TGA THERAPEUTIC GOODS ADMINISTRATION

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Commonwealth Department of Health and Aged Care

Labelling project 99/00

Effective by design

A discussion paper on possible reforms to the regulation of the labelling of medicines in Australia

April 2000

You are invited to comment

All interested parties are invited to respond to this paper. Specific questions and recommendations are placed within the text as a guide for responses. However, while answers to these will be helpful to us, your responses do not have to be restricted by these.

Please send submissions to:

Labelling Project 99/00
Review of Drugs and Poisons Legislation Branch (MDP88)
PO Box 100
WODEN ACT 2606

Submissions will normally be regarded as public documents. If you wish any material to remain confidential, please identify this material and provided the basis for its confidential nature.

Because comments on the matter of moving warnings on medicine labels out of the Standard for the Uniform Scheduling of Drugs and Poisons is required to feed into the Review of Drugs, Poisons and Controlled Substances Legislation, but stakeholders may need more time to consider the other issues, it is necessary to split the comments deadline dates.

Closing dates for submissions:

Friday 26 May 2000 for comments on SUSDP warnings movement to therapeutic goods legislation

Friday 23 June 2000 for comments on the paper as a whole

Contents

Summary

Labels make an important contribution to the safe and effective use of medicines. The labelling of medicines is regulated to ensure that labelling is of a sufficient standard to make that necessary contribution.

The Therapeutic Goods Administration has initiated a Labelling Project in recognition of the problems with the current system of regulation of labelling. The TGA was asked also to consider taking label warnings out of the SUSDP and adopting them under therapeutic goods legislation. Industry finds the labelling requirements complex and consumers seek better and more understandable information from labels. The regulations may not only be costly to industry, but may also impede industry in meeting the objectives for labels in supporting safe and effective use of medicines. A check of the current system to ensure it meets the benefits originally sought, for handlers or users of medicines, is perhaps overdue.

This discussion paper has been prepared for a wide consultation process to obtain the best solutions for these problems. We need information on the costs and benefits of the current system and for predicting costs and benefits of any changes. Under competition policy the objectives of the regulation must be clearly identified to assess benefits. In accordance with best practice in standard setting, the minimum necessary regulation should be used to reduce costs.

Labels are intended to be the first line of communication with all users. The three broad categories of labels are: labels for consumers of over-the-counter medicines, labels for dispensers and administrators of prescription medicines and labels for dispensed medicines for use by consumers. The current requirements could be working counter to achievement of best communication for safe and appropriate use of medicines (see 3.7 **Effective Communication**). There are indications that poor labelling of prescription medicines contributes to errors in dispensing and administration. However, in designing the regulation for labelling, we have to be aware of the limitations of labelling in the supporting the safe and effective use objective.

The first question that we want to clear about is what can we expect labelling to achieve. The role of labelling may sit somewhere in the risk management of the supply of medicines in the community, but we must accept that labelling cannot solve all risk issues.

Issues

The issues linked to costs are:

- the current complexity of labelling regulation;
- the capacity for taking warnings from the Poisons Standard (Standard for the Uniform Scheduling of Drugs and Poisons, SUSDP) to the Commonwealth therapeutic goods legislation;
- the relationship between regulation of claims in advertising and regulation of labelling;
- social costs of poor use or choice of medicines; and

- international trade issues, particularly harmonisation with New Zealand, including the use of labels to reduce or remove a poison classification for a substance, which is known as reverse scheduling.

The issue which is linked more closely to improving the benefits is:

- how to support more effective labelling, possibly through regulation which sets out the outcomes to be achieved (performance-based regulation) rather than prescription of the detail which may not be linked to achieving those outcomes.

Issue 1 Complexity

Commonwealth labelling requirements for medicines are currently derived from multiple sources, including requirements specifically for medicines and requirements from additional legislation such as occupational health and safety and Customs and Trade Practices. The documents that must be referred to include:

- the Therapeutic Goods Regulations,
- the Therapeutic Goods Orders,
- the Poisons Standard,
- the Advertising Code and
- other guidelines.

In addition, State and Territory legislation may apply.

All industry associations deplore the multiple sources of requirements for labelling and seek consolidation into one document. The Consumers' Health Forum also noted the lack of access to what the requirements are.

One approach to consolidation of the different sources of requirements is to link them within a Guideline document. Another is to draw the requirements into one legislative system. This would be helped by the movement of Poisons Schedule requirements to the therapeutic goods legislation. The paper recommends that the labelling requirements which apply to sponsor labels be included in the Therapeutic Goods Act. Dispensing labels would remain under State and Territory Poisons legislation.

Issue 2 Warnings out of the Poisons Schedule

The National Drugs and Poisons Schedules Committee (NDPSC) asked the Therapeutic Goods Administration (TGA) to consider the possible means of taking the warnings for medicines out of the SUSDP. Currently, the allocation of a substance in a Schedule may be associated with requirements for warnings in Appendix F of the Poisons Schedule, Appendix K and/or the warnings, which qualify a classification and reduce or remove a schedule classification (reverse scheduling). (e.g. vitamin A)

These warnings are given effect by incorporation into State and Territory law and Therapeutic Goods Order 48 also gives recognition to these warnings.

To make this change, a mechanism to require the warnings and a means of maintaining those warning requirements has to be found. It may be more efficient if these functions were incorporated into the evaluation processes for medicines. Under the current system, there is

potential for duplication of effort by the NDPSC and the TGA. Both undertake evaluations of medicinal substances and make decisions for the safe and efficacious use of medicines.

The discussion paper recommends that the TGA should take the responsibility for all labelling as integral to its responsibility for the quality, safety and efficacy of medicines. This means that the TGA may need to engage the appropriate expertise and processes, to take over the administration of all warnings, including those currently in the SUSDP, in order to coordinate and rationalise this area of label requirements.

There are implications for the States and Territories in removing warnings for medicines from the SUSDP. For example, their references to the SUSDP would become insufficient to include warnings for therapeutic goods not covered by the Therapeutic Goods Act 1989. A reduction in uniformity would occur unless the legislation adopts the Commonwealth Act by reference or alternatively, requires such products to be in the ARTG before being supplied in that jurisdiction.

Issue 3 Claims in advertising and labelling

A label is an advertisement in so far as it may promote a product for sale. Nonetheless, a label is regulated differently from advertising. Indications as claimed on labels are treated differently from claims in advertisements, in that the exemptions for labels, from prohibitions in the Advertising Code, are based on different criteria. Provided an indication is approved after evaluation of the efficacy, the Secretary may grant an exemption from the Advertising prohibition for that indication to be included on the label, if it is necessary for the appropriate use of the good (Regulation 9). An exemption for wider advertising claims (clause 4 TGAC) must pass the additional criterion of whether it provides a public good.

The process and criteria for acceptance of claims under the new advertising regulation system are being clarified separately from this labelling review. Acceptance of claims on entry in the Australian Register of Therapeutic Goods, permitted claims on labels and the consequent permitted advertising is of pertinence to the labelling project.

Label requirements could be regulated separately from advertising appearing on the label if there were clear demarcation rules between the two. All advertising claims on the label, as opposed to claims made in the Register for the product, could be regulated as for other advertising, with exemptions and complaints handled by those mechanisms. The paper recommends that the demarcation be clarified.

Issue 4 Harmonisation and international trade issues

Removal of the impediment to harmonisation with New Zealand, occasioned by the use of reverse scheduling, could be achieved with a shift to a similar system as New Zealand (i.e. for labelling controls through the registration process). As for the other warnings in the Poisons Schedule mentioned above, an expansion of the evaluation process within TGA may be required.

We are particularly interested in removing any unnecessary labelling requirements for dietary supplements from New Zealand which are otherwise eligible for inclusion in the Australian

Register of Therapeutic Goods for supply in Australia. Some International trade issues such as this may be resolvable with performance-based labelling regulation.

Issue 5 Basing the regulation on the required performance of a label

Performance-based regulation emphasises intended outcomes rather than the means of achieving those outcomes. Competition policy recognises the public interest, which also forms the basis for the object of the *Therapeutic Goods Act 1989* under which labelling requirements are made. Quality labelling is intrinsic to the quality use of medicines and some mandatory elements can always be justified, but the design of labels is as important as the content for the label to be an effective tool. Performance-based regulation that promotes better design of labels is worthy of consideration.

In setting a performance standard we have to be clear about what we expect from labelling and what the desired outcomes are. We also need to be clear about the limitations of the role of labels. The aim is to have quality and safe use of medicines regardless of their type. The discussion paper recommends that regulation of labelling be consistent with the level of risk anticipated, and reduce any specific risks associated with each category of medicine (prescription, non-prescription registered, non-prescription listed).

There has been sufficient research work to support the hypothesis that readability and comprehension can be significantly improved with changes to design (some studies are discussed in the paper). Whether it necessarily follows that performance-based labelling, which does not prescribe how the outcomes are to be achieved, is the best way to take advantage of effective communication research to improve design is open to debate. However, if labels are to contribute to the quality use of medicines, it is essential that legal requirements support effective communication.

The APMA does not support performance-based regulation of labelling for prescription medicines, because it regards this approach as only applicable to potential improvements of consumer comprehension of warnings. Warnings to consumers on sponsor labels of prescription medicines are limited. As mentioned above, labels of prescription medicines are generally tools for communicating with professionals. Labels added by the dispenser are intended to provide information for consumers. However, performance-based labelling could be used for the approach to the overall design of the label, not just the expression of warnings, which may, in any case, be added to the dispensing label. The overall design is important for communication to all users, professional and consumers and these groups may benefit from the establishment of a clear statement of the performance sponsor labels are intended to achieve.

Both PMAA and CHC whose members supply non-prescription products for self-medication, involving greater reliance on the label information, support performance-based labelling in some form or other for their products. Performance-based labelling is intended to provide flexibility without reducing the level of regulation.

There have been several reviews in which performance-based regulation was considered. The Industry Commission (1995) recommended performance based-labelling and the Consumer Affairs Division of the Department of Industry, Science and Tourism considered the issues of performance-based labelling in a study, including therapeutic goods, and prepared a draft report including the problems with a prescriptive approach (not finalised).

The recent review of analgesics highlighted the need to consider performance-based labelling as a better approach, for circumstances in which consumer comprehension and willingness to take note of warnings is important for safety in the community.

Each category of medicine needs to be analysed separately for effective labelling requirements. Consumers of prescription medicines may be moderately well served, in being provided with information for safe and effective use of medicines, by Consumer Medicine Information leaflets as well as by prescriber and pharmacist counselling. Consumers of pharmacist-only medicines have opportunities through labelling and the retail pharmacist to obtain appropriate and sufficient information. Consumers of listable and S2 scheduled medicines should be assumed to have only the information currently provided on the labels.

Prescription medicines

- Little change may be necessary for sponsor labelling responsibilities for consumer use, but requirements for dispensing labels regulated by the States and Territories need to be taken into account in assessing the overall result for professional users and consumers.

- Some recommendations such as for removal of competition between the sponsor label and the dispensing label and more attention to be given to the naming process and branding for medicines are made in the paper.

- Help from stakeholders is required in clarifying the problems and suggesting improvements for identifying medicines by professionals in institutions, especially in critical situations.

Non-prescription registered medicines

- The evaluation of individual non-prescription medicines as part of the pre-market registration process allows for labels to be assessed for compliance with the Standard.

- The PMAA anticipates that testing of performance could be done by category rather than by individual product.

- By the use of examples in the Registration Guidelines, acceptable pre-tested label designs could be given to indicate acceptable labelling. The registration system provides a measure of flexibility where departure from any prescribed requirements can be evaluated.

Non-prescription listed medicines

- It is difficult to establish a performance-based process scheme for listed medicines because they are included in the ARTG with a self-assessment process with respect to labelling.

- Nonetheless by use of the Performance Standard and Guidelines, regulation of Listed product labels for best design elements can be introduced without requirements for costly testing by the sponsors in this sector.

- However, for a fee, sponsor election to use variations from prescribed requirements could be cleared prior to listing. Suggestions for meeting other concerns of this sector are given.

These approaches to the different categories are incorporated in the amendments to the Regulations and the development of Orders and Guidelines as discussed below.

Proposals

This paper puts forward a recommended proposal as well as some options for handling the different concerns and issues. There is an emphasis on allowing for different requirements for different categories in a risk-based approach where self-medication carries additional risks. They have been prepared using maxims derived from the recommendations put forward in the discussion paper.

These maxims can be summarised as follows:
- the TGA is responsible for all labelling items (other than dispensing labels);
- outcomes for labelling in relation to quality use of medicines should be stated in the legislation;
- a risk-based approach is appropriate allowing for different labelling requirements for different categories of medicines;
- regulation should facilitate effective label design;
- consolidated labelling requirements should be implemented to improve cost-effectiveness; and
- labelling requirements should take product user interests as priority.

A recommended proposal for all labels other than dispensing labels is formulated from these options.

Scope of labelling regulatory system

Option 1.1 (Status quo)
Keep the current definition of label such that a label must comply with both labelling and advertising regulation. This would retain the current confusion over indications, claims, advertising and labelling statements of purpose.

Option 1.2
Differentiate the "label" information from advertising on the label leading to clear demarcation of applicable regulation i.e. define "label" according to a certain set of information and all else is advertisement. This would allow for the possibility of the TGACC administering the regulation for those parts of the label seen as exclusively an advertisement.

Action required

The Act would need amendment to redefine "indications" to differentiate from "claims". The amendment would distinguish between registered indication and listed good claims in relation to those indications (see 3.3 **Claims: advertising and labelling**).

The label claim would be the indication as included in the ARTG. An **advertising claim** is any extension or variation of the accepted **ARTG claim** and 'representations' can include pictures and symbols with the claim.

The Regulations may need amendment to make this clearer with respect to "other advertisements" and to ensure that the presentation of label and advertisement do not conflict.

Amendments to the legislation to resolve issues of warnings and the operation of a performance-based scheme

Option 2.1 (Close to status quo)

Improve the efficiency of the system by bringing all labelling requirements together.

Retain the prescriptive emphasis of the current system, with some increased use of alternatives to precise wording. Prescriptiveness provides certainty for industry in that little interpretation of the regulations is required, but prevents a flexible approach. For this option, performance outcomes would not specified in the legislation, but use of the phrase "or words to that effect" to state requirements at certain points could be used. This would allow some degree of flexibility but would provide no guidance on desired outcomes.

Action required

Either:

> Make amendments to the Regulations, possibly to the Schedules, to include the required warnings from the SUSDP and other documents. This would be a direct transfer from other documents with a identification of additional points for inclusion of " or words to that effect" where possible. Warnings would be maintained and developed by TGA through normal consultative processes.

or

> Leave warnings in SUSDP but reference made in Regulations. The SUSDP is using the flexibility of "or words to that effect" for some warnings. The NDPSC would remain responsible for developing and maintaining those warnings.

In addition, retain TGO48 (as amended 2000 with some points of flexibility). Additional amendments to TGO48 giving reference to warnings required as per Schedules to Regulations (if no longer included in SUSDP) would be required.

Option 2.2 (Prescriptive, but mandated elements based on best communication design)

This option would be based on the recently adopted FDA scheme for OTC medicines.

Action required

A Therapeutic Goods Order would be prepared, setting out the requirements. Note also that for this option, the 'label' information would have to be demarcated from other elements of the label such as promotional material.

Option 3 (Performance-based scheme)

Establish an overall performance-based scheme using a statement of desired performance, applicable to the whole label and to warnings as included in the Schedules to the Regulations or in Therapeutic Goods Orders. Labelling and advertising would be separated but must work together to achieve the desired outcome.

Action required

The Regulations would need amendment to include the performance statement and the level of flexibility in setting out and wording with respect to warnings listed in the Schedules.

A new Therapeutic Goods Order for a performance standard would be established, including expression of warnings. This standard would be supported by a Code of Practice for testing against the performance criteria and Guidelines with the level of detail currently in TGO48. Such Guidelines could more easily be amended than Orders but would be administered with advice from the Therapeutic Goods Committee's subcommittee for labelling. See figures 1 & 2 for an overview.

The multiple parts of this scheme could be regarded as a package for distribution together and seen as a way of dividing the regulatory parts according to level of detail and ease with which they could be amended. Alternatively all guidance could be placed in the Performance Standard to avoid the multiplicity of documents.

Something similar to the FDA scheme could be used as a basis for requiring better design elements in the Guidelines.

Other considerations

Any potential for co-regulation for labelling should be explored. For example, the CHC mentions the co-regulatory process for advertising. In consideration of the artificial division between advertising and labelling for point of sale information, one of the proposals in this paper is to more clearly delineate labelling from promotional material on a container/package and leave promotional material for regulation as for advertising.

Finally, the TGA will need to consider administrative changes to mirror legislative changes, such as a central labelling coordinator. There will be set up costs to establish the scheme, but ongoing administrative costs should be similar to the current system, and the Listing process costs should decrease. There may be additional costs for industry if they wish to deviate from the Guidelines.

Summary Proposed Recommendations

That:

1. Therapeutic Goods Act 1989 already provides the power to regulate labelling with this scheme but an amendment to the definition of “indication” will clarify the confusion with “claims”.

2. Therapeutic Goods Regulations 1991be amended involving insertion of a statement of “required representation with the label” giving performance principle and inclusion of all warnings in a Schedule.

3. Therapeutic Goods Order NoX be developed for a Performance Standard to be mandatory i.e. labels must achieve certain outcomes.

4. Guidelines be prepared for the detail for compliance with the Standard. For Listed products, adherence to the Guidelines will be deemed compliance with the Standard, while any variations would be possible only with pre-approval and submitted evidence of testing against the Standard. Such testing could be evaluated as part of the normal Registration process.

5. Code of Practice be prepared for detailing the testing against the Performance Standard.

Introduction

The TGA believes it is timely to review labelling regulation, which is complex and problematic for industry and may not provide the best outcomes for consumers.

The objective of the project is:

To develop more effective and efficient labelling regulation that fosters safe and appropriate use of medicines

This project is a in-depth, broad review of labelling regulation for medicines and its administration, designed to ensure we have a clear view of what labels are intended to achieve and that the regulations support that achievement with minimum costs.

Why are we doing this project?

The labelling project will enable important reform of the labelling regulations for both prescription and non-prescription medicines. Labelling plays an important role in the safety and quality of medicinal products and contributes to their effective use. The regulations in place, intended to maintain this role, however, may not be cost-effective. The project is being undertaken to identify the costs and benefits of the current regulatory system to develop better alternatives.

The project arose in part from the request from National Drugs Poisons Schedule Committee (NDPSC) for the TGA to consider moving the warnings and safety directions for therapeutic goods currently in the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) to the auspices of the TGA under the *Therapeutic Goods Act 1989*. The TGA decided that to undertake this task, it was necessary to review the whole of the framework for the regulation of labelling, because of the recognised complexity of current requirements and multiplicity of sources of regulation and guidelines.

Labelling regulation has limited implications for competition. However, labelling does impose costs on industry and professionals which are passed on to consumers and government (for subsidised medicines). In line with Government policy, we need to ensure that any restrictions are the minimum necessary to achieve the benefit desired.

What is involved in undertaking the project?

Undertaking a review of regulation follows the process of:

- identifying the problems with the current regulation;
- specifying the objectives of the regulation;
- identifying the likely costs and benefits of changes compared with those of the current situation; and
- comparing alternative measures for addressing the problem and an assessment of those measures.

The project is considering:

- cost-effectiveness of the controls and their alternatives,
- the complexity of the regulation,
- National Competition Policy,
- best practice in setting standards and regulation,
- the relationship of advertising regulation to labelling regulation,
- harmonisation objectives,
- the role and responsibilities of the State and Territories, and
- other relevant legislation.

Consultation with stakeholders is an essential part of this process. Hence, this discussion paper was prepared to elicit responses from stakeholders on the issues and options available, and this paper was itself prepared with information informally gathered from industry associations, consumer organisations and States and Territories.

This discussion paper puts forward proposals for reform in the regulation of the labelling of medicines. It discusses the reasons behind these proposals and the expected benefits. Your comments on any part of this paper are welcome. There are questions and recommendations throughout the text to be used as a guide in making submissions.

What can I expect in reading this paper?

The purpose of this discussion paper is to expose the current problems and propose solutions so that readers may give feedback on a new regulatory system for the labelling of medicines supplied in Australia.

The discussion paper is arranged in three sections with Appendices for reference to further detail if required:

1. First, the reasons for exploring possibilities for change are given.

2. The proposals for changes are then presented for stakeholder comment. The proposals include possible changes to the existing regulatory tools and possible new documents such as guidelines which may be necessary for a completely new system. Briefly, the changes address the need for consolidations of warnings, the consideration of performance (outcomes)-based regulation and the differences in use of the different categories of medicine.

3. The last section (Issues and Concepts) provides the information and arguments behind the proposals for those who wish to see more detail.

1 Why is there a need for change?

The environment for change

Legislation should not restrict competition unless it can be demonstrated that the benefits outweigh the costs and the objectives of the legislation can only be achieved by imposing requirements that have the consequence of restricting competition. Labelling requirements need to be tested to confirm that they achieve consumer health benefits sought. (see 3.**1 The policy environment**)

A change in regulation is generally required to meet changing circumstances and/or to rectify or improve the current system. Circumstances for the regulation and supply of medicines are indeed changing and problems with the current system for labelling have been identified.

