation to the supply of clinical samples. MA considers that this could be achieved by December 2002 for subsequent endorsement by the NCCTG. Some States will have to repeal legislation that requires licensing of medical representatives and adopt the endorsed industry code of practice by reference.

Parts (e) and (f) of this recommendation relates to the supply of samples of poisons in Schedules 5 and 6 of the Poisons List to the general public.

The Working Party supports the concept that it is not unreasonable for poisons included in Schedules 5 and 6 to be supplied as a free sample to the general public. However, such supply would need to be subject to certain conditions, which may be incorporated in a Code, which could prohibit any unsolicited supply such as through letterbox drops, but permit the supply direct to adults, in a public place where they have a right of refusal. Supply should also not be permitted to children.

The development of a Code for poisons included in schedules 5 and 6 would be difficult due to the diverse nature of substances and the limited membership of manufactures to industry associations. Enforcement of the Code would also be difficult.

Supply of these poisons, free of charge, could always occur at the retail premises normally supplying the poison where the supply would be subject to the usual restrictions for labelling, packaging and age of purchaser. This supply process would result in the same outcome as a Code of Practice. The Working Party concluded, that on balance, it would be impractical to develop and implement a Code of Practice for the supply of samples of poisons included in Schedules 5 and 6.

PIMC notes that the current legislative provisions for agvet products do not permit the provision of sample packs in the same way as permitted for human medicines**.** Any proposal to allow supply of small "sample packs" would require further examination by PIMC and appropriate risk analysis on a case by case basis.

NCP Implications for States and Territories

Yes, for some States and Territories.

Recommendation to COAG

That recommendation 12 (a) to (d) be accepted and that (e) and (f) be rejected with clarification that these recommendations apply only in relation to medicines for human use.

Action to implement

Some States and Territories will need to amend legislation. Medicines Australia to prepare a Code of Practice for subsequent endorsement by the NCCTG.

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

Comments and Discussion

Agreed by all.

NCP Implications for States and Territories

Yes, for some States and Territories.

Recommendation to COAG

That Recommendation 13 of the Review be accepted.

Action to Implement

Some States and Territories to amend legislation.

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 1975;*

to make the licence requirements uniform.

Summary

The Review has 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.

Comments and Discussion

All States, Territories and Commonwealth, (including PIMC) agree with this recommendation.

This is an administrative issue.

NCP Implications

Nil

Recommendation to COAG

That recommendation 14 of the Review be accepted.

Action to Implement

States and Territories, through the NCCTG, to agree to administrative changes to allow for the application of uniform conditions to licences.

TGA to ensure uniformity of Customs regulations with State and Territory legislation.

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 has 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 is recommended that the MSC define those products which licensed poison sellers are not allowed to sell by inclusion in an appropriate Appendix to the SUSDP.

Comments and Discussion

In some comments received by the Working Party there was preference for an inclusive list of allowable substances rather than a list of substances to be excluded. The Working Party is of the view that the same outcome is achieved with an excluded list as recommended by the Review.

The new appendix will have to be created by MSC. However the NDPSC can commence this now, prior to the formation of the MSC. Jurisdictions may need to amend legislation or may achieve the same outcome by conditions of licence.

This is a national uniformity issue.

NCP Implications

Yes, for some States and Territories.

Recommendation to COAG

That recommendation 15 of the Review be accepted.

Action to Implement

NDPSC/MSC to implement through development of appropriate appendix that will list substances that may not be sold. States and Territories may need to amend legislation to adopt the decision of MSC or implement by administrative action.

RECOMMENDATION 16

Recording and reporting

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

- *retain the requirements for recording of all wholesale and retail transactions of Schedule 8 medicines and to specifically enable such records be kept electronically;*
- *continue the consistency of the recording 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 has recommended that the current recording of the sales of narcotic drugs be retained. It has also recommended the retention of the recording of wholesale sales of products in Schedules 2, 3 and 4. In the latter case it recommends that the form of recording should not be mandated so as to allow for electronic recording. Additionally it has recommended the repeal of legislation that requires the recording of retail sales of substances in Schedules 3, 5 and 6.

