TGA THERAPEUTIC GOODS ADMINISTRATION

Commonwealth Department of Health and Ageing

Review of the Labelling Requirements for Medicines

Consumer-focused Labelling – A Way Forward?

Consultation Report
March 2002

Review of the Labelling Requirements for Medicines

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Executive Summary

The TGA is interested in fostering a consumer-focused approach to the labelling of consumer medicines in Australia. A medicine's label is the single most important source of information available to consumers. It is important, therefore, that labels have the correct information about how, when and why to use the medicine and when not to use it or when to seek advice. It is also important that this information is presented in a way that can be understood and acted on by the consumer.

Consumer-focused labelling means improved label effectiveness for the benefit of consumers by the adoption of a label design based on appropriate consumer research.

The TGA's discussion paper released in April 2000, *Effective by Design* discussed a number of proposals for improving the effectiveness of medicine labels including a consolidation of warning statements under the Therapeutic Goods Act and options for basing regulation on the performance of labels when used by consumers. The report was distributed widely and comments sought from stakeholders.

The potential benefits of consumer-focused labelling can only be achieved by a cooperative approach between the TGA, industry and consumers. This paper summarises stakeholder's views and puts forward the TGA's proposals for a consumer-focused approach.

Stakeholders' Views

Fifteen stakeholders responded to *Effective by Design*. Most stakeholders expressed a general desire for a reduction in the complexity of labelling requirements. A complete performance-based labelling scheme was not supported, although there was support for the development and use of performance principles in the labelling of medicines, especially for products intended for self-medication. At the same time, it was acknowledged that certain mandatory requirements are essential to ensure that consumers have the necessary information for safe use.

Stakeholders from industry were in favour of retaining the current system of labelling approval as part of the registration process while also retaining the self-assessment process for listable medicines. The development of consolidated label warnings and the introduction of more flexible labelling requirements based on performance principles were the most significant changes sought. The Consumer Health Forum and Society of Hospital Pharmacists of Australia supported the introduction of Consumer Medicine Information (CMI) for all medicines.

A list of stakeholders who responded to the discussion paper and a summary of their comments are included as Attachments 1 and 2 to this report.

TGA Proposals

1. Warning Statements

The TGA supports the NDPSC's proposal for inclusion of mandatory warning statements (other than signal headings) in the *Medicines Labelling Order* rather than the *Standard for the Uniform Scheduling of Drugs and Poisons* (SUSDP). The aim is to consolidate all mandatory requirements into the *Medicines Labelling Order*. To achieve this aim the TGA will produce detailed proposals for consideration by the National Drugs and Poisons Schedule Committee (NDPSC) and the Therapeutic Goods Committee (TGC). These proposals will be discussed with stakeholders before submission to the committees.

2. Improving the Effectiveness of Labels

The TGA supports the concept of improving label effectiveness by the adoption of principles of label design based on appropriate consumer research. For most non-prescription medicines, labels are the primary source of information and it is important that consumers are able to clearly read, understand and act on the information presented on the label.

New labelling requirements have been implemented in the US[1] and Europe[2] with the aim of improving the readability and comprehensibility of medicine labels. These requirements may be of assistance in developing benchmarks for Australian consumer-focused labelling.

For registered non-prescription medicines the TGA is required to evaluate the label "presentation" under Section 25 of the *Therapeutic Goods Act 1989*. For listed medicines this is the responsibility of the sponsor. In both cases there is considerable flexibility for sponsors to adopt performance-based principles within the current labelling requirements. The TGA is willing to work with stakeholders to determine the best way for performance-based principles to be applied with the aim of improving the performance of labels for the benefit of consumers.

The introduction of Consumer Medicine Information (CMI) for 'prescription' and 'pharmacist only' medicines provides a model that could be followed for labelling. This model was developed by industry in partnership with Government and a wide range of stakeholders. It is based on consumer research with performance testing and incorporates a set of "useability guidelines" with specific recommendations on format and content and a glossary of 'user-friendly' terms.

The TGA proposes a consumer-focused approach to the labelling of medicines on a similar basis to that adopted for CMI. The performance-based elements could be essentially self-regulated under industry codes of practice with all mandatory requirements set out in the *Medicines Labelling Order*.

3. Additional Information for Consumers

The introduction of CMI for 'prescription' and 'pharmacist only' medicines has potentially given consumers access to a wider range of information than is currently available on labels. Some sponsors have chosen to include CMI as a package insert in 'pharmacy only' or open-selling medicines but this is the exception rather than the rule.

The TGA supports the introduction of CMI for all registered medicines in the form of a package leaflet or on the label itself if this can be achieved without compromising the readability or comprehensibility of the label. Consumers of 'pharmacy only' and open-selling medicines have an equal or greater need for information about their medicines in the absence of advice from a doctor or pharmacist. The TGA will work with stakeholders to further develop strategies to facilitate this outcome

4. Measuring Success

An evaluation phase should be built in to the development process to ensure that outcomes in the community match those predicted from pre-market research.

[1] Over-the-Counter Human Drugs; Labeling Requirements; Final Rule (21 CFR Part 201, et al.)

[2] European Commission, Pharmaceutical Committee: A Guideline on the readability of the label and package insert of medicinal products for human use

Next Steps

The TGA will convene an internal working party to clarify any technical, procedural or legal issues in removing warning statements from the SUSDP and including them in the *Medicines Labelling Order*. Consideration will also be given to transferring other warning statements (e.g. in AGRD2 or Schedule 4 to the Regulations) into the Labelling Order at the same time. The process and timetable for transferring the warning statements into the Labelling Order is detailed in the table below. The intention is to coordinate the introduction of the new Labelling Order with the phasing out of TGO 48 in July 2004.

TGA will also consult with major stakeholders during the third quarter 2002 with a view to gaining agreement on the process for adoption of consumer-focused labelling. Issues will include:

- The scope of the project;
- The use of the CMI process as a model;
- Involvement of Departmental committees (eg. APAC, PHARM);
- Sources of funding;
- International considerations – WSMI, WHO proposals;
- CMI for all medicines;
- Benchmarking against the US and Europe;
- Arrangements for further consultation;
- Harmonisation with New Zealand; and
- A timetable for completion and implementation.

The TGA would like to see an industry code of practice for labelling and packaging together with an amended *Medicines Labelling Order* and SUSDP in place by July 2004 with an agreed implementation timeframe for existing products.

