



THE PROPRIETARY MEDICINES ASSOCIATION OF AUSTRALIA INC.

RETTER HEALTH THROUGH RESPONSIBLE SELF-MEDICATION

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To: Mr Gary Hones	Date: 31 August 1993
Location: TPC Canberra	Fax: (06) 264 2803
Originator: Juliet Seifert	No of pages : 9 (incl cover sheet)

Attached, for your information, as discussed earlier today, are copies of the following three items:

- 1 General brochure outlining the purpose and activities of the PMAA;
- 2 Membership brochure outlining benefits of belonging to the Association; and
- 3 Information on annual subscription to PMAA.

Should you have any further information needs please do not hesitate to contact me. Actual copies of these items will be put into the mail today for your file records.

It is pleasing to note that our application for Code authorisation is being progressed. As you will appreciate the Association is keen to implement effective operation of an authorised version of the Code. I would therefore seek an indication from you as to the likely timing of a draft determination.

Yours sincerely

Juliet Seifert

Executive Director

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products - and with the information to use them wisely.

In doing so, PMAA seeks a constantly improving system of responsible self-medication, so that Australians can participate more fully in their own health care.

The PMAA structure

The PMAA is governed by a Committee of Management made up of representatives elected by active member companies — those firms which manufacture and distribute proprietary medicines.

Associate members of PMAA are companies which supply goods and services to active member companies. Associates include regulatory consultants, advertising agencies, advertising media, and manufacturers of bulk chemicals and medicine containers, among others.

The work of the Association is conducted under the direction of subcommittees. These committees attend to the scientific and technical, public affairs, inver-industry relations and other functions of the Association. Coordinating the work of the Association is the Secretariat staff.

The function of responsible self-medication

Self-treatment with proprietary medicines hilfills a series of valuable and sometimes crucial functions for individuals, the health care system, and the national economy.

For the individual, self-medication is a familiar, inexpensive and convenient method of dealing with ordinary health problems which cause discomfort and interfere with the routines of daily living. Self-medication is the first line of defence in health care.

For health professionals, self-medication provides a shield against a flood of minor, self-limiting complaints. It functions as a selective screening mechanism through which self-treatable disorders are sorted out from those requiring professional

Studies conducted both here and overseas show that individuals can distinguish those conditions which require professional help. Proprietary medicines are not seen as a substitute for professional care.

Proprietary medicines differ in significant ways from prescription drugs. Most OTC medications have the following in common:

Margin of safety:

Since their use is unsupervised by a medical practitioner or other prescriber, proprietary medicines must have a higher margin of safety, as indeed they do.

Availability:

Some proprietary medicines are available from a number of retail outlets, including pharmacies and supermarkets. Others are restricted to pharmacy sale or pharmacist sale-only.

Label information:

Proprietary medicines are labelled to ensure that they carry all the information which the ordinary consumer needs for safe and effective use of these products under customary conditions of purchase and use: The name of the medicine; the type of medicine (antacid, laxative, etc.); directions for use and the purposes for which it is used; when and how often to use it; how much of it to use; when not to use it and when to stop using it; side effects; the active ingredients in the medicine; net quantity of its contents; and the name and address of its manufacturer or distributor.

Where indicated, printed inserts may provide supplemental information to help consumers make better use of the proprietary medicines they purchase.

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Since its formation in 1974, the Proprietary Medicines Association of Australia has represented those companies which manufacture and distribute proprietary medicines. These products are also called nonprescription medicines or over-the-counter (OTC) medicines.

Through PMAA, the profrietary medicines. industry is working to ensure that safe and effective OTC medications are readily available to all Australians; to provide such products at reasonable cost to the consumer; and to serve as a source of information in order to encourage responsible and cost-effective self medication.

