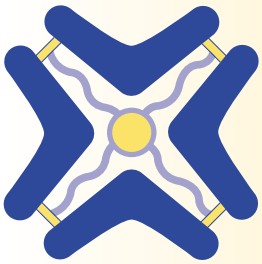
# ANNUAL REPORT 1999–2000

AUSTRALIAN SELF-MEDICATION INDUSTRY

BETTER HEALTH THROUGH RESPONSIBLE SELF-MEDICATION

# Our New Look



Noted contemporary indigenous artist Tracey Bostock worked with the Secretariat and Committee of Management to design a logo for our new Association name. Tracey lives and works in Sydney and belongs to the Boomalli artists' collective in Leichhardt, NSW. Her art is primarily contemporary in character with an abiding influence from the artistic vocabulary of her aboriginal heritage.

Tracey's brief was to develop a uniquely Australian identity – distinctive, contemporary and relevant – embracing the concepts of:

- responsible self-medication
- the Australian National Medicines Policy[1]
- nurturing, health and well-being
- intelligence, humanity, integrity
- balancing science and nature.

Tracey explains the significance of the final logo thus:

> The four arcs represent the four 'arms' of the Australian National Medicines Policy. The central circle denotes core values. The lines radiating from the centre are paths of reason. The bridges between the four arms employ a motif of supporting structures that connect the whole and allow the passage of knowledge among people.

[1] The four elements or arms of the Australian National Medicines Policy are: Timely and affordable access to the medicines Australians need; Medicines meeting appropriate standards of quality, safety & efficacy; Quality Use of Medicines; and Maintaining a responsible & viable medicines industry.

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# Our Mission

*Better health through responsible self-medication*

# Our Vision

ASMI - the one voice of the Australian non-prescription consumer healthcare products industry, nationally and internationally, supporting a credible and expanding self-medication market, generating cost-effective health solutions.

ASMI represents companies involved in the manufacture and distribution of non-prescription, consumer healthcare products.
ASMI also represents companies actively involved in providing manufacturers with services, such as advertising, public relations, regulatory consultancy, vending and industry statistics.

# Our Members as at 30 June 2000:

1. Allergan Australia Pty Ltd
2. Aventis Pharma
3. Bayer Australia Ltd
4. Biovital Pty Ltd
5. Boehringer Ingelheim Pty Ltd
6. Boots Healthcare Australia Pty Ltd
7. Carter-Wallace (Australia) Pty Ltd
8. CB Fleet Co (Australia) Pty Ltd
9. Colgate-Palmolive Pty Ltd
10. Combe International Ltd
11. Dermatech Laboratories Pty Ltd
12. Ego Pharmaceuticals Pty Ltd
13. Estee Lauder Pty Ltd
14. Faulding Healthcare Consumer
15. Galderma Australia
16. Glaxo Wellcome Australia Pty Ltd
17. H W Woods Pty Ltd
18. Janssen-Cilag Pty Ltd
19. Key Pharmaceuticals Pty Ltd
20. Mentholatum Australasia Pty Ltd
21. Merck Sharp & Dohme (Aust) Pty Ltd
22. Novartis Consumer Health Australasia Pty Ltd
23. Pfizer Pty Ltd
24. Pharmacia Australia
25. Reckitt Benckiser
26. Roche Products Pty Ltd
27. R P Scherer Holdings Pty Ltd
28. Searle Australia Pty Ltd
29. Smith & Nephew Pty Ltd
30. SmithKline Beecham
    International Consumer Healthcare
31. Soul Pattinson (Manufacturing) Pty Ltd
32. Stiefel Laboratories Pty Ltd
33. 3M Health Care Pty Ltd
34. Warner Lambert Consumer Healthcare
35. Whitehall Laboratories Pty Ltd
36. Whiteley Industries Pty Ltd