Comments and Discussion

There was general agreement by the States and Territories and PIMC for this recommendation However it was recognised that there are circumstances where Pharmacy Boards impose some restrictions on retailers. Comments to the Working Party were the same as those supplied to the Review. The recommendations in the Review were made in the full knowledge of these issues.

PIMC noted that if the NRA needs to continue specific recording of the retail supply of Schedule 4 veterinary products under its risk management regime, it has the capacity to do so under its own powers under the agvet legislation, as do the States.

The Working Party supports the recommendation.

NCP Implications

Yes, for some States and Territories.

Recommendation to COAG

That recommendation 16 of the Review be accepted.

Action to Implement

States and Territories need 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. Some states may need to amend legislation.

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

Comments and Discussion

Agreed by all States and Territories and PIMC.

This is an administrative issue. In some States, Queensland and WA, S2 products are stored in a way which prevents direct patient access. Consequently, there are differences between States on how drugs are stored. The S2 and S3 schedules will be retained only if the outcome of the research provides justification for the two schedules (Recommendation 5). Therefore it is appropriate to wait until the outcome of the research is known before making any changes that assume that the two schedules will be retained.

The Working Party could not identify differences in the handling of S4 medicines. There are some differences in the storage requirements for Schedule 8 substances in pharmacies due to local circumstances.

NCP Implications

Not immediately but it may following the outcome of the implementation of recommendation 5.

Recommendation to COAG

That recommendation 17 of the Review be accepted.

Action to Implement

It would be premature to implement this recommendation on Schedule 2 and 3 pending the results of Recommendation 5.

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:

- *prevent 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 has 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 has also recommended that the legislation be amended to make compliance with the Code mandatory.

Comments and Discussion

Agreed by all States and Territories.

The Working Party supports the recommendation and notes that the Code of Good Wholesaling Practice (GWP) has been adopted as a national standard by the NCCTG and has been reviewed by industry. States can either adopt in legislation or achieve compliance with as a condition of licence.

PIMC notes 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. The Working Party agreed that PIMC should consider how to address this gap to ensure the safe transport of all controlled substances.

NCP Implications

Yes, for all States and Territories.

Recommendation to COAG

That recommendation 18 of the Review be accepted, while recognising that further consideration will need to be given to transport controls on controlled substances used in agricultural and veterinary products.

Action to Implement

Some State and Territories may need to amend legislation. Others can achieve the same outcome administratively, as a condition of licence.

PIMC to consider how to adequately address the need for secure transport of controlled substances in agricultural and veterinary products.

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 agvet chemicals and household chemicals respectively to make the labels more effective communication tools.*

Summary

The Review has recommended that labelling should be outcomes focussed and simplified. It noted that the Therapeutic Goods Administration is currently undertaking a review of the labels for medicines with a view to making them more effective communication tools. It has recommended that once the review is finalised, the National Coordinating Committee on Therapeutic Goods consider the report and if appropriate, approach the National Registration Authority, with a view to applying the principles to agvet and household chemicals as well.

Comments and Discussion

There was general agreement by all States and Territories.

PIMC recommended that to the extent that any proposed changes to the TGA labelling Code might impact upon the agvet scheme, the TGA should engage the PIMC as early as possible to ensure that mutual outcomes are possible.

This is administrative issue. No legislative amendment is required.

NCP Implications

Nil

Recommendation to COAG

That recommendation 19 of the Review be accepted.

Action to Implement

TGA and NRA to implement via administrative arrangements or amendment of Commonwealth legislation as identified by the outcome of the review of labelling.

PIMC to be consulted on any proposed labelling changes which may impact on agricultural or veterinary products.

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 has 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 Poisons List 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.

Comments and Discussion

Some States and Territories may require legislative amendment to implement. Others may be able to deal with it administratively within existing legislation.
If a sponsor obtains approval from the TGA to use a non-Australian label then States/Territories should be able to recognise the TGA approval.

If following a scheduling change a sponsor requests from one jurisdiction a labelling exemption for a short period of time to implement the label change then an administrative decision by that jurisdiction should be able to be recognised by all States and Territories.