From its national Secretariat in Sydney, PMAA:

- Provides leadership in the science of proprietary medicines. The Association's Technical Subcommittee and staff work to ensure that OTC medications have a sound scientific have.
- Prontotes self-regulation. The Association's
 voluntary programmes and guidelines, endorsed
 by the membership, add further consumer
 saleguards in the areas of packaging,
 advertising and marketing.
- Represents its members before parliamentary enquiries and in discussions with government officials. PMAA works to establish reasonable and responsible regulations to best serve Australia's health needs under a free-enterptise system of manufacturing and marketing.
- Transmits current information to its membership on developments in science, legislation and regulation.
- Supplies useful information to the professions and the public about proprietary medicines and self-medication.
- Commissions research on self-care attitudes and the appropriate use of self-medication ir Australia.
- Represents members on a number of government and industry bodies within Australia and plays its part internationally through membership of the World Federation of Proprietary Medicines Manufacturers (WFPMM). For more than a decade, WFPMM has enjoyed 'Non Government Organisation' (NGO) status with the World Health Organisation (WHO), which has officially recognised the role of self-medication as a separate entity in health care.

The Proprietary Medicines Association of Australia and its members are dedicated to providing consumers with safe and effective



History of use: Many proprieta

Many proprietary medicines are formulated from ingredients whose long and widespread history of use assures a well-established record of safety and effectiveness.

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For a variety of reasons, including their great number and their availability from a wide source of competing manufacturers and retailers without a visit to a medical practitioner or a prescription dispensing fee, proprietary medicines are relatively low-cost products. They are paid for by the individual and make no drain on the National Health bill.

Self-medication:

a joint responsibility

Escalaring health care costs and growing interest in self-care have assured a future for self-medication. But realising all its benefits will require joint action by industry, government, the health professions and consumers.

The responsibility of industry is to continue to produce both new and established products, demonstrated to be safe and effective, manufactured according to the high standards of quality control, labelled with all the information which consumers need for proper use, and advertised accurately, truthfully and informatively.

The responsibility of government is to exercise cost/effective regulatory controls over proprietary medicines. The industry is already one of the most closely regulated and government must recognise that proprietary medicines are utilised in a different setting, and often for different purposes, than are prescription medicines. Consumer experience must be weighed along with evaluation in assessing the safety and efficacy of OTC products.



The responsibility of health professionals is to become stronger advocates of self-care, including self-medication. Their incentives are to help contain health care costs and to empower consumers to become more confident in personal health matters. The future lies in self-reliance in health care matters not paternalistic attitudes which deny the knowledge, responsibility and natural caution which consumers demonstrate in relation to OTC medicines.

Finally, consumers must assume responsibility for continuing to use proprietary medicines wisely. Studies carried out both in Australia and overseas show that consumers recognise the importance of reading medicine labels carefully, know what information can be found on labels and are more likely to tolerate rather than treat everyday health problems.

The future of self-medication

Millions of Australians are showing a new interest in their own health and well-being. People are discovering themselves to be the prime component of the health care system. They have a strong desire to achieve well-being and vigor, to accept greater personal responsibility for health and to participate more fully in making medical decisions.

Thus self-medication is impelled forward by two powerful waves of development: scientific progress on the one hand and societal attitudes and values on the other.

The Proprietary Medicines Association of Australia will continue to act as the advocate of better health through responsible self-medication, to create a climate in which the legitimate and vital role of responsible self-medication is more fully appreciated, understood and accepted and to press governments for decisions to be based on demonstrable cost effectiveness and good science.

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Finding it difficult to clearly differentiate PMAA's role from other industry associations?

Here is what makes PMAA unique!

PMAA is the ONLY organisation in Australia specifically designed and totally geared to look after the interests of your OTC business.

Broadly, PMAA's role is to:

- build a positive climate for OTCs with government, opinion leaders and the community
- act as an effective lobby and the acknowledged point of consultation with state and federal governments on OTC affairs
- provide a review mechanism and early warning system on technical, regulatory, legal and social developments affecting OTCs, both in Australia and overseas
- ensure members' compliance with industry codes to maintain the OTC industry's high level of performance in relation to self regulatory matters
- commission research to assist in promoting understanding of the role of responsible self-medication in Australia's health care system

In addition to the benefits provided by its broader role, PMAA can provide members with information and advice on specialised OTC issues involving marketing, advertising, promotion, distribution, individual regulatory or technical problems and can, where appropriate, act as an advocate or conciliator or lobby — at arm's length — on a particular issue.