Timetable for transferring warning statements from the SUSDP to the Labelling Order

Step	Issue	Start date	Finish date
1	Publish Consultation Report		Feb 02
2	Convene working group within TGA to identify issues (CNPMB, CAB, DSEB, BSB Legals)	Mar 02	Jun 02
3	Review Regulations & guidelines to identify warning statements	Apr 02	Jun 02
4	Consult with stakeholders	Jul 02	Sep 02
5	Get in-principle agreement from TGC Label Sub-commitee to proceed		Apr 02
6	Get in-principle agreement from NDPSC to proceed		Feb 03
7	Draft new Labelling Order, consult further with stakeholders (including NDPSC)	Nov 02	Nov 03
8	Get approval of TGC Label Sub-committee to proceed		Nov 03
9	Table new Labelling Order in Parliament		Mar 04
10	New Labelling Order comes into effect (label warnings immediately)		Jul 04
11	Decision to remove warning statements from SUSDP		Aug 04
12	New SUSDP published with warning statements removed		May 05

Summary of Recommendations

Recommendation	Page Reference
1. All SUSDP label warnings, including reverse scheduling warnings (but excluding signal headings) to be placed on medicine labels for therapeutic goods should be taken out of the SUSDP and incorporated into the *Medicines Labelling Order*. The current flexible approach to wording of warning statements in the SUSDP should be retained.	p. 8
2. A TGA working party be established to clarify any technical, procedural or legal issues in removing warning statements from the SUSDP and to ensure that existing products are not inadvertently rescheduled.	p. 8
3. Consideration should be given to the introduction of CMI for all registered medicines in a suitable form or on the label if this can be achieved without compromising the readability or comprehensibility of the label.	p. 12
4. The *Medicines Labelling Order* should be retained as the labelling standard but the mandatory label requirements should be reviewed to ensure that they assist consumers in clearly reading, understanding and acting on the information provided on the label. Consideration should be given to consistency with New Zealand.	p. 20
5. A consumer-focused approach to the labelling of medicines should be established using a similar approach to that adopted for CMI. The performance-based elements should be co-regulated under an industry code of practice with mandatory requirements set out in the *Medicines Labelling Order*. The TGA should work with stakeholders to examine the how performance-based principles may be applied with the aim of improving the performance of labels for the benefit of consumers	p. 24
6. An evaluation phase should be built in to the development process so as to ensure that outcomes in the general community match those predicted from pre-market research and that better readability and comprehensibility will result from any changes made.	p. 24

1 Background to the Project

In 1999, the Therapeutic Goods Administration (TGA) initiated the Labelling Project to review the current system of regulation of medicine labelling. The project arose in part from a request by the National Drugs Poisons Schedule Committee (NDPSC), for the TGA to consider moving the warnings and safety directions for therapeutic goods, from the *Standard for the Uniform Scheduling of Drugs and Poisons* (SUSDP), to the auspices of the TGA under the *Therapeutic Goods Act 1989*. In order to effectively undertake this task, it was necessary to review the current framework for the regulation of labelling.

The review did not include requirements under the control of States and Territories, such as dispensing labels or signal headings (which indicate the SUSDP schedule status), therapeutic goods other than medicines (eg. devices) or other general consumer protection legislation such as the *Trade Practices Act 1974*. However, comments that were received from stakeholders on these topics are included for completeness and information purposes.

In April 2000 a discussion paper, *Labelling Project 99/00: Effective by Design*, outlined the current status of the regulation of medicine labelling and put forward several proposals for discussion, as follows:

- All labelling requirements for medicines, other than dispensing labels, be drawn under the *Therapeutic Goods Act 1989*, consolidated for easier reference, and be administered by the TGA through the processes for evaluation and assessment of products for entry in the Australian Register of Therapeutic Goods (ARTG).
- All warnings placed on medicine labels, including reverse scheduling warnings, be taken out of the SUSDP and placed in legislation administered directly by the TGA.
- All States and Territories establish complementary legislation to the *Therapeutic Goods Act 1989*, and where this is not possible the legislation be amended so that compliance with labelling under the Therapeutic Goods Act is deemed compliance with State and Territory Requirements.
- Regulation of labelling be consistent with the level of risk anticipated and be designed for its role in helping to reduce any specific risks associated with each category of medicine. The use of Consumer Medicine Information leaflets should be encouraged for all medicines, including S2 and non-scheduled medicines.
- Establish a performance-based scheme. 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.

2 The Current System

2.1 The Regulatory Framework

The States and Territories' drugs, poisons and controlled substances legislation, as well as Commonwealth legislation control medicine labelling. Some of the documents, which cover Commonwealth labelling requirements for medicines, include:

Therapeutic Goods Act 1989
Therapeutic Goods Regulations 1991
Therapeutic Goods Order (TGO) 69
Therapeutic Goods Advertising Code (TGAC)
The Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP)
TGA Approved Terminology for Drugs

The ***Therapeutic Goods Act 1989*** defines the label and makes provision for:

- The establishment of a medicines labelling standard (the Labelling Order);
- A definition of unacceptable presentation;
- Statements of purposes of use of the product on the label are restricted by what is included in the Register for that good;
- Defining what products are required to be registered or listed in the ARTG and what goods are exempt from the requirement to be included in the Register; and
- Ensuring that compliance with applicable Standards (including advertising requirements) is a factor in determining eligibility for inclusion in the Register.

The label is defined in the *Therapeutic Goods Act 1989* (section 3.1) as:

> 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.

The label is also included in the definition of the presentation of 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.

Section 3. (5) of the Act lists the circumstances where the presentation of therapeutic goods is unacceptable.

An order establishing a standard for therapeutic goods "may … 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." [Section 10].

The ***Therapeutic Goods Regulations 1991*** define prohibited and required representations, including a schedule (Schedule 2) of specific items. The Regulations include provisions relating to

advertising that are also applicable to labels (since labels fall within the definition of advertising) and also require additional patient information for prescription medicines.

In general, the labelling of all medicines (registered or listed) must meet the specifications of Therapeutic Good Order 69 *General Requirements for Labels for Medicinal Products* (the *Medicines Labelling Order*).

The *Medicines Labelling Order* provides for:

- The requirements as to what must appear on the label including names and quantities of active ingredients; dosage form; batch number and expiry date, and the AUSTR or AUSTL number;
- How to express quantities and what labelling is regarded as adequate for special packs and small containers;
- References to warnings required by the SUSDP;
- Additional labelling where the route of administration attracts special safety precautions;
- Labels to be clearly visible, written in durable characters not less than 1.5mm, and use metric units of measurement.

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

The TGAC does not apply to advertisements 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).

The legislative requirements are administered through the use of several agencies and committees.

The Therapeutic Goods Administration, within the Department of Health and Aged Care is responsible for the administration of the controls permitting the supply of medicines in Australia under the *Therapeutic Goods Act 1989*. This includes controls over labelling. Individual evaluation areas within the TGA are responsible for different categories of medicines including making recommendations on the labelling of individual products as part of the registration process. These evaluation areas are supported by advice from the following expert advisory committees:

- Australian Drug Evaluation Committee (ADEC);
- Medicines Evaluation Committee (MEC); and
- Complementary Medicines Evaluation Committee (CMEC).

The Therapeutic Goods Committee (TGC) gives advice to the Minister on standards, including labelling standards, under section 10 of the Act.

The Therapeutic Goods Advertising Code Council (TGACC) makes recommendations to the Minister on several aspects of advertising, such as changes to the advertising code, standards for advertising and the review of decisions of the Secretary when approving advertisements.

The National Drugs and Poisons Schedules Committee (NDPSC), administered by the TGA, is responsible for the *Standard for the Uniform Scheduling of Drugs and Poisons*. The SUSDP currently includes requirements for:

- Signal headings;
- Warning statements and safety directions to be included on the labels of medicines containing scheduled substances;
- Exemptions from scheduling (reverse scheduling) gained by placement of prescribed warnings on labels

The National Coordinating Committee on Therapeutic Goods (NCCTG) co-ordinates the development of national policy on the regulation of therapeutic goods. Changes to the labelling of medicines are issues 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.