It has already been agreed, in principal, by the NCCTG that it would work towards the development of common criteria for the granting of a labelling exemption. Administrative arrangements will need to be developed to facilitate mutual recognition of exemptions relating to packaging and labelling. Some States and Territories may need to amend legislation to allow for the recognition of a decision by the TGA or another State or Territory.

PIMC advised that a mechanism within the Agvet legislation is being established to facilitate smoother and systematic changes to labels should there be scheduling changes. To the extent that this recommendation impacts on the agvet scheme, PIMC considers that the intent to have labelling changes consistent nationally has been met.

NCP Implications

Yes, for some States and Territories.

Recommendation to COAG

That recommendation 20 of the Review be accepted.

Action to Implement

The NCCTG to develop the administrative arrangements to enable approvals from TGA for use of a non-Australian label and for a label exemption following a schedule change to be recognised by States/Territories. Some States and Territories may need to amend legislation.

RECOMMENDATION 21

Packaging

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

Summary

The Review has recommended that the current packaging controls be retained.

Comments and Discussion

Agreed by all States and Territories and stakeholders, including PIMC.

No action required.

NCP Implications

Nil.

Recommendation to COAG

That recommendation 21 of the Review be accepted.

Action to Implement

No action required.

RECOMMENDATION 22

Commonwealth legislation

That the Commonwealth amend:

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

Summary

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

Comments and Discussion

This recommendation is linked to Recommendations 11 and 23.

The Working Party supports moves to have the packaging and labelling requirements primarily set by the regulators (TGA and NRA) and notes that the NDPSC and TGA have agreed to a process to move the warning statements currently in the SUSDP to the regulator's rules and guidelines. However, as PIMC points out the agricultural and veterinary legislation already has a national basis for labelling of agvet products. It is therefore unnecessary to amend the agvet legislation in order to implement the aspects of this recommendation relating to labelling and packaging.

As previously indicated at Recommendation 11, advertising controls on Schedule 4 veterinary medicines require further consideration. PIMC has indicated that it does not support proposed amendments to the agvet legislation and would prefer all controls for schedule 4 substances (both for human and veterinary use) to be included in the Therapeutic Goods Act and Regulations. Cognisant of the development of new legislation under the proposal for a Trans Tasman Joint Agency for therapeutic goods for human use, it is the view of the Working Party that it is appropriate for *the Agricultural and Chemical Code Act 1994* to be the primary legislative instrument for controlling advertising of veterinary medicines.

NCP Implications

Nil

Recommendation to COAG

That recommendation 22 of the Review be accepted, with deferral of the second dot point as it applies to Schedule 4 medicines for veterinary use until further analysis by PIMC.

Action to Implement

Commonwealth to amend legislation or administrative arrangements.

PIMC to undertake further analysis and consultation specifically on legislative changes required to the *Agricultural and Veterinary Chemicals Code Act 1994* to impose advertising controls on Schedule 4 veterinary 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 has recommended that, in the interests of uniformity, all states adopt the Commonwealth Therapeutic Goods Act by reference.

Comments and Discussion

All States and Territories agree but in cases where complementary legislation has not been introduced there may be a delay in preparation of legislation and implementation of changes by States and Territories.

So far only NSW, Tasmania and Victoria have complementary legislation. NSW and Tasmania, which adopt the Therapeutic Goods Act by reference, would not need to make any amendments. As Victoria has mirror legislation (its own provisions), and does not simply adopt by reference the Therapeutic Goods Act as in force from time to time, it must prepare amendments each time the Commonwealth Act is amended. ACT has drafted its legislation but it has low parliamentary business priority. The Northern Territory and Queensland are in the drafting phase. The remaining States support the concept of complementary legislation but are not yet at the stage of drafting.

As well as putting in place complementary legislation, legislative action is needed to ensure that all the provisions can be enforced. If the Commonwealth is to enforce the provisions of State or Territory laws, all jurisdictions may need to enact provisions to deal with a recent High Court case, *Hughes.* This case casts doubt about Commonwealth officers' ability to exercise powers under certain State and Territory laws. The TGA has begun the legislative process to amend the Therapeutic Goods Act to make it clear that Commonwealth officers may take action under State or Territory provisions, but do not have a duty to do so. To demonstrate that no duty exists it must be clear that other persons can take the action. If State or Territory laws do not give enforcement powers to State officials, it is most likely that those laws will require amending to insert provisions permitting those officials to exercise the powers and perform the functions under the State legislation.