Problems and concurrent change

Several activities are coinciding to create the timeliness of this review of the regulation of labelling of medicines: the Review of Drugs, Poisons and Controlled Substances Legislation; the establishment of the NDPSC as a statutory committee and the granting of legal status of the SUSDP under the *Therapeutic Goods Act 1989*; the Review of advertising regulation; and the developments towards harmonisation with New Zealand. It is also a time of recognition that to truly address current problems, a broad review is required which starts with the basic questions and sets up a framework for ensuring the detail satisfies the overall principles.

In examining possibilities for change, it is the balance of benefit for the cost involved that is important. The project has to clearly identify what outcomes we seek from labelling, and thus from the regulation of labelling, before we can be in a position to judge either efficiency or effectiveness.

A cost is any adverse impact on individuals, groups or government as a result of the labelling requirements. Costs may be direct or indirect, such as the costs of hospitalisation of someone poisoned as a result of poor labelling. A benefit may similarly be conferred on individuals or groups and be direct or indirect. A benefit for labelling would be safer use of medicines.

- What market failure does labelling regulation address?
- Does the label still hold the same pivotal role in supplying consumers with sufficient information to choose and use their medicines appropriately and safely?
- Have the increased use of the Internet, healthcare magazines, and electronic media for discussion of substances and their uses and multimedia advertising reduced the importance of the label?
- What are the problems with the current regulations and their administration?
- Are we looking at different problems for different sectors of the industry requiring different solutions?
- What are the costs for industry, for government, professionals and consumers? and
- Can the regulations be improved for the users' maximum benefit from labelling?

The asymmetry of information for consumers

The lack of access to the same amount of (and ability to interpret) information about medicinal substances and products by consumers compared to manufacturers and health professionals is an asymmetry of information. Labelling is supposed to partially address this asymmetry to enable consumers to make reasonable decisions at the time of purchase and subsequently to use the products appropriately.

The design of the label as well as the content is important. In establishing labelling regulation we must identify what is truly essential to be placed on a label for effective and safe use and ensure that the regulation does not impede the achievement of effective design in communicating those essentials. Rogers et al. (1995) believe that the information designer is not concerned with a single feature, but in bringing together a variety of elements which together produce the desired useability outcome.

It is expected that the trend towards a greater interest in self-medication will continue. The consumer is increasingly reliant on labels when deciding to purchase and when electing to use without professional help. Where the professional intervention takes place or is required to take place, the importance of the label information is reduced and may simply be reinforcement of the professional advice.

Therefore, labelling should address the different risks associated with the different categories of medicines. The risks are related to whether the decisions of end-users in the use of the product have been guided by professionals and/or consumer information leaflets, as well as the nature of the ingredients and the purpose for use of the medicine. For all take-home medicines the consumer takes the responsibility for use and storage once purchased. Labels should support this responsibility (see 3.2 **The role of labelling**).

Prescription medicine issues

While dispensing labels (regulated under State and Territory law) provide essential and customised information, and consumer medicine information leaflets are becoming increasingly available, the sponsor's label on a prescription good is also important to the consumer. The sponsor label is extremely important for appropriate handling and use for situations when no dispensing label is involved. An example is in the correct selection of the medicine by a professional such as the pharmacist when dispensing.

Problems for prescription medicine labelling have been identified and this project is an opportunity to gather suggestions for improvement. The lack of allowance in some cases for a dispensing label on the package, without covering important sponsor labelling, may require some coordination between State and Territory and Commonwealth laws.

Identification of prescription products by professionals and consumers is crucial to safe use. Confusion in identifying products, arising from either similarities between ingredient names or use of brand image designs which blur distinctions between products of the same company, has occurred. This is a problem beyond Australia's borders but some local solutions may reduce the risks.

Clear labelling is important in minimising errors by health professionals administering medicine in hospitals or other settings. Ampoules for injection have been identified in anecdotal reports at high risk for mistaken identity, leading to deaths.

The Pharmaceutical Society of Australia has been working with the Australian Pharmaceutical Advisory Council and the Australian Pharmaceutical Manufacturers' Association since 1995 to alleviate these problems. A checklist is available for manufacturers when designing labelling and packaging in preparation for dispensers' needs. It appears that further work is required for full implementation of risk management policies by all concerned.

Prescriptive or performance-based regulation for sponsor labels

Content without attention to the design of a label to a higher level of consumer useability is counter-productive. Several studies have addressed questions of effectiveness of words used and overall design to create an effective communication tool for consumers (see 3.7 **Effective communication**). While this work was reported around 1992 to 1995, there has been no incorporation of the results in the way the labelling of medicines is regulated under the *Therapeutic Goods Act 1989*.

Although further research is probably needed, there may be some way to permit incorporation of ideas for better effectiveness of communication into labels without affecting compliance with regulations. If the label can be shown to be more effective, the imperative is to make sure regulation does not impede implementation of this research.

In *Designing better medicine labels*, (1995) the Communications Research Institute of Australia used evidence that different designs could be more effective to support performance-based regulation. Performance-based regulations give specified outcomes but do not necessarily stipulate how those outcomes must be achieved (e.g. labels on substances must be legible and draw the attention of the user to all hazards involved in their use, whereas prescriptive regulation stipulates letter height etc).

Performance-based requirements can set very high compliance standards to protect consumer health and welfare, while allowing manufacturers more responsibility for designing labels that are based on sound consumer research and which meet the readability and information needs of consumers and facilitate effective administration by regulators.

On the other hand, the Food and Drug Administration of the United States adopted a prescriptive approach to ensuring labels were designed for effectiveness. The FDA has made its final rule for the labelling requirements for Over-the-Counter human drugs (March 1999) to establish a standardised format for the labelling. Their intention is to make the labelling easier to read and understand but use a different regulatory approach. The format is based on research into the factors that influence comprehension.

Advertising changes

The regulation of labelling has to be consistent with the regulation of advertising, which has been reviewed recently. The issues surrounding claims made about a product affect both

advertising and labelling. The relationship between the acceptance of indications and claims included in the Register for a good, the permitted claims on the label and the permitted presentation of an advertisement requires clarification. This is particularly so in the light of anticipated new advertising regulation, the revised schedule of listable claims and the reformed ELF process.

An indication is a distinct term from claim, although currently these two terms are commonly used interchangeably. Neither advertisements nor labels are permitted to make reference to any **indication(s**) (specific use of the product) other than what is(are) accepted on inclusion of the good in the Australian Register of Therapeutic Goods (Act, section 22 (5)). However, a **claim** made in promotional material (label or advertisement) has the potential to use extensions of language or imagery whose consistency with the Register indication entry may have to be assessed.

The approval process for advertisements for such extensions within a claim is in place. The process for labels is not so clear.

See 3.3 **Claims: labelling and advertising** for a discussion of the implications arising from the advertising amendments and in particular the effects on the listing of products.

As currently regulated, labelling and advertising cannot be considered as totally separate issues. There may be advantages in clarifying the divide.

International issues

The anticipated harmonisation with New Zealand creates issues for labelling for all categories of product, prescription and non-prescription. The harmonisation of poisons scheduling is impeded by the practice in Australia of including label requirements in the reverse scheduling of substances. Reverse scheduling refers to the system whereby substances in the Poisons Standard attract a lower classification based on qualifications such as pack size, dose size or labelling with warnings (see 3.5 **Harmonisation Objectives).** Harmonisation of the Poisons Schedules means that more products now attract the same level of restriction in many areas.

The ability to trade across the Tasman without having to change labels is a huge cost-saving for industry. The complementary medicines category in Australia is roughly equivalent to the "dietary supplement" category in New Zealand. In addition to discussion about the possibility of regulating these products in a similar manner across the Tasman, separate consideration can be given to labelling for increased acceptance of Trans-Tasman trading without compromising the needs of users in Australia.

It is also appropriate to ensure that Australia is as consistent as possible with the international trends for labelling. Barriers to consistency lie in the different regulatory frameworks between countries and cultural differences in the approach to use of foods and medicines. Points of built-in flexibility in Australia may reduce the problems for importers and exporters of medicines.

Warnings

The National Drugs and Poisons Schedules Committee (see 3.4 **Poisons Scheduling**) has asked that the TGA consider taking the warnings for scheduled substances (included in Appendices, SUSDP) and those warnings involved in reverse scheduling (within a Schedule itself) out of the SUSDP. This would not only involve finding a suitable legal mechanism for them, such as the Labelling Order or Regulations under the Act, but would also involve a shift in administration of those warnings to the TGA.

Other issues with the use of warnings on labels have arisen. It is becoming complex in: decisions for mandating warnings, use of legislation to effect requirements, access to information by industry, and design of effective labels on which warnings will be read and understood. There would be benefits in the centralised administration of warnings in effecting uniformity, coordination of ad hoc requirements and greater possibilities for effectiveness.

Recommended approach

All labelling requirements for therapeutic goods (medicines), other than dispensing labels, should be drawn under the *Therapeutic Goods Act 1989*, (where not part of other general consumer protection legislation such as *Trade Practice Act*), and consolidated for easier reference. They should be administered by the TGA through the processes for evaluation and assessment of products for entry in the ARTG.

The next section sets out proposals to meet the requirements for change.

2 Proposals

2.1 Basis for a new model for regulation of labelling

Maxims

These maxims can be summarised as follows:

- the TGA is responsible for all labelling items other than dispensing labels;
- outcomes for labelling in relation to quality use of medicines should be stated in the legislation;
- a risk-based approach is appropriate allowing for different labelling requirements for different categories of medicines;
- regulation should facilitate effective label design;
- consolidated labelling requirements should be implemented to improve cost-effectiveness; and
- labelling requirements should take product user interests as priority.

Regulatory tools

The regulatory tools which could be used (drafted or amended) in developing a new system of regulation for labelling are:

1. the *Therapeutic Goods Act 19*89,
2. the *Therapeutic Goods Regulations 1990*,
3. the Labelling Standard (Therapeutic Goods Order No 48) or other Order
4. Labelling Code of Practice (none currently applicable)
5. Labelling Guidelines (no legal force)

The legal status of Codes of Practice or Guidelines can be augmented by declaring that conformity with such documents is deemed as compliance with the Standard, or the Regulations, as appropriate.

A Therapeutic Goods Order could be used to establish a performance standard and a Code of Practice could be used for the detail involved in testing performance deemed to comply, and Guidelines for the application of effective communication to label design.

The Regulations can be used to further qualify the goods required to be included in each part of the Register, should this qualification include warning statements on the label. Any requirements for additional information to be supplied with the goods could be included in Regulations. Schedule 2 of the Regulations could be used to declare a required representation or warning for a good containing a substance that would otherwise be poison scheduled or higher poison scheduled.

No additional powers in the Act may be required. The Act currently gives the power to establish applicable standards. However, there may be merit in amending the definition of indication to enable the labelling – advertising elements of the label to be separately regulated.

2.2 Warnings from the Standard for the Uniform Scheduling of Drugs and Poisons

The reasons for moving warnings out of the SUSDP to be directly administered under the Therapeutic Goods Act are:

- for consolidation of different sources, with attendant advantages to industry
- to support harmonisation of scheduling with New Zealand
- to mimic the precedent move of Ag/vet warnings to National Registration Authority (separate guidelines)

Where State and Territories legislation picks up the SUSDP warnings, the State and Territory legislation may need to refer to the Commonwealth Therapeutic Goods Act to provide a uniform approach to labelling of products not covered by the Therapeutic Goods Act 1989.

TGA is already determining some warning statements with advice from Australian Drug Evaluation Committee, Medicines Evaluation Committee and Complementary Medicines Evaluation Committee. This process could be extended to administer all the warnings. The registration process undertaken for prescription and non-prescription OTC can take up the necessary assessment of labelling for a product. Thus the implications of maxim 1 can be undertaken.

Listable products provide a different situation in that they contain no scheduled substances and individual product data are not evaluated on entry into the Register. Assessment of Listable products involves checks against a set of requirements but does not include sighting of the label. There are some substances which are Listable only when certain warnings are included to either de-schedule them or to otherwise satisfy the TGA that the product, in use, containing the substance is sufficiently low-risk. Warnings for listed goods have to be generically designated.

The appropriate regulatory tool has to be flexible for timely changes several times per year. The Therapeutic Goods Regulations or the Therapeutic Goods Orders may be the appropriate tools for developing this system It would also be advisable to establish an agreed process for such amendments to ensure that they occur in a timely manner and with an appropriate level of consultation.

For example:

- a list of warnings appropriate for registrable products containing certain scheduled substances (taking SUSDP Appendix F warnings) in a new Schedule 15. Registrable products could be granted exemptions as appropriate at the time of evaluation; and

- taking reverse-scheduling warnings:

- by making qualifications on substances permitted low-risk only with warnings, in Schedule 4 for Listable substances; and
- including in Schedule 2 Part 2 any required representations for registrable products with certain substances that would be otherwise poisons scheduled.

Any proposed changes to the Regulations with any new warnings or amendments can be Gazetted and then be subject to challenge later as for any Regulations amendment. Gazettal would allow for timely changes. All warnings required for Listable substances could be handled in the same way.

There is a need for consistency between committees and a need for a location within TGA for application for amendments to warnings etc. Perhaps there could be a "central warnings and labelling issues body" within the TGA that could refer a matter to the relevant advisory committee as required.

Does this address the issues?

There is still a need to have a consolidated document eg Guidelines. Perhaps such a document could provide such advice that compliance with it is deemed to comply with the relevant regulation.

Signal Headings would stay with the SUSDP, although the purpose of these needs to be identified in the context of the preferred approach which addresses all user needs, including consumers. The National Drugs and Poisons Schedule Committee does not wish to lose control of Signal Headings, but if they are to be part of the performance standard, they should be shown to contribute to the desired outcome. However, we need to give a clear reference to these from the TGA administered Regs/TGO.

The potential loss of uniformity in States and Territories arising because the *Therapeutic Goods Act 1989*, without complementary legislation at the State level, does not provide uniformity to the same level as does the SUSDP, is an issue (see Implications for States and Territories). Despite the potential for this to be a stumbling block, the TGA is considering the technical options for taking the warnings out of the SUSDP.

- What are the consequences for different stakeholders of this course of action?
- Can costs of regulatory changes be reduced?
- Would templates for evaluation committees provide a mechanism for consistency without being too limiting when devising appropriate warnings?

2.3 What would performance-based regulation look like?

Dispensing labels are not discussed specifically as these will remain under State and Territory legislation

Statement of performance required

Regulation based on a statement of what needs to be achieved must start with just that and with the appropriate level of authority/power. Under Therapeutic Goods Regulations, an additional regulation "Required representation with the label" could be formulated to express the essence of what should be achieved. The statement could be, for example:

In relation to eligibility for inclusion in the Register (Registration or Listing as applicable) a therapeutic good must carry a label with information suitable to meet the needs of users and other affected parties, according to the established standard, in identification of the good, and the appropriate and safe use and handling/storage of the good, but with no information or representation to conflict or confuse with that information.

Performance standard

A performance standard as a Therapeutic Goods Order would be more detailed, and would identify the mandatory elements and the extent of the flexibility allowed in designing those elements. It would give the level of testing required to ensure that the required performance level has been achieved.

Non-prescription product requirements

The mandatory elements on a label of a **non-prescription** medicinal product would include:

Information to enable clear identification of product:
- The name of the product
- List of ingredients
- Manufacturer/sponsor contact
- Batch number and Register number for traceability

Information to enable safe use:
- The intended use of the product, including dosage
- When and when not to use
- When, and when not, to stop using
- Warnings and precautions
- First aid treatment

Information to maintain the quality of the product:
- Where and how to store
- When to discard

Other
- How to discard

Prescription product requirements

The mandatory elements on a sponsor's external label of a **prescription** medicinal product would include:

Information to enable clear identification of product:
- The name of the product
- List of ingredients
- The pharmaceutical category of the product eg antibiotic
- Manufacturer/sponsor contact

Proposals

Information to maintain the quality of the product:
- Where and how to store
- When to discard

Other
- How to discard

and certain warnings

The Consumer Medicine Information (CMI) leaflet will be mandatory for sponsors to prepare by 2002 for prescription medicines. Ensuring that patients receive the CMI is another matter.

Performance criteria

The desired qualities for an effective label to be set down in the performance standard would be:

- legible
- understandable i.e. effectively communication tool
- consumer can readily identify essential elements
- consistent of message
- flexible to allow for marketing needs
- distinctive for different products
- clear of message eliminating confusion

Flexibility in achieving these criteria is permitted, but compliance with the Code of Practice for testing or Guidelines for detailed requirements is deemed to be compliance with this Standard.

Evaluation against criteria (level of testing)

If prescriptive elements are met, then the label is deemed to meet outcomes, but testing is required if the label deviates from these elements.

Broad rules in testing will apply, such as
- subjects must be from groups most likely to have difficulty with labels in general
- at least ten participants should be used
- a second round of testing must be conducted using a different group incorporating the improvements derived from the results of the first round
- an independent arbitrator to provide an interpretation of the results

Reference could be made to established methods of testing of consumer leaflets (see ECC guidelines and *Writing about medicines for people* 2nd edition by Sless and Wiseman) and interpreted for labels in a Code of Practice

Guidelines

The purpose of the Guidelines for labelling of medicines would be to explain or illustrate in detail how to comply with the Performance Standard. The detail would be similar to the

current TGO48. Compliance with the Guidelines would be deemed compliance with the Performance Standard.

The Guidelines could include details of the design of labels required to achieve maximum effectiveness based on communication research. This is further explored below.

Certain guidelines will be applicable to specific categories of medicine based on the role of the label in that category (see **The role of labelling).**

Code of practice for the testing of label performance

The aim of such a Code would be to provide practical guidance for testing that a medicine label not designed according to the Labelling Guidelines nonetheless meets the Performance Standard.

Under a scheme for performance based regulation of labelling, the sponsor is responsible for the testing of a label against the performance criteria, unless the label was prepared according to prescribed requirements for that product, or in some case for that type of product. Such prescribed requirements appear in the relevant Guidelines. Results of testing should be submitted with other required data at the time of registration of the product for evaluation.

The labels of products which are not evaluated on entry in the Register i.e. Listed goods, would have to meet the Guidelines, unless the sponsor of a Listed good wishes to subject the label to performance testing and submit the test results to the TGA.

- If design elements for more effective communication can be conclusively identified, should they be mandated?
- What are the arguments for and against permitting flexibility in design (while still achieving objectives)?

2.4 Do we need to mandate elements of more effective communication for non-prescription medicines?

The emergence of recent communications research has been used as an argument for establishing performance-based labelling. The argument is that the research supports the notion that labels could be more effective if sponsors are not compelled to follow the current prescriptive requirements. It is, however, possible to make use of the results of communications research in mandating the better design elements or basing the Guidelines on these elements, as opposed to allowing sponsors total choice from research findings in meeting desired outcomes. This option may be appropriately applied when there is no evaluation of the product on inclusion in the Register and when sponsors would find the testing of individual designs too costly.

The FDA new Final Rule 1999 prescribes label design based on performance testing (see 3.7 **Effective Communication**) for legibility etc.

FDA model for OTC Medicines

This is considered here only as an example of this approach developed into regulation. There are obviously other results from studies, which could be used to improve communication. In considering the potential for of FDA model for Australia, we have to consider that:

- there are legislative differences for OTC medicines in US, including regulation by use of monographs not individual evaluation;
- the labelling definition in US includes packaging, CMI etc; and
- US places an emphasis on post-market monitoring.

Therefore, there is likely to be an emphasis on more information rather than less because of the responsibilities weighted to post-market regulation and consumer use. The consumer, not only needs to know how and when to use the product, but what to do in the event of a problem.

The arguments in favour of such an approach to labelling for Australia are:

- it would be easier to establish consistency of labels which has benefits for consumers
- it may be helpful to industry to identify requirements
- consumers have a right to know all ingredients of product, including excipients, especially multi-component products
- the establishment of acceptable monographs as the basis for label claims may streamline the registration process.

The arguments against the approach for Australia are:

- too much information which could swamp the consumer, create problems for small containers and set the scene for loss of discrimination in warnings
- less flexibility
- not practical for multi-component products (possibly up to 30 different ingredients)

Thus, the complete mandated design model from FDA may not be appropriate for all non-prescription products. There are parts of this approach to label design, however, which are worthy of further consideration:

- the use of headings to alert the consumers to different types of information
- the concise statement about the purpose of each active ingredient and the uses for the product
- the use of dot points and simple language in warnings, potential side-effects and directions for use
- the inclusion of a full list of excipient ingredients
- the demarcation of this set of information, for regulation as label information, from other parts of the label, which might be regarded as advertisement.

    - In the interests of streamlining wording on labels for both claims and warnings, should both be produced according to respective templates?

    - If labelling information is separated from advertising material for regulatory purposes, will this reduce costs for industry in streamlining the Listing process,

minimising the design aspects of compliance with labelling requirements, and in providing for the advertising elements of the label to be regulated in the same way as other advertising?

2.5 What improvements for labelling of prescription medicines are required?

Sponsor label

The issues for consideration in improving the label the sponsor places on the product are:

- the physical design of label, taking note of need to add dispensing label

It should not be necessary for the dispenser label to compete with or compromise the sponsor label. i.e. the components of the sponsor label required by law should not be compromised by the dispensing label.

- naming of medicines and lack of differentiation within brands, which lead to mistaken identity by professionals and consumers

Some creative thought is required for development of a mechanism to counteract this.

- cater for aged and other groups

eg Small font size can be a problem for aged consumers.