In addition, State and Territory Departments of Health each contain areas responsible for controls over the level of access to medicines, pharmacists and other health practitioners, supply of poisons and relevant retail outlets for pharmaceutical services and products.

2.2 Labelling Requirements for Various Categories of Medicines

Prescription Medicines

Prescription medicines, containing substances scheduled as S4 or S8, must comply with Therapeutic Goods Legislation, the *Medicines Labelling Order*, and the SUSDP. The advertising of prescription medicines is not permitted other than to healthcare practitioners.

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 from January 2002).

Labels are examined at the time of registration to ensure that the presentation of the goods is acceptable and that appropriate warnings and other label statements are added.

There are other requirements for products used in hospitals; these may be subject to National Occupational Health and Safety Commission (NOHSC) and/or State and Territory requirements. Dispensing labels are controlled by State and Territory legislation.

Non-Prescription Medicines

This category includes complementary medicines and “over-the-counter” (OTC) medicines.

Advertising to the general public is permitted for S2, certain S3 and all unscheduled medicines. Labels of all non-prescription medicines must comply with the Therapeutic Goods Legislation, the *Medicines Labelling Order*, the SUSDP and the *Therapeutic Goods Advertising Code* (TGAC).

Registered non-prescription medicines undergo registration because they contain scheduled substances or they are so formulated, or intended for use, that evaluation is considered necessary for reasons of safety.

Labels are examined at the time of registration to ensure that the presentation of the goods is acceptable, and that the goods conform to any standard applicable to the goods, or any requirements relating to advertising.

Listed products contain no scheduled substances and contain only those substances identified as low-risk by inclusion in Schedule 4 to the Regulations. This category includes most complementary medicines and some OTC medicines such as sunscreens.

Indications for listed goods are restricted to non-serious forms of disease or conditions that are appropriate for self-diagnosis and management. Listed medicines are entered into the Register with a declaration from the sponsor that they meet the relevant Standards and advertising requirements, and have acceptable presentations. Labels are not examined at the time of listing, but may be assessed following listing either as a result of a random review or if a problem arises.

2.3 Stakeholders' Responses to the Current System

Stakeholder responses to the discussion paper were unanimous in describing the sources of labelling requirements as too complex and some stakeholders view the current system as too prescriptive. However, there were some aspects that almost all felt should be preserved. These were:

- Labelling requirements should make product users' interests a priority.
- The TGA should be responsible for all labelling items, excluding signal headings and dispensing labels, which are under State and Territory control.
- Certain mandatory elements are desirable, to preserve consistency in medicine labelling. Consistency in labelling requirements makes it easier for the consumer to find information on the label and facilitates comparisons between products.
- The current requirements should continue to apply within all medicine categories. This is considered to be fair to sponsors as it ensures a level playing field.
- For registrable medicines, labelling should remain part of the registration process.
- For listable medicines, the self-assessment principles of listing should be maintained.

Problems identified by sponsors

The most common labelling problems identified by sponsors were:

- Difficulty in negotiating/reading the Labelling Order.
- Difficulty in designing user-friendly labels because of the prescriptive nature of the warning statements.
- Inequity between complementary and prescription medicines (e.g. "why should complementary medicines carry warfarin warnings on the label if warfarin is not required to include complementary medicines warnings on its label?")
- The cost of label changes, particularly for slow moving products.

- Prescriptive label placement and formatting. e.g. AUST R/AUST L placement on the front panel of the label.

Other points raised were:

- The majority of sponsor requests for exemptions from the Labelling Order are for a reduction in letter height from 1.5 mm to 1 mm, usually on the basis that the container (and therefore the label) is too small to fit all the required text on it. The time and costs involved in considering these requests may be reduced if some objective (and transparent) criteria for allowing a reduction in size were included in the Labelling Order. Any criteria should be based on measurable performance outcomes for the benefit of consumers.
- Less frequent are requests from sponsors of listable medicines to place the name of the active ingredient(s) on the back of the label.
- Harmonisation with New Zealand, consistency with international trends for labelling and more flexibility in Australia requirements would facilitate international trade. Barriers to consistency lie in the different regulatory frameworks between countries and differences in the approach to use of foods and medicines.

Problems identified by Pharmacists

- For prescription medicines, there is often difficulty in allowing sufficient space for the dispensing label, especially on small containers.
- For prescription medicines, the similarity between product names and lack of distinction (e.g. by colour) of different strengths can cause confusion and lead to errors.
- Hospital pharmacists have experienced problems with labelling of ampoules for injection, particularly when they must be removed from a package and used singly.
- For prescription medicines in flat packs, many pharmacists prefer to stack these with the end flap facing outwards and would prefer to have the product name and strength on the end flap as well as the front panel.

Problems identified by Consumers

- The most frequent complaint from consumers is that the print on labelling is too small to read. This problem may be compounded if the text is unfamiliar. This complaint was emphasised in the International Year of Older Persons Platform for Action (1995), which recommended that manufacturers and pharmacists be encouraged to increase the print size on their labels, especially for contraindications.
- Another common complaint is that label information is not easy to understand. The majority of people surveyed by Russell and Antill (1992) said they were happy with the amount of information provided on medicine labels, but needed information that is more easily understood. Consumers have also identified a need for interpretation of label instructions, such as information about how to maintain medicines at recommended storage temperatures when at work or outdoors.
- Consumers have also expressed the need for the pharmacological category to be placed on prescription medicines. There is difficulty, particularly in older people, who may be taking a number of different prescribed medicines, in knowing which medicine is for a particular condition. One stakeholder commented that the problem is exacerbated by generic

substitution, eg. where a patient has been taking a particular brand name for some time, and suddenly receives a medicine with an unfamiliar name.

- The Consumers' Health Forum (CHF) also noted the lack of access 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.

3 Reducing the Complexity

3.1 Consolidating Mandatory Requirements

Labelling requirements for medicines are specified in a number of different documents including Commonwealth therapeutic goods legislation, State drugs and poisons legislation, Commonwealth and State trade legislation as well as a number of TGA guidelines documents. It has been suggested that consolidating all of these requirements in one document would assist sponsors in understanding and implementing them. In reality such a document would be very long, complex and difficult to maintain.

Much of the complexity of the current system can be addressed by moving the label warning statements currently specified in the SUSDP and associated State legislation to *The Labelling Order.*

3.2 Transferring the warning statements from the SUSDP

The National Drugs and Poisons Schedules Committee (NDPSC) has requested the TGA to consider taking out of the SUSDP the warnings for scheduled substances (included in appendices of the SUSDP) and those warnings subject to reverse scheduling and place them under Commonwealth therapeutic goods legislation. The transfer of the warning statements will reduce complexity and support the harmonisation of scheduling with New Zealand.

Reverse scheduling means that a substance is placed in a schedule of the SUSDP except when it is labelled with a relevant warning statement. The following therapeutic goods are currently the subject of reverse scheduling:

Schedule 2	*Schedule 4*	*Schedule 6*
Aspirin	Guaiphenesin	Bay oil
Guaiphenesin	Pyridoxine	Cineole
Iodine	Tryptophan	Cinnamon leaf oil
Paracetamol	Vitamin A	Clove oil
Pyrithione zinc	Zinc compounds	Eucalyptus oil
Silver salts		Eugenol
		Melaleuca oil
		Pennyroyal oil
		Sage oil (Dalmation)

Some of these substances also have dose/strength/quantity restrictions, and these would remain as scheduling criteria. Where substances are made exempt from scheduling, NDPSC would require assurance that the warning statements would be placed on all products, to ensure that the criteria for exemption (i.e. the presence of warning statements) remain in force.