The PIMC submission notes that the this recommendation may be relevant to the agvet scheme, dependent on whether the Therapeutic Goods Act is amended to include advertising controls on Schedule 4 medicines for veterinary use.

NCP Implications

Yes, for some States and Territories.

Recommendation to COAG

That recommendation 23 of the Review be accepted.

Action to Implement

Some States may need to make legislative changes.

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 systems 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 has recommended, in the interests of uniformity, that for the controls that remain a state responsibility, model legislation should be developed and adopted by reference by the States. Existing legislation should then be repealed.

Comments and Discussion

The concept of Model legislation is the key issue. All States and Territories support the concept of uniformity. However, given that existing drugs and poison legislation in many states is often complemented by or reliant on other State legislation, it may not be possible to achieve model legislation. The view was expressed that model legislation was only one approach that could be used to achieve uniformity and that there were other methods, which could also be used and were more likely to be implemented.

The Review acknowledges this is difficult. Galbally accepts that adoption by reference of model legislation " may not be supported by all jurisdictions, however, [she] thinks that one of the purposes of the Review is to set some benchmarks for movement towards an nationally uniform system of regulation."

While noting that some States and Territories have not supported the use of model legislation as the preferred method of achieving uniform legislation, the Working Party supports the adoption of this recommendation but recognises that further consultation is required. It does note however, that those States and Territories (QLD, WA and NT) who did not support the use of model legislation to achieve uniform legislation have proposed alternative strategies to achieve the same outcome.

Nevertheless the recommendation should be closely examined. The Review recognises this difficulty and accepts that if model legislation cannot be achieved, then uniformity must be pursued by other means.

To the extent that this recommendation would impact on the agvet scheme, consultations on an agreed model should also include AFFA as a stakeholder.

NCP Implications

Yes.

Recommendation to COAG

That recommendation 24 of the Review be accepted, recognising that further consultation is required and that failing agreement uniformity be achieved by other means.

Action to Implement

The NCCTG to consider the potential for model legislation to be developed and adopted or develop an agreed process for legislative harmonisation that will achieve national uniformity now and into the future.

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 responsibility, model legislation should be developed and adopted by reference by the States. Existing legislation should then be repealed.

Comments and Discussion

This follows on from Recommendation 24.

NCP Implications

Yes.

Recommendation to COAG

That recommendation 25 of the Review be accepted subject to the limitations set out under recommendation 24.

Action to Implement

Dependent on implementation of recommendation 24.

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 has recommended that products be more clearly identified to distinguish between those whose principal intended use is in the workplace and those whose intended principal use is domestic. Product labelling depends on this distinction as the safety requirements are different. Workplace products are subject to Occupational Health and Safety requirements whereas domestic products are subject to Drugs and Poisons requirements. The Review has also recommended that where possible, the labelling requirements be harmonised.

Comments and Discussion

There was general agreement by all States and Territories.

The key issue is the need for national coordination. No action is required of States and Territories. Any action is premature until a national decision is made to adoptthe Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) as recommended. This is an administrative process. The international outcome should be awaited and then dealt with by NCCTG while ensuring that there is adequate consultation with PIMC on the consequences for the agvet industry

NCP Implications

Nil.

Recommendation to COAG

That recommendation 26 of the Review be accepted.

Action to Implement

NCCTG to coordinate between NOHSC and NICNAS.

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 has recognised the importance of the close relationship between drugs and poisons legislation and legislation regulating professional practice. It has 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 has 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.

Comments and Discussion

Pharmacy Guild and PSA agreed to the recommendation. AMA disagreed believing practice standards are a matter for self-regulation. In recording its interest and responsibilities for veterinary practices, PIMC wished to be consulted on matters relevant to professional standards for veterinarians.

NCP Implications

Nil because it refers to legislation other that drugs and poisons legislation.

Recommendation to COAG

That recommendation 27 of the Review be accepted**.**

Action to Implement

Some States and Territories to amend relevant professional practice legislation.