Suggested information that could be shown on label

- web site

At the time of formal registration, perhaps the more important consumer information could be posted on a website, accessed by the AUSTL or AUSTR number.

- warning graphic

e.g. for medicines with pregnancy category X the label could include a small graphic indicating that the medicine must not be taken during pregnancy.

- reference to Consumer Medicines Information leaflet for further info

A statement (on the sponsor label) to this effect may reinforce the importance of the CMI and reduce consumer expectations that 'everything should be on the label'. At the time of dispensing, the pharmacist should draw attention to the CMI, advise where it can be obtained and warn the consumer NOT to discard the CMI.

- information line telephone number

Dispenser label (regulated under State and Territory laws)

Requirements:

- readability (clear)
- dosage information

- warning statement
- patient's name

Hospital/professional user (regulated under State and territory laws)

Poor readability of some labels may lead to errors. For example, ampoules removed from the box which has the details not on the ampoule.

❑ Any comments on this would be appreciated.

Labelling should address the need for accurate identification and any relevant warnings at the point of use of a medicine by a professional in hospital and other settings.

2.6 Putting it together

How can we integrate performance-based regulation with the need for taking all warnings and the needs for the different categories of medicines?

1 Scope

Option 1.1 (Status quo)
Keep the current definition of label such that a label must comply with both labelling and advertising regulation. This would retain the current confusion over indications, claims, advertising and labelling statements of purpose.

Option 1.2
Differentiate the "label" information from advertising on the label leading to a clear demarcation of applicable regulation i.e. define "label" according to a certain set of information and all else is advertisement. This would allow for the possibility of the TGACC administering the regulation for those parts of the label seen as exclusively advertisement.

Action required

The Therapeutic Goods Act would have to be amended with a new definition of "indication" to differentiate it from claims (see 3.3 **Claims: labelling and advertising**).

Leave 'indication' as the required entry item for all categories according to the Act but amend the definition. The amendment would distinguish between registered and listed good indications. For example:

Indications *in relation to registered therapeutic goods, means specific uses of the goods and in relation to listed goods, the claims made as to the specific uses of the goods.*

The label claim would be the indication as included in the ARTG. An **advertising claim** is any extension or variation of the accepted **ARTG claim** and 'representations' can include pictures and symbols with the claim.

The Regulations may need amendment to make this clearer with respect to "other advertisements" and to ensure that the presentation of label and advertisement do not conflict.

Amendments to the legislation to resolve issues of warnings and the operation of a performance-based scheme

Option 2.1 (Close to status quo)

Improve the efficiency of the system by bringing all the labelling requirements together.

Retain the prescriptive emphasis of the current system, with some increased use alternatives to precise wording. Prescriptiveness provides certainty for industry in that little interpretation of the regulations is required, but prevents a flexible approach. For this option, performance outcomes would not specified in the legislation, but use of the phrase "or words to that effect" to state requirements at certain points could be used. This would allow some degree of flexibility but would provide no guidance on desired outcomes.

Action required

Either:

> Make amendments to the Regulations, possibly to the Schedules, to include the required warnings from the SUSDP and other documents. This would be a direct transfer from other documents with a identification of additional points for inclusion of " or words to that effect" where possible. Warnings would be maintained and developed by TGA through normal consultative processes.

or

> Leave warnings in SUSDP but reference made in Regulations. The SUSDP is using the flexibility of "or words to that effect" for some warnings. The NDPSC would remain responsible for developing and maintaining those warnings.

In addition, retain TGO48 (as amended 2000 with some points of flexibility). Additional amendments to TGO48 giving reference to warnings required as per Schedules to Regulations (if no longer included in SUSDP) would be required.

Option 2.2 (Prescriptive, but mandated elements based on best communication design)

This option would be based on the recently adopted FDA scheme for OTC medicines.

Action required

A Therapeutic Goods Order would be prepared, setting set out the requirements. Note also that for this option, the 'label' information would have to be demarcated from other elements of the label such as promotional material.

Proposals

Option 3 (Performance-based scheme)

Establish an overall performance-based scheme using a statement of desired performance, applicable to the whole label and to warnings as included in the Schedules to the Regulations. Labelling and advertising would be separated but must work together to achieve the desired outcome.

Action required

The Regulations would need amendment to include the performance statement and the level of flexibility in setting out and wording with respect to warnings listed in the Schedules.

A new Therapeutic Goods Order for a performance standard would be established, including expression of warnings. This standard would be supported by a Code of Practice for testing against the performance criteria and Guidelines with the level of detail currently in TGO48. Such Guidelines could more easily be amended than Orders but would be administered with advice from the Therapeutic Goods Committee's subcommittee for labelling. See figures 1 & 2 for an overview.

The multiple parts of this scheme could be regarded as a package for distribution together and seen as a way of dividing the regulatory parts according to level of detail and ease with which they could be amended. Alternatively all guidance could be placed in the Performance Standard to avoid the multiplicity of documents.

Something similar to the FDA scheme could be used as a basis for requiring better design elements in the Guidelines.

Other considerations

Any potential for co-regulation for labelling should be explored. For example, the CHC mentions the co-regulatory process for advertising. In consideration of the artificial division between advertising and labelling for point of sale information, one of the proposals in this paper is to more clearly delineate labelling from promotional material on a container/package and leave promotional material for regulation as for advertising.

Finally, the TGA will need to consider administrative changes to mirror legislative changes, such as a central labelling coordinator.

2.7 What would this mean for the different categories of medicines?

Prescription medicines

The APMA does not recommend performance-based labelling regulation for prescription products because:

- their members do not want another change in labelling regulation, and
- the issue of readability of warnings from the package is not as pertinent with the limited warnings mandated for the sponsor to place on their products and the use of the CMI.

The labelling of prescription medicines could be excluded from a performance-based scheme but closer attention could be given to the items identified in 4.5 above, for improvement of the end result, in a revised prescription standard for this category only. Any changes to requirements could be phased-in.

However, the rational for rejection of performance-based regulation for prescription medicines based on the situation for warnings may not have taken different models for "performance-based" into account. The performance criteria may be used for more than the warnings. See the section above on a possible Performance Standard.

From the discussion above about the potential improvements for the sponsor label of prescription medicines perhaps the TGA could work with the APMA on a revised "checklist" for sponsors, covering design. The design aspects needing more attention are identified so far as allowance for the dispensing label, readability for aged and use by date significance for rapidly deteriorating medicines once opened. These could be phased in over several years.

Non-prescription registered

The PMAA prefers performance-based regulation for labels of their members' registered products. The evaluation of individual products as part of the pre-market registration process allows for labels to be assessed for compliance. The PMAA anticipates that testing of performance could be done by category rather than by individual product, and by the use of examples in the Registration Guidelines, acceptable pre-tested label designs could be given to indicate acceptable labelling.

Non-prescription listed

The listing process is an electronic application lodgement registration, involving self-certification of compliance with labelling requirements. The electronic lodgement process operates by checking sponsor information against a range of pre-determined compliance elements but does not include the submission of labels to the TGA. It is therefore difficult with Listing to establish a performance-based scheme involving assessment of performance.

However, the prime areas of concern raised by the Complementary Healthcare Council can be addressed as follows:

- for the use of warnings that can be understood, that are not lost in meaning within the label design, a pre-determined format could be devised that identified flexibility of expression as well as mandatory elements, and allowed rationalisation of multiple warnings for ease of consumer comprehension;

- for problems with use of approved names of a) pharmaceutical forms and b) ingredients, further research may be planned to gain an understanding of consumer comprehension in this area;

- the use of claims consistent with a product's advertising could be handled by clearly delineating label items from advertising on the label, allowing regulation of promotional aspects of the label in the same way as advertising and simple expression of the intended use of the product on the non-promotional part of the label; and

- a broad performance standard would apply to the whole label.

Administration of labelling regulation

Coordination within TGA through a labelling group or labelling officer may be necessary for the development of the relevant documents, designing templates for committees to use in establishing required warnings, and reporting to the Therapeutic Goods Committee. There would need to be a central means of reviewing the effects of conditions of registration and listing on the overall label design.

Additional options

Change AUSTL/AUSTR, which is a meaningless item for consumers unless they are directed to look specifically for it in the case of a problem, to TGA Listed Authorisation or Registration Number. Mention of TGA on the label is currently not permitted but this could be amended.

Grandfathered products would not be permitted to change to this format unless their ARTG status was confirmed against current requirements.

Another option for listed medicines could be that, for a fee, sponsor election to use variations to prescribed requirements could be cleared prior to listing.

Recommended proposal

The following scheme is recommended as the one to minimise costs and improve benefits. This scheme could be called *Performance-based regulation with inclusion of all warnings under therapeutic goods legislation.* It is summarised in the following figures 1 & 2.

The current system is not cost-effective in requiring warnings and statements without analysis of the capacity of the resultant label to meet objectives. Costs appear to lie in achieving compliance with changing requirements. Comprehension of the intended messages and best use of the products is questioned.

With information supplied in response to this paper, we hope to clarify whether a performance-based scheme would be too costly for industry and consequently, consumers, in comparison to the benefits expected. Under a performance-based scheme, the costs of design and testing would be borne by industry. Those not wishing to participate to this extent may opt for use of Guidelines in order to meet the required Standard. Another way to avoid the additional costs, would be to develop category by category approaches to any desirable variations from the guidelines. This would minimise the costs per product.

- How would costs be affected by each of the options?

- What would be the benefits for industry? for consumers? for regulators? Community?
- Are there any other options, and could they be justified on competition grounds?

Figure 1 Recommended Proposal

Performance-based scheme legislation	
Therapeutic Goods Act 1989	currently gives the power (amend "indications")
Therapeutic Goods Regulations 1991	insert under Div 4 Advertisements a statement of "required representation with the label" giving performance principle include all warnings in Schedule
Therapeutic Goods Order NoX	Performance Standard
Guidelines	detail for compliance with the Standard, mandated compliance for Listed products, exemptions only with approval
Code of Practice	testing against the Performance Standard

Figure 2 Recommended proposal

Performance-based scheme operation

Registration prescription

Sponsor label

as for registration non-prescription, but with recognition given that limited information is required

Registration non-prescription

must comply with the Performance Standard,

but may deviate from the Guidelines.

Applications for Registration must include a copy of the label, and

if variant from Guidelines

the results and testing methods used must be submitted for evaluation

Listing through Electronic Lodgement

must comply with the Performance Standard and the Guidelines

variations from Guidelines could be handled as for Registered, with fee

Rationalisation of multiple warnings

Registrable: either separately determine design from use of performance standard and tested design elements

or, use developed generic design for that category eg analgesic

Listable: use generic proforma with guidelines for combination of warnings

3 Issues and concepts

3.1 The policy environment

The National Competition Policy

In refining our objectives there is a need to appreciate the environment in which the Review of Drugs, Poisons and Controlled Substances Legislation and the labelling project is taking place. The Commonwealth and all State and Territory governments signed a *Competition Principles Agreement* in April 1995 that is designed to implement a broad-ranging program of micro-economic reform. The aim is to lower business costs, enhance competitiveness and provide conditions for more sustainable economic and employment growth. A major obligation given by all governments was to review restrictive legislation by the year 2000, and where necessary to reform it.

The guiding principle is that legislation should not restrict competition unless it can be demonstrated that:

(a) the benefits of the restriction to the community as a whole outweigh the costs; and
(b) the objectives of the legislation can only be achieved by restricting competition.

Competition policy also recognises the public interest, where competition might be inconsistent with the weighting placed by the community on particular social objectives. Under this test, the need for a general set of legislation and regulations to protect and promote public health is likely to be acknowledged, although specific legislation will still be subject to scrutiny.

We seek to confirm the specific consumer health benefits the various restrictions are intended to achieve. For example, the requirement for ingredients to be listed would allow consumers informed choice and assist in preventing inappropriate use.

Regulations may restrict competition where they indirectly or directly:

1. Govern the entry or exit of firms and individuals into or out of markets.
2. Control prices or production levels.
3. Restrict the quality level or location of the goods and services available.
4. Restrict advertising and promotional activities.
5. Restrict price or type of inputs used in the production process.
6. Are likely to confer significant costs on business and may provide advantages to some firms over others by, for example, sheltering some activities from the pressures of competition.

Best practice in standards setting and development of regulations

The aim of any national standards setting process should be to achieve the minimum standards necessary, taking into account economic, environmental, health and safety concerns. The application of best practice in regulatory design is consistent with the objectives of national competition policy.

Amendment of regulation or the development of a new regulatory system requires an analysis of the regulatory impact of such action. We hope that responses to this discussion paper will provide data from stakeholders which may be used in this type of analysis. Regulatory action has to be shown to be necessary. This will be done through an analysis of the risks, benefits, effectiveness and efficiency of proposals.

We also need to plan for the management of the provisions included in standards once the general level of regulation has been decided. Transparency and procedural fairness are sought. The intention is to find the appropriate means of managing the risks.

Regulation and its review 1994-95, Industry Commission, includes the following extract:

> "Regulatory design has three elements: standards, enforcement and cost recovery.
> When designing a standard, there is often a choice between:
> - rules which prescribe how an outcome is to be achieved (the focus is on the methods of operation or inputs);
> - performance-based rules which specify a particular outcome without the method to be used; or
> - principle-based goals which indicate the broad intention and rely on agents to meet the 'spirit', rather than the letter of, the law."

From Council of Australian Governments (COAG) *Principles and guidelines for national standard setting and regulatory action,*
the principles of good regulation within which standards and regulations should be developed are:

- regulatory measures and instruments should be the minimum required to achieve the desired outcomes;
- regulation should have minimal impact on competition;
- regulation should have clearly identifiable outcomes, and where possible, the standards should specify those outcomes and avoid prescription;
- regulatory measures and standards should be compatible with relevant international standards and consistent with Australia's international obligations;
- regulations should not restrict international trade;
- regulation should be reviewed and should be capable of being amended; and
- good regulation should not be so flexible that it encourages discrepancies and uncertainty.

Recommendation

Identify intended outcomes separately for each category of medicine and express that outcome as a performance standard, which can be followed by prescriptive instructions for how the outcomes might be achieved where necessary.

Safety and quality use objective

The regulation of labelling under the *Therapeutic Goods Act 1989* shall be consistent with the objects of this Act.

Therapeutic Goods Act 1989
Section 4

(1) The objects of this Act are to do the following, so far as the Constitution permits:

(a) provide for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods that are:

(i) used in Australia , whether produced in Australia or elsewhere; or

(ii) exported from Australia;

(b) to provide a framework for the States and Territories to adopt a uniform approach to control the availability and accessibility, and ensure the safe handling, of poisons in Australia.

(2) This Act is therefore not intended to apply to the exclusion of a law of a State, of the Australian Capital Territory or the Northern Territory to the extent that the law is capable of operating concurrently with this Act.

National Medicines Policy

Australia has a National Medicines Policy, which was developed and implemented following a recommendation for national governments from the World Health Organisation during the 1980s. A partnership of a wide range of stakeholder groups based the policy on four central objectives:

1. the supply of medicines of established and acceptable quality, safety and efficacy;
2. timely and reliable access to the medicines that Australians need, at a cost individuals and the community can afford;
3. quality of use of the medicines; and
4. maintenance of a viable and responsible pharmaceutical industry.

The policy is currently being updated but this will not substantially affect the policy on the quality use of medicines.

Quality Use of Medicines

The policy on quality use of medicines is built around the following principles:

- judicious use, ensuring the best possible treatment plan is chosen;
- appropriate use, ensuring that when medicines are needed they are carefully selected, managed, monitored and reviewed;
- safe use, minimising misuse and under-use of medicines; and
- efficacious use, ensuring that medicines achieve the goals of therapy by delivering beneficial changes in actual health outcomes.

The development and implementation of this policy is the responsibility of the Pharmaceutical Health and Rational Use of Medicines Committee (PHARM).

Education is seen as the primary tool for achieving optimal use of medicines with professional and consumers all having a role in ensuring that medicines are used wisely. The program funds initiatives designed to achieve the policy objectives. The Australian Pharmaceutical Advisory Council (APAC) also actively promotes a partnership approach to achieving quality use of medicines, particularly through the development and dissemination of guidelines for best practice.

Contribution of the drugs, poisons and controlled substances legislation to the quality use of medicines

The scheduling of potentially poisonous substances used in the community provides for a classification system which attracts prescribed risk-based restrictions affecting:

- access of consumers to the goods,
- packaging and storage, and
- information available to consumers through professional contact, labelling and advertising.

All these factors are intrinsic to the quality use of medicines, but the application of the controls arising from scheduling do not provide the education programs necessary to promote the strategies by which the Quality Use of Medicine policy is being achieved. These strategies are: increasing understanding of the relative roles of the full range of medicines from off-the-shelf to prescription; encouraging the appropriate choice of medicine and dosage regimen when they are needed; and providing people with the knowledge, skills and encouragement to use medicines wisely and safely. That is, education, beyond provision of information, is essential.

Education is also supported, but indirectly, through scheduling. Where a certain classification mandates access to, or use of, professional interaction education opportunities may arise. Ensuring the full use and success of those opportunities is a matter of professional standards, outside the scope of the *Therapeutic Goods Act 1989* and drugs and poisons scheduling controls.

Quality care pharmacy program

The pharmacy industry has introduced a Quality Care Pharmacy accreditation program to address problems such as the need for improvement in the standard of professional service and advice, for improvement of performance in retailing in the face of increasing competition and for preparedness for self-regulation. The Quality Care Program is an integrated system of performance standards and supporting tools and processes. The pharmacy standards include standards of counselling and advice for customers.

Pharmacists are among a large team of professionals who could be involved in providing the necessary information and counselling for quality use of medicines over and above labelling.

3.2 The role of labelling

We need to consider the role of the label at different stages in the life of the medicinal product. Each stage attracts a different kind of risk for the product. For example, the label must enable the product to be unambiguously identified, may play a role in the decision to purchase (not S4), must say how to use the medicine safely and effectively, and should include "after sales" advice on open shelf life and first aid.

The Therapeutic Goods Administration regulates medicines according to the level of risk of the products. The regulation of labelling should also be risk-based. The level of risk of a product depends, not only on the substances used, but also on the intended use of the product and the way in which it is likely to be used. The labelling is a highly significant factor warranting standardisation when it affects the risk classification of a product.

The assessment of the level of risk has been a complex process involving both the NDPSC and the TGA and its evaluation committees. A guide to the TGA evaluation process of goods is found in Schedule 10 to the Therapeutic Goods Regulations. The Schedule specifies which Branch or Section of the TGA is responsible for conducting an evaluation of which category of goods.

The label forms an integral part of the overall risk of the product once available in the community. The appropriate warnings on the label can lower the risk of a product. We must, however, be aware that labelling cannot provide the antidote to all risks. The information gained by a consumer, even when understood does not necessarily remove the hazard, particularly when the consumer fails to follow the directions given.

Conversely, provision of excessive information, including all possible, but unlikely, reactions, does not fulfil the purpose of the label. Manufacturers may seek to include too much information to avoid liability but this may reduce the effectiveness of the label.

The following table sets out the points in the life of the product for which the label helps manage the associated risks. The table highlights the increasing reliance on the sponsor's labelling as the risk category of the product category shifts from Registered to Listed.

Category	**Evaluation**	**Risk points managed with label (and CMI)**	**Label responsibility**
Highest risk Prescription only S4 and S8 substances Registered AUSTR	Drug Safety and Evaluation Branch with advice from Australian Drug Evaluation Committee	Prior to dispensing As dispensed On consumer use and Other e.g. hospital Storage	sponsor pharmacist (CMI) sponsor and professional practice sponsor and pharmacist
Moderately High risk	Chemicals and	Purchase	sponsor and

non-prescription S2 and S3 substances, or higher risk claims warranting individual product evaluation Registered AUSTR	Non-prescription Medicines Branch (CNPMB) with advice from Medicines Evaluation Committee or CMEC	 Use Storage	pharmacist for S3 sponsor sponsor
Low-risk non-prescription Non-scheduled substances, individual products not evaluated. Listed AUSTL and AUSTR grandfathered	Chemicals and Non-prescription Medicines Branch (CNPMB) with advice from Complementary Medicines Evaluation Committee (CMEC)	Purchase Use Storage	sponsor sponsor sponsor

All medicinal products carry some risk of harm, whether incidental to normal use or attributable to accidental or deliberate misuse, whether they be predictable adverse events that are attributable to the pharmacological actions of a medicinal drug or idiosyncratic reactions such as allergies. Listed medicines are regulated on the assumption of low-risk but supply of these products with sufficient information about who, when and how much to use and when not to use is integral to this assumption.

As well as events which may be related to the predictable pharmacological actions of a medicine, or to infrequent but life threatening allergic events, one also needs to consider that failed efficacy is also accepted as an adverse reaction. Lack of efficacy may have safety implications if an alternative treatment that might be more likely to be effective had been considered. Medicine misadventure can include inappropriate use or wrong dosage. Moreover many substances are capable of causing interactions with concurrent medication. These substances include apparently innocuous beverages such as grapefruit juice, herbs (eg (*Hypericum perforatum*) which may affect liver enzymes and OTC medicines such as aspirin. Grapefruit juice may interact with prescription medicines that are metabolised by CYP 3A4, interference with normal liver breakdown of substances may exaggerate pharmacological activity of other medicines, and aspirin will interact dangerously with anticoagulant drugs e.g. warfarin.

