Australian Government

Department of Health and Ageing

Therapeutic Goods Administration

REGULATORY IMPACT STATEMENT

FOR A

PRICE INFORMATION CODE OF PRACTICE

CONTENTS

1. BACKGROUND

The Council of Australian Governments National Competition Policy Review of Drugs, Poisons and Controlled Substances Legislation (the Galbally Review)[1] make 27 recommendations for change in the areas of increasing national uniformity, improving efficiency, reducing the level of control where possible and improving the net benefit to the community as a whole of those controls which rely on professional practice. The Galbally Review considered that it would be in the public interest to allow the provision of this information to consumers in certain circumstances. The Galbally Review recommended that the National Co-ordinating Committee on Therapeutic Goods (the NCCTG) develop a standard for the provision of such price information (see para 1.1 below).

This Regulatory Impact Statement (RIS) has been prepared to assist with the development of the most appropriate regulatory mechanism for the provision to consumers of price information about medicines available from pharmacies with professional advice or a prescription. At present, the publication of information about the price of these prescription only and certain pharmacist only medicines that can be construed as promotional is prohibited.

Although the Galbally Review has assessed the appropriate levels of regulatory control of the provision of price information for these medicines to some extent, this RIS is necessary in order to examine more fully the rationale for imposing restrictions on the provision of this information, and, if such restrictions should be imposed, what those restrictions should be.

All comment provided in response to the three regulatory options canvassed in the draft RIS has been taken into consideration, including in relation to Option 3, the draft Price Information Code of Practice that has been developed in response to Galbally Review Recommendation 11 (see **Attachment A**).

The selected option will be implemented under the legislative arrangements for the establishment of the joint Australia-New Zealand regulatory agency. The selected option will apply in Australia only, with New Zealand retaining its current regulatory regime for direct to consumer advertising of therapeutic products.

1.1 The Galbally Review

The Galbally Review concluded that advertising the price of prescription medicines and certain pharmacist only medicines to consumers should be allowed, so long as it did not promote use of the products, and was for information only. It recommended that the NCCTG develop a Standard for Informational Price Advertising of medicines included in schedule 3, 4 and 8 of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) to be underpinned by the *Therapeutic Goods Act 1989* (the Act). **Attachment B** provides details of the recommendation.[2]

[1] *Review of Drugs, Poisons and Controlled Substances Legislation*, A Council of Australian Governments Review, Rhonda Galbally, Commonwealth of Australia, December 2000.

[2] The types of therapeutic products for which new regulatory arrangements are being considered are those listed in, or containing substances or preparations listed in, the following schedules of the SUSDP: Schedule 3 (pharmacist only medicines - but not those listed in, or containing substances or preparations listed in Appendix H of the 19th Edition of the SUSDP, that is Schedule 3 substances that are allowed to be advertised, for example, patches or lozenges containing nicotine), Schedule 4 (prescription only medicines) and schedule 8 (controlled

A working group comprising representatives of the following organisations has greatly assisted the NCCTG with the development of a draft of the recommended Code:

- Pharmaceutical Society of Australia;
- Pharmacy Guild of Australia;
- Medicines Australia;
- Australian Self-Medication Industry;
- Generic Manufacturers Industry Association;
- Consumers' Health Forum;
- Therapeutic Goods Advertising Code Council;
- Council of Pharmacy Registering Authorities;
- Therapeutic Goods Administration; and
- The NSW and Western Australian Health Departments.

Option 3 of this RIS is the Price Information Code of Practice as developed by this Working Group. The draft Code developed by the Working Group is at **Attachment A**.

The following work of the Commonwealth Department of Health and Ageing may have implications when determining the most appropriate regulatory mechanism for the medicines under consideration:

- The Pharmaceutical Benefits Scheme;
- The Quality Use of Medicines Strategy; and
- The Review of Advertising Therapeutic Products in Australia and New Zealand.

1.2 The Pharmaceutical Benefits Scheme

The Commonwealth Government's Pharmaceutical Benefits Scheme (PBS) ensures all Australian residents have access to necessary and lifesaving medicines at an affordable price. Most medicines available on prescription are subsidised under the PBS.

The PBS provides equity of access to medicines and is one of four elements of a national medicines policy framework. The other elements are:

- supply of medicines of acceptable quality, safety and efficacy;
- quality use of medicines by providers and consumers; and
- maintenance of a viable pharmaceutical industry in Australia.

Under the PBS, patients pay a subsidised price for medicines available only on prescription and the government pays any additional costs of the medicines (provided they exceed the patient co-payment) up to the dispensed price, excluding any delivery or after hours fee, brand or therapeutic group premium, which are paid for by the patient.[2]

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drugs eg amphetamines and methadone). The SUSDP is published by the Commonwealth under the *Therapeutic Goods Act 1989*.

[2] Further, more complete information regarding the operation of the PBS can be found on the internet at http://www.health.gov.au/pbs .

1.3 Quality Use of Medicines

The National Strategy for Quality Use of Medicines (QUM) aims to improve positive health outcomes for all Australians through their access to and wise use of medicines. It has developed some key principles in relation to the use of medicines. These principles are to:

- *select management options wisely* by:
  - considering the place of medicines in treating illness and maintaining health, and
  - recognising that there may be better ways than medicine to manage many disorders.
- *Choose suitable medicines if a medicine is considered necessary* so that the best available option is selected by taking into account:
  - the individual;
  - the clinical condition;
  - risks and benefits;
  - dosage and length of treatment;
  - any co-existing conditions;
  - other therapies;
  - monitoring considerations; and
  - costs for the individual, the community and the health system as a whole;
- *Use medicines safely and effectively* to get the best possible results by:
  - monitoring outcomes;
  - minimising misuse, over-use and under-use; and
  - improving people's ability to solve problems relating to medication, such as negative effects or managing multiple medications.

1.4 The Review of Advertising Therapeutic Products in Australia and New Zealand

The development of a joint regulatory scheme for the advertising of therapeutic products in Australia and New Zealand commenced in 2002 with a report into a review of advertising therapeutic products in Australia and New Zealand being publicly released in March 2003. Following the release of the report, the Australian and New Zealand Health Ministers agreed to the establishment of an Interim Advertising Council (IAC) to further develop the Review's recommendations prior to consideration by the Australian and New Zealand governments of a proposal for a trans-Tasman therapeutic products advertising regulatory scheme.