TGA already determines some warning statements with advice from the Australian Drug Evaluation Committee, the Medicines Evaluation Committee and the Complementary Medicines Evaluation Committee. The process of determining and maintaining all warning statements could be incorporated into the evaluation processes for registered medicines.

Listable medicines provide a different situation in that they contain no scheduled substances and individual product data are not evaluated on entry onto the ARTG. Assessment of listable medicines 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 exempt them from scheduling or to otherwise satisfy the TGA that the product, in use, containing the substance is sufficiently low-risk. Warnings for listed goods are generically designated.

Recommendation 1

All SUSDP label warnings, including reverse scheduling warnings (but excluding signal headings) to be placed on medicine labels for therapeutic goods should be taken out of the SUSDP and incorporated into the *Medicines Labelling Order*. The current flexible approach to wording of warning statements in the SUSDP should be retained

Recommendation 2

A TGA working party be established between the NDPSC secretariat, the OTC Medicines Section and the Office of Complementary Medicines to develop a process to clarify any technical, procedural or legal issues in removing warning statements from the SUSDP and to ensure that existing products are not inadvertently rescheduled.

4. Risk Management and the Role of the Label

Therapeutic goods in Australia are regulated according to perceived risk. The TGA evaluates the quality, safety and efficacy of registered medicines, with decreasing levels of pre-market scrutiny for known or presumed "low-risk" products. The NDPSC determines which schedule is appropriate; the scheduling process controls the availability of the substance. Associated with the availability is the amount and level of the professional verbal and written advice the consumer receives.

New listable medicines are assessed for quality and safety. Listed medicines are regulated on the basis of low-risk but products must comply with all relevant labelling requirements. The process is supported by targeted post-market surveillance.

Controls, level of risk and information sources for various categories of medicines

SUSDP	*ARTG*	*Includes:*	*Level of risk*	*Consumer gets information from:*
Schedule 8 Controlled Drug	Registered (ADEC, NDPSC)	Substances which should be available for use but require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence.	Very high	Doctor Pharmacist CMI Label
Schedule 4. Prescription Only Medicine	Registered (ADEC, NDPSC)	Substances, the use or supply of which should be by or on the order of persons permitted by State or Territory legislation to prescribe and should be available from a pharmacist on prescription	High	Doctor Pharmacist CMI Label
Schedule 3. Pharmacist Only Medicine	Registered (MEC, NDPSC)	Substances, the safe use of which requires professional advice but which should be available from a pharmacist without a prescription	Moderate	Pharmacist CMI Label
Schedule 2. Pharmacy Medicine	Registered (MEC, NDPSC)	Substances, the safe use of which may require advice from a pharmacist and which should be available from a pharmacy or, where a pharmacy service is not available, from a licensed person.	Low to moderate	Pharmacist Label
Unscheduled	Registered (MEC, CMEC)	Unscheduled OTC medicines, some complementary medicines, antiseptics.	Low	Label
	Listed	Most complementary medicines, sunscreens	Low	Label Other - friends, relatives, books, magazines and advertising. (see Bouldin, Smith et al (2000).

4.1 The Role of the Label

The role of medicine labelling is to enable identification of the goods and to provide consumers with sufficient information to choose appropriately (for self-medication products) and to use the products safely and effectively, throughout the lifetime of the product – at purchase, during use and storage, to disposal.

For the consumer, it must be clear what the product is, what it is used for, how to use it, how to store it, and any hazards associated with the use of the product. For the self-medicating consumer, the label should enable consumers to make appropriate choices and compare products. The label must also provide information to a person dispensing or administering the product (e.g. pharmacist or nurse) to enable them to select the correct product.

The label should also provide all necessary information about storage and shelf life to ensure the maintenance of product quality. Other information, e.g. batch number, AUST L/R number is important for tracking purposes and to demonstrate that the medicine has been registered or listed on the ARTG.

As well as the practical uses that a label must serve, there are several independent variables that have import for the required information on the label. These are: the perceived risk, the provision of professional advice and the role of the consumer in making decisions.

4.2 Perceived Risk

The labelling of medicines should identify any known, significant risks associated with the substance. Labelling regulation should also take into account the availability of additional information from professionals and/or consumer information leaflets.

Labelling – consistency with the level of risk

	Prescription	*Non-prescription*	*Listable*
toxicity of the active	Well known and identified in product literature	Usually known and formulated accordingly	Generally regarded as low risk
Ineffective in serious disease	N/A	Warning on label (if condition persists see your doctor)	Indications for serious disease not allowed
Drug interaction	Well known and identified in product literature	Warning on label	Where known and significant, warning required on label
Disease interaction (eg. Use in hypertension)	Contraindicated or warning in PI & CMI	Contraindicated on label (do not use if...)	Where known and significant, warning required on label

4.3 Professional Advice

In the case of Registered medicines which are included in Schedules 3, 4 and 8 of the SUSDP, counselling is provided by the doctor and/or the pharmacist. Patient counselling is available for purchase of S2 (pharmacy only) products. However, advice need not be sought or given; pharmacists do not always directly hand out medications to consumers, or deal with non-prescription medication requests. Verbal advice may not be remembered, especially if the medicine is only used occasionally. It is important that information for the safe and effective use of medicines appears on the label and / or package insert.

A Consumer Medicine Information (CMI) document will become mandatory for prescription only medicines by 1 January 2002, and for Schedule 3 medicines by 1 January 2004. This will ensure that, for Schedule 3, 4 and 8 medicines, additional sources of information besides the information on the label must be made available by the sponsor. It should be noted, however, that many sponsors choose to only make this information available in electronic form which means that consumers do not usually get the CMI unless they specifically request the pharmacist to make a printed copy available.

Therapeutic goods that have lower levels of scheduling (Schedules 2, 5 and 6), or are unscheduled, are not required to have CMI, although some sponsors choose to provide this information.

For listed medicines the listing process requires that the label contains all necessary information to help ensure that Listed medicines are safe. However, consumers may consider it necessary to have access to more information to assist their decision-making. Advertising may fulfil some of this role, although it appears to concentrate on efficacy rather than safety.

A study in the UK has shown that requests for pharmacy advice by consumers of non-prescription medicines is more often for information on efficacy than on safety (Hassell *et al*, 1998).

4.4 Role of the Consumer in Making Decisions Based on Label Information

For the self-medicating consumer, labels should contain information that enables the consumer to elect whether or not to take a particular medicine. In particular, they need to know whether the medicine is the right one for their condition (indications) and whether it is the right one for them (contraindications). The label should provide this information.

Stakeholder submissions have indicated that self-medicating consumers would like more information than is currently required on the label, such as levels of evidence available to support use of the medicine and its place in therapy. Conflicting or alternative sources of information may be available. Where does the consumer get advice on these products, if it is needed?