Professional advice

Patient counselling is provided in the purchase of those medicines that are Registered that is, those which normally would be included in Schedules 3 and 4 of the Standard for the Uniform Scheduling of Drugs and Poisons. Patient counselling is available for purchase of S2 (pharmacy only) products. The consumer's independence at purchase is somewhat diminished by the role of a learned intermediary (prescriber and pharmacist) in making decisions on behalf of the consumer or, at best, in assisting the consumer to arrive at an informed choice about which alternative is most suitable for the individual concerned.

As per Schedules 12 or 13 of the Therapeutic Goods Regulations, a Consumer Medicine Information document will become mandatory for all such medicines by 1 January 2002 for prescription only medicines, although in practice most of these medicines have a Consumer Medicine Information leaflet already. Therefore, for Schedule 3 and Schedule 4 medicines, there are sources of information available to the patient besides the information on the label. For this reason, it might be reasonably expected that the package label for the prescription only medicine should contain the least information and that the package label for a pharmacy only medicine (S2) should include more information than necessary with a prescription only medicine.

There are some therapeutic goods that have lower levels of scheduling (S2 – Pharmacy Medicine) or none at all. There will not necessarily be a pharmacist or other professional available to provide patient counselling in the case of medicines which may be bought from supermarkets and health food stores. These include a range of drugs such as aspirin, paracetamol, antacids, topical antifungals, sympathomimetics (e.g. in cough medicines) and various antiseptics, vitamins and herbals. Devices that might occasion significant psychological impact - such as pregnancy diagnostic kits - are also available in supermarkets.

The decision to buy these therapeutic goods is one that will rest largely with the individual consumer. In this case, it would seem that more information should be available than for a pharmacy only medicine, as there is no learned intermediary available to interpret the information about the therapeutic goods concerned. Currently, this is not the case.

The position is somewhat less certain for listed goods. From the purely economic point of view, that of economic efficiency, as well as the right to an informed market place, it is possible that a degree of market failure is occurring with some listable goods. That is, insufficient information is available for consumers to make appropriate choices in purchasing and using.

Although claims for listable goods have limits placed upon them, there is, in practice, a large amount of advertising material and self help literature available in health food stores that make generic claims i.e. does not make reference to any branded product. The labels for these listable goods do not necessarily canvass the possibility of rare adverse effects or state the place of the therapeutic good concerned amongst therapeutic alternatives or give advice about the duration of therapy and when it might be prudent to cease therapy.

It is with this last category of goods that the responsibility of the individual consumer is greatest. To make an informed choice, the consumer ought to have information available on the likelihood that it will work for them, the kinds of adverse events that might be expected and how long it might take to see actual benefit. More importantly, listable goods may interact with prescription only or pharmacy only medicines. This should be disclosed where known or managed through education of consumers with particular conditions.

There is an additional class of person who may administer therapeutic goods that will here be referred to as a “user”. The user may be a learned intermediary or carer who administers a medicine or device or other therapeutic good to a third party. Such users may administer therapeutic goods ranging from sunscreens to sterile intraocular irrigation solutions. The labelling will need to address this type of use, as well as subsequent self-administration by the consumer, where relevant.

Role of the consumer in making decisions based on label information

As part of the market mechanism, labels should contain information or be accompanied by information in the same packaging, that enables a consumer to elect whether to take or not take a particular medicine. Consumers need to have some way of choosing one particular product over another by reference to information that may not be generally available. It should be the role of the label to provide this information.

The Consumer Medicine Information leaflet provides a first step to indicating how to take the medicine accurately and what adverse effects and beneficial actions might result from taking the product, this amount and nature of information would be insufficient on its own. It is possible that consumers might request that a higher level of information, such as levels of evidence available to support use of the medicine and its place in therapy are necessary since the consumer is medicating himself/herself or his/her family. Presently there are only a limited number of OTC medicines that require CMI.

A list of "desirables" from the consumer's perspective is likely to include, but not be limited to, sufficient data to enable an informed choice about purchase and necessary first aid steps (these exceed the data requirements of a CMI) and other matters consistent with a CMI (storage, disposal).

Summary and Conclusions

- The aim is to have quality and safe use of medicines regardless of their type. Each category of medicine needs to be analysed separately in terms of the need for effective labelling that will ensure the quality and safe use of a medicine in that category. All medicines are capable of evoking idiosyncratic adverse events. The risk assessment process will take account of the manner of use and of the substances included.

- Manufacturers will also be able to define better their product liability by addressing labelling and consumer/user information requirements adequately.

- Consumers have a right to comprehensible and clear and effective labelling and related information. This must enable consumers to make a choice about commencing or not commencing a course of treatment with a given therapeutic good. This is consistent with the principles of trade practices legislation and is consistent with the broad aims of the *Therapeutic Goods Act, 1989*. It is also consistent with prevailing economic libertarian beliefs.

- Consumers of prescription only medicines are moderately well served by the provision of the Consumer Medicine Information leaflet but are also served by the process of informed consent when obtaining a prescription from the prescriber as well as the availability of patient counselling from the dispenser (the pharmacist).

- Consumers of pharmacy-only medicines are well served by information on the labels of medicines as well as by the potential availability of a Consumer Medicine Information

leaflet as well as by the *possibility* of counselling from the dispenser (the retail pharmacist).

- Consumers of listable and lower level S2 scheduled medicines should be assumed to have only the information currently provided for by the labels. Conflicting or alternative sources of information are available and there is no requirement to have a consumer medicine information leaflet.

Recommendations:

that regulation of labelling:

- be consistent with the level of risk anticipated;
- encourage the use of Consumer Medicine Information leaflets for all medicines, including S2 and Listables; and
- be designed for its role in helping to reduce any specific risks associated with each category of medicine.

3.3 Claims: labelling and advertising

Label claims and advertising both stem from the indication recorded against a product on inclusion of the product in the Australian Register of Therapeutic Goods (ARTG). Labelling and advertising are regulated differently but both are bound by section 22 (5) of the Act which says that a sponsor must not advertise the goods for an indication other than those accepted in relation to the inclusion of the goods in the Register.

The definition in the *Therapeutic Goods Act 19*89 of an "advertisement" includes any statement, pictorial representation or design that is intended, whether directly or indirectly, to **promote** the use or supply of the goods. This definition therefore encompasses the product label, which includes the label on the container, the outer packaging and any packaging inserts or leaflets.

For self-medication products, advertising, including labelling, is the primary mechanism that enables consumers to understand the purpose of products, the difference between them, and to compare claims before they make a purchase. Advertising also provides an important source of information that helps people make rational decisions on the use of non-prescription medicines.

The Therapeutic Goods Advertising Code

Details and restrictions relating to the advertising of non-prescription medicines [including unscheduled, Schedule 2 (pharmacy only) and some Schedule 3 (pharmacist only products)] are set out in the Therapeutic Goods Advertising Code (TGAC). Prescription medicines (Schedules 4 and 8) may not be advertised directly to the public.

The indication (claim) for a Listed medicine entered in the ARTG is currently restricted (Schedule 4 to the Therapeutic Goods Regulations) to the claims permitted for advertising to the public permitted by the TGAC. Medicines which are Listed in the ARTG cannot be associated with the treatment of the conditions referred to in clause 4 of the current TGAC. The TGAC is therefore used as the guide for acceptable claims recorded against a product on entry in the Listed section of the ARTG.

The TGAC is applicable to advertising directed to the public only. The TGAC does not apply to advertisement directed to professionals. However, advertisements to any person, public, professional or trading, may only refer to those indications which are included in the ARTG for that specific product (s22(5) *Therapeutic Goods Act, 1989* refers). Advertisements are assessed for compliance with the TGAC in relation to the overall presentation and any extensions or word variations of the ARTG entry. Responsibility for this rests with the industry associations, which have the delegations under the Act (the Advertising Services Managers of the PMAA and CHC). All advertising of medicines to consumers via broadcast or the print media must comply with the TGAC and be issues with an approval number prior to publication.

In some situations, the TGAC permits certain claims to be made provided that warning statements are also included on the label. For example if a sponsor wishes to make a claim for the indication "fluid retention", it is only acceptable if the following warning statement is also included: "If fluid retention persists, seek medical advice". Where products are referred

to the Medicines Evaluation Committee (MEC) or the Complementary Medicines Evaluation Committee (CMEC), recommendation for approval of the product may also be conditional upon the inclusion of a particular warning statement on the product label.

The Therapeutic Goods Advertising Code Council

The Therapeutic Goods Advertising Code Council (TGACC) has been established under the Therapeutic Goods Regulations with a membership covering industries, consumers, TGA, advertising and health care professionals. The TGACC makes recommendations to the Minister on several aspects of advertising, such as changes to the TGAC, standards for advertising and the review of decisions of the Secretary when approving advertisements.

It is also possible that MEC or CMEC may recommend the approval of indications based on substantiation of the proposed claims, but the TGAC does not allow the claims to be made in general advertising to the public. In this situation a sponsor could make label claims, provided they obtain an exemption, but not be able to advertise them. In rare cases, an exemption from the prohibition in general advertising may also be obtained from the TGA.

Current system

Section of the ARTG	**Restrictions on indications on entry in ARTG**	**Exemptions from TGAC clause 4**
Listed	indications must not be "in the treatment of a condition referred to in clause 4 of the TGAC" (item 3, Schedule 4, TG Regulations), but evidence does not have to be submitted for evaluation. Sponsors must hold supportive evidence.	cannot be made because evidence not submitted for evaluation and Schedule 4 of Regs. defines what must be listed (otherwise Registrable)
Registered non-prescription.	indications for each product have to be supported by evidence submitted for evaluation	For the label: if indications prohibited by clause 4 accepted on registration for a product, Secretary may allow inclusion on its label (Reg 9). For more general advertising the exemption has to meet additional criterion of fulfilling a public benefit (Clause 4 TGAC, TGA decision)
Registered prescription only	indications for each product have to be supported by evidence submitted for evaluation	Indications not permitted on the label. Advertising to the public not permitted

Proposed New Code

The proposed new TGAC has a very different format, with an important difference in the prohibitions clause (now clause 5) being split into Prohibited diseases and Restricted diseases. The Code now expands and sets out Minimum Requirements separately from Principles, both of which were previously together under General Principles. It has an amended section on the prohibition of conditions and diseases for advertising to the public. It has revised wording in line with WHO and New Zealand systems and documents.

The following table highlights the proposed changes for the new Code relating to indications/claims.

New system

Section of the ARTG	**Restrictions on indications on entry in ARTG**	**Exemption for claims on label**	**Exemptions for advertising**
Listed	Schedule 4 of Regs to be amended to refer to clause 5 of the Advertising Code for the non-Listable indications. Evidence* does not have to be submitted for evaluation but has to be held by sponsor and be available on request.	cannot be made: must be according to Register claims	cannot be made for clause 5: must be according to Register claims
Registered non-prescription.	indications for each product have to be supported by evidence submitted for evaluation	If indications for a product go beyond what claim may be advertised to the public according to the TGAC, a label exemption is no longer required provided it is approved for registration with this indication	The Therapeutic Goods Advertising Code Council may make a recommendation to the Secretary (generally exercised by delegation to a TGA officer). The public interest question will also remain.
Registered prescription only	indications for each product have to be supported by evidence submitted for evaluation	Indications not permitted on the label.	Advertising to the public not permitted

*** Note that concurrent with this new system, sponsors are more explicitly required to hold evidence in support of whatever claims they are making. A new guidance document is being prepared to explain to sponsors what kind and level of evidence they**

must hold for certain classes of claims. Thus, sponsors may choose general or medium levels claims depending on the evidence they hold (for accepted non-serious conditions). Further, as part of the new electronic lodgement facility being developed, sponsors will be self-certifying labelling requirements for their products.

Claims and indications

Clarification of the terms: claims and indications will greatly assist the development of options for change to the labelling requirements. It should also facilitate the use of these terms and clarify the administration flowing from recent amendments to the Act and Regulations, revised advertising regulation, and revamped ELF. The interpretation of the meaning of the terms is important for the processes for registration, advertising control and labelling regulation.

An indication is a disease or condition, or symptom of a disease or condition, while a claim about a product is an assertion of what that product will do in relation to that disease or symptom.

In the current legislative arrangements, entries in the ARTG must include an **"indication"** which is **legally** defined as, the use of the good. For registered goods these indications are evaluated. However for listed products these indications are self assessed by the sponsor.

In practice for Listing, claims are accepted as indications. Only claims are made for Listed goods even though each entry in the ARTG must include an **indication** for the good and an advertisement must contain an **indication**. In the Electronic Lodgement process for Listing, including an indication usually means making a choice from a pull-down list, plus the use of free text for elaborative 'claims'.

Option

Leave 'indication' as the required entry item for all categories according to the Act but amend the definition. The amendment would distinguish between registered and listed good indications:

Indications *in relation to registered therapeutic goods, means specific uses of the goods and in relation to listed goods, the claims made as to the specific uses of the goods.*

The label claim would be the indication as included in the ARTG. An **advertising claim** is any extension or variation of the accepted **ARTG indications claim** and 'representations' can include pictures and symbols with the claim.

Only pre-agreed **indications claims** need be included in the ARTG (ie the pull down menu). This menu need not be static and could be changed from time to time after negotiation with industry and advice from CMEC/MEC, and possibly the TGACC. This would mean that the TGA staff assessing a listing application for compliance would not need to interpret, case by case, an **indication claim** for compliance with the advertising code. This should make the Listing process more efficient.

Further, any dispute about **claims** because of variations from the ARTG record or additional text on the label could then be handled as an advertisement and be subject to the approval (if that was thought necessary) or the advertising complaints mechanisms.

The option can be summarised in the following table covering labels:

ELF	TGACC process
Label information, including TGO requirements, eg indications, directions for use, list of ingredients etc	all other information pictures symbols additional text total image

A change of the regulation of "free text" currently included in an ELF Listing application from the Listing process to the same process as advertising, will have the advantages for industry of:

- simpler use of ELF;
- faster processing of ELF applications;
- maximum flexibility for additional representations with the consolidation of all such material under advertising; and
- with the provision of a consultative process for changing the coded indications in ELF as required, a more consistent list of accepted indications to suit both industry and consumers.

Recommendation

That claims to regulated as "label" claims be restricted to the entry in the Australian Register of Therapeutic Goods for the product, while any variations of the wording and imagery to these be regulated as advertisement which may also appear on the label.

3.4 Poisons Scheduling

The National Drugs and Poisons Schedule Committee

The National Drugs and Poisons Schedule Committee is established as a Commonwealth statutory committee under the *Therapeutic Goods Act 1989*. It comprises jurisdictional and professional representatives and expert members.

The functions of the Committee include making decisions in relation to the classification and scheduling of substances, maintaining the Poisons Standard (SUSDP) and facilitating harmonisation between Australia and New Zealand of the legislative provisions relating to the classification and scheduling of substances. The Committee also provides advice to governments in relation to the legislative restrictions on substances and the policies to be adopted with respect to the labelling, packaging and advertising of substances.

Section 52E to the Act:

The matters the Committee must take into account in exercising powers under the Act are:

(a) the toxicity and safety of a substance;
(b) the risks and benefits associated with the use of a substance;
(c) the potential hazards associated with the use of a substance;
(d) the extent and patterns of use of a substance;
(e) the dosage and formulation of a substance;
(f) the need for access to a substance, taking into account its toxicity compared with other substances available for a similar purpose;
(g) the potential for abuse of a substance;
(h) the purposes for which a substance is to be used; and
(i) any other matters that the Committee considers necessary to protect public health, including the risks (whether imminent or long-term) of death, illness or injury resulting from its use;

and may take into account the labelling, packaging and presentation of a substance.

The Committee also undertakes public consultation with respect to their functions and is obliged to consider public submissions made by the published closing date and addressing any of the matters given above (a) to (i). The Secretariat to the NDPSC within TGA may arrange for an evaluation of a submission together with other material such as published papers.

Scheduling process

Applications, with suitable evidence, may be made to the NDPSC for scheduling or rescheduling of a substance (guidelines published for the purpose). New substances to be used in prescription medicines are considered for scheduling separately from the registration process with the TGA by NDPSC.

New medicinal substances that may be suitable for non-prescription medicines were historically evaluated by the Drug Safety and Evaluation Branch as were prescription substances. However, the establishment of the new Medicines Evaluation Committee and the Complementary Medicines Evaluation Committee has enabled new substances, potentially for use in non-prescription products, to be evaluated separately from the DSEB. In practice recently, MEC, CMEC and NDPSC have been mutually referring matters to seek advice and to enable consistency of decisions about scheduling.

Overlap of TGA and NDPSC

There is potential for duplication of effort by these Committees and the NDPSC and for duplication of evaluation and secretariat work. In considering new substance approval for use in non-prescription medicines, both registered and listed, all the matters that the NDPSC takes into account should be taken into account by MEC and CMEC. The issue of greater integration is being considered by the Review of Drugs and Poisons and Controlled Substances Legislation.

The NDPSC wishes the TGA to consider transferring the responsibility for warning statements on both scheduled and reverse-scheduled substances to TGA.
The NDPSC applies requirements for warning statements to scheduled preparations via Appendix F of the Poisons Standard and to non-scheduled preparations by including warning statements in the schedule entry as part of the exemption from scheduling. This second process is sometimes known as reverse scheduling. Examples of this practice include the Schedule 2 entries for paracetamol and aspirin, and the Schedule 4 entry for vitamin A.

If the warnings are taken out of the Poisons Schedule as requested by the NDPSC, and the TGA takes responsibility for the administration of the warnings aimed at reducing the potential risks of a product, this would be an extension of the work already being undertaken by the TGA.

Recommendation

that all warnings, including reverse scheduling warnings, to be placed on medicine labels for therapeutic goods be taken out of the SUSDP and placed in legislation administered directly by the Therapeutic Goods Administration.

3.5 Harmonisation objectives

There are issues of major concern that affect harmonisation with New Zealand objectives, to be addressed in the labelling project: poisons scheduling, names for ingredients and dietary supplements regulated as medicines in Australia.

Reverse scheduling

The NDPSC Trans-Tasman Harmonisation of Scheduling Working Party has identified 'reverse scheduling' as an impediment to the harmonisation process. Reverse scheduling refers to the system whereby substances attract a lower classification based on qualifications such as pack size, dose size or labelling with warnings. The use of qualifications on the scheduled status of substances in the Australian SUSDP creates difficulties in making comparisons with the New Zealand schedules, which appear more as lists of substances.

Examples of reverse scheduling are:

Schedule 2 - SILVER SALTS for therapeutic use **except:** …..(b) in solutions for human oral use containing 0.3 per cent or less of silver when labelled with the statement: overuse may stain skin or mouth"; or…..

Schedule 4 – VITAMIN A for human therapeutic or cosmetic use, **except**: …..(c) in other preparations for internal use labelled (i) with a recommended daily amount of 5 000IU or less of vitamin A; and…etc.

Labelling is not the only means of creating exceptions to reverse the schedule classification. Some are dependent on dose size or route of administration.

Products in New Zealand may still be exempt or down-scheduled if certain conditions are met. It is just that the process is different and the legislative reference correspondingly differs.

The New Zealand process

In New Zealand the labelling requirements for scheduled medicines are covered as part of the registration process. The Medicines Classification Committee (MCC) in New Zealand specifies to the Ministry of Health, responsible for registration, that if certain products are to be exempt from scheduling, they must carry warnings or comply with specific requirements such as pack sizes. The exemptions are not included in the Poisons list but are included in guidelines for the registration of those products.

The *Medicines Act 1981* section 57 (1) refers to requirements intended to ensure consistency between package labelling and any advertisement for the medicine. It specifically refers to the use of statements that are contrary to, or prohibited by, or required by, (or the omission of), information required by the labelling requirements of the Medicines Regulations 1984. In addition there are self-regulatory Codes of Practice: Advertising Standards Authority Code

for Therapeutic Advertising, Non-prescription Medicines Association Code of Practice and researched Medicines Industry Code of Practice.

The MCC is a Ministerial advisory committee whose terms of reference are to make recommendations to the Minister of Health regarding the classification of medicines and access to medicines by professionals and the public. The three categories of medicines are: prescription medicines, restricted or pharmacist-only medicines and pharmacy-only medicines. The schedule of classification categories is a Schedule to the Medicines Regulations 1984. Narcotics and certain psychotropic agents are regulated under the *Misuse of Drugs Act 1975*.

Most new active substances are initially classified as prescription medicines. To qualify for a shift from prescription to over-the-counter classification, a prescription medicine should have been marketed for three years or more, have had wide use during those three years, have a low serious reaction profile with serious reactions occurring only rarely, and be suitable for OTC sale. The factors taken into account in the reclassification of medicines are consumer convenience, potency, the availability of products with a similar therapeutic use, toxicity and the margin between toxicity and therapeutic effects, abuse potential, suitability for self-treatment, precautions and potential for communal harm.

Approved Names

There is no equivalent process in New Zealand to the development of Australian Approved Names. New Zealand uses International Nomenclature as their first preference. Officers in both countries are working through the problems which arise as a result.

Harmonisation of naming is more difficult in the complementary medicines arena where there may be no INN. Australia has developed its own herbal naming system based on botanical names rather than the latinate versions often used elsewhere.