The Interim Advertising Council was established in May 2003 by the TGA and Medsafe and met nine times over the period May 2003 – October 2004. The Council delivered a report on its recommendations for a proposed trans-Tasman regulatory model to the TGA and Medsafe at the completion of this process, following extensive stakeholder consultation in Australia and New Zealand. The IAC report recognises the need for common, stream-lined complaint handling processes in Australia and New Zealand and the need for complaint panels to have sufficient powers to bring about timely action where regulatory breaches are identified.

The Therapeutic Products Interim Ministerial Council (comprising the Australian and New Zealand Health Ministers) is considering this report and is expected to shortly approve a new trans-Tasman regulatory model for the advertising of therapeutic products.

1.5 The Australian Pharmaceutical Industry

In 2002 the turnover of the Australian pharmaceutical industry was approximately $6.1 billion. There are around 143 separate firms listed as suppliers to the PBS, employing up to 16 000 people. Australia has approximately 1 percent of the global pharmaceutical market, and is a net importer of pharmaceutical products.[3]

The Australian market for human use pharmaceuticals is small in the context of global demand. While the PBS allows for universal access to prescription products, the size of the population means that sales are small. Australia's population represents 0.3 percent of the world yet consumes around 1 percent of total global pharmaceuticals sales. This means that in 2000 Australia was the 18th largest pharmaceutical market by sales, while being 50th out of 187 countries ranked on population.

It should be noted that despite the size of the Australian pharmaceutical market, due to the subsidisation of prescription medicines under the Pharmaceutical Benefits Scheme (PBS), there can only be limited price variation between pharmaceutical medicines (see "Assessment of Impacts" below).

1.6 Current Arrangements for the Regulation of Price Information

Currently, if price information is published in relation to prescription and pharmacist only medicines (except those in Appendix H to SUSDP Schedule 3) in a way that indirectly promotes the use of these products, the matter is dealt with as illegal advertising under the current advertising arrangements. Both State and Commonwealth health agencies are involved in the regulation of price information.[4]

The Commonwealth Therapeutic Goods Administration (TGA) has observed a steady increase in complaints relating to price lists and the advertising of prescription medicines. The majority of complaints are received from retail pharmacists (and State/Territory Pharmacy Boards, on behalf of retail pharmacists) and relate to catalogues, flyers, internet sites or brochures produced by retail pharmacists or stores which include 'prescription price lists', and appear to breach the current regulations.

TGA has considered at least seventeen of these types of complaints during the past 12 months (to June 2005) and has resolved them through administrative procedures without the need to proceed to prosecution. The 'price lists' offered appear to contain lower prices than those

[3] Australian Government Department of Industry, Tourism and Resources (2005), *Pharmaceutical Industry Profile*, Australian Government Department of Industry, Tourism and Resources, Canberra, accessed June 2005, http://www.industry.gov.au/content/itrinternet/cmscontent.cfm?objectID=24609551-65BF-4956-B6F1C624779E7CF8.

[4] Section 42DL (1)(f) of the Therapeutic Goods Act 1989 (Cwth) prohibits a person from publishing an advertisement about goods for therapeutic use that refer to goods, or substances or preparations containing goods, mentioned in schedule 3, 4 or 8 of the SUSDP. Section 42DL (3) (b) makes it a defence to a prosecution under Section 42DL (1) (f) if the goods, substances or preparations referred to in the advertisement are in Appendix H of Schedule 3. "Advertisement" is defined in the Act as "in relation to therapeutic goods, including any statement, pictorial representation or design, however made, that is intended, whether directly or indirectly, to promote the use or supply of goods." State and Territory therapeutic goods legislation also prohibit the advertising of prescription medicines and some non-prescription medicines. General advertising to consumers has never been prohibited for 'pharmacy-only over-the-counter (Schedule 2) medicines provided it meets prescribed requirements. Advertising of prescription medicines to health professionals is also exempted from the prohibition on advertising under Commonwealth, State and Territory legislation.

offered by other more mainstream retail outlets. Where pharmaceutical manufacturers are involved in the complaints, the Medicines Australia Code of Conduct Committee may also deal with complaints involving their members under their Code of Conduct. Where there is a public health or safety risk the TGA will also take action directly with the sponsor involved.

1.7 Overseas Regulatory Arrangements

New Zealand and the United States of America are the only industrialised countries that allow the advertising of prescription medicines to the public.

New Zealand's Code of Therapeutic Advertising (developed and managed by the Advertising Standards Authority (ASA)) requires that advertisements not only comply with advertising provisions in the NZ *Medicines Act 1981* and Medicines Regulations 1984 (eg that they include prescribed messages), but are also truthful, socially responsible and not misleading or deceptive. This Code applies to advertising of prescription and non-prescription medicines, medical services, complementary medicines, and foods and cosmetics where a therapeutic claim is made. ASA also manages a well-developed self-regulatory system for handling complaints about advertisements, including those making therapeutic claims.

The US Food and Drug Administration regulates (promotional) labelling of drugs and devices, and advertising of prescription and 'restricted' medical devices under their Food, Drug and Cosmetic Act. Historically, most prescription drug and device advertising has been directed at physicians (for example, through professional meetings and journals). However, advertising these products to the public is no longer prohibited and constitutes a significant proportion of the advertising of therapeutic goods. Recently, the FDA commenced a review of the relevant legislation to establish whether it is relevant in today's market, particularly due to the wide use of internet advertising.

The advertising of medicines in the United Kingdom is controlled by a combination of statutory measures, enforced by the Medicines Control Agency (MCA), and self-regulation through Codes of Practice for the pharmaceutical industry. Advertising to the public is permitted for non-prescription medicines (classified 'pharmacy only' or 'general sale List'). Advertising to the public is prohibited for prescription medicines (the Regulations prohibit the issue of any advertisement to the public that is likely to lead to the use of a prescription medicine). However, under the definition of 'advertising' in the Regulations, "reference material, a factual, informative statement or announcement, a trade catalogue or a price list" is not classified as advertising provided it "makes no product claim" [5] ie is not promotional.

2. PROBLEM IDENTIFICATION

Market behaviour is generally enhanced when accurate and relevant information is provided to consumers (including information about price). At present, consumers can only receive information about the price of prescription and certain pharmacist only medicines from health professionals (eg doctors or pharmacists), as the publication of price information (including by health professionals) in a way that promotes the use or supply of such medicines is prohibited.

[5] The Medicines (Advertising) Regulations 1994 (UK).