Bouldin, Smith *et al* (2000) surveyed 200 consumers to find out which information sources they used when choosing a herbal supplement. Respondents were asked whether they "have used", "might use" or "would NOT use" each of 15 sources of information. They were also asked to rate the perceived value of each source, regardless of whether they used the source or not.

The most frequently mentioned sources of information were friends and relatives followed by the product label, books, magazines and advertising. However, the information sources that had the highest perceived value for herbal supplements were the doctor and pharmacist. The perceived value of the label was ranked quite low (6th).

Label useability research also indicates that the most easily readable labels are those that have the minimum required information. Too much information on the label is counter-productive and this applies across all medicine categories. Therefore, although the information available for listable medicines is limited and variable compared with higher risk categories, there may be little

benefit in increasing the mandatory labelling requirements above those required under the current system, ie. compliance with the Labelling Order.

4.5 Consumer Medicine Information

Consumer Medicine Information is required for all new S3, S4 and S8 medicines and will be required for existing medicines in these categories by 2002 (S4 and S8) or 2004 (S3). The Consumer Health Forum and Society of Hospital Pharmacists of Australia support the introduction of CMI for **all** medicines. The CHF submission indicated that consumers would like to have more information than is provided on the label, and that some product groups (eg. analgesics) have been identified as having insufficient information. The CHC and ASMI do not support the introduction of CMI for Schedule 2 and unscheduled medicines.

Consumers of prescription and S3 medicines have the benefit of professional advice from the pharmacist and / or doctor as well as the information in the CMI and (potentially) PI. Consumers of S2 and unscheduled medicines usually have only the label for information. It can be argued that the consumer of an analgesic bought in a supermarket has an equal or greater need for comprehensive written information than the consumer who buys an S3 analgesic with advice from the pharmacist.

The TGA supports the introduction of CMI for all registered medicines in a suitable or on the label itself if this can be achieved without compromising the readability or comprehensibility of the label and will work with stakeholders to develop strategies to facilitate this outcome.

Recommendation 3
Consideration should be given to the introduction of CMI for all registered medicines in a suitable form or on the label if this can be achieved without compromising the readability or comprehensibility of the label.

5 Improving Label Effectiveness

An over-the-counter medication to relieve premenstrual tension, which is available in the US, comes with the following advice on the label: "Do not take this product for menstruation-related pain if you are pregnant." New Scientist 13/1/2001.

The discussion paper proposed that where clear principles have emerged from research these should be applied:

- In the first instance to mandatory requirements where they are needed;
- To formulating standards for performance requirements where these are possible; and
- Such that labelling should be designed for its role in helping to reduce any specific risks associated with each category of medicine.

The discussion paper also proposed that a detailed evaluation of published research should be done and additional research planned to meet shortfalls.

The Review of Drugs, Poisons and Controlled Substances Legislation, in its draft report, supported the improvement of the effectiveness of labels as communication tools, by allowing sponsors greater flexibility and incentive to design labels with the consumer in mind, rather than simply adhering to a list of requirements.

In the past, regulators have required that labelling be legible, without paying much attention to the comprehensibility of mandatory information. Label layout and design was largely left up to sponsors, albeit with some restrictions on the placement of the information. The result was a range of good and bad labels; some sponsors spent considerable effort in producing excellent labels, while others merely ensured that they complied with the regulations.

Recently, the EU (1998) and the Non-prescription Drug Manufacturers' Associations in Canada (1999) and the USA (1992) have provided guidance on improving readability *and* comprehensibility of label copy.

What information *must* the label carry?

The current requirements for the information which must be on the label are set out in T*herapeutic Goods Order No. 69. General requirements for labels for Medicinal Products.*

Certain information is generally accepted by industry and regulators as being essential to enable the clear identification and the quality and safe use of medicines. This information forms the basis of the mandatory requirements for labelling in most countries, including the EU, USA, Canada and New Zealand. These mandatory elements are:

i). Information to enable clear identification of product:

- Name of the goods
- Name and quantity of all the active ingredients

- Manufacturer/sponsor name and address
- Batch number
- Register number
- Quantity of the goods

ii) Information to enable safe use:

- Dosage form or route of administration
- Any required warnings and precautions
- The names of certain excipients
- Indications (for self-medication products)
- Directions for use (for self-medication products)

iii) Information to maintain the quality of the product:

- Where and how to store (and, if relevant, how to discard)
- Expiry date

Most countries require a "keep out of reach of children" statement and have special wording or a coloured border to distinguish prescription and non-prescription medicines (the equivalent of the SUSDP signal headings). Most specify that the label must be legible, and mandatory minimum letter heights are generally between 1 and 1.5 mm. Some countries require the text to be in two languages, and some specify that the label must not contain any promotional material.

In order to be effective, the information should be legible and understandable. Any warnings should be easily noticed and understood by the user, and should be consistent with the hazard. Although the EU, Canada and the USA have provided guidance on good label design, the only country to mandate label design is the USA, for the labelling of OTC drugs.

In its submission to this review, Australian Self Medication Industry (ASMI) said: "There are advantages in having some prescriptiveness: it is easier to decide what to include on the label, and it can cut time/production costs. Consistency in assessment of compliance is important. But is it achieving the goal of labelling?"

5.1 Principles from Research

Demographics and Literacy in Australia

The *Survey of Aspects of Literacy* (1996) conducted as part of the International Adult Literacy Survey (OECD) revealed that :

- 56% of Australians have adequate to excellent reading skills (Levels 3-5),
- 27% experience some difficulty in printed materials encountered in daily life (level 2),
- 17%, representing 2.5 million people, experience considerable difficulty (Level 1).

Of those that experience considerable difficulty, about 40% (1 million) are from a non-English speaking background. Some of this group may benefit from incorporation of reading medicine labels (particularly dosage and warnings) as part of English language/literacy classes, or from placement of brochures in pharmacies which contain lists of essential phrases translated into their own language.

Simplifying the layout and language on labels may assist those with Level 2 skills. For those at Level 1, which includes those with severe visual impairment (1% of Australians), the functionally

illiterate and non-English speakers, improving label readability alone is not going to help very much.

A recent development in assisting those with severe visual disability is the so-called "smart label", a computer chip embedded in the label which can be read by a voice synthesiser. The smart label is printed out by the pharmacy software along with dispensing label and contains all pertinent information such as the name of the patient, name of the drug, the dosage, general instructions, warnings, doctors name and phone number. The smart label is expected to be trialled in the USA this year. In the future, developments such as this could benefit those with visual disability (and possibly the illiterate).

The Elderly

Most prescription drugs are used by the elderly. In 1993-4, people older than 65 years represented 12% of the population but this group accounted for 35% of overall health expenditure (data from the Australian Institute of Health and Welfare (AIHW)). The literacy skills of people aged 45 and over decline markedly with age.

About 43% of those aged 65-74 had very poor skills (Level 1) and 35% were at Level 2. In addition, vision generally deteriorates in the elderly, as light transmission is reduced. Older people have difficulty reading small print, discriminating blue colours and, because vision is poor in low light, glossy surfaces are particularly problematical.

The Australian Bureau of Statistics estimates that, by the year 2016, the proportion of the Australian population aged 65 years or more is expected to reach 16% (3.5 million people), with the proportion of people older than 80 years increasing from 16% to 25% of older people.