Dietary Supplements in NZ

To be sold as medicines in Australia, dietary supplements have to be included in the register (ARTG) and meet the appropriate labelling standards. Eligibility to be included in the ARTG as a Listed good (no product evaluation) is judged on several criteria set out in the legislation, including a low-risk classification of the ingredients. The substances used in Listed goods are restricted to those included in the Regulations. New substances are being added to the list all the time, but new substances used in dietary supplements will not be accepted as low risk without evaluation of safety data. The types of claims permitted for Listed goods are also restricted.

There is currently no equivalent to Australia's Listed category in the regulation of medicines in New Zealand. Dietary supplements are regulated under food law. Under the labelling regulation for NZ dietary supplements, therapeutic claims are not permitted. Dietary supplements carrying a claim of therapeutic purpose are therapeutic products as defined by the *Medicines Act 1981*. Dietary supplements in Australia can be regulated as foods if there is a prescribed food standard for such products in the Australia New Zealand Food Standards Code. At present most of these products are regarded as therapeutic goods in Australia.

Once the eligibility for Listing issues are resolved, then labelling differences can be discussed. Under the current scheme there would be a number of requirements in the Therapeutic Goods Order 48 which would mean the food centred labelling of NZ dietary supplements would be unacceptable. For example, a statement of therapeutic purpose would be required and the ingredients would have to be named with Australian Approved Names.

Under reformed labelling regulation in Australia, once a performance standard in developed, flexibility may be built in to the system. Further, if a standardised label format could be designed to meet the performance standard, over-labelling of a New Zealand label may be more feasible. Any material still exposed could be judged as advertisement.

The TGA and the New Zealand Ministry of Health are both committed to facilitate harmonisation of complementary medicines/dietary supplements regulation and will continue to liaise closely.

Other differences in labelling requirements between Australia and New Zealand include, the necessity in NZ to make a statement of purpose of a prescription medicine, measurement of minimum letter height on labels and the rules for trade names and signal headings.

Other countries

The FDA has just introduced revised requirements in the form of a standardised format for non-prescription (over-the-counter) medicines based on the latest communication research. A “drug facts” box with prescribed headings and details such as print size, is now mandatory for non-prescription medicines (see Appendix 4).

There is no “Listed” category in the USA. The labelling of dietary supplements is regulated under the *Dietary Supplement Health and Education Act 1994*. Claims about the effect of a dietary supplement on the structure or function of the body, including organ systems, for good health and nutrition are permitted, but stated or implied benefits for a disease are not permitted. Claims to diagnose, treat, prevent or cure a disease make a product a medicine to be regulated under the Food, Drug and Cosmetic Act.

The European scheme for the regulation of the labelling of medicines (prescription, non-prescription, but not dietary supplements) is a performance-based one, in which a Council Directive requires legibility, comprehensibility etc, supported by the *Guideline on the readability of the label and package leaflet of medicinal products for human use*, operating from January 1999. A guideline on the necessary information placed on the package, as incorporated into a submission for the purposes of gaining authorisation of a product, is in final stages of development. The Council directive on the labelling of medicinal products for human use lists a set of required particulars to be placed on the label but the manner in which they are included is derived from the guidelines.

In Canada, general and prescriptive labelling requirements are set out in the Food and Drug Regulations given power under the Food and Drugs Act 1981. As they are in Australia, inner and outer labels are differentiated. The Regulations also include specific requirements such as cautionary statements for groups or classes of medicines. In this manner, the Canadian Regulations take the role of standards and the SUSDP currently setting out requirements in Australia for some substances.

Canada established the Office of Natural Health Products in 1999 after the release of the Report of the Standing Committee on Health making 53 recommendations for changes to the regulation of these products. The Standing Committee views extensive information on labels as a cornerstone of its risk management approach. The Office of Natural Health Products is in the process of implementing the recommendations, three of which relate to labelling. The Office is consulting with its Expert Advisory Committee to determine what information is to be included on labels.

3.6 Implications for the States/Territories

In the process of moving responsibility for warnings and safety directions out of the SUSDP and under therapeutic goods regulation, issues of uniformity may arise where there is no complementary legislation.

Differences between the States and Territories may arise from:

- Differences between "label" definitions and between "advertisement" definitions
- Differences in references to SUSDP

The necessity for industry to seek labelling exemptions in eight jurisdictions

To date, only New South Wales and Victoria have implemented State and Territory therapeutic goods legislation complementary to the Commonwealth *Therapeutic Goods Act 1989*. Only New South Wales has adopted the Commonwealth legislation by reference, thereby picking up all amendments. Victoria has to keep amending their legislation every time the Commonwealth passes an amendment to remain consistent with the purpose, which is to maintain uniformity.

States and Territories maintain separate jurisdiction over poison scheduling and associated labelling. Some States adopt the SUSDP by reference while others require an amendment to their legislation each time there is an amendment to the SUSDP. This results in delays and non-uniformity in uptake of the recommendations from the NDPSC.

Some substances are scheduled differently between the States and Territories resulting in costs for industry in supplying different labels.

If a sponsor cannot comply with a labelling requirement under poisons scheduling for some reason, they could potentially become involved in negotiation with eight different regulatory bodies to apply for exemptions. An amendment to the effect that any exemption granted by the Commonwealth from a Labelling Order or from the warnings etc for scheduled poisons, would also be exempt in that State or Territory might solve this issue.

Reduction of the SUSDP to a list without the warnings and safety directions

If these warnings and safety directions were to be removed from the SUSDP and placed in a labelling Order (eg TGO48), there is potentially a problem for regulation of products from sole traders, trading within State borders. The States and Territories would have to refer to TGO48 in place of the current reference to the SUSDP for the purposes of regulating therapeutic goods traded only within a State border by a sole trader to achieve uniformity.

However, it may be possible to overcome the problem if State legislation requires all such products to be included in the ARTG. All warnings could be administered under Commonwealth legislation for these products.

The *Therapeutic Goods Act 19*89 is now the legislative basis for both the SUSDP and Labelling Orders.

The additional removal from the SUSDP of labelling conditions that reverse the scheduling of a substance would not be a problem for NSW.

Conditions such as labelling requirements can be dealt with as part of the pre-market registration process administered by the TGA. The process could include taking advice from NDPSC, especially for new substances. The evaluation committees for non-prescription medicines already undertake an evaluation of the safety of the substances used as ingredients and assess their risk status provided certain warnings and statements are made on the label.

The table in Appendix 3 sets out the related legislation for each State and Territory.

Regulation at State level is at retail outlets and of professionals. With an outcomes focus, consideration should be given to all the influences on use of medicines. Labelling is but part of these. For prescription medicines, the dispensing labelling should be considered in the final outcomes analysis.

Recommendation

that all States and Territories establish complementary legislation to the Therapeutic Goods Act 1989, and where this is not possible that the legislation be amended to accept compliance with labelling under the Therapeutic Goods Act to be deemed compliance with the State or Territory requirements.

3.7 Effective communication

Several studies have pointed to the importance of effective communication to deliver the desired outcome.

Proprietary Medicines Association of Australia

***Making medicine labels work* 1992** Graeme Russell and John Antill, Psychology, Macquarie University

The PMAA sought improvement in the system of regulation of labelling. They commissioned a research project in 1992 on two high-consumption categories of over-the-counter (OTC) medicines to investigate the relationship between the design and content of product labels and consumer understanding of the information in them and thus the effects on the use of the medicines. They intended to help define the purpose and scope of guidelines which could be prepared for the labelling of OTC medicines.

Different label designs for an analgesic and a cough mixture were tested on 253 people from different consumer groups. The sorts of design changes were tabulation of dosage instruction, recommended dosage interval made clear, bullet points and lower case for warnings and use of plain English terms.

The authors concluded that readability and understanding of important information on the product label and people's recollection of it can be significantly improved by changing the label's design and content. By the use of appropriate research, the features of more readable labels can be determined. Agreement on a standard Readability Formula is needed.

National Drugs and Poisons Schedules Committee

Report by Professor Philip Ley, University of Sydney
Effectiveness of label statements for drugs and poisons July 1995

This project was about assessing the effectiveness of signal words and the amendment of warnings, safety directions and first aid instructions. The process included analysis of vocabulary, and typographical and format factors.

Using published research, Prof Ley summarised the factors affecting the success of warnings and safety directions and gives guidance on how to make warnings noticed, legible, readable, believable and comprehendible. He also discussed the assessment of reading difficulty of statements and text for the purposes of making amendments to compulsory wording and gave the detailed results for currently used wording.

For example, legibility of warnings is improved if the text is not all in capitals, is not in italics, the print size is not less than 8 point and there is good contrast between letters and background.

The reading ease for warning statements such as in Appendix F of the SUSDP can be improved by giving consideration to any difficult words, ambiguity or passive voice:

For example, change:

This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol.
to
This medicine may make you drowsy. If it does, don't drive a car, and don't work with machinery. Don't have any drinks with alcohol in them.

Injury Prevention and Control Section

Environmental Health and Safety Unit
Department of Human Services and Health, Report prepared by Rush Social Research, November 1995
Signal Headings, Warning and First Aid Statements and Safety Directions

The overall objective of the research was to ensure that label statements mandated by States/Territory Poisons legislation are clearly understood by the reader. Chemical household and garden products, as well as pharmaceuticals, were considered. A combination of qualitative and quantitative data was collected using consumer volunteers in different reading ability groupings.

Barriers to reading and comprehension of label statements were identified.

Respondents believed they noticed the information most relating to the use by date, the correct dosage and other directions on correct use. Respondents indicated that when using products, signal words and cautionary statements were glossed over as standard information that they already knew. The signal headings and warning statements were not perceived to provide the information respondents consider vital. The length of the label inhibits people reading it.

PHARM (Pharmaceutical Health and Rational Use of Medicines)

Health Benefits
Pharmaceutical Benefits
Department of Health and Aged Care

Report: ***Designing better medicine labels*** by Communication Research Institute of Australia February 1995

This study was commissioned to examine possibilities for improving labelling of over-the-counter medicines. The authors believe that improvement is possible, even to as much as 80% reading and comprehension, if the following steps are taken:

1. Existing label regulations need to be changed so that regulatory standards become performance standards. Under existing regulations, the content, sequencing, and layouts that improve a label's performance are not allowed.
2. Useability should become the criterion of the size of the labels and not vice versa.

Eighty percent is acceptable for Consumer Product Information but the authors raise the possibility that even higher should be demanded of labels which are the, or perhaps the only, line of contact.

An important observation made by these researchers was that the useability of each element in a label is dependent on the other elements. Label elements cannot be treated in isolation, so that an emphasis on label content in the regulations, avoiding design performance, significantly reduces label effectiveness. Earlier research concentrated on the effectiveness of the wording of individual statements.

The components of a performance standard should include the expected level of correct responses to test questions, the choice of vulnerable group to be tested and the test questions themselves.

However, before such performance standards are introduced, regulators working with industry and with consumer representatives will need to establish the level of performance that is acceptable and the required precision of measurement of the performance standard.

US Food and Drug Administration (21 CCFR Part 201, Fed Reg Wednesday March 17, 1999)

Study A Evaluation of proposed over-the-counter label format comprehension study 1998
Study A consisted of a survey of more than 1,200 consumers on the influence of variations in labelling formats on the communication of directions for use and required warnings. Respondents were asked to evaluate the presentation of label information on one OTC sample and were asked questions about the labelling to determine their knowledge, opinions and willingness to read the label. The proposed new format took less time to read and understand than the old format.

Study B Evaluation of revised formats for over-the-counter drugs
Study B consisted of more than 900 respondents to evaluate consumer preference for 16 design variations in drug labelling formats. The presence of a title for the label information was the most important factor in determining preference.

The FDA used these studies to formulate the proposed rule put out for discussion and they formed the basis for their 1999 final rule for the labelling of OTC medicines. They concluded that the use of less complex terminology, presented in shorter sentences with an organised or chunked structure, is likely to improve consumer processing of the information. Consumers are more likely to engage in behaviour that they believe they can successfully complete, than in behaviour that appears overwhelming, or that presents a "cognitive load" such as the task of reading densely worded consumer information.

Australia New Zealand Food Authority

National consumer survey on food labelling August 1996

The Authority commissioned Yann Campbell Hoare Wheeler to undertake research into labelling issues for foods of concern to consumers and the usefulness of current labelling requirements. Points taken from the Summary:

- The primary use of labels on foods is at the point of purchase. Their use is for comparison within a product type or to decide whether or not to buy that particular product.

- Usage of labels differs with product category, which also determines the label elements consulted.

- Date marking, country of origin and ingredient and nutrition information are the most commonly consulted label elements; date marking is consulted on every purchase as a guide to freshness; other elements tend to be used for an initial purchase or for occasional queries.

- Nutrition and ingredient information is regarded as relatively less clear and is slightly less trusted than other elements such as date marking or usage or storage instructions.

Simplicity and clarity of label information is a primary concern to consumers.

Recommendation

Where clear principles have emerged from research these should be applied, in the first instance to mandatory requirements where they are needed, and to formulating standards for performance requirements where these are possible.
Detailed evaluation of published research is required and additional research planned to meet shortfalls.

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Acronyms

AAN	Australian Approved Name
ADEC	Australian Drug Evaluation Committee
APAC	Australian Pharmaceutical Advisory Committee
APMA	Australian Pharmaceutical Manufacturers of Australia
ARTG	Australian Register of Therapeutic Goods
CHC	Complementary Healthcare Council of Australia
CHF	Consumers' Health Forum
CMEC	Complementary Medicines Evaluation Committee
CMI	Consumer Medicine Information
COAG	Council of Australian Governments
MEC	Medicines Evaluation Committee
NCCTG	National Coordination Committee for Therapeutic Goods
NDPSC	National Drugs and Poisons Schedules Committee
OTC	over the counter
PHARM	Pharmaceutical Health and Rational use of Medicines
PMAA	Proprietary Medicines Association of Australia
SUSDP	Standard for the Uniform Scheduling of Drugs and Poisons
TGA	Therapeutic Goods Administration
TGAC	Therapeutic Goods Advertising Code
TGACC	Therapeutic Goods Advertising Code Council
TGC	Therapeutic Goods Committee
TGO	Therapeutic Goods Order

Appendix 1 Current regulation of the labelling of medicines

The legislation

Commonwealth labelling requirements for medicines are currently derived from multiple sources:

- The Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP)
- Therapeutic Goods Order (TGO) 48 (Labelling Standard for medicines) which includes reference to warnings required by the SUSDP.
- Therapeutic Goods Regulations 1991
- the Therapeutic Goods Advertising Code
- Relevant guidelines for listed or registered non-prescription medicines
- *TGA Approved Terminology for Drugs*

The *Therapeutic Goods Act 1989*:

- makes provision for the establishment of the labelling standard (TGO48) which contains the general requirements for labels for medicines;
- defines unacceptable presentation;
- states that statements of purposes of use of the product on the label are restricted by what is included in the Register for that good (as well as by advertising regulation);
- allows for the Regulations to define what products are required to be registered and what products are required to be listed in the Australian Register of Therapeutic Goods; and
- ensures that compliance with applicable Standards is a factor in determining eligibility for inclusion in the Register.

The *Therapeutic Goods Regulations 1991*:

- define prohibited and required representations, including a schedule (Schedule 2) of specific items and stipulates that presentations which confuse a good with confectionery or toys are unacceptable;
- nominate those therapeutic goods required to be in each of the registered part (Schedule 3) of the Australian Register of Therapeutic Goods (ARTG) and the listed part (Schedule 4) of the Register, and goods exempt from the requirement to be included in the Register (Schedule 5);
- include regulations relating to advertising that are also applicable to labels; and

current labelling regulation

- require additional patient information for prescription medicines.

[see below for the extracts of the relevant parts of the *Therapeutic Goods Act 19*89 and the *Therapeutic Goods Regulations 1990*]

A label could be regarded as an advertisement if it is intended for promotion of supply or use of the product and the leaflets supplied inside a pack or with the product by the retailer are labels.

The labelling of all medicines (registered or listed) must meet the specifications of Therapeutic Good Order 48 *General requirements for labels for drug products* (TGO48) TGO 48, as amended by TGOs 55.55A and 62. It is possible, however, to gain exemptions to these Orders. The TGO 48 sets out requirements for what must appear on the label, how to express quantities and what labelling is regarded as adequate for special packs and small containers. The Order also requires additional labelling where the route of administration attracts special safety precautions. Examples of requirements in TGO48 are:

- Labels must be clearly visible, written in durable characters not less than 1.5mm, and use metric units of measurement.

- Specific information must be on the label: names and quantities of active ingredients; dosage form; batch number and expiry date, and the number given to the medicine as a product included in the Australian Register of Therapeutic Goods (ARTG) which is either an AUSTR or AUSTL number.

Approved names

Australian Approved Names (AAN) must be used for naming ingredients on the label. An AAN may be a Chemical Substance AAN, a Biological Substance AAN or an Herbal Substance AAN. These AANs are listed in the *TGA Approved Terminology for Drugs* which has recently been revised.

Herbal AANs are more complicated than Chemical or Biological names. The herbal section explains how to create the complete AAN, containing the Australian Herbal Name and the Preparation AAN, for a herbal substance.

It also explains when a Herbal Component Name (HCN) for an active ingredient of a herb is needed. The HCN is required for all standardised and quantified ingredients. A herbal preparation may be standardised to a chemical group, which may or may not be an active constituent. If this chemical group differs within preparations from the same herb (eg can differ in breadth of the chemical family group assayed) then the HCN must differ.

Administration of the legislation

Multiple parties and two levels of government are involved in the administration of labelling requirements.

Agencies (Commonwealth and State/Territory)

The Therapeutic Goods Administration, within the Department of Health and Aged Care is responsible for the administration of the controls for the supply of medicines in Australia under the *Therapeutic Goods Act 1989*. State and Territory Departments of Health each contain areas responsible for the regulation of medicines, pharmacists and other health practitioners, supply of poisons and relevant retail outlets for pharmaceutical services and products.

Committees

The Therapeutic Goods Committee (TGC) is established to give advice to the Minister on standards, including labelling standards, under section 10 of the Act. The TGC undertakes particular work on labelling through a specialist sub-committee for that purpose. An Order, published in the *Gazette* determines a standard for therapeutic goods. TGO48 derives its authority from this section of the Act and from the consultation possible through the TGC. The secretariat for the TGC is in the Conformity Assessment Branch of TGA.

The evaluation committees responsible for the different categories of medicines are also responsible for the labelling of individual products as part of the registration process or for recommendations on warnings and directions for use, to be applied to categories of products or with certain substances. Each evaluation committee has a secretariat in TGA: Australian Drug Evaluation Committee (ADEC) secretariat in Drug Safety and Evaluation Branch, Medicines Evaluation Committee secretariat in Chemicals and Non-prescription Medicines Branch, Complementary Medicines Evaluation Committee (CMEC) secretariat in Office of Complementary Medicines.

The National Drugs and Poisons Schedules Committee (NDPSC) now administered by the TGA, is responsible for the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP). The SUSDP currently includes requirements for signal headings, warning statements and safety directions to be included on the labels of medicines containing scheduled substances. It also sets out the exemptions from scheduling (reverse scheduling) gained by prescribed warnings on labels. The NDPSC comprises representatives from the States and Territories, the agencies in Australia and New Zealand responsible for medicines and agricultural and veterinary chemicals, industry, consumers, pharmacists, and various relevant experts.

The National Coordinating Committee on Therapeutic Goods (NCCTG) provides advice for the development of national policy on the regulation of therapeutic goods. The labelling of medicines is a significant issue for this committee, not only because of the importance of labelling in meeting public health and safety objectives, but because of their interest in the coordination of Commonwealth - State/Territory regulation under national policy.

Different categories of medicines

current labelling regulation

Prescription medicines

Prescription medicines, containing substances scheduled as S4 or S8, must comply with TGO48 and the Regulations and with the SUSDP until dispensed. The advertising of prescription medicines is not permitted other than to prescribed health practitioners (Division 1, Part 2 of the Regulations). Information such as instructions for use is not required on the label if this information is in the Consumer Medicines Information(CMI) leaflet, which should be in the pack or supplied by the pharmacist (compulsory January 2002). There are other requirements for products used in hospitals.

Non-prescription (registered) medicines (complementary and non-complementary medicines)

Many non-prescription medicines must be registered, which means they undergo an individual evaluation prior to inclusion in the ARTG. This is performed because they contain scheduled substances (S2, S3, S5 and S6) or they are so formulated, or intended for use, that individual product evaluation is necessary based on safety. Non-prescription medicines, which are required to be Registered, must comply with the following:

- SUSDP
- TGO48
- Therapeutic Goods Advertising Code
- Therapeutic Goods Regulations,

and sponsors need to also refer to the *Australian guidelines for the registration of medicines* as revised 1999.

The matters that have to be taken into account on registering these products, include whether the presentation of the goods is acceptable, and whether the goods conform to any standard (including labelling standards) applicable to the goods, or any requirements relating to advertising (section 25 of the Act).

Non-prescription (listed) medicines

Listed products contain no scheduled substances and contain only those substances identified as low-risk by inclusion in Schedule 4 to the Regulations. Claims for listed goods are currently limited by the Advertising Code (to be amended to a therapeutic claims guide for acceptable claims). Most of these products are complementary medicines but some are sunscreen products. Besides the requirements provided in TGO48 and the Act, these medicines must also comply with Conditions of Listing, the Advertising Code, and the Regulations. Sponsors should also refer to the Listing Guidelines for Applicants and the Ancillary Code Tables for use in the electronic lodgement of applications. Reference to the Sunscreen Standard may also be required if relevant.