The difficulty, however, is that little guidance is currently provided as to how price information can be provided without also promoting the use or supply of the goods.

The provision of price information to consumers would enable consumers of pharmacist only medicines, and certain prescription only medicines to choose these products on the basis of price as well as service. However, the need to provide consumers with useful information about the price of these medicines must be balanced against the need to ensure that the information is not provided in a way that prompts consumers to inappropriately use medicines.

In relation to medicines available only on prescription, competitive effects should result only in relation to those medicines that are not subsidised at all under the Pharmaceutical Benefits Scheme or the Repatriation Pharmaceutical Benefits Scheme, or that are PBS/RPBS subsidised but whose dispensed price is less than the co-payment amount. As a percentage of total prescriptions supplied in Australia in 2000:

- 6.5% were private prescriptions;
- 77.5% were PBS/RPBS subsidised; and
- 16% were PBS/RPBS items that were not subsidised (ie the base dispensed price was under the general co-payment amount).[6]

In summary, the need to assist consumers to choose their suppliers of these medicines on the basis of price must be balanced against the need to protect their health and safety.

3. OBJECTIVE

The cost-benefit review of current restrictions on the advertising of therapeutic products listed in Schedules 3, 4 and 8 that was conducted as part of the Galbally Review identified a need for government to reconsider its current ban on the price advertising of these medicines. The Galbally Review suggested that the prohibition "be modified to a limited extent to permit advertising that is in the public interest, as this will provide a benefit to the community as a whole"[7]. It went on to recommend that in permitting limited advertising, price advertising[8] also be permitted where it meets required standards.

An extract of the relevant recommendation is at **Attachment B**.

The objectives of government action are:

- to allow consumers to choose the pharmacists that supply their prescription and certain pharmacist only medicines on the basis of price as well as service, by enabling pharmacists and dispensing doctors to provide consumers with accurate price information; and

[6] These are the latest available figures for this breakdown. These figures were provided by the Medical and Pharmaceutical Services Division of the Department of Health and Ageing, and have been taken from actual prescription data obtained from a statistical representative subset of pharmacies across Australia.
[7] Galbally Review, Final Report Part A, p65.
[8] The Galbally terminology 'price advertising' has not been used in this RIS except within quotes from the Galbally Report. Instead, the terms 'price information' is used. This is to distinguish between prescription medicine 'advertising' that could be used to promotes the sale or use of a product, and the provision only of information about the price of such products.

- to ensure this information is provided in a way that does not cause consumers to use these medicines in a manner that risks their health and safety.

4. REGULATORY OPTIONS

There are essentially three options for the regulation of the provision of price information of the identified medicines.

Option 1

Maintain the existing prohibition on the publication of promotional price information, with no guidance provided as to what is promotional.

Option 2

Allow the provision of price information, without any constraints (ie allow advertising).

Option 3

Allow the provision of price information, within constraints consistent with recommendation 11 of the Galbally Review, to ensure it is not promotional.

A draft Code (see Attachment A) has been written by the stakeholder Working Party in accordance with the constraints specified by the Galbally Review. Aspects of the Code that are of particular note are:

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

As proposed by the Galbally Review, the Code would extend to products listed on the Pharmaceutical Benefits Scheme (PBS), although there can be little price variation between these products.

Some explanation as to why the Code has been drafted in this way can be found in the Impact Analysis section for Option 3 below.

5. ASSESSMENT OF IMPACTS

As reliable quantitative data is not available, the analysis of this RIS is based on a qualitative assessment.

5.1 Groups likely to experience the benefits and costs

The groups likely to experience the benefits and costs of the regulation of the provision of price information about these medicines are:

- **Consumers** - of prescription medicines and relevant pharmacist only medicines.
- **Industry** – retail pharmacists, dispensing doctors and therapeutic products manufacturers.
- **Government** – State and Territory Governments (particularly the State/Territory Health Departments) and the Commonwealth Government (particularly the Trans-Tasman Regulatory Agency).

5.2 Impact Analysis

Impacts of Option 1: Maintain the existing prohibition on the publication of promotional price information, with no guidance provided as to what is promotional.

There may be a continued increase in complaints relating to price lists and the advertising of prescription medicines, as observed by the TGA. There would continue to be uncertainty for suppliers of price information as to what is considered 'promotional' and thus illegal, and what is acceptable.

Benefits of Option 1

To consumers: Consumers would continue to be protected to some extent from selecting medicines that are inappropriate for their health needs due to the prohibition on price information that promotes the sale of such products. However, without guidance as to what is considered promotional, provision of price information compliant with the existing prohibition would be difficult to achieve.

To industry: None. There would be no change in current practices, so there would be no added economic benefit for retail pharmacists (as suppliers of prescription and pharmacy-only medicines) or manufacturers. Pharmacists, manufacturers and dispensing doctors would not have the benefit of guidance as to what is 'acceptable' price information ie information that could not be considered promotional 'advertising' of these products.

To government: None. However, regulators would continue to be responsible for the enforcement of the non-promotional provision of price information without the benefit of legislated guidance as to what is to be considered promotional.

Costs of Option 1

To consumers: Consumers will not be able to benefit from the price competition expected to result from allowing the provision of price information, particularly in relation to the pharmacist only medicines which are not subject to PBS subsidy.

Consumers will continue to have a reduced ability to make purchasing decisions about prescription medicines, and the relevant pharmacist only medicines with the benefit of price information. They will continue to choose a pharmacy to supply their medicines based only on matters such as proximity to home or work, loyalty, and the service provided, and the limited price information they currently receive.

At present, consumers can become price sensitive through making similar earlier purchases, or by receiving information through word of mouth or from their doctor (regarding prescription medicines) or pharmacist. However, the Code would allow them access to additional price information by means such as posters in chemist windows, and in newspapers, pharmacy catalogues and on the internet.

To industry: There are costs to retail pharmacists in not being able freely to promote their products through the provision of price information in a way that would improve sales and profits.

To government: Increased costs to government would be unlikely as the level of regulation would not increase.

Impacts of Option 2: Allow the provision of price information, without any constraints (ie allow advertising)

Under this option there would be no constraints on the advertising of prescription and pharmacist only medicines except those that apply generally to all forms of advertising (eg the requirement of trade practices law that advertising cannot be misleading or deceptive).