**ASSOCIATE MEMBERS**

1. AirRoad Distribution Pty Ltd
2. Sue Akeroyd & Associates
3. Chep Australia
4. Contract Pharmaceutical Services of Australia Pty Ltd
5. Cormack Group Pty Ltd
6. Curtis Jones & Brown Advertising Pty Ltd
7. Engel, Hellyer & Partners Pty Ltd
8. Grey Healthcare Group
9. Hahn Pharma Pty Ltd
10. Hammond & Thackeray Pty Ltd
11. HealthCom Gracie Pty Ltd
12. IMS Australia Pty Ltd
13. CWFS McCann
14. Nature's Herbals
15. PharmAction Holdings Pty Ltd
16. Quay Pharmaceuticals Pty Ltd
17. Regulatory Concepts Pty Ltd
18. Reader's Digest Australia Pty Ltd
19. Singelton Ogilvy & Mather
20. Technical Consultancy Services Pty Ltd
21. Young & Rubicam
    (Sudler & Hennessey and Burson-Marsteller)

# President's Review

You have probably already noted the new look of the Australian Self-Medication Industry publications. What a difference a year can make.

Last year, I told the membership of the Association's intention to get member input on their directions, activities for and expectations of PMAA. This was done through the April member survey.

Results showed clearly that our prime strategic focus should be three-fold:

1. to become a cohesive non-prescription industry, one voice representing manufacturers of both OTC and complementary healthcare products;
2. to advance the goals of the industry as a whole; and
3. to strengthen and deepen understanding of the association's role to its members.

The results have already and will continue to be used, as necessary, to reallocate resources to better meet the needs of members, refine strategic objectives, make adjustments to structures of the Secretariat and committees, and adjust work practices – particularly in terms of communication and information provision.

Reflecting on the past year, several key achievements must be mentioned.

- We set out to minimise the impact on industry of **GST** by clarifying the initial exemption categories and optimising the mechanism for approval by the Minister to exempt products from GST.

  We have had success to date in both minimising the impact and generating the maximum number of exemption categories possible given the political climate. We were successful in getting exempt status for S2 products plus some analgesic unscheduled packs. Sunscreens, folate, condoms and personal lubricants also emerged GST-free. Compared to most countries that have introduced GST or some similar form of tax, the Industry in Australia will be substantively better off.

  Nevertheless, our position has consistently been to have *all products on the Australian Register of Therapeutic Goods* GST-free. Our Executive continues to put this position to politicians and senior bureaucrats at every opportunity.

- We sought to have input into the Terms of Reference, structure and process of **the National Review of Drugs, Poisons and Controlled Substances Legislation.**

  This we successfully accomplished.

  Our aim is to achieve national uniformity in areas of scheduling, labelling, packaging, sampling, storage and advertising. We are also seeking efficiency in the scheduling process and separation of medicines from other chemicals and poisons.

- Our overriding objective during the major **Advertising Review** was to achieve a clear separation between advertising and other regulatory processes. We also set out to ensure appropriate transitional arrangements were effected and that the new system of controls created and maintained a level playing field for all advertisable products.

  As an extension of this Review, we also worked to achieve the incorporation of complementary healthcare products into the National Medicines Policy.

  These objectives have been largely realised and we are now at the stage of testing the results during the period of transition.

- Taking on the opportunity and responsibility of **hosting the 4th Asia Pacific Regional Conference** was an activity designed to serve to broaden the relevance and influence of the Association. We are ensuring that the conference structure and program represents the entire spectrum of the self-medication industry in Australia.

- Another part of improved service provision was the development of an Association **website**. The first stage was launched in January this year. An expanded offering is on track for a November 2000 launch. This whole exercise has been carried out effectively through staff education and extremely cost-effective application of the learnings.

- Our strategic plan mandated increased efforts and resources in the area of **information gathering and provision.** ASMI has been developing low cost initiatives to provide immediately useful data. This year has seen a substantial effort in the information management area.

Looking ahead, one of our key tasks is to continue to review the Association's strategic plans in line with the feedback from the member survey. On an ongoing basis, however, we will maintain close communication with all members, encouraging continuous feedback, as we ensure that ASMI's work meets members' needs.