Listed products are entered into the Register with a declaration from the sponsor that they meet the relevant Standards and have acceptable presentations.

Other related legislation

There are numerous other laws which affect or potentially affect the legality of labelling of medicines. Examples are:
Hazardous substances
Transport regulations
Weights and measures legislation under Trade Practices.
Customs

Therapeutic Goods Act 1989 (extracts)

Part 1 Preliminary

Section 3 Interpretation (1)

***label**, in relation to therapeutic goods, means a display of printed information:*
(a) on or attached to the goods; or
(b) on or attached to a container or primary pack in which the goods are supplied; or
(c) supplied with such a container or pack.

***advertisement**, in relation to therapeutic goods, includes any statement, pictorial representation or design, however made, that is intended, whether directly or indirectly, to promote the use or supply of the goods.*

***presentation**, in relation to therapeutic goods, means the way in which the goods are presented for supply, and includes matters relating to the name of the goods, the labelling and packaging of the goods and any advertising or other informational material associated with the goods.*

***standard**, in relation to therapeutic goods, means a standard that:*
(a) is specified in an order under section 10 that is applicable to the goods; or
(b) if no such order is applicable to the goods but the goods are the subject of a monograph in:

(i) in the case of goods for use in humans - the British Pharmacopoeia; or
(ii) in the case of goods for use in animals - the British Pharmacopoeia (Veterinary);

is constituted by the statements in that monograph.

Section 3 Interpretation (5)

For the purposes of this Act, the presentation of therapeutic goods is unacceptable if it is capable of being misleading or confusing as to the content or proper use of the goods and, without limiting the previous words in this subsection, the presentation of therapeutic goods is unacceptable:

(a) if it states or suggests that the goods have ingredients, components or characteristics that they do not have; or

(b) if a name applied to the goods is the same as the name applied to other therapeutic goods that are supplied in Australia where those other goods contain additional or different therapeutically active ingredients; or
(c) if the label of the goods does not declare the presence of a therapeutically active ingredient; or
(d) if a form of presentation of the goods may lead to unsafe use of the goods or suggests a purpose that is not in accordance with conditions applicable to the supply of the goods in Australia; or
(e) in prescribed cases.

Part 2 Standards

Section 10

Determination of standards
(1) The Minister may, by order published in the Gazette, determine that matters specified in the order constitute a standard for therapeutic goods identified in the order (whether or not those goods are the subject of a monograph in the British Pharmacopoeia or the British Pharmacopoeia (Veterinary)).

(2) Without limiting the generality of subsection (1), an order establishing a standard for therapeutic goods may:
……
……..(c) require that therapeutic goods or a class of therapeutic goods identified in the order be labelled or packaged in a manner, or kept in containers that comply with requirements, specified in the order.

(3) Without limiting the generality of paragraph (2)(c), the Minister may, in an order establishing a standard, direct that there be set out, in a manner specified in the order, on:
(a) therapeutic goods or a class of therapeutic goods identified in the order; or
(b) a container or package containing therapeutic goods or a class of therapeutic goods identified in the order; or
(c) a label of therapeutic goods or a class of therapeutic goods identified in the order;

such particulars as are required by the order.

(4) *The Minister must not determine a standard or maned or revoke a standard unless the Minister has consulted with respect to the proposed action with a committee established by the regulations to advise the Minister on standards.*

Section 17 Australian Register of Therapeutic Goods

(4)The regulations may:

(a) prescribe the therapeutic goods, or the classes of therapeutic goods, that are required to be included in each part of the Register; and
(b) prescribe the ways in which goods that are included in one part of the Register may be transferred, or may be required to be transferred, to the other part of the Register; and

(c) *prescribe the ways in which goods that have been assigned a different registration or listing number.*

Part 3 Australian Register of Therapeutic Goods

Section 22 General offences relating to this Part

(1) A person must not intentionally or recklessly set out or cause to be set out, on a container or package that contains therapeutic goods or on a label of goods of that kind, a number that purports to be the registration number or listing number of the goods in relation to a person if the number is not that number

(5) A person, being the sponsor of therapeutic goods that are included in the Register, must not, by any means, intentionally or recklessly advertise the goods for an indication other than those accepted in relation to the inclusion of the goods in the Register.

Section 25 Evaluation and registration of therapeutic goods
……..
the goods are to be evaluated for registration having regard to:

…….; and
(e) whether the presentation of the goods is acceptable; and
(f) whether the goods conform to any standard applicable to the goods, or any requirements relating to advertising applicable under the regulations; and
…..

Section 26 Listing of therapeutic goods

the Sectretary is not to refuse to list goods in relation to the person except where the Secretary is satisfied that:

…; or
(e)the presentation of the goods is unacceptable; or
(f)the goods do not conform to a standard applicable to the goods or to a requirement relating to advertising applicable under the regulations; or
…..

Therapeutic Goods Regulations 1990

Part 2 Advertisments

Division 3 Other advertisments

Reg 6 Advertising offences
(1) A person must not publish an advertisement about goods for therapeutic use:
(a) that contains a prohibited representation (whether in express terms or by necessary implication) about those goods; or
(b) that does not contain a required representation about those goods; or
(c) that is a contravention of a notice……

….; or
(d) that contains:
a reference to the Act, other than in a statement of the registration number or listing number of the goods; or
a statement suggesting or implying that the goods have been recommended or approved by or on behalf of a government authority, other that a statement of their availability as a pharmaceutical benefit or a statement authorised or required by a government or government authority; or….

Division 4 General

Reg 6A
Unacceptable presentations
For the purposes of paragraph 3 (5) (e) of the Act, any labelling, packaging or presentation of therapeutic goods (including novelty dosage forms in the shape of animals, robots, cartoon characters or other similar objects) that is likely to result in those goods being mistaken for or confused with confectionery or toys is an unacceptable presentation of the goods.

Reg 8
Prohibited and required representations
(1) For the purposes of this Part, the representations specified in column 2 of an item in Part 1 of Schedule 2 are prohibited representations about the therapeutic goods specified in column 3 of that item.
(2) For the purposes of this Part, a representation specified in column 2 of an item in Part 2 of Schedule 2 is a required representation about the therapeutic goods specified in column 3 of that item.

Reg 9
Use of prohibited representations
The Secretary may, by notice published in the Gazette, permit a prohibited representation to be included on the label of therapeutic goods, or in information included in the package in which the therapeutic goods are contained, if the representation is necessary for the appropriate use of the goods.

Part 2A Patient information
Information about certain therapeutic goods to be supplied (PI for prescription medicines)

Schedule 2
Prohibited and required representations for the purposes of paragraphs 6(1) (a) and (b)

[refers to Clauses 4 and 7 of the current Advertising Code with specific prohibitions for vitamins and minerals, disinfectants and analgesics]

Therapeutic Goods Order No48
General requirements for labels for drug products {currently under revision}

Interpretation

defines Australian Approved Names List and label items such as directions for use and warning statements.

" warning statements" means
(a) any relevant warning statement specified in Appendix F-Part 1 of the Standard for the Uniform Scheduling of Drugs and Poisons of the National Health research Council[reference out of date];
(b) any warning statements specified in the standard for the goods; or
(c) a warning statement where incorrect route of administration may be hazardous;

Appendix 2 Other relevant reviews

Where relevant, previous work need not be repeated and should be taken into account. There have been several other reviews that have included labelling in their terms of reference. The information derived and the recommendations made in previous reports should be reconsidered here.

Industry Commission

The Industry Commission conducted two important reviews in 1995, one on packaging and labelling regulation for products in Australia, including medicines and the second on the pharmaceutical industry, including regulatory matters. This work identified problems associated with complexity and degree of prescriptiveness. There is obviously a need for more public debate about the recommendations for performance-based regulation.

1. *Packaging and labelling* 1995
A report on the regulatory, institutional and other arrangements that impede efficiency in Australia's packaging and labelling activities.

Chapter 7 Packaging and labelling regulation:

> **Recommendation 12**
> **Legislatures and regulatory agencies involved in setting packaging and labelling standards should consider drafting regulations in terms of specific objectives or outcomes which producers are required to satisfy, instead of prescriptive standards.**
>
> **When regulating on this performance basis, regulatory authorities should have the capacity to deem prescriptive standards to comply with the performance standard.**
>
> Other relevant passages include:
> **7.5.1 Uniform regulation and 7.5.2 Mutual recognition**
> **Approaches to uniform regulation involving the referral of power and parallel legislation seem superior on the grounds of timeliness, cost and accountability. There are inefficiencies when Ministerial Councils constitute a second step in a regulatory process as in food standard development. Mutual recognition has filled gaps between and within regulatory systems.**
>
> The review noted:
> Strict adherence to requiring re-labelling increases the price of imported goods.
>
> Therapeutic goods have been exempt from mutual recognition arrangements within Australia and between Australia and New Zealand.

2. The Pharmaceutical Industry 1995 Report No 51 AGPS

The Industry Commission reported on the pharmaceutical industry in Australia, its relationship to the global industry and its potential for further development.

Chapter 15 Regulatory issues – scheduling and advertising

15.4 Labelling and advertising

Consumers need information and advice on which to base their self-medication decisions. Labelling and advertising are two of the major sources of information on diseases and their treatments.

15.4.1 Labelling

"Many Commonwealth and State regulations control a label's content. These arrangements have been criticised on several grounds:

. their complexity and lack of uniformity; and

. a tendency to be overly prescriptive.

The present arrangements allow for commercial additions such as corporate packaging which results in different products looking the same, with any associated safety issues not addressed by the regulations. Statements of performance outcomes would overcome this.

National Drugs and Poisons Schedule Committee

New harmonised requirements 1995 (implementation due to be completed June 2000)

Outcome
Guide to labelling of drugs and poisons in accordance with the standard for the uniform scheduling of drugs and poisons July 1995
This review resulted in changes such as use of "Pharmacy Medicine" instead of "S2" and "Pharmacist only medicine" instead of "S3" for signal headings.

TGA

Labelling of analgesics

Review of non-prescription analgesics by David Newgreen February 1998

This is a review arising from the concern about the potential abuse and misuse of analgesics sold over the counter and the extent to which this may be addressed through labelling and other measures at point of sale.

Some prescriptive recommendations in relation to labels were made. Eg chosen units for doses.
(Recommendations 2.8, 2.9, 2.10, 2.13, 3.2, 4.4)

The report also includes recommendations about amendments to warnings and the movement of warnings and safety directions from Appendix F of the SUSDP to the *Therapeutic Goods Act 1989*. (Recommendations 6.1 to 6.9 and 7.1, 7.2 and 7.3)

The recommendations of the Analgesic Review that have implications for the Labelling Project are:

Recommendation 2.1

This recommendation is about avoidance of a variety of dosage strengths on the market, if (new) strengths of paracetamol oral liquids appear, in order to avoid confusion with dosing. The PMAA would not like to lose flexibility in product development and believes that the focus should be on overall label improvement to existing and new products, reinforced by agreed community messages about the importance of the label and the need to always read it.

The TGA response supports a system through registration evaluation, whereby a new strength would be checked against safety criteria. Registration also provides an opportunity for evaluation of the label, as part of the assessment of the risk of the new product.

Under the current paradigm of established fixed warnings via the SUSDP, the TGA considers other factors such as strength of active or larger pack sizes in the process of registering the product.

Current action: referred to MEC re clarity on this to be provided in AGRD2.

Recommendation 2.7

Community service announcements must refer to the need for consumers to read the label and tell them what to do if they do not understand the label.

The PMAA believes that public education must work towards an understanding of the label as a key reference point for safe and responsible use.

Current action: to refer this issue and other relating to education and communication to PHARM responsible for quality use of medicines.

Recommendation 2.13

This concerns the requirement for warnings about limiting number of doses to 4 in 24 hours, and not for more than 48 hours, without medical advice. The wording is not prescriptive and this recommendation is supported by industry and is already occurring on new products. It is consistent with AGRD2. TGA is negotiating with industry regarding old products. There is, however, a question remaining about a mechanism to make this mandatory.

Recommendation 6.1.1
Warnings statements for analgesics should remain in the SUSDP for the time being.
And 6.1.2
When all States and Territories have complementary legislation, Appendix F to move to TGO48 or new Order.

TGA response at the moment is based on the worry about the lack of applicability of Commonwealth legislation without complementary legislation in the States/Territories. Thus in this context, TGA wanted to leave Appendix F in SUSDP.

PMAA is urging that all obtain complementary legislation. They do not want loopholes for unincorporated bodies and sole traders within borders.

Current action: TGA to advise NDPSC of TGA view

Recommendation 6.2

The proposed new analgesic warning labels should be tested for useability before being incorporated into the SUSDP.

Recommendation 6.3 highlights the value of existing publications for guidance on performance based labelling and testing.

The PMAA believes that there is a need for a fundamental change in the approach to the regulations pertaining to labelling for the concept of useability and performance-based labelling to be fully embraced.

Current action: TGA to refer to NDPSC

If TGA takes responsibility for the warnings on labels, TGA should also take responsibility for examining the value of, and ability to, implement performance-based labelling. Because NDPSC wants the warnings out of the SUSDP, this committee will refer the matter back to the TGA.

Recommendations 6.4, 6.5, 6.7, 6.8

Prescribed warnings about use, when not to use etc for paracetamol, aspirin and ibuprofen, naproxen, mefanamic acid are to go into Appendix F SUSDP

Current action: TGA to refer to NDPSC

Industry Science and Tourism (Consumer Affairs Division)

1**. Review of the trade practices (consumer product information standards)(cosmetics) regulations** 30 June 1998

A review of mandatory cosmetic labelling was undertaken in accordance with the National Competition Principles Agreement in 1998. The Committee, comprising representatives from the Department of Industry, Science and Tourism, the Australian Competition and Consumer Commission and the then Department of Health and Family Services, concluded there was a need for mandatory cosmetic labelling regulation as already in place.

The Committee recommended retention of the current regulations with minor amendments in the interests of facilitating international harmonisation of mandatory requirements and increasing trade opportunities.

The purpose of the mandatory standard is to:

- enable consumers to identify those products containing ingredients which may irritate them or may cause an allergic reaction;
- identify products which contain ingredients which are found to be potentially harmful after the product has been manufactured;
- reduce the cost to governments of medical and pharmaceutical benefits which arise when consumers seek treatment for allergic reactions to cosmetics;
- satisfy consumer needs for ingredient information about cosmetic products, especially at retail outlets, such as supermarkets, where information cannot be obtained from sales assistants; and
- enable consumers to make value comparisons between similar products.

The issues considered in the review included nomenclature and listing of all incidental ingredients. The Committee agreed that the adoption of the International Cosmetic Ingredient Dictionary names, an internationally recognised system of nomenclature, would ensure consistency of ingredient labelling across countries and facilitate international trade. On the matter of listing every incidental ingredient on the label, the Committee decided that there was no evidence on which to justify such an extension of the regulations. Compliance could well be impossible in any case.

2. Performance-based product labelling regulation project 1997-1998

The following is extracted and abridged from a draft report which was not finalised nor released

This project included a case study of over-the-counter medicines (analgesics)

The brief was to consider whether a performance-based approach to product labelling regulation could improve label information for consumers and help reduce administrative complexities and expenses faced by business.

The project was based on the following:

- consumers experience difficulty with the terminology used on labels;

- labelling performance criteria could identify what regulators want industry to communicate to consumers and what consumers should be able to do with labels;

- there is a need to address the lack of information available to consumers and small manufacturers on the regulation processes;

- the need for communication expertise to be represented on regulatory bodies to ensure that labels convey the most useful information to consumers; and

- the need to harmonise Commonwealth, State and Territory and, where appropriate, international laws.

Product labelling regulation in Australia includes general legislation (e.g. section 52 of the *Trade Practices Act 1974* which prohibits misleading and deceptive conduct) and specific

legislation (which may cover labelling of a particular product). The range of goods subject to specific labelling requirements is vast and includes food and beverages, prescription and non-prescription medicines, agricultural, veterinary and garden products, clothing, tobacco and toys for children under three.

Any given package or label might be subject to regulation by several bodies, possibly from different jurisdictions. Where a product is regulated by more than one regulator or more than one jurisdiction, the different objectives of each regulator/jurisdiction can result in complex and confusing situations. These complexities can potentially negate the objectives of product labelling, reducing the benefits and increasing costs to business and consumers. There seemed to be a feeling among stakeholders that labelling objectives are being best met in areas where there is a single regulator and where there is good communication between regulators, business and consumers.

Defining Performance-based Labelling Regulation

The project identified a great deal of confusion about the meaning of the term 'performance-based labelling regulation'. Some stakeholders, for example, took 'performance-based labelling regulation' as meaning a move towards deregulation or a lowering of standards protecting public health and safety.

For the purposes of this project, the Consumer Affairs Division, Department of Industry, Science and Tourism used the following definitions to distinguish performance-based (i.e. outcomes-based) regulatory approaches from prescriptive ones.

- **Prescriptive requirements** specify the manner in which a product is to be labelled (e.g. labels on a substance shall contain particular words, sized and positioned as specified).
- **Performance-based/outcomes-based requirements** give specified outcomes but do not stipulate how those outcomes must be achieved (e.g. labels on substances must be easily legible and draw the attention of the user to all hazards involved in their use).

Performance-based requirements can set very high compliance standards to protect consumer health and welfare, while allowing manufacturers more responsibility for designing labels that are based on sound consumer research and which meet the readability and information needs of consumers and satisfy the requirements of regulators. Performance based labels are, however, open to interpretation about the level of compliance.

Business concerns

One of the strongest findings of the project was that existing and potential businesses, particularly small businesses, are likely to have difficulties in locating, accessing and using information about product labelling. The project also found that most current labelling regulation for products affecting human health and safety tends to contain mandatory and very prescriptive elements. While there seems to be strong support for a continuation of mandatory requirements in these areas, the requirements do not necessarily have to be expressed as prescriptive instructions. There is also a clear indication that the current prescriptive approach is resulting in a highly complex set of labelling rules that are difficult to negotiate and quite expensive to administer.

The project also had difficulty substantiating and quantifying claims of excessive cost in the regulatory process. Three problematic areas of costs associated with current product labelling regulation were highlighted:

- costs associated with changes to legislation or regulatory requirements;
- costs imposed by time delays associated with the regulatory process; and
- indirect or unexpected costs associated with inadequate understanding of regulatory obligations and requirements.

The project found that, while there is strong support for a continuation of mandatory requirements in some areas, there is also a clear indication that the level of prescription demanded for the wording of some labels may be resulting in labels that are unhelpful or confusing for consumers. Prescriptive requirements could mean that a manufacturer may be locked into using phrases or words on a label which research with consumers may show to be ineffective.

Australia New Zealand Food Authority

The Authority has been undertaking a Review of the Australian Food Standards Code for several years. Under that Review, individual reviews of specific labelling statements, naming of food, health claims, nutrition statements and percentage labelling have been undertaken. Most of this work is near completion.

Appendix 3

State and Territory regulation of the labelling of medicines

State	Legislation	Labelling provision	Comment
NSW	Poisons and Therapeutic Goods Act 1966	S45C power for the Governor to make regulations, including for labelling of therapeutic goods	Complementary to Cw'th Act (amendment Act 1996)
	Regulations 1994	States labelling obligations of dealers of poisons and pharmacists supplying S3 And unscheduled subs	Reference to "uniform standard" and TGO20 And Appendix A
	Appendix A	Labelling requirements for therapeutic substances including on dispensed prescription medicines	Ref to Appendix F SUSDP and includes some additional warnings for nominated substances
SA	Controlled Substances Act 1984	S63 Power for the Governor to make regulations, including those covering labelling of therapeutic substances S24 packaging and labelling of ther. subst. sold or supplied	
	Controlled Substances (Poisons) Regulations 1996	For the purposes of s24 of the Act	Ref to SUSDP requirements and dispensing label requirements for s4 and selected s3 substances
Vic	Drugs, Poisons and Controlled Substances Act 1981	S12 Minister may prepare a Poisons Code which may contain labelling provisions S12A Poisons list to contain 9 schedules S12B determining suitability for inclusion of a Cwth standard in the	

Vic continued		Poisons Code S27A must comply with poisons code for supply of poisons S132 Governor may make regulations, incl. labelling	
	Therapeutic Goods Act 1994	S72 Governor may make regulations incl. labelling of ther.goods.	Mirrors Cw'th
	Pharmacists Act 1974	S37 Governor may make regulations on prescribing labelling requirements	
Northern Territory	Poisons and Dangerous Drugs Regulations 1986	Part II labelling consistent with SUSDP (detailed requirements)	
	Food and Drugs Act 1984	Part II Adulteration, labelling and false description of foods or drugs	"drug" includes cosmetics
Australian Capital Territory	Poisons and Drugs Act 1978	S29 refers to Drugs and Poisons Standard	
	Poisons Act 1933	S54 Executive may make regulations incl for labelling of poisons	
	Public Health (Sale of Food and Drugs) Regulations	Reg 5 Labelling of package of a drug	
	Public Health (Private Hospitals) Regulations	Reg 21 responsibility of the proprietor for safe custody and labelling of drugs used	
Western Australia	Poisons Act 1964	S3 powers of the Poisons Advisory Committee whose functions include matters relating to labelling of poisons; The Governor may make regulations incl. for labelling for poisons.	
	Poisons Regulations 1965	S26 The Commissioner of Health may for safety reasons prevent the use of certain labels or	

		packaging.	
Queensland	Health Act 1937	S152 Regulations about drugs, articles, substances etc. incl. prescribing the mode and content of labelling of drugs	
	Health (Drugs and Poisons) Regulation 1996	S85 labelling dispensed medicines (schedule 8) s198 (schedule 4) s276 (schedules 2&3)	Prescriptive elements picks up AppK and F warnings
	Health Regulation 1996	S156 labelling requirements for ther. goods S157 advertising and further labelling requirements	Similar to current Advertising Code
Tasmania	Poisons Act 1971	S34 Hazardous poisons not to be left unlabelled	

Appendix 4 Stakeholder perspectives

Australian Pharmaceutical Manufacturers Association

The Australian Pharmaceutical Manufacturers Association represents sponsors of prescription medicines.