Retail pharmacists and manufacturers of these medicines would be likely to experience increased sales under this option, but there would be a risk that consumers would inappropriately use medicines that they may not need, or that are a risk their health and safety, prompted by claims made by advertisers.

Benefits of Option 2

To consumers: Consumers would have access to information that would help them select their supplier of prescription medicines and certain pharmacist only medicines on the basis of price as well as service and convenience. Increased competition amongst suppliers would be expected to reduce prices of some pharmacist only medicines and possibly, to a very limited extent, of PBS subsidised medicines available on prescription.

To industry: There would be increased sales of products because of the provision of promotional price information. Retail pharmacists would be able to compete more effectively by advertising the price competitiveness of their products. Manufacturers may also gain greater market exposure for their products and thus gain sales and profits. There would negligible impact on dispensing doctors.

To government: Small financial savings might be made as no regulatory action would need to be taken by government regulators to prevent the provision of promotional price information.

Costs of Option 2

To consumers: The health and safety of consumers would not be as protected by this Option.

As mentioned in the Galbally Report:

> "Removing the restrictions may lead to increased problems caused by the inappropriate selection of medicines prompted by claims made by advertisers in promoting their particular products. Consumers may not have the knowledge or skills to critically evaluate the claims product sponsors might make in promoting their medicines"[9].

The Galbally Report also notes that:

> "Advertising prescription medicines is reported to have led to increased costs in the United States and New Zealand as a consequence of increased problems caused by the misuse of medicines. … From research so far in the United States, there is some evidence that patient behaviour does alter in response to advertisements (Mintzes, 2000;NIHCM, 1999; Wilkes et al., 2000). It appears that when a prescription medicine is advertised, there is an increase in sales as a result of people going to their doctors, discussing and requesting advertised medicines, and receiving prescriptions."[10]

The removal of the limitation on the advertising of pharmacy-only medicines might result in the inappropriate selection of these medicines by consumers.

The removal of the limitation on the advertising of prescription medicines would not ensure that their use is based on objective, expert advice. Consumers might attempt to have prescribed to them medicines that may not be appropriate for their particular medical conditions, due to advertising claims. Health professionals (ie those with training and knowledge that would assist with the evaluation of such material) would no longer be able to play 'gatekeeper' in the assessment of advertising material for prescription medicines.

To industry: There would be increased advertising costs for retail pharmacists but these would need to be weighed against increased sales for them and manufacturers (private net benefits). There would be no costs for dispensing doctors, apart from receiving requests from patients to prescribe advertised medicines.

To government: It is possible that there would be increased costs to government in relation to the operation of the PBS due to the advertising of medicines subsidised under the PBS.

Impacts of Option 3: Allow the provision of price information, within constraints set out in a Code of Practice consistent with recommendation 11 of the Galbally Review, to ensure it is non-promotional

Under this Option consumers would have greater access to price information regarding prescription and pharmacy-only medicines, and would experience negligible risk to their public health and safety due to increased or inappropriate use of these medicines. Industry would be provided with clear guidance as to how it could provide price information regarding these medicines in a way that is not promotional.

[9] Galbally Report, Part B, p90
[10] Ibid, p91.

Benefits of Option 3

To consumers: The Galbally Review acknowledged that the regulation of the provision of price information would be difficult, given the 'fine line' between that which is promotional and that which is informational. However, it considered this was a "small inconvenience relative to the advantages of improved consumer knowledge and the competition between suppliers that this would enable".

Consumers would have access to information that would help them select their supplier of prescription medicines and certain pharmacist only medicines on the basis of price, as well as service and convenience.

Consumers would benefit from the opportunity to use price information in purchasing decisions for medicines, and from the competitive effects that may be expected to result. This would be most likely to occur in relation to non-prescription 'pharmacist only' medicines and prescription medicines not subsidised under the Pharmaceutical Benefits Scheme (6.5% of total prescriptions in 2000), but may also occur to a limited extent with PBS medicines where the price to consumer differs as a result of product premiums or differences in discretionary charges. For example, additional recording and administrative fees (currently up to $0.95 and $3.36 respectively) may be charged for PBS items for general patients where the base dispensed price is less than the general patient co-payment amount (16% of total prescriptions in 2000).

The draft Code would help enable consumers to choose their medicines consistent with QUM principles. They would be less likely to inadvertently choose medicines inappropriate for their health needs as a result of promotional advertising. Price information provided to consumers in accordance with the Code would be balanced, ensuring that no products are promoted over others.

The Code would provide the same advantages to persons who are prescribed controlled substances[11] by allowing price information to be provided about these products. The provision of price information of itself will not promote the increased supply of these products, as they are available only upon prescription after consultation with a medical practitioner. State and Territory poisons legislation would continue to prevent the sale of controlled drugs without a prescription. A Review of the operation of the Code, proposed to begin twelve months after it commences, would re-examine this approach if necessary.

The Code attempts to define the 'fine line' between that which is promotional and that which is informational when providing price information. For example, the Code would prevent promotional price information being provided by:

- preventing manufacturers, distributors or sponsors from providing price information to consumers about their range of medicines, other than pharmacy marketing groups or retail pharmacists who are sponsors of their own brand products; and
- not allowing price information to be provided on TV, radio or 'outdoor advertising' (eg on billboards and buses). This is consistent with the view of the Galbally Review that

[11] eg methadone (subsidised under the PBS), and amphetamines and methylphenidate (Ritalin) which are not subsidised under the PBS.

> "such advertisements (sic) on television or radio would, by the nature of the media, be considered promotional."[12]

The restriction on manufacturers, distributors or sponsors prevents them from providing price information about their range of medicines in isolation. The draft Code does enable pharmacy marketing groups who also sponsor their own products to publish price information lists, provided these do not focus only on those brands of products, or include misleading information about the price competitiveness of those products. This provision enables these sponsors to include their own brand products in their price information lists, otherwise these products would not be included in any price list given that they are not retailed by other pharmacists.

To industry: Retail pharmacists would have clear guidance as to what type of price information they could or could not supply in relation to prescription medicines and certain pharmacist only medicines. Pharmacists may also be able to compete more effectively in the areas of price particularly in relation to pharmacist-only medicines.

To government: The costs to regulatory authorities will be less. This is because the Code will outline to industry what is appropriate and inappropriate price information. Self-regulation by industry would see regulatory authorities incurring costs only through their involvement in investigating particularly serious breaches of the Code.