We know that in order to maintain and increase relevance, the "must do's" over the next couple of years include:

- looking beyond 'traditional' distribution channels, recognising the increasing role of the grocery channel and the potential of the Internet, thereby extending responsible product delivery and promotion whilst appropriately minimising access restrictions and differences;
- removing or reducing regulatory burdens;
- implementing a tailored and focussed program of activities reflecting the member survey outcomes; and
- securing the Association's future as the peak body representing the entire spectrum of the self-medication Industry in Australia.

I must mention the shadow of extortion that now hangs over our Industry. Our Association's Crisis Management Guidelines stood the test of reality with the recent Panadol recall. While some of us have our own Corporate Guidelines, we would be well served indeed, for the sake of preparedness, to blend those with these locally developed procedures.

Via a high level task force that included Industry, consumers, regulators and police, ASMI's guidelines are now being used as the template for a broad Industry approach to crisis management and tamper evident packaging. In June, I urged our membership to ensure its continued commitment to our 20 years of the Tamper Evident Packaging Compliance Program that also looks like becoming an Industry benchmark. I repeat that call.

Despite these issues, we have had a good year. Looking forward, I believe that there will be a need for heightened partnerships: with consumers, in the area of product education, information, communication and packaging vigilance, as well as with regulators, to continue to develop what I believe is an increasingly enlightened approach to co-regulation.

Kevin Darke
ASMI President

# ASMI Committee of Management 1999-2000

David Armstrong,
*Reckitt Benckiser (part year)*

Geoff Bolland,
*RP Scherer Holdings Pty Ltd*

Kevin Darke,
*SmithKline Beecham International Consumer Healthcare*

Graham Gale,
*Reckitt & Colman (part year)*

John Gurney,
*Mentholatum Australasia Pty Ltd*

Mitchell Laing,
*Faulding Healthcare Consumer*

David Lion,
*Roche Products Pty Ltd (part year)*

David Murphy,
*Combe International*

Alan Nash,
*Carter-Wallace (Australia) Pty Ltd*

Arne Nordström,
*Pharmacia Australia*

David Stephens,
*Boots Healthcare Australia Pty Ltd (part year)*

Elizabeth Treble,
*Aventis Pharma*

Derek Tye,
*Warner Lambert Consumer Healthcare*

Sue Williams,
*Boots Healthcare Australia Pty Ltd (part year)*

Front Row (left to right): *David Murphy, Kevin Darke, Elizabeth Treble*
Back Row (left to right): *Arne Nordström, Mitch Laing, Alan Nash, Sue Williams, John Gurney, Geoff Bolland, Derek Tye*

# By Any Other Name

**The desire to take medicine is perhaps the greatest feature which distinguishes man from animals.**
**--H. Cushing in**
***Life of Sir William Osler***

**One of the first duties of the physician is to educate the masses not to take medicine.**
**-- Sir William Osler,**
***Aphorisms from his Bedside Teachings***

Soon after the membership voted unanimously to change the name of the Association to the Australian Self-Medication Industry (ASMI), trade journals began to provide coverage of the change. Most of this coverage was informational and benign in character.

But one article appeared which challenged not only the change of name, but also the long held tag line "better health through responsible self-medication" which has been motto, mission and mantra to the Association for many years.

Entitled "Wot's in a Name?" after the pastiche in "The Sentimental Bloke" of Shakespeare's *Romeo & Juliet* (II. ii. 3), the article calls into question whether our mission to promote better health through responsible self-medication is in fact "a potential oxymoron" or whether it promotes quality use of medicine. The author goes on to wonder how "responsible" industry can be in the face of "marketplace temptations" in an increasingly deregulated environment—and in particular how ASMI can promote responsible use.

While it is tempting to say that the pharmacist author could also turn this question on any of the health professions with any pecuniary interest in medicines, on governments with their ubiquitous health funding problems or even on consumers with their complex motivations, that would be merely to sidestep the real challenge here.

## The challenge

The challenge implicit in the article is to live up to our statement of values and show that self-medication can indeed be responsible. Junctures such as these are good times for self-examination, for renewing commitment to our core principles and for shedding any methods or habits that distract from the agreed strategic direction of the Association.