Because of the need for a prescription in order to obtain these medicines, consumers do not require the same sponsor labelling as for non-prescription medicines. The prescribing doctor, the pharmacist and the Consumer Medicine Information are alternative sources of information for the consumer. Further, the dispensing label from the pharmacist carries essential information for the safe and appropriate use of the medicine. However, it was recognised that some information on the sponsor's label is important for consumers, such as the batch number, expiry date, storage conditions and product name.

Therefore, the APMA is not concerned with performance-based labelling and in fact it may not be in their members' best interests. The concept of performance-based labelling arose from the need to make sure warning statements on the label could be understood and correctly interpreted by consumers. These warning statements are not required for prescription products, except those containing specifically nominated substances and those in Appendix K of the SUSDP. APMA would generally prefer to have requirements clearly set out so that interpretation is unambiguous and can be consistently applied.

Self-regulation or co-regulation of labelling such as under a Code of Conduct regulated by industry would need to be considered in the context of the onus on the industry to implement a mechanism for self-regulation with associated monitoring and dealing with non-compliance.

There are two specific issues for sponsors of prescription medicines: the dispensing label and the Consumer Medicines Information (CMI) leaflet which will have to be supplied for all prescription medicines and provides a comprehensive set of information to help consumers use their medicines safely and appropriately.

The need to add a dispensing label is a potential problem, if the sponsor label does not allow sufficient space, devoid of the essential information consumers require in using the medicine. There is a standard size for dispensing labels and the necessity to add this label could be allowed for in sponsor label design. The application of additional labels by the pharmacist, is described in the Australian Pharmaceutical Formulary for prescription products.

The APMA also notes that there is potential for confusion between products by the pharmacist in dispensing and the consumer at time of dosing. Confusion can occur because of lack of differentiation between products when the corporate image predominates over the presentation of the medicine name, or the names are sufficiently similar, even of separate brands, to be mistaken under times of stress or by consumers with difficulty in reading.

The APMA does not consider the label in isolation when seeking to achieve the best outcome in consumer compliance. The health professionals such as pharmacists, hospital staff and

other learned intermediaries also have a role and may require additional information about prescription products.

The additional legislation that their members have to take into account includes Occupational Health and Safety legislation (usually compliant if compliant with TGO48), and Customs (Prohibited Imports) Regulations. For example, country of origin labelling is required on importation into Australia. Trade Practices legislation is also relevant in relation to claims such as "Made in Australia".

The APMA requests:

- The development of a single document which sets out all the labelling requirements.
- Trans-Tasman harmonisation of labelling – resolution of remaining differences as exemplified by the letter height issue. (see submission to Drugs Poisons and Controlled Substances Review)
- No changes to labelling unless demonstrated as necessary as there have been multiple changes in the last few years.
- If there have to be changes, a lead-in time of 3 years.
- Do not make regulations which result in requirements that are more restrictive for one sponsor over another.

Proprietary Medicines Association of Australia

The PMAA represents manufacturers and distributors of non-prescription medicines.

The PMAA is a non-profit organisation actively involved in the work of the World Self Medication Industry (WSMI) which is officially recognised by the World Health Organisation.

The mission of the PMAA is to promote the role of responsible self-medication in Australia's health care system.

The PMAA works to
- ensure that safe, effective non-prescription medicines are available to all Australians,
- maintain such products at reasonable cost,
- encourage responsible and cost-effective self medication,
- engender effective industry/government consultation,
- actively establish liaison with all relevant stakeholders,
- achieve national and trans-Tasman harmonisation of regulations,
- provide better information to consumers about medicines, and
- enhance exports of non-prescription medicines.

Throughout these activities, the PMAA provides an authoritative and unified voice for the non-prescription industry and acts as the acknowledged point of consultation with governments and regulators, healthcare professionals, consumer groups and other stakeholders.

The Proprietary Medicines Association of Australia (PMAA) has been devoting resources to the improvement of labels for some time. The PMAA commissioned research into making labels more effective (see Effective communication section 2 above *Making Medicine Labels Work* 1992) and have continued to make submissions to review of labelling based on the findings. The PMAA acknowledges that research in this area is not complete but believes that there are sufficient data to support its commitment to recommending improvements.

The role of the label is to give the necessary information for safe and effective use of medicines. Reference should be made to *Writing about medicines for people. Useability guidelines for consumer medicine information* 2nd edition. David Sless and Rob Wiseman Communication Research Institute of Australia 1997 and the further work undertaken by CRIA (see Attachment).

There are other sources of written information for consumers such as the Internet from which information about substances and overseas products can be obtained.

Prescriptive elements in labelling requirements have been the basis of regulation to date. There are advantages in having some prescriptiveness: it is easier to decide what to include on a label, and it can cut time/production costs. Consistency in assessment of compliance is important. But is it achieving the goal of labelling?

Performance-based requirements are sought by industry as the general rule. This means labelling that can be easily understood and acted upon by consumers to achieve appropriate behaviour in line with the product's indication(s). As has been achieved with Consumer Medicine Information, it may be preferable to develop performance-based requirements for product categories, as product by product performance evaluation may be too costly. The mandatory/flexibility balance should be more in favour performance based requirements.

The disadvantages of the current situation are the number of places from which information about labelling requirements must be sourced and the extent of the prescriptiveness in these requirements. The intended changes to TGO48, which permit some relaxation of prescriptiveness for batch numbers for example are applauded. The number of regulatory documents is particularly confusing to newcomers to the industry who can face costly omissions. It is not always practical, from the view of the development of a product, to wait until a label has been approved as part of the registration process before printing it.

SUSDP:
The PMAA has difficulty with the situations, which occur for some products where the prescribed warnings are not always appropriate for that product. An example is the inclusion of warnings for substances (e.g. included in the SUSDP) against activity normally only undertaken by adults such as driving a car. These are then mandatory on children’s products as well.

TGO48:

Stakeholder views

There are disadvantages in the current processes and administration of TGO48. It takes too long for change to occur, but the time taken in consultation is acknowledged as necessary. This should be the rate-limiting step, not the decision making at TGA and committee level.

Suggestions

- Some flexibility of language would be appropriate such as recommending "doctor and pharmacist" instead of “medical” on labels for additional sources of information. In general, the language could be simplified. Sometimes the language can work counter to objectives for the label information.

- Lead-in times are highlighted as crucial to reduce costs and need to be negotiated for any changes to the regulation of labelling. Sometimes two years may be appropriate.

- Increasing the carton size to accommodate all the required wording is not feasible, as this does not comply with deceptive packaging requirements. Variants of the normal label should be considered when the carton space is limited. For example, a concertina pull-out section, or a lift-up section or use of the inside of a carton as well. These would need to be tested for consumer acceptability and usefulness. The requirement for Consumer Medicine Information should be limited to Schedule 3, 4 and 8 medicines, as is the current situation.

- Under trans-Tasman harmonisation, consideration should be given to consistency of warnings so that separate packs are not required for the two countries.

- Use work already undertaken for the establishment of standards and the means to achieve standards. The Federal Bureau of Consumer Affairs has worked in this area. Regulations under the Trade Practices legislation specify labelling requirements for cosmetics, and as mentioned already, the CMI guidelines by Sless and Wiseman are an appropriate resource.

- Take note of work done in other countries so that consistency internationally may be more possible.

Improvements to the system would result in reduced costs by reducing the time taken in ensuring compliance and verifying the required elements for the label. The development of a single consolidated labelling guideline containing all the requirements and introduction of performance based labelling are the most important improvements sought.

PMAA addendum

Complementary Healthcare Council of Australia

1. The role of Labelling of Medicines
The main role is to identify the goods and provide sufficient information to consumers in order to achieve safe use and desired health outcomes. A secondary role is to enable consumers to compare products.

2.Advantages and Disadvantages of the current situation.

Advantages
- apply uniformly,
- allow comparisons between products
- the system is documented
- assists safety.

Disadvantages

- plethora of sources of requirements
- complexity
- Australian specific – formats, unique warnings, etc.
- open to interpretation
- too much information – not read by consumers or meaningless
- act as a trade barrier to imported products
- label changes are costly
- lack of consistency across food/medicines interface
- keeping labels in compliance at all times with ever changing requirements is a huge resource and cost burden.
- inequity and lack of a level playing field between complementary and prescription medicines. e.g. why should complementary medicines carry 'warfarin' warnings if warfarin is not required to include complementary medicines warnings?
- changes to labelling requirements very costly to implement on slow moving products. e.g. addition of maltodextrin to TGO#48 schedule 2, led to destruction of 1000's of stock labels, and large compliance costs.
- waste of resources both TGA and Sponsor in seeking exemptions to unnecessary prescriptive requirements – eg. changes to type size. TGA gazettal costs alone must run to many 1,000s of dollars.

Sources of information about labelling requirements
- TGO#48
- SUSDP
- Herbal expression guideline
- Therapeutic Goods Advertising Code
- NCCTG Guidelines
- Gazettals of individual substance requirements
- State Weights and Measures legislation
- Therapeutic Goods Regulations
- ACCC – Country of Origin Guidelines
- Fair Trading Act

- Dangerous Goods Act
- Excluded Goods Order
- Published and unpublished internal TGA policies
- AAN list
- National Registration Authority
- Commerce (Trade Descriptions) Act
- Medicines in Pregnancy Handbook

Do any requirements work counter to health & safety for users?

- Meaningless and unnecessary warning statements
- Prescriptive statements to describe dosage forms – eg. multipurpose liquid, tanning oils must be called lotions, lipbalms must be called sticks, etc.
- The wording of many warning statements appears to be pitched at the 'lowest common denominator'. The people such statements are presumably aimed at are the least likely to read them. e.g. 'vitamin supplements should not replace a balanced diet'
- Prescriptive label placement and formatting. e.g. AustR/Aust L placement, warning placement, formatting – type sizes, colours etc.
- Warning statements which alarm consumers rather than reassuring. e.g. many customers think they should be on warfarin if they are buying Co-Enzyme Q10
- Mandatory name changes which cause confusion with BP altered terminology or AANs. e.g. thiamine mononitrate not Vitamin B1.

3. *Is there a role for mandatory labelling items?*
The CHC supports a single minimal uniform labelling standard containing all the requirements for labelling of therapeutic goods.
The objective should be to achieve consistency, safe and appropriate usage, and consumer choice.

4. *What labelling standards should we be trying to achieve?*
A single broad set of performance based standards rather than highly prescriptive guidelines. Reasonable periods of consultation and for implementation of changes. Runout of existing label stocks to be permitted if there is no safety issue. Where possible, harmonisation with the label requirements of international trading partners (NZ, EU, US) should be pursued. Industry and consumers do not require overly prescriptive formatting specifications. Many pages of such requirements in the existing requirements could be replaced by two words – prominent and legible.

5. *How can these standards best be achieved?*
Negotiation with all other authorities for a single control over therapeutic goods labelling centralised in the therapeutic goods program. Identification of the essential elements required on labels. Efforts should be made to find out what consumers need.

6. *Benefits to industry & consumers.*
Industry requires certainty and consistency in requirements and long lead times to implement change. Consumers require adequate plain information to assist the making of informed choices, not paternalistic and overly conservative 'protection'.

7. Are there alternative means of achieving the same objectives and standards?

Self-regulation
Once a new labelling standard is determined, the administration of labelling of low risk complementary healthcare products could be handed back to industry to self-regulate in the same way that advertising is regulated. This would be less adversarial and lead to less 'tinkering' with the requirements.

Definition
The definition of 'label' needs review with regard to international consistency. In the USA, 'label' includes all of the information used in the marketing of the product. The complementary healthcare products industry at present does not want to see CMI's but they should be allowed as an option for any Sponsor wishing to provide more factual information about a product for the benefit of the consumer. There is a need for any review of labelling to take into account recognition of Sponsor Information Services, Web Sites and Supplementary Information provided in association with a product.

Other Issues:
Signal terms on complementary healthcare labelling
Informal discussions may have raised the issue of the use of "signal" terms or disclaimers on complementary healthcare products eg. a requirement that a label carry the words 'complementary medicine', or a disclaimer to the effect that 'this product has not been evaluated by the TGA'. The complementary healthcare industry is opposed any moves to require separate identification of its products.

Above all industry compliance costs must be kept at the forefront of this Review and any recommendations should be directed towards achieving efficiencies and cost savings. What industry seeks is minimum effective regulation and a genuine co-regulatory environment.

Consumers' Health Forum

1. What do you see as the role of labelling medicines?

Generally:
Labelling of medicines provides identification of the medicines, information about usage and any warnings.

Over-the-counter and complementary medicines:
More information to help make decisions about what product to take, how effective it will be, levels of active ingredients so that eg different brands can be compared, recommended dosage is needed. The information on the label may be the only information available to consumers when they make their purchase.

Prescription medicines:
Consumers still need the same sort of information about their medicines, but with increased risk, additional information may also be needed.

The pharmacist adds dosage instructions on the pharmacy label according to the doctor's prescription. This is not so useful if this covers over the information on the manufacturers label, such as expiry date, active ingredient.

The additional information provided as Consumer Medicines Information (CMI) for prescription medicines and some over the counter medicines is particularly valued by consumers to help them make decisions about their medicines, provide information about adverse events and what to do if something goes wrong and so on. However because CMI is physically separate, or separable, from the medicine it is not a substitute for information on the label.

2. What are the advantages and disadvantages of the current situation?

- *where do you get your information about labelling requirements*

As a consumer organisation, it is difficult to find what information should and shouldn't be available on a label. TGO48 is not readily available; it is not on the Internet. The Standards for Uniform Scheduling of Drugs and Poisons has to be purchased, and is not readily available for consumers, although it does include the required warning statements they should be able to recognise. There is a real need for an easily accessible source of information for consumers about what they should be able to expect to find on medicine labels and where to go if the information seems to be missing.

- *do any requirements work counter to health and safety for users*

The amount of information required on a small label can mean that print is very small and difficult for many consumers to read. Putting the labelling information on a larger outer container or in a separate leaflet such as CMI is not a solution for small containers as both are separable from the medicine.

Sometimes the warning statements are not easy for consumers to understand and can lead to confusion. Expert committees could benefit from the support of people expert in communication to assist with drafting and testing of the effectiveness of warnings. A single consumer representative on such a committee does not provide adequate consumer feedback to ensure that the warning will achieve the desired outcome.

Sometimes brand names are very similar so mistakes can be made in dispensing. If there are several different strengths or presentations of the same medicine in similar packaging, dispensing mistakes can also occur. The Pharmaceutical Society of Australia has provided several reports to the Australian Pharmaceutical Advisory Council regarding this problem.

3. Is there a role for mandatory labelling requirements?

Consumers need to know they can obtain basic information from the labels on medicines and count on it. They need to know that the labels will not include any false claims, there will be appropriate basic warnings (eg medicines that should not be given to children, medicines that may be addictive) and dosage information including limits.

4. What labelling requirements should we be trying to achieve?

We should be trying to achieve labelling that supports wise and appropriate use of medicines. The labelling should be comprehensive, understandable, readable and achieve reasonable safety objectives.

5. How can the standards best be achieved?

The model used effectively for developing CMI could be adapted. Consumers are consulted about the information they need on the labels and how it could best be provided, with follow-up testing of the text and layout with small groups of consumers to ensure that it is easy to read and understand, and that instructions and warnings are interpreted as intended. The standards could be supported by developing and promoting an easily accessible source of information for consumers about what they should expect to find on medicine labels and where to go with problems.

6. If the system could be improved, how would it benefit you?

Improvements to the system to ensure that consumers really understood the significance of the information on the labels would provide benefits in assisting with informed choices about medicines and in supporting quality use of medicines. This would also improve confidence in the system amongst consumers and may contribute to improving compliance and reducing the risk of inappropriate use.

7. Are there alternatives for achieving the same objectives and standards?

CMI, consumer drug information services, other ways of providing information provide valuable supportive information, but do not replace labelling which is intimately associated with the medicine at the time it is being taken.

OTC Industry Consultant (personal view)

Drug labelling is certainly a ubiquitous problem. In my view, this is due principally to four things:
A drug label has to meet 8 different criteria at once (see below);
There is no attempt made to educate and re-educate the writers of drug labels;
TGA and State reviewers of labels often are not aware of all these requirements and so give limited advice/ demands which can subject an applicant/complainant to more demands after responding to one;
There are overlapping and potentially conflicting or confusing requirements, but only in the field of warnings.

Observations:
Labelling is an important consumer issue, even if only 1% of consumers read or understand labels---and it may even be higher! The things that are required now are necessary for consumer education and protection.
Self-regulation will not work because it will lead to the well-known antics of artwork and advertising persons to position their products to beat the opposition: there has to be a 'referee'. Given that, to referee countless variations is impractical while fixed rules (even if there must be concessions or exemptions) are workable and fair.
Any move to consolidate the present requirements should take into account that allocation of products into a Poisons Schedule, with the consequent prescription of some of the labelling, is essentially to control access, handling and distribution of drug products and not merely to

classify them on some scale or merely to provide a mechanism for label warnings. Thus, the input of State pharmacists and poisons control officers is indispensable: they have to deal with implementation of the access, handling and distribution rules.
I would suggest that trying to condense the many facets into a single system (which seems to be the thrust of the present project) should be put on hold while internal and external education (in the broadest sense) is given a try.
The most important facet of the problem is, in my view, to bring Poisons warnings, Registration warnings and Advertising prohibitions and required statements together. Co-operative means to harmonise these aspects should be explored first, but if there is to be a legislative change, then possibly bringing these aspects together would be sufficient.

Label Requirements

Poisons regulations (several matters such as signal headings and including warnings)
Label order (several matters including warnings)
Advertising prohibitions and compulsory statements
Consistent with registered claims and other registration particulars including warnings
Trade Practices regulations statement of weight, measure or count (except Rx)
Pharma Code (except Listed products)
Artwork code (the latter two under GMP)
Over-riding Trade Practices requirements regarding deceptive statements

Designing product information for people

A summary of research into product labelling and product information carried out by the Communication Research Institute of Australia

Consumer Product Information

In 1992, the Australian Commonwealth Government introduced laws making Consumer Product Information (CPI) a legal requirement for all medicines supplied on prescription.

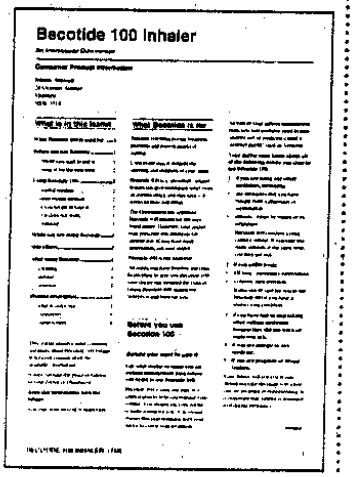
In 1993, our Institute was commissioned to prepare a set of Guidelines for pharmaceutical manufacturers, to help them write easily understood CPIs for their medicines.

We worked with all of the parties involved in the supply, use and regulation of medicines: government, industry, community groups, and the medical profession. Throughout the project, we were struck by the willingness to collaborate, and the unanimity of opinion amongst those we talked to on issues such as the need for CPI, what CPIs should contain, and how they should be distributed. Many people and organisations, particularly manufacturers and pharmacists, were generous in contributing their experience and expertise.

As part of our research, we developed and tested model CPIs for a range of different medicines. Our aim was to develop a structure for CPIs that would be suitable for all types of medicines, and consistently easy for consumers to use, find, and understand information.

Consumers will normally be given their CPI by their pharmacist when they buy their medicines. The pharmacist will print out the CPI at the same time as the medicine label. For our tests, we prepared two formats for CPIs produced in this way—one for CPIs printed on dot matrix printers, the other on laser printers.

Research carried out in Australia and other countries suggested that between fifty and sixty per cent of people using existing CPIs would be able to find and understand information on how to use their medicine properly. Eighty-five per cent of consumers were able to use successfully the CPIs we developed, meeting benchmark performance standards set jointly by us and the Department of Human Services and Health. ■


Becotide 100 Inhaler

Labels

In 1994, the Institute was commissioned by the Department of Human Services and Health to develop 'medicine labels for quality use of medicines'. To allow us to compare our design procedures with others advocated for improving labels, we began our research with two labels used in previous research commissioned by the Proprietary Medicines Association of Australia (PMAA).

We began with an analysis of all of the tasks that medicine users should be able to carry out using the labels. These actions were the criteria that our labels would be tested against.