Studies on Label Effectiveness

Earlier research concentrated on the effectiveness of the wording of individual warning statements. Recently, more attention has been paid to the layout and design of information, to determine what is optimal for reader comprehension.

- The PMAA commissioned a research project (Russell and Antill, 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. Design changes included tabulation of dosage instruction, recommended dosage interval made clear, bullet points and lower case for warnings and use of plain English terms. Only small improvements in label useability were found.
- Ley (1995) assessed the effectiveness of signal words, warnings, safety directions and first aid instructions in the SUSDP, using published research and a detailed analysis of vocabulary, typographical and format factors. The main findings were as follows:
  - Warnings are noticed on average by about 50% of people.
  - Many warnings are difficult to read.
  - About 54% of people claim to read the information on the products they buy. About 20% of people who start to read a warning don't get beyond the first line.

- Warnings are not understood by 25% or more of their target audience. Warnings are more likely to be understood if they are easily legible, have high "readability" (short words, short sentences, familiar words), are written in the active rather than the passive voice, and are specific and concrete in their language.
- About 50% of Australians at whom the warnings are targeted are sceptical about warnings on products, or do not take them too seriously. Warnings are more likely to be believed if they are thought to come from sources high in credibility, expertness and attractiveness, and if they deal with arguments likely to be advanced against heeding them.
- Warnings are often forgotten. They are more likely to be remembered if they are repeated, have high "readability" and use specific concrete language.
- About 50% of people follow the safety advice or heed the warning. Compliance with advice in this area is at similar levels to that in other areas of health care. People are more likely to follow advice if they are not familiar with the product or product class, they perceive the product as dangerous, (perhaps) if the rationale behind the warning is explained and (perhaps) if specific details of the consequences are given.

Studies conducted by Rush Social Research for the Commonwealth Department of Human Services and Health (1995) and Rogers, Shulman et al (1995) produced a similar result. A study by Wickert (1989) showed that only 54% of 1496 adult Australians were able to identify correctly the dose for a child from a sample medicine label (10% of participants were functionally illiterate). The available data also suggest that improving label useability may assist a large number (some 30-40%) of consumers who have poor or developing literacy skills.

An important observation made by these researchers was that the label useability depends in part on the juxtaposition of the elements. Label elements cannot be treated in isolation, so that an emphasis on individual element content in the Labelling Order, avoiding design performance, significantly reduces label effectiveness. 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.

Developments in the USA

- Consumer research undertaken by the US Environmental Protection Agency (EPA), relating to labelling of chemicals, showed that many consumers found the print size too small to read (minimum 6 pt), and contrast was inadequate. Consumers always looked at the back panel for ingredient labelling, and none suggested any information that could usefully be deleted.

In 1992, the USA Nonprescription Drug Manufacturers Association (NDMA) produced a document titled *Label Readability Guidelines*, to assist manufacturers to improve the readability of OTC medicine labels. The guidelines were based on a search of the technical literature on readability, and listed 17 technical factors affecting label readability that should be considered when designing labels:

Layout and design:
Design, layout and placement, columns, paragraphs, justification, hyphenation, boldface, colour highlights and boxing, bullets and numbering, uppercase/lowercase letters;

Typography and printing
Type size, type style, type spacing, contrast, printing process, substrate, brightness and colour.

The NDMA guidelines have now been largely superseded by the new Food and Drug Administration (FDA) rule on labelling of OTC medicines, but were important in that it was probably the first real attempt to provide useful guidance on label design.

- In 1998, the US Food and Drug Administration commissioned two studies which were used as a basis for the 1999 final rule for the labelling of OTC medicines (21 CFR Part 201, Fed Reg Wednesday March 17, 1999).

  The studies 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 comply with directions that are easy to read than with large amounts of text that appears overwhelming, or that presents a "cognitive load" such as the task of reading densely worded information.
  In March 1999 the US FDA introduced new rules for the labelling of OTC drugs. The format includes standardised graphical features such as use of a sans serif font and bullet points to introduce key information, and minimum standards for font size and spacing. Specific headings and subheadings presented in a standardised order under the title **"Drug Facts"**, as follows:
  - A list of **active ingredients** and the purpose of each, listed by established name and quantity per dosage unit or proportion.
  - A list of the drug's intended **uses**.
  - **Warnings**. This section includes the dosage route, ingredient-specific warnings and "ask your doctor or pharmacist before use" regarding drug interactions, use in pregnancy/breastfeeding etc.
  - **Directions** If there are 3 or more age groups, these should be tabulated.
  - **Other Information** regarding storage and tamper evidence, declaration of certain excipients.
  - **Inactive ingredients** are listed in alphabetical order.
  - **Questions?** Telephone number.

  The revised labelling requirements include a list of 21 "connecting terms" that manufacturers may omit from product labelling and 79 "interchangeable terms" to facilitate the use of more concise and easy to understand language in OTC drug product labelling. Some warnings (pregnancy/lactation, "keep out of reach of children" and accidental overdose/ingestion) were also amended to make them as direct and understandable as possible. The rule took effect in April 1999 and will be phased in over 2-6 years, a longer time period being allowed for small volume products (less than $25,000 annual sales).

Is the Order of Label Components Important?

Vigilante and Wogalter (1997) examined the preferred order of OTC label components, to find out consumer preferences and whether placement of warnings could influence behavioural compliance. The *Non-prescription Drug Manufacturers Association of Canada* (*NDMAC)*

Technical Research Paper for Improving Label Comprehension (1999) examined the order that information should be presented on the label.

Consumers preferences for the order of label components, as reported in the above studies, have been for indications to appear first, followed by side effects/contra-indications then contents/ingredients. An interesting confirmation of the preferred ordering of label information is provided by a study conducted into labelling of herbal products in the USA (Bouldin, Smith et al, 2000).

These studies indicate that consumers, especially those with poor reading skills, are helped if the information is positioned in a standardised order on the label, and simple, standardised wording is used, so that the phrases can be found and recognised easily. Too much variation in the label layout and/or text may work against improved label useability.

Letter Height

Arriving at a suitable font size is a balance between the interests of the consumer, especially the elderly and the self-medicating consumer (who may wish to compare different products before purchase or know if it safe for them to use) and the sponsor, who may need to fit a large amount of information into a small space.

The majority of requests from sponsors for exemptions from the Labelling Order are for a reduction in letter height, mostly for small containers. In contrast, consumer surveys invariably reveal that the most common consumer complaint about medicine labels is that the print size is too small.

The Labelling Order specifies a minimum letter height of 1.5 mm, based on the height of upper case letters or lower case letters having an ascender or descender. New Zealand, until recently, specified a minimum font size where the lower case "x" is at least 1.4 mm in height (as for the EC) but in 2000 revised its requirements to a minimum height of 1.5 mm, with 0.75 mm for small containers (20 mL or less).

The EC, in *A Guideline on the Readability of the Label and Package Leaflet of Medicinal Products for Human Use* (1999) specifies a minimum letter size of at least 7 pts Didot (or of a size where the lower case "x" is at least 1.4 mm in height), leaving a space between lines of at least 3 mm.