To all stakeholders: The Price Information Code would benefit all stakeholders in that a separate regulatory system to ensure industry compliance would not be required. The Code can be regulated within the regulatory framework proposed for the regulation of the advertising of therapeutic products (see below under Implementation).

Publication of any price information that is inconsistent with the Code will be illegal advertising and will be dealt with in accordance with the regulatory framework proposed for illegal advertising. Under that framework complaints about price lists thought to be breaches of the Code may be made to the Central Complaints Panel in Australia, as described in the new trans-Tasman regulatory model for the advertising of therapeutic products.

Costs of Option 3

To consumers: No costs. This Option only provides benefits to consumers through the appropriate provision of price information to assist them in purchasing prescription and some pharmacist only medicines. This Option will not allow promotional advertising of these medicines and therefore there will be no risk of misuse of medicines by consumers.

To industry: As implementation of this option would give retail pharmacists, pharmacy marketing groups or dispensing doctors the opportunity to provide price information in a manner in which they can be confident is non-promotional, the only cost would be that of the actual provision of price information. For those pharmacists, etc, that already provide price information eg on the internet or in catalogues, there may be some costs in ensuring that this information is provided in a manner that complies with the Code.

[12] Report of the Galbally Review, Part A, p64

To government: Government may need to provide funds to assist State/Territory Pharmacy Boards to assist with the initial education of retail pharmacists, pharmacy marketing groups and dispensing doctors regarding the proposed new arrangements. The Commonwealth would also incur the usual costs involved in developing legislation, to enable the Code to be enforced.

6. CONSULTATION

Submissions were invited on the Terms of Reference, Options Paper, Draft Report and Final report of the Galbally Review. Comments received in relation to Recommendation 11 supported Galbally's conclusion that consumers stood to benefit from allowing price information to be provided to consumers on prescription and certain pharmacist only medicines. This conclusion was supported with the proviso that such information did not also promote the sale or inappropriate use of those products.

The draft Code was prepared by the Working Group representing key stakeholder groups, including representatives of state health departments, the key pharmacy representative organisations (PSA, PGA, COPRA), the Therapeutic Goods Advertising Council, the Consumer's Health Forum, and key industry umbrella organisations (ASMI, Medicines Australia, Generic Medicines Industry Association) together with the TGA. Stakeholders were actively engaged in the consultation process, through representation on the Working Group and through targeted consultation. The draft RIS and draft Code were also published on the TGA website and interested parties were invited to make submissions.

The TGA received fifteen written responses to the Consultation Regulation Impact Statement across the therapeutic products industry, healthcare professionals and State/Territory governments

Support for Option 3

Of the responses received, six stakeholders expressly confirmed their support for option 3 described in the RIS. None of the other respondents raised any objection to option 3. The specific issues which were raised by stakeholders are outlined in Attachment D.

The responses from stakeholders were considered by the NCCTG at their 9 September 2004 meeting. The NCCTG agreed to endorse the Price Information Code of Practice for consideration for development of the new trans-Tasman legislation. Many of the stakeholder submissions supported the proposal outlined in the draft RIS that the Code be reviewed after it has been in place for twelve months.

7. CONCLUSION AND RECOMMENDED OPTION

Consumers should be able to be provided with information concerning the price of prescription and pharmacist only medicines when they decide to purchase such medicines. If the provision of such information were to increase competition amongst retailing pharmacists and, as a result, possibly reduce the prices of these particular products, this would be in the public interest.

However, the provision of price information to consumers should not result in the inappropriate or increased unnecessary use of these medicines. Any regulatory option must be consistent with the National Strategy for Quality Use of Medicine principles.

The attached Price Information Code of Practice (Option 3) attempts to balance these two requirements in a manner consistent with the recommendation of the Galbally Review and taking into consideration the comments submitted by stakeholders.

The Galbally Report's conclusion was that the **benefit** to the wider community of the availability of this information (through greater choice to consumers and increased competition for retail pharmacists), outweighed the **cost** to industry (the need for manufacturers to respond to any change in the market as a result of increased competition for retail pharmacists), and to government (for the implementation of appropriate mechanisms for facilitating the provision of the information).

Implementation of the Price Information Code of Practice is of benefit to the wider community and is supported by both the findings of the Galbally Review and stakeholders. It is recommended that Option 3 be adopted.

8. IMPLEMENTATION AND REVIEW

The Code will be implemented and enforced under the new legislative arrangements for the Trans-Tasman Regulatory Agency. The Code will be regulated in a manner consistent with the new proposed advertising arrangements.

Terms of reference will be developed for a review of the Code, to be undertaken when the Code has been in place for twelve months.

REFERENCES

Australian Government Department of Industry, Tourism and Resources 2005, *Pharmaceutical Industry Profile,* Australian Government Department of Industry, Tourism and Resources, Canberra, accessed 3 June 2005, <http://www.industry.gov.au/content/itrinternet/cmscontent.cfm?objectID=24609551-65BF-4956-B6F1C624779E7CF8>

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Information relating to regulatory arrangements for advertising therapeutic goods in the United States of America and the United Kingdom was taken from: www.fda.gov and www.mca.gov.uk.

ATTACHMENT A

Draft Price Information Code of Practice

This Code of Practice implements Recommendation 11 of the Council of Australian Governments' Review of Drugs, Poisons and Controlled Substances Legislation. The recommendation relates to informing consumers of the prices of medicines included in Schedules 3, 4 and 8 of the *Standard for the Uniform Scheduling of Drugs and Poisons* (the SUSDP).

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(1) In this Code, unless the contrary intention appears, terms have the same meaning as in the Commonwealth *Therapeutic Goods Act 1989* and Commonwealth Therapeutic Goods Regulations, as in force from time to time.

Explanatory Note: As it is intended that the Therapeutic Goods Act 1989 be replaced by the trans-Tasman legislation for the Joint Therapeutic Products Agency, some terms used in this Code will need to be amended to reflect these new regulatory arrangements.

(2) Explanatory Notes are provided to assist compliance with the Code.