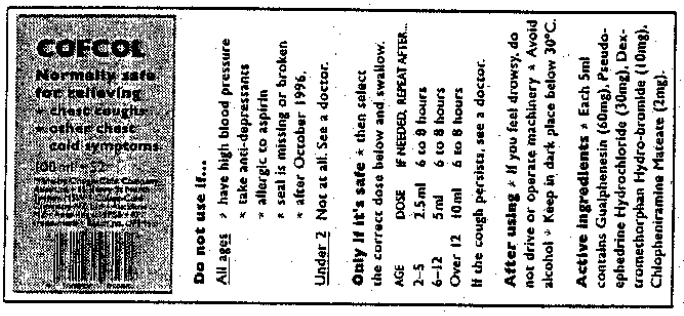
We then analysed the information on the label—identifying what was missing, what was superfluous, and what the function of each element was. We then separated elements of the design that related to different users. For instance, we placed the Poison Schedule number on surfaces where the pharmacist could see it when on the shelves, but away from information for the consumer (as previous research had shown that consumers consistently misunderstood what the Poison Schedule numbers were for).

Once we had prepared draft designs, we put them through three rounds of testing and modification. In this process of modification, we developed several innovations. For instance, on one label,

continued over ➤

which had to appear on a bottle only five centimetres in diameter, we abandoned the convention of printing the text vertically, and printed it so that users would have to hold the bottle sideways and scroll the bottle to read the text. This gave readers a clear order in which to read—top-to-bottom—rather than a choice of three panels as on the original label. It also gave us slightly more text space to work with, allowing us more flexibility in a highly confined space.

Our test results showed that our design process would produce labels that would consistently and significantly out-perform labels consistent with current Australian labelling regulations. Our labels also were significantly better on many criteria than labels developed for the same products using plain English principles. Our labels were frequently much less prone to such misreading and misinterpretation than the original labels. ■



Median percentage of participants who gave fully correct responses		
	Prinsol	Cofcol
Original	44%	40%
Plain English	60%	58%
CRIA	71%	82%

Funding

Both projects were commissioned by the Pharmaceutical Health and Rational Use of Medicines (PHARM) Committee, and funded by the Pharmaceutical Education Branch of the Commonwealth Department of Human Services and Health. ■

About the Institute

The Communication Research Institute of Australia was founded in 1987 as a non-profit making body dedicated to improving the quality of human communication through research, training, publications and debate. It is the major centre for independent research in Australia into all aspects of communication. It has no affiliation with any particular political, social or industry groups.

Over one hundred public and private organisations in Australia and overseas support the Institute.

It is an approved Commonwealth Research Institute with an international reputation for research and innovation. Its research findings are widely cited by governments, private industry, decision makers and researchers. ■

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Appendix 5

Federal Register OTC medicines labelling

federal register

Wednesday
March 17, 1999

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 201, et al.

Over-The-Counter Human Drugs; Labeling Requirements; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201, 330, 331, 341, 346, 355, 358, 369, and 701

[Docket Nos. 98N–0337, 96N–0420, 95N–0259, and 90P–0201]

RIN 0910–AA79

Over-The-Counter Human Drugs; Labeling Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule establishing a standardized format and standardized content requirements for the labeling of over-the-counter (OTC) drug products. This final rule is intended to assist consumers in reading and understanding OTC drug product labeling so that consumers may use these products safely and effectively. This final rule will require all OTC drug products to carry the new, easy-to-read format and the revised content requirements within prescribed implementation periods.

DATES:

Effective Date: April 16, 1999.

Compliance Dates: For compliance dates see section V of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Debra L. Bowen, Food and Drug Administration, Center for Drug Evaluation and Research (HFD–560), 5600 Fishers Lane, Rockville, MD 20852, 301–827–2222, or email ''BOWEND@cder.fda.gov''.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 27, 1997 (62 FR 9024), FDA proposed to establish a standardized format for the labeling of OTC drug products that included: (1) Specific headings and subheadings presented in a standardized order, (2) standardized graphical features such as Helvetica type style and the use of ''bullet points'' to introduce key information, and (3) minimum standards for type size and spacing. The proposal included an extensive list of ''connecting terms'' that manufacturers may omit from product labeling, and an expanded list of ''interchangeable terms'' to facilitate the use of more concise and easy to understand language in OTC drug product labeling. The agency also proposed to amend several specific warnings, including the required pregnancy-nursing warning, the ''keep out of reach of children'' warning, and the accidental overdose/ingestion warnings, to make these warnings as direct and understandable as possible. Finally, the agency proposed to preempt State and local rules that establish different requirements than those in the proposed rule, to promote a national, standardized format for all OTC drug product labeling.

The agency discussed at length its basis for proposing to improve labeling design (62 FR 9024 at 9027 through 9031). The agency stated that a standardized labeling format would significantly improve readability by familiarizing consumers with the types of information in OTC drug product labeling and the location of that information. In addition, a standardized appearance and standardized content, including various ''user-friendly'' visual cues, would help consumers locate and read important health and safety information and allow quick and effective product comparisons, thereby helping consumers to select the most appropriate product.

The agency reviewed literature studies that confirmed that OTC drug product labeling often lacks the graphical features and visual cues needed to ensure readability and comprehension. These and other studies recommended ways to make labeling easier to read and understand, described the importance of adherence to directions for use, and reported on a number of preventable adverse drug reactions from OTC drug products (see 62 FR 9024 at 9027 and 9028).

The agency also has benefitted significantly in this proceeding from the experience it gained in redesigning food labeling under the Nutrition Labeling and Education Act of 1990 (NLEA) (Pub. L. 101–535, November 8, 1990). The agency's required nutrition labeling panel (§ 101.9 (21 CFR 101.9)) provides a standardized graphic presentation for food nutrients, allowing consumers to judge the significance of the level of a particular nutrient in a product in the context of a total daily diet. Since its implementation in 1993, the agency has received praise from consumers and nutritionists, noting the impact and utility of the standardized food label.

The agency provided over 7 months for interested persons to comment on the OTC labeling proposal, which included an extension of the comment period from June 27, 1997, to October 6, 1997, published in the **Federal Register** on June 19, 1997 (62 FR 33379). In addition, the agency solicited public comment on two labeling studies it conducted. In the **Federal Register** of December 30, 1997 (62 FR 67770), the agency sought comment (until February 13, 1998) on a study entitled ''Evaluation of Revised Formats for Over-the-Counter (OTC) Drugs'' (Study B). Study B consisted of a survey of more than 900 respondents to evaluate consumer preference for design variations in drug labeling formats. In the **Federal Register** of February 13, 1998 (63 FR 7331), the agency solicited comment (until March 30, 1998) on a second study entitled ''Evaluation of Proposed Over-the-Counter (OTC) Label Format Comprehension Study'' (Study A). Study A consisted of a survey of more than 1,200 consumers on the influence of variations in labeling formats on the communication of directions for use and required warnings.

In response to the proposed rule and the publication of Studies A and B, the agency received more than 1,800 comments from health professionals and students, professional organizations, trade associations, manufacturers, consumers, and consumer organizations. An overwhelming majority of the comments supported the agency's initiative to standardize the format of OTC drug product labeling and to make the labeling easier to read and understand by requiring a minimum type size, user-friendly headings, and other well-accepted visual cues.

However, a number of specific points in the proposal generated extensive, and sometimes divergent, comment: (1) Whether pharmacists, nurses, or other health professionals should be specifically referenced in certain of the proposed headings; (2) an appropriate minimum type size for the required labeling information; (3) application of the proposed labeling format to products traditionally marketed in small containers and products marketed as both drugs and cosmetics; and (4) continued reference to Poison Control Centers in the required accidental ingestion warning. These and other comments are addressed at length in section IV of this document.

The agency has considered the information presented in the proposed rule, the comments received, the results from Studies A and B, and all other relevant information, and concludes that the standardized format and content requirements for OTC drug product labeling, as set forth in this final rule, will enable consumers to better read and understand the information presented and apply this

information to the safe and effective use of OTC drug products.

As discussed in the proposed rule, research on reading behavior and document simplification shows that the use of less complex terminology, presented in shorter sentences with an organized or ''chunked'' structure, is likely to improve consumer processing of the information (Refs. 1, 2, and 3). Research also shows that consumers are more likely to engage in behavior that they believe they can successfully complete than in behavior that appears overwhelming (Ref. 4) or that presents a ''cognitive load,'' such as the task of reading densely worded consumer information (Ref. 5).

The new OTC drug product labeling is expected to decrease ''cognitive load'' by, among other things, decreasing the memory demands necessary for processing the information. This, in turn, will allow consumers to process the information faster. In addition, the new format offers a more structured, organized, and compact presentation, which places fewer and less imposing processing demands on the reader. The consumer's self-perceived ability to read the labeling will increase significantly and, thereby, result in an improved overall understanding of the information presented. Finally, the new labeling is expected to provide clear signals regarding important information, leading to increased processing and communication of this information.

II. Prototype Labeling Based on This Final Rule

An outline of the various labeling provisions for OTC drug products is shown below:

BILLING CODE 4160–01–F

OTC Drug Product Labeling Outline

Drug Facts

Active ingredient (in each dosage unit) **Purpose**

xxxxxxxxxxxxxxx mg.....xxxxxxxxx

Uses
- xxxxxxxxxxxxxx
- xxxxxxxxxxxxxx

Warnings

Do not use xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Ask a doctor before use if you have
- xxxxxxxxxxxxxx
- xxxxxxxxxxxxxx

Ask a doctor or pharmacist before use if you are xxxxxxxxxxxxx

When using this product
- xxxxxxxxxxxxxx
- xxxxxxxxxxxxxx

Stop use and ask a doctor if
- xxxxxxxxxxxxx
- xxxxxxxxxxxxx

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Drug Facts (continued)

Directions
- xxxxxxxxxxxxxx
- xxxxxxxxxxxxxx

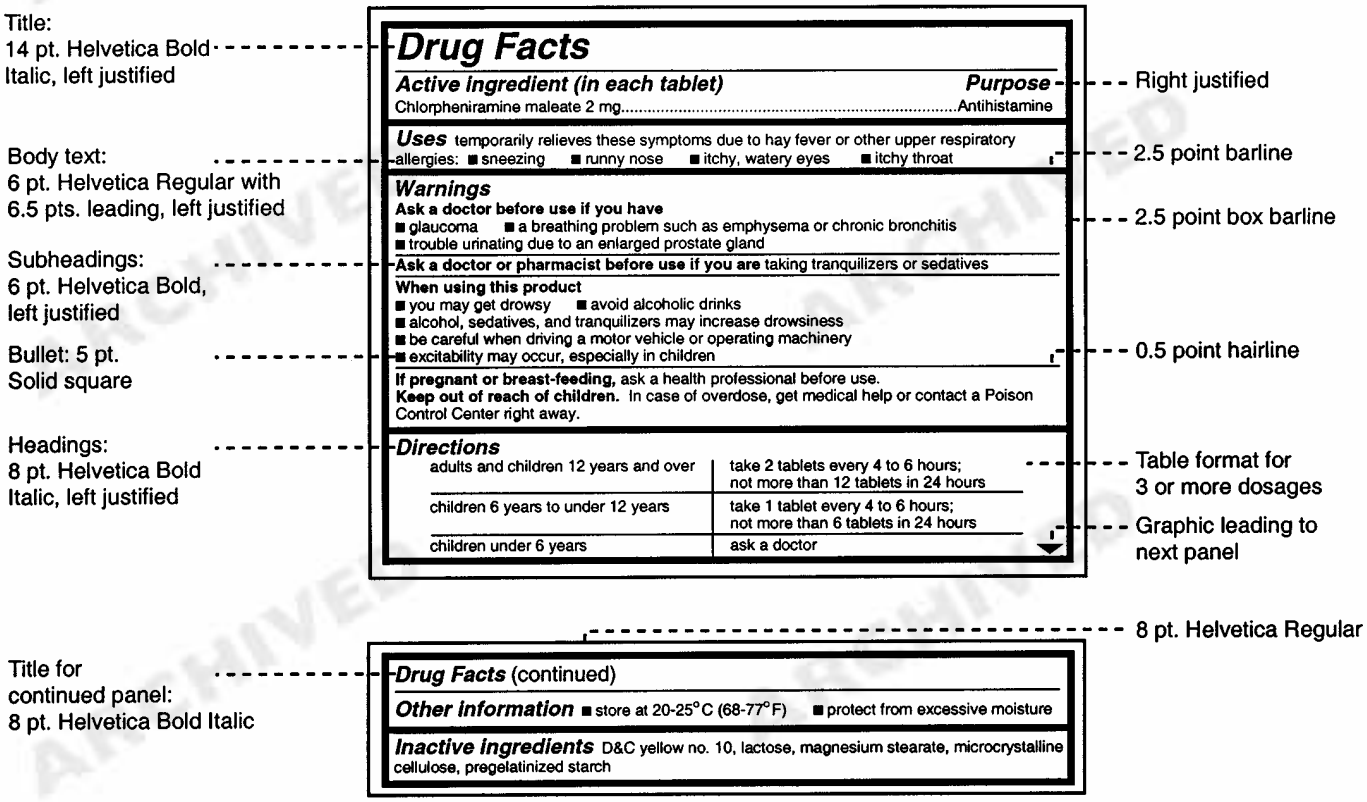
Other information
- xxxxxxxxxxxxxx
- xxxxxxxxxxxxxx

Inactive ingredients xxxxxxxxxxxxx

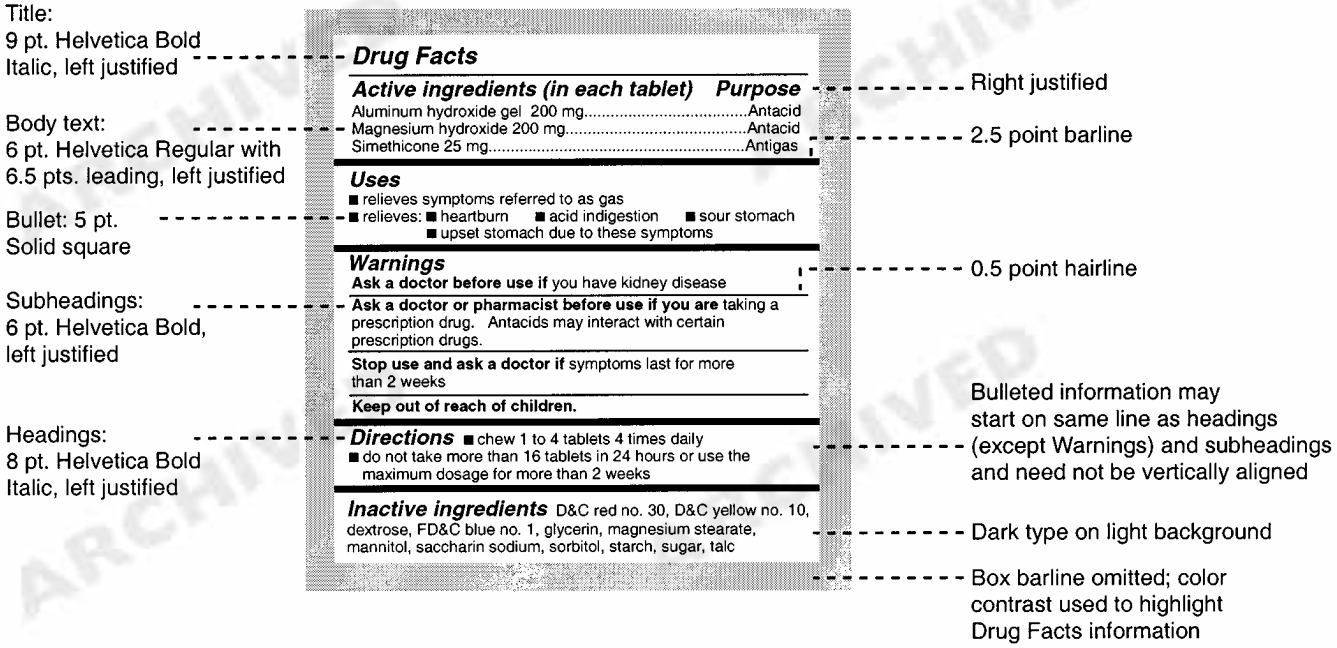
Questions? 123-555-1234

BILLING CODE 4160–01–C

An example of labeling for a single ingredient antihistamine OTC drug product, annotated for illustrative purposes, is shown below. FDA recommends use of the type style and font sizes shown below:



An example of labeling for an antacid OTC drug product, applying the modified, small package labeling provisions in this final rule and annotated for illustrative purposes, is shown below. FDA recommends use of the type style and font sizes shown below:



BILLING CODE 4160–01–C

Examples of prototype OTC drug product labeling are attached in Appendix A of this document. The information in these examples is presented using ordinary package sizes for these types of products. These examples are for illustrative purposes only and are not intended to depict specific products. Some are based on proposed monograph requirements only. Example 1 depicts sample labeling for a single ingredient antihistamine product, using the format and content provisions set forth in this final rule. Example 2 depicts labeling for a combination cough/cold product using the format and content provisions set forth in this final rule. Example 3 demonstrates how the same information shown in Example 2 can be presented directly on the package label for an 8-ounce bottle of syrup, using the small package modifications specified in the final rule. Example 4 depicts a toothpaste that is marketed as a standing tube without an outer carton, using the format and content provisions set forth in this final rule. Example 5 demonstrates labeling for a drug product that is also marketed for cosmetic uses using the format and content provisions set forth in this final rule. Example 5 also demonstrates an acceptable ''similar enclosure'' to a box. Example 6 depicts labeling for a topical acne product that is marketed in a tube and packaged in a carton with a riser, in order to provide additional labeling space. Example 7 depicts labeling for an antacid product, applying the small package modifications.

III. Summary of Studies A and B

Studies A and B tested whether the proposed format improves the readability and understandability of OTC drug product labeling and investigated consumer preference for certain format variations. The studies confirm that the new labeling format will increase communication of OTC drug product information.

A. Study A

Study A examined the influence of labeling formats and the use of selective highlighting on the communication of directions for use and warnings. The study examined two levels of four independent variables in a factorial design: (1) Labeling format (prototypical existing format versus proposed new format), (2) drug type (cough-cold versus pain reliever), (3) the use of highlighting (more versus less emphasis on graphic design features), and (4) consumer attention (divided versus focused). Highlighting, label format, and drug type were varied in the design of the sample product label. Attention (focused or divided) was varied through instructions given to the respondents. Study participants were asked to read a food label, then a drug label to test for divided and focused attention. Half of the participants were told they would be asked questions about both labels (divided attention); the other half were told they would be tested only on the drug label (focused attention) and that the food label was to serve only as reading practice.

The study included 1,202 respondents in 8 geographically distributed shopping malls in the United States, with approximately equal numbers of respondents from each location. Respondents were asked to evaluate the presentation of label information on one OTC drug sample and were asked questions about the labeling to determine their knowledge, opinions, and willingness to read the labeling.

Dependent measures were analyzed using a general linear model analysis of variance. The study demonstrated that the proposed new format took less time and was easier to read and understand than a product that did not follow the new format. Study respondents indicated a general preference for the proposed format and, when their attention was divided, respondents felt more confident in their ability to use the proposed format labeling. When more graphical design features were used, respondents who were instructed to focus on the labeling made more correct product use decisions, compared to respondents whose attention was divided. There were no conditions under which a product with an existing labeling format outperformed the proposed new format.

The results from Study A suggest that consumers who are presented with the new labeling format will be: (1) More confident in their ability to use the information in the labeling, and (2) better able to make correct product use decisions.

B. Study B

This study investigated consumer preferences for format and graphical design variations. The study examined two levels of each of four independent variables in a factorial design: (1) The order of the ''Warning(s)'' and ''Direction(s)'' section (i.e., warnings before directions or warnings after directions), (2) the placement of the ''Active ingredients'' section at the top of the labeling versus bottom, (3) the use of a title as an introduction to the required information (''Medication Facts'' versus no title), and (4) the use of dividing lines between sections (thick versus thin lines).

This study included 904 respondents in 8 geographically distributed shopping malls in the United States, with approximately equal numbers of respondents from each location. The respondents were asked to evaluate 16 labeling variations of either a sample cough-cold or sunscreen drug product. The respondents were also asked to rank the randomly ordered labels from most to least preferred, to specify the reasons for their first and second choices, and to rate a current OTC drug product that did not follow the new format.

The study showed that the presence of a title was the most important factor in determining preference, as participants were more likely to choose labeling with a title than without. When asked why they preferred the label ranked as number one, the respondents indicated that it: (1) Was easy to read, and (2) begins with ''Medication Facts.''

The agency performed a primary conjoint analysis on the preference rankings. A conjoint analysis simultaneously weighs multiple variables and allows for a determination of the relative importance of each particular attribute of a variable, in addition to the level at which each attribute is preferred (SPSS Categories, 1994). Results indicated that, of the four factors examined, title had the greatest impact on rankings, with a utility range from -1.83 for no title and +1.83 for the ''Medication Facts'' title. In this primary analysis, the effect of the other three variables was not significant.

The agency also performed a secondary analysis of the data, to look at differences between variables, independent of context. For labeling with a title, the mean ranks were 6.67 and 10.33 ($Z=-20$, $SD=1.95$, $p<0.001$), clearly confirming that the presence of a title was the most important factor in determining preference rankings. The secondary analysis of the other three format variables showed mean ranks in the middle range (between 8.18 and 8.82, $SDs=0.94$ to 1.97). However, as stated previously, the primary analysis of these three variables showed that none had a statistically significant influence on preference when the variable was considered in context. Again, the presence of an introductory title proved to be the preferred variable.

IV. Summary and Response to Comments

This section summarizes each section of the final rule and provides the agency's response to comments.

Appendix 6

References

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