The new FDA format for OTC drugs specifies 14 pt or 9 pt Helvetica (sans serif) bold italic for the main *Drug Facts* heading, with subheadings in 8 pt or 6 pt Helvetica bold and the information in 6 pt Helvetica Regular with a 6.5 pt leading (line spacing). The height of letters having an ascender or descender in 6 pt Helvetica is 1.5 mm.
The new format was based on research which indicated that if the font size is reduced, readability can be maintained if:

- The space between the lines is increased
- The space between the characters is increased
- The thickness of the letters is increased

In this context, it is interesting to note that the height of letters in the Australian telephone directory is also 1.5 mm, and the typeface has changed in recent years to a slightly thicker sans serif font with slightly increased spacing between the letters, making it easier to read.

Reducing the letter size can be achieved without reducing legibility if other factors, such as the letter thickness and spacing between the letters and lines of text is increased slightly.

In a report to Worksafe Australia, Adams and Collingwood (1992) recommended that "Print should never be less than 8 pt in size, and should be of high contrast", for the reason that "the use of 6 pt print is shown by legibility research, as well as comments from the public, to cause difficulty in reading for a large number of people".

Symbols and Pictograms

There was no support from stakeholders regarding the use of symbols on labels, and there is little evidence to suggest that the use of warning symbols improves label useability. Symbols and pictograms take up valuable space on the label. However, they can be used to advantage on labels in certain circumstances, for example to illustrate how to use a product.

In a study by Sojourner and Wogalter (1997), participants showed an equal preference for text-only or partial pictorial (text with an incomplete set of pictorials), rating both formats more effective and easier to understand than a pictorial-only format.

Do the Current Labelling Requirements Facilitate Good Label Design?

A survey of the labels on a pharmacy shelf will show that some labels are easier to read than others, even though they all comply with the Labelling Order. It is evident that, although the Labelling Order may permit good label design, it does not necessarily assist it. Sless (2001) has suggested that the reason why labels are poorly designed is the many regulations surrounding labelling in Australia.

In the report to PHARM entitled *Designing Better Medicine Labels*, Rogers *et al* (1995) tested the performance of different label designs for two categories of product – soluble aspirin tablets and cough/cold tablets.

Overall, grouping similar information together under headings, and use of better font and spacing resulted in improved ability to locate and understand information.

The study demonstrates that it is possible to make significant changes to labels with improved readability, at the same time complying with the Labelling Order.

Harmonisation Issues

The simplification of labelling requirements depends upon uniform requirements within Australia and harmonisation of the Australian and New Zealand requirements.

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, eg. in language and 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, although it is unlikely that harmonisation will reach a point where one label is acceptable worldwide, at least in the near future.

During 1992-94, Australian and New Zealand drug and poison schedules label format requirements (letter height, signal words etc.) were harmonised. At the same time, harmonisation of the schedules themselves and the associated warning/first aid/safety directions statements was begun. Although there are still some outstanding issues, the progress made to date has facilitated trade between the two countries. Therefore, any changes to Australia's labelling requirements must be consistent with the harmonisation process.

The draft report of the Regulatory Reform Taskforce (2001) has recommended the establishment of a joint Australia/New Zealand agency to regulate therapeutic goods in both countries. Such an agency would adopt a common regulatory approach to labelling.

Summary

Stakeholders acknowledged that some prescriptiveness in labelling is necessary. The *Medicines Labelling Order* should be retained as the Standard (what must be on the label) but layout and design (how it should be set out) should not be mandated unless these are essential for the safe use of medicines. In other words, the *Medicines Labelling Order* should include a requirement for legibility and comprehensibility, but should not direct the layout and design elements. The mandatory elements should be reviewed to ensure that they are based on best label design.

From the published results of research have emerged some common criteria for good label design, including:

- Arranging like information together on the label;
- Separating "chunks" of information;
- Using simple language and short sentences;
- Keeping information to the minimum necessary for safe use;
- Consistent order of information; and,
- Technical factors (layout and design, typography and printing).

Published studies indicate that flexibility in layout and some flexibility in language is necessary if the above factors are to be used satisfactorily. This means that the mandatory warning statements should be reviewed to ensure that they can be easily understood or that some flexibility be allowed in their expression to improve comprehensibility.

Recommendation 4

The *Medicines Labelling Order* should be retained as the labelling standard but the mandatory label requirements should be reviewed to ensure that they assist consumers in clearly reading, understanding and acting on the information provided on the label. Consideration should be given to consistency with New Zealand.

5.2 The Testing of Labels for Performance

The discussion paper outlined a scheme for performance-based regulation, which "gives specified outcomes but does not necessarily stipulate how those outcomes must be achieved (e.g. labels must be legible and draw the attention of the user to all hazards involved in their use, whereas prescriptive regulation stipulates letter height etc.)".

There has been sufficient research work to support the hypothesis that readability and comprehension can be significantly improved with changes to design. 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 has been the subject of considerable debate.

Stakeholder Responses

The proposal to introduce a performance-based assessment scheme (as outlined in the discussion paper) as an alternative to the current system was, in general, not supported by stakeholders, and there was unanimous opposition to its use for prescription medicines. There was qualified support for the adoption of performance principles, and strong support for its use in the layout of multiple warning statements and in providing guidance on good label design and performance testing.

The opposition was based, in part, on concerns that it would be more difficult for companies to justify exemptions in the absence of prescriptive label design elements. There was concern that the scheme was complicated and the level of compliance was questionable and open to interpretation; that it could lead to delays to the registration process; and that it would lead to variation in labelling format, which would mitigate against useability. There was also concern that the scheme would result in additional cost for industry and more work for TGA, who would have to evaluate the results.

The Australian Pharmaceutical Manufacturers of Australia (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. Standard corporate labelling (often global) means there is less need for local variation in prescription medicine labelling. Therefore, the current requirement for having only the essential/mandatory information on the prescription medicine label appears to be satisfactory. There appears to be little incentive (indeed little enthusiasm) for performance-based regulation of labelling for prescription medicines. However, the APMA considers that performance-based labelling could be used for the approach to the overall design of the label. The overall design is important for communication to all users, professionals and consumers and these groups may benefit from the establishment of a clear statement of the performance sponsor labels are intended to achieve.

ASMI suggested 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.

Some stakeholders suggested that performance-based requirements for labelling could be designed in a similar manner to those developed for Consumer Medicine Information. In other words, maintain an essential core of mandatory elements, but establish guidelines for the design and layout of labels and a method for testing the label. These guidelines should be simple and user-friendly. In general, there was strong support for examining the ability of the current system to facilitate best label design, and for examining the required warning statements for readability. That is, any mandatory requirements should be based on best label design.

If the current mandatory requirements are the minimum necessary to ensure the safe and effective use of the product, little is to be gained from individual companies varying a particular requirement, and then testing to make sure it can be read and understood. It may be more cost effective to test the mandatory requirements and arrive at a "best label element" design.

Australia and New Zealand have already harmonised their labelling requirements and are currently harmonising the drugs and poisons schedules (and associated warning statements), to facilitate trade between the two countries. We need to consider the effect of any changes on the harmonisation process. Common labelling is fundamental to the success of harmonisation.