(3) In this Code:

medicine means a product, or a substance or a preparation containing products, included in Schedule 3 (other than substances in Appendix H), Schedule 4 or Schedule 8 of the Standard for the Uniform Scheduling of Drugs and Poisons;

Explanatory note: this definition includes the therapeutic devices included in those schedules, and medicines available under the Pharmaceutical Benefits Scheme (PBS) and Repatriation Pharmaceutical Benefits Scheme (RPBS). Most medicines available on prescription are subsidised under the PBS or RPBS. This subsidy is received when the prescription is filled.

price information means information about:
(a) the total purchase price of medicines that is to be paid by consumers of those medicines; and
(b) in relation to medicines that are subsidised under the Australian Government's PBS (or RPBS), the price paid by the consumer when the prescription is filled.

sponsor, in relation to therapeutic goods, means:
(a) a person who exports, or arranges for the exportation of, the goods from Australia; or
(b) a person who imports, or arranges the importation of, the goods into Australia; or
(c) a person who, in Australia, manufactures the products, or arranges for another person to manufacture the goods, for supply (whether in Australia or elsewhere); but does not include a person who:

(d) exports, imports or manufactures the goods; or
(e) arranges the exportation, importation or manufacture of the goods;
on behalf of another person who, at the time of the exportation, importation, manufacture or arrangements, is a resident of, or is carrying on business in, Australia;

SUSDP means the *Standard for the Uniform Scheduling of Drugs and Poisons* published by the Commonwealth under the *Therapeutic Goods Act 1989*, that is, the document known as the "current Poisons Standard" under the *Therapeutic Goods Act 1989*;

total purchase price means:
(a) the total cost to the consumer and includes pharmacy mark-up, additional fee and allowable extra fee if applied by the pharmacist; and
(b) in relation to PBS and RPBS prescriptions, also includes any brand or therapeutic premium which must be paid by the consumer.

2 Purpose

The purpose of this Code is:
(a) to set out the conditions under which information about the price of prescription medicines and certain pharmacist only medicines may be provided to the general public; and
(b) to provide a mechanism by which such information, consistent with the National Medicines Policy[13] and in particular the Quality Use of Medicines Principles, can be provided that will enable consumers to take into account the price of a medicine when deciding where to obtain their medicine.

3 Application

(1) Subject to subclauses (3) and (6), this Code applies to all price information directed to consumers of products, or a substance or a preparation containing products, included in Schedule 3 (other than substances in Appendix H), Schedule 4 or Schedule 8 of the SUSDP.

Explanatory note: Except as provided in clause 11.3 and 11.4, this Code does not regulate the provision of price information for medicines that are permitted to be advertised, such as over-the-counter medicines in Schedule 2 of the SUSDP, medicines in Schedule 3 that are in Appendix H of the SUSDP, or medicines that are exempt from scheduling.

(2) Price information may only be provided for medicines that are included on the Australian Register of Therapeutic Goods.

Explanatory note: This is to ensure that price information may only be provided for those medicines that are approved by the Therapeutic Goods Administration.

(3) Price information may not be provided for medicines that are included in Schedule A to the Code.

[13]Commonwealth of Australia, 1999, available on the Australian Government Department of Health and Ageing website at www.health.gov.au

Explanatory note: This requirement provides for exclusion of certain substances on public health and safety grounds.

(4) This Code does not apply to price information directed exclusively to health professionals.

(5) In subclause (4), "health professionals" includes medical practitioners, psychologists, dentists, veterinary surgeons, pharmacists, physiotherapists, dietitians, scientists working in medical laboratories or nurses; or persons who are engaged in the business of wholesaling therapeutic goods; or purchasing officers in hospitals; or herbalists, homeopathic practitioners, chiropractors, naturopaths, nutritionists, practitioners of traditional Chinese medicine, podiatrists or osteopaths registered under a law of a State or Territory.

Explanatory note: Advertising of prescription medicines to health professionals is exempted from the prohibition on such advertising under Commonwealth, State and Territory legislation.

(6) Price information may not be provided for PBS medicines supplied through alternative arrangements under Section 100 of the National Health Act 1953, other than dispensing fees for buprenorphine hydrochloride and methadone hydrochloride.

Explanatory note: These medicines are supplied through specific arrangements for special needs access or specialised drugs and include Highly Specialised Drugs. Price information on dispensing fees for buprenorphine hydrochloride and methadone hydrochloride should be available in support of the treatment of opiate dependence.

4 Who may provide price information

(1) Price information may only be provided by retail pharmacists, agents acting on behalf of pharmacists including pharmacy marketing groups, or dispensing doctors.

(2) Price information may not be provided by manufacturers, distributors or sponsors of medicines, other than pharmacy marketing groups as per subclause (1).

Explanatory Note: This is consistent with the purpose of this Code of providing price information for consumers to consider when purchasing their medicine. It also prevents manufacturers or sponsors from providing price information about their range of medicines in isolation, which could be considered promotional. Pharmacy marketing groups, who are also sponsors of products, are permitted to provide price information on behalf of nominated pharmacists.

5 Responsibility for compliance with this Code

Those persons whose name and contact details accompany price information are responsible for ensuring that the price information complies with this Code.

Explanatory notes:

1. ***See clause 10 below. Persons who distribute price information are not responsible for its compliance with this Code unless they are also the suppliers of the price***

information. For example, doctors or pharmacists who provide patients or customers with price information pamphlets that identify other suppliers of the medicines referred to in that information are not responsible for ensuring that the information complies with this Code. Those identified in the information as the suppliers of the medicine are responsible for compliance.

2. ***Where a pharmacy marketing group prepares and arranges for the publication of price information on behalf of a group of pharmacists, the pharmacists identified in the price information will be responsible for its compliance with the Code.***

6 Methods for provision of price information

Price information to which this Code applies may be provided by any method except:

(a) transmission using radio or television, or

(b) displays, including posters:

(i) in shopping malls (except inside individual shops);

(ii) in or on public transport; and

(iii) on billboards.

Explanatory Notes:

1. Methods by which price information may be provided include newspapers, magazines, leaflets, and the Internet.

2. Suppliers are not precluded from generally advertising their services and indicating that price lists are available on request, provided that the advertisement does not mention particular prescription medicines or classes of medicine, or the substances that they contain.

7 General requirement prohibiting promotion

(1) Price information, and any information accompanying price information, cannot promote the sale or use of a medicine referred to in the price information.

(2) A medicine referred to in price information shall be taken to be promoted if it is presented or described in a way that gives it prominence over and above any other medicine, whether or not that medicine is also referred to in the price information being provided.

Explanatory Notes:

1. ***This requirement is designed to prevent promotion or indirect sponsorship by a manufacturer/sponsor of its range of medicines or of a single medicine.***

2. Set out in the box below are examples of the promotion of the sale or use of a medicine that would contravene clause 7. Some examples are of the promotional presentation or description by price information, and others are of information accompanying price information (eg examples (d) and (g)).