PMAA offers regular confidential mailings to members on issues of current interest and concern as well as regular Newsletters covering OTC subjects in a more general way. PMAA's service to members also includes updates on regulatory matters affecting OTC products.

Over 50 companies operating in the OTC market in Australia support PMAA and receive its strategic information flow and other benefits.

As a condition of membership, companies are required to abide by the PMAA Rules, adhere to the PMAA Code of Practice and comply with the PMAA Guidelines for Tamper Resistant Packaging of certain specified OTC products.

Members are also urged to provide comments to PMAA whenever input is sought, to strengthen the Association's case in responding on behalf of members.

Members are also encouraged to involve themselves in the affairs of the Association, through membership of sub-committees, working parties and project teams.

PMAA MEMBERSHIP — SUPPORT ON A MACRO AND MICRO LEVEL FOR YOU OTC BUSINESS



The Proprietary Medicines Association of Australia Inc. 11th Floor, 65 Berry Street, North Sydney 2060 (Private Bag 938, North Sydney 2059) Telephone: (02) 922 5111 Fax: (02) 959 3693



THE
PROPRIETARY
MEDICINES
ASSOCIATION
OF AUSTRALIA
better health
through responsible
self-medication

MEMBERSHIP
— what if offers,
how your company
can benefit

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PMAA ANNUAL SUBSCRIPTION

ORDINARY MEMBERS 1

Ordinary members are companies conducting in Australia the basic manufacture, formulation, importation, registration and/ or marketing of proprietary medicines.

Ordinary members are required to calculate their subscription rate on the basis of their annual turnover of proprietary medicines (please see below for definitions). The 1993/94 fee scale is attached.

Under the PMAA Rules, the Executive Director may seek verification of the above calculation.

DEFINITION: ANNUAL TURNOVER 2

Annual turnover, for the purposes of calculating subscriptions, is defined as the net invoice price of goods (proprietary medicines) sold during the period 1 July 1992 through to 30 June 1993. This figure should be confirmed by the signature of the Finance Director on the invoice.

DEFINITION: PROPRIETARY MEDICINES 3

Proprietary medicines (including those products classified as S2 and S3) are defined in Part I of the PMAA Rules as those products used for the purpose of or in connection with:

- preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in (a) persons; or
- influencing, inhibiting or modifying a physiological process in persons; or (b)
- testing the susceptibility of persons to a disease or ailment; (c)

and includes use in, or in connection with, contraception or testing for pregnancy; and which are available to the public without medical prescription.

4 ASSOCIATE MEMBERS

Associate members include wholesalers, suppliers of fine chemicals to the industry, suppliers of packaging equipment, contract manufacturers, regulatory affairs consultants, etc.

Associate members are not required to submit their turnover as they are covered by the minimum fixed fee (please refer attached fee scale).

5 DUE DATE

Annual subcriptions, payable to the Proprietary Medicines Association of Australia, become due on 1st July 1993 and payable without default on or before 1st August 1993 (See Rule 10.2).

6 FORWARDING INSTRUCTIONS

Subscriptions should be forwarded direct to the Executive Director of the Association. Please mark the envelope "Private & Confidential".

Proprietary Medicines Association of Australia

MEMBERSHIP SUBSCRIPTIONS

FEE SCALE 1993/94

Ordinary members

Minimum rate

\$2,500

General rate

Category

1	Less than \$800,000	\$ 2,500
2	\$800,000 - 10m	.33%
3	\$10 - 15m	\$33,000
4	\$15 - 20m	\$34,000
5	\$20 - 25m	\$35,500*
6	\$25 - 30m	\$37,000*
7	\$30 - 35m	\$38,500*
8	\$35 - 40m	\$40,000*
9	\$40 - 45m	\$41,500*
10	\$45 - 50m	\$43,000*
11	Above \$50m	\$45,000

Associate members

\$2000

^{*} Between \$20-50 million - Add \$300 for each \$1 million additional turnover in category