Several studies (e.g. Ley, 1995) have addressed questions of effectiveness of words used and overall design to create an effective communication tool for consumers. While this work was reported around 1992 to 1995, the incorporation of the results into labelling regulation has been slow. Although the warning statements in the SUSDP have been made more readable, and "problem" areas such as the analgesics warnings are being simplified, warnings on medicine labels are derived from a number of sources and are not routinely tested for readability before use.

The DIST Project

In 1998, the Department of Industry, Science and Tourism (DIST) published the results of a project undertaken to investigate 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 identified a great deal of confusion about the meaning of the term "performance-based labelling regulation". Some stakeholders took it to mean a move towards deregulation or a lowering of standards protecting public health and safety. For the purposes of the project, the following definitions were used 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 requirements give specified outcomes but do not stipulate how those outcomes must be achieved (e.g. labels must be easily legible and draw the attention of the user to all hazards involved in their use).

One of the reasons for the DIST project was to address claims by small business of excessive red tape and complexity, and cost in complying with labelling regulation. The project had difficulty substantiating and quantifying these claims; however, one of the strongest findings of the project

was that businesses, particularly small businesses, had difficulty locating, accessing and using information about product labelling. While there was strong support for a continuation of mandatory requirements for the labelling of medicines, there was a clear indication that the current prescriptive approach had resulted in a highly complex set of labelling rules that are difficult to negotiate and quite expensive to administer. The costs to business were associated with inadequate understanding of regulatory obligations and requirements.

Overall, the project found that although large organisations may have sufficient resources to cope with regulatory requirements, there is a need for small business to have better access to user-friendly information about the regulatory process to ensure that it understands its compliance obligations and avoids costly mistakes.

Consumer and community organisations wanted labels to be more useable for consumers. While there was strong support for a continuation of mandatory requirements in some areas, there was also a clear indication that the level of prescription demanded for wording of some labels may be resulting in labels that are unhelpful or confusing for consumers.

The responses of consumers, industry and regulators may be summarised as follows:

- Certain information must be on a label, to enable appropriate choice and safe use of a medicine.
- What industry wants most is access to clear information to enable them to meet their obligations without costly mistakes.
- Both consumers and industry would like to have those prescriptive elements which are complicated (e.g. multiple warning statements) either; revised to make them easier for consumers to read and understand; or, flexibility provided to enable sponsors to alter the text/layout so that they are easier for consumers to read and understand

The EU System

The European requirements for the labelling of medicines (Council Directive 92/27/EEC, covering prescription and non-prescription medicines, but not dietary supplements) has been cited as an example of a performance-based scheme. In essence, the EU system mandates what information must be on the label but does not mandate how it must be set out. The mandatory elements (name of product, batch no., etc.) are the same as those required in Australia, with the exception of the following:

- "Keep out of reach of children" is required on all medicinal products (in Australia it is required only on scheduled products and a few unscheduled products).
- The outer packaging may include symbols or pictograms designed to clarify certain information mentioned in paragraph 1 *(mandatory elements)* and other information compatible with the summary of the product characteristics which is useful for health education, *to the exclusion of any element of a promotional nature*."

Information which is specific to Member States and includes the equivalent of the SUSDP signal headings and AUST R/L no. (price, reimbursement conditions, legal status for supply,

identification and authenticity) is placed in a boxed area (the so-called "blue box") on one side of the package.

Council Directive 92/27/EEC requires that "The particulars referred to in Articles 2 and 3 shall be easily legible, clearly comprehensible and indelible." The Directive is supported by the *Guideline on the readability of the label and package leaflet of medicinal products for human use*, operating from January 1999. 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. The guidelines include a model product leaflet and an example of a method for testing the readability of the leaflet (based on Sless & Wiseman, 1994).

The preferred option

It is clear from the comments received from stakeholders that change to a total performance-based system is not supported. However, the establishment of a consumer-focused approach to the labelling of medicines on a similar basis to that adopted for CMI would have significant benefits and would lead better designed labels. The performance based elements should be essentially self regulated under industry guidelines with mandatory requirements set out in the medicines Labelling Order.

Recommendation 5

A consumer-focused approach to the labelling of medicines should be established using a similar approach to that adopted for CMI. The performance-based elements should be self regulated under an industry code of practice with mandatory requirements set out in the *Medicines Labelling Order*. The TGA should work with stakeholders to determine the best way for performance-based principles to be applied with the aim of improving the performance of labels for the benefit of consumers

Measuring the Success of the Project

The success of the proposed changes should be measured by monitoring labels for compliance, both before and after the recommendations of the report are implemented.

Recommendation 6

An evaluation phase should be built in to the development process so as to ensure that outcomes in the general community match those predicted from pre-market research and that better readability and comprehensibility will result from any changes made.

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Attachment 1: Stakeholder consultation

Submissions were received from the following stakeholders:

Ms Mary Emanuel	Australian Self Medication Industry
Ms Zephanie Jordan	Australian Self Medication Industry
Mr Bren Milsom	Complementary Healthcare Council
Dr Brian Chauncy	Therapeutic Goods Administration
Dr David Thirlwall	Pharmacy Board of Victoria
Ms Karen Kaye	NSW Therapeutic Assessment Group
Mr Mathew Blackmore	Consumers' Health Forum of Australia
Mrs Sally Allan	Eaton, WA
Mrs Beryl Evans	National Council of Women of the Australian Capital Territory
Prof. Ric Day	Pharmaceutical Health and Rational Use of Medicines
Ms Simone Healey	Drugs and Poisons Services, Queensland Health
Ms Rhonda Galbally	Australian International Health Institute, University of Melbourne
Ms Penny Thornton	Society of Hospital Pharmacists of Australia
Ms Deborah Monk	Australian Pharmaceutical Manufacturers Association
Mr John Daffey	Pharmaceutical Society of Australia
Mr John Bronger	Pharmacy Guild

Attachment 2: Summary of stakeholder views on main questions (at May 2001)

	Industry				Consumer		Professional/Gov			
	APMA	ASMI	PSA & PG	CHC	CHF	NCW	SHPA	PHARM CSC	QLD Health	Pharmacy Board of VIC
Current system of pre- evaluation for registered products and self evaluation for listed products	Retain	Retain		Retain						
TGO48	Retain	Retain		Retain						
Move warnings from SUSDP	Yes	Yes	Yes	Yes	Yes		Yes		Yes	Yes
Consolidate labelling requirements into single document	Yes	Yes	Yes	Yes	Yes		Yes	Yes		
Performance labelling as described in discussion paper*	No	No	No	No	No			No		
Performance principles incorporated in current system (As was done for CMI)?	N/A	Yes mandatatory elements but flexibility in placement	Yes Support prescriptive labelling	Yes	Yes		Yes Mandate design elements but provide flexibility	Yes Retain & improve the current system		
Use results of research to improve effectiveness of labels?	Yes	Yes		Yes standard label format		Yes				
Harmonisation with NZ	Yes (and standardise warnings)	Yes			Yes					
States & Territories – complementary legislation or "national uniformity"	Yes	Yes		Yes	Yes					
Separate label claims and advertising?	N/A	Yes	Yes Exclude *all* advertising	Yes	Yes					
CMI for all products?	N/A	No		No	Yes (all OTC)		Yes			

N/A = not considered applicable by stakeholder

* That is, specify mandatory elements and any deviation from these must demonstrate compliance with performance testing.