(a) Description

Using terms such as the following to describe a medicine:

(i) adjectives such as "new" or "improved" to describe characteristics of the medicine; or

(ii) adjectives such as "small", "large" or "jumbo" to describe the pack size; or

(iii) terms indicating the predicted length of supply, such as "one month's supply" or "thirty normal doses".

(b) Pack price

Using terms that promote the purchase of particular quantities or multiple packs, such as "two for one", or "save on the 100 tablet pack" or that indicate that the price of the medicine is particularly cheap eg "now only".

(c) Text type

Providing the name, description or price of a medicine in text that is bolded, italicized, of a different colour, font or size, or in any other way distinguished, from the remainder of the price information text.

(d) Promotional initiatives

Offering rewards or bonus points, or including price information in any catalogue or other document that promotes rewards or bonus points.

(e) Price comparisons

Presenting the price information in a way that allows for the promotion of price comparisons, particularly between:

(i) normal price and "members" price, and/or

(ii) other retail pharmacy outlets,

for example by statements such as "we are the cheapest" or "we will not be beaten on price".

(f) Graphics

Using a border, colour or some other means of distinction, to highlight a medicine, or a range of medicine.

(g) Duration of offer

Using terms such as "today only" or "this week only" to describe the time period during which medicines referred to in the price information can be obtained at the price referred to in the information. Only the term "price/s valid until" is acceptable.

8 Price information to include a sufficient number of products

(1) Price information must include a sufficient number of medicines, from three or more sponsors, so that no promotional emphasis is given to any medicine referred to in the price information.

(2) Where a pharmacy marketing group publishes price information which includes both a PBS subsidised medicine with a brand premium or therapeutic group premium and their own generic product, that information must include at least one other bench-mark price brand of that medicine in addition to their own product (where such products exist).

Explanatory note: This requirement is intended to prevent any misleading implication that the pharmacy marketing group's product is the only bench-mark price product.

9 Description of medicines

(1) Medicines must be described in price information using:
(a) the brand name of the medicine; or
(b) if there is no brand name, the name of the sponsor of the medicine and the names of the active ingredients of the medicine as they appear on the Australian Approved Names List for Therapeutic Substances.

Explanatory note: The two options for describing medicines by brand name or sponsor's name are provided because some medicines (eg some generic medicines) may not have a brand name, but all medicines on the Australian Register of Therapeutic Goods will have a sponsor. The names of the active ingredients of the medicine will need to be provided where the medicine is described by the name of its sponsor. This does not preclude also describing branded medicines using the names of active ingredients.

(2) Price information must include the strength of the active ingredients as they appear on the label of the medicine if there is more than one strength; and
(a) the form in which the medicine is presented (eg tablets, capsules which must be included in the Australian Register of Therapeutic Goods); and
(b) the pack size - only sponsors pack size is permitted; and
(c) the price - prices for multiple packs are not permitted.

(3) The need for a prescription for a particular medicine may also be indicated.

(4) Medicines subsidised under the Pharmaceutical Benefits Scheme must be identified and the total purchase price must be specified as the general or concessional price.

(5) Price lists which include a Pharmaceutical Benefits Scheme subsidised medicine must include an indication that the price is subsidised by the Australian Government, and only applies when prescribed for the medical conditions listed in the Pharmaceutical Benefits Scheme Schedule for that medicine.

Explanatory Note: Some products on the PBS are only available on restricted benefit at the subsidised price for the treatment of certain medical conditions.

10 Information to accompany price information

Price information must be accompanied by the names and contact details of the retail suppliers from whom the medicine referred to in that price information may be obtained at the listed price.

The contact details referred to in subclause (1) may only be provided with the agreement of the person to whom they refer.

11 Presentation of price information

11.1 Format

Price information must be provided in a legible and consistent format.

11.2 Alphabetical order

Medicines must be listed in alphabetical order using their brand name, or names of their active ingredients. Medicines must be set out in alphabetical order in each list according to only one of these classifications. More than one alphabetical list may be provided at the same time.

Explanatory note: The Galbally Report recommended that sponsors not be able to place price information. To allow a price list of medicines in order by sponsor name would circumvent that recommendation.

11.3 Inclusion of non-prescription medicines

Medicines that are un-scheduled or that are included in Schedule 2 or Appendix H of Schedule 3 of the SUSDP, may be included in price information together with medicine to which this Code applies provided they are described and presented in a way that complies with clauses 7, 10, 11 and 12 of this Code.

11.4 Medicine grouping

(1) Subject to subclause (2), medicines may be grouped according to the Schedule in the SUSDP in which they are included, provided that:
   (a) there are a sufficient number of medicines from each Schedule in each grouping so that no promotional emphasis is given to any one product; and
   (b) there are medicines from three or more sponsors included in the price information.

(2) The following medicines may be grouped according to indication, provided that no grouping includes any medicines to which this Code applies:
   (a) unscheduled medicines;
   (b) medicines that are included in Schedule 2; and
   (c) substances in Appendix H of Schedule 3.

12 Information that may not accompany price information

12.1 Indications

A medicine referred to in price information cannot be accompanied by, or be located in proximity to, the giving, implying, or referring to other sources of, information regarding approved or unapproved indications, diseases, conditions, ailments or defects so that a reasonable person could infer that the medicine will cure or alleviate those diseases, conditions, etc.

12.2 Illustrations

(1) Price information of medicines cannot be accompanied by, or be located near, pictures, photographs or illustrations of any of the medicines to which this Code applies.

Explanatory note: Set out in the box below are examples of the location of pictures, photographs or illustrations that would contravene paragraph 12.2(1).

(a)	a picture of a medicine listed in price information (eg of a pill, bottle or pack) that is in the same catalogue put out by a group of pharmacists as the price information list.
(b)	A photograph of a medicine listed in price information in a newspaper that is on the adjacent page or the next page following the list.
(c)	A price information list located within a 'background collage' of illustrations of medicines to which this Code applies.

(2) Subclause (1) does not preclude price information from being accompanied by pictures or graphics in relation to medicines to which this Code does not apply where those pictures or graphics:

(a) comply with all the relevant legislative requirements; and

(b) are not positioned so that it is implied/ imply that they are pictures of the medicines included in the price information or that they relate to those medicines.

12.3 Other sources of information

(1) Price information cannot be accompanied by, or located in proximity to, an article, editorial, testimonial or other similar material covering any of the medicines referred to in the price information, or substances included in those medicines, so that a reasonable person could infer that a particular medicine in the range of medicines referred to in the price information is being promoted over any other medicine.

(2) Price information cannot be accompanied by any reference to other sources of information on the medicines, or substances included in the medicines, that are referred to in the price information.

12.4 Complaints

Publication of a price list which includes prescription medicines and certain pharmacist only medicines which does not comply with this Code will be considered to be an advertisement for those therapeutic goods. Complaints will therefore be dealt with through the usual complaint processes for advertising of medicines. Any person may submit a written complaint about price lists thought to be in breach of this Code with the Complaints Resolution Panel for advertisements published or broadcast in Australia.

Explanatory Note: Under the proposed model for a trans-Tasman regulatory scheme for advertising of therapeutic products developed by the Interim Advertising Council, complaints would be handled by a Central Complaints Panel in Australia.

Schedule A

Price Information may not be provided for the following substances, or preparations containing those substances:

(Explanatory Note: this list is currently blank and is to be developed in consultation with stakeholders)

Attachment B

REPORT OF THE COUNCIL OF AUSTRALIAN GOVERNMENTS REVIEW OF DRUGS, POISONS AND CONTROLLED SUBSTANCES LEGISLATION.

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 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 APMA Code of Conduct and the press release is accompanied by the CMI for the product;
• where such advertisements comply with the Standard for Informational Price Advertising and Publication of CMIs (see d) below); and
• where Commonwealth, State and Territory governments decide to include information about specific products as part of a public health education initiative and have authorised the content, placement, timing and nature of such informational advertisements.

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

For price advertising:
• how permitted advertisements can be presented including:
- the maximum print size;
- must be part of a list of medicines from multiple medicine manufacturers;
- must not be juxta-positioned with information such as articles about the substance in the medicine; and
- should not be accompanied by illustrations or pictures;
• the content of the advertisement (name, brand, strength, pack size and price);
• who can place the advertisements (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 CMIs, that the information:

• is presented in its entirety in the form required by *Schedules 12* and *13* of the Therapeutic Goods Regulations;
• is not embellished in any way or accompanied by pictures; and
• is not juxtapositioned with other information, such as articles about the substance in the product; and
Such other matters, as the National Coordinating Committee on Therapeutic Goods (NCCTG) considers necessary.

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

Attachment C

Stakeholder Submissions to the Price Information Code of Practice and Regulatory Impact Statement Consultation

Group	Stakeholder
Consumers	Australian Consumers' Association (ACA) *
Pharmacy	The Pharmacy Guild of Australia (PGA) Pharmacy Board of the Northern Territory * Pharmaceutical Society of Australia (PSA) The Pharmaceutical Council of Western Australia* Pharmacists Board of Queensland*
Industry	Australian Self-Medication Industry*
GPs	Australian Divisions of General Practice (ADGP) The Royal Australian College of General Practitioners (RACGP) *
Government	Drug Programs & Population Strategies Branch, South Australian Department of Human Services Health Department of Western Australia Drugs, Poisons and Therapeutic Goods, Queensland Health Pharmaceutical Access and Quality Branch. Australian Government Dept of Health and Ageing ACT Health*
Website mail order pharmacies	Pharmacy Direct

Those respondents marked with an * have confirmed their support for option 3 of the RIS.

Attachment D

Key Issues Raised by Stakeholders from the Consultation Process

Issue: Coverage of PBS listed medicines by the Code

The Pharmacy Guild of Australia were concerned about inclusion of medicines listed on the PBS as unsolicited price information may be confusing for consumers who do not understand the complexity of the pricing of medicines. However, other stakeholders submitted that all S3 (except those in Appendix H of the SUSDP), S4 and S8 medicines should be covered by the code. Medicines subsidised under the PBS should be included, and all premiums payable should be included so that the consumer is aware of the "total cost at the cash register" and not be faced with a series of confusing add-ons at the time of purchase.

Response:

As outlined in the Regulatory Options section, price information will be defined as information about the cost to consumers "at the pharmacy till', that is, after subsidies and any applicable premiums and concessions have been applied.

Issue: Involvement of health professionals in the regulatory process

The Pharmacy Guild of Australia was concerned about the level of involvement of pharmacists as experienced health professionals in the regulatory process.

Response:

Options for involving pharmacy boards in the regulatory process were initially explored but were not pursued further due to complexity of regulation and resourcing implications. It is expected that where the Complaints Panel considers a complaint about a price list that the Chair of the Panel will ensure that membership of the Panel includes appropriate expertise in pharmacy.

Issue: Enforcement of the Code

Several stakeholders mentioned that penalties should be in place and enforced so that the spirit of the Code is maintained and consumers are not subject to dubious promotional practices.

Response:

The new Code will be a legislative instrument underpinned by the Australian-only part of the trans-Tasman legislation. With the commencement of the new legislation, price information which is in breach of the Price Information Code of Practice will be considered illegal advertising in Australia and will be subject to the processes and penalties for illegal advertising.

Issue: Price as an inappropriate component in the selection of medication

Whilst price may be a component of the decision to purchase medicines, some stakeholders submitted that for all prescription medicines and pharmacist only medicines, decisions to purchase medicines should not be made on price information alone and that quality use of medicines is best supported if the person's doctor or pharmacist discusses the price of the medicine at the point of initial prescribing, dispensing or supply.

Response:

The Code applies to medicines listed in Schedule 3 of the SUSDP (other than those included in Appendix H), the supply of which requires advice from a pharmacist, and Schedule 4 medicines, which require a prescription, therefore the level of professional intervention required in the supply of these products should ensure that price is not the only information used in the decision to purchase.

Issue: Promotion of medicines that are of higher risk of abuse or misuse.

Comments received from some stakeholders emphasised the need for particular caution in permitting price information to be published on medicines that are at higher risk of abuse or misuse.

Response:

Particular note was made by the NCCTG in their meeting of 9 September 2004 of stakeholder comments regarding the need for particular caution in permitting price information to be published on medicines that are at higher risk of abuse or misuse. The Code includes provision for Schedule A as a list of substances which cannot be included in a price list, where it has been demonstrated that inclusion on a price list will lead to a higher risk of abuse or misuse. However, it was agreed that these concerns needed to be balanced against the potential advantage to consumers with a legitimate need for these products should publication of prices lead to a decrease in price.