In some cultures, a person is given a new name when he or she undergoes a fundamental change of life. The name is a symbol of the tribes' recognition of who that person is *now* – the new name is not confused for the change itself nor is it thought to have brought about the change.

## Our internal compass

In the case of the PMAA, we had long been representing products with little or no affinity with the term "proprietary medicines". In fact, not even the most mainstream over-the-counter manufacturer much liked or used the term any more. We had the feeling that we had already moved on and that the name suggested a narrower, more old-fashioned entity.

It was vital to check this internal perception with the whole membership. Through the member survey and some focus groups, we were able to do that. Though a few lauded the recognition and heritage of "PMAA", not a tear was shed for "proprietary medicines".

The advance work of the Committee of Management and Secretariat on the proposed name was rewarded. Members noted that the new name "said it all", "explained to the layperson who we are", "allowed identification by a wider spectrum of product manufacturers."

Some also noted the challenge inherent in the new name. In some ways, all medicine administered outside a hospital setting is "self-medication." It was noted that consumers decide whether or not to follow doctor's orders, for instance. While ASMI does not represent these prescription products, we would note that there is a lesson in this example—the principles of good non-prescription self-medication have wide application. Consumers must have the information available to them to help them participate in the quality use of their medicines—no matter how they are scheduled. Manufacturers must listen to consumers about their actual use of products.

Internally, the challenge was to make sure that all of the Association's objectives and strategies are in line with our vision and that that vision is agreed by the membership. The member survey played its

# By Any Other Name (cont.)

part in this "reality check". The other vital component was a revised strategic plan for the next few years that reflects member needs and environmental trends.

**Strategic Direction**

Beginning in May and completed in stages over the months that followed, the revised strategic plan was the culmination of internal and external analysis. This analysis provided recommendations for immediate implementation.

Concrete examples of the changes that were made include:

- reworked publications reflecting our mission as well as our members' desire to receive pithy information and less paper;
- electronic provision of publications to those who wanted it;
- development of the website to include a "members only" area;
- increased face-to-face meetings with members through company visits, specialised and general interest seminars, member dinners with the Committee of Management;
- appointment of a Regulatory and Technical Manager with the mandate to specialise in services for complementary medicines;
- invitations to key international networks, such as the Dietary Supplement Network to Sydney for the WSMI Conference in November 2000;
- improved balance of interests and product ranges on the Committee of Management by strategic filling of vacancies; and
- an initial project in aboriginal health targeting the roots of ill health by addressing problems of access to proper nutrition.

In short, we are pro-actively moving in the directions set forth in our plan.

The name change thus *confirms* our direction rather than announcing a change in course. It helps us to achieve "one voice" for the manufacturers of consumer healthcare products. This in turn enhances our perception as the peak body by all relevant stakeholder groups. These gains are achieved also through:

- strengthened representation of the membership on all our subcommittees,
- increased presence on the web,
- greater face-to-face contact with our membership, and
- enhanced recognition of our peak role through hosting the 4th Asia Pacific Regional Conference of WSMI and
- through our seats on high level external advisory and expert committees (such as Medicines Evaluation Committee, TGA-Industry Consultative Committee, Australian Pharmaceutical Advisory Council, Therapeutic Goods Advertising Code Council and others).

While these will strengthen us internally and will speak to some important outside constituencies, some of our stakeholder groups will know us better from other sorts of efforts. To health professionals, Government, the Therapeutic Goods Administration, consumer groups and all the other parties interested in health, we are best known through our participation in reviews and our actions in times of crisis.

**By their deeds ye shall know them**

It has been a year with plenty of opportunity to be known by our deeds. Though we made largely successful representations to Government on issues as diverse as GST and trans-Tasman harmonisation, three cases will illustrate the point:

- the Advertising Review;
- the Galbally Review (National Review of Drugs, Poisons and Controlled Substances Legislation); and
- the whole-of-industry discussions on Crisis Management and Tamper Evident Packaging Guidelines.

*The Advertising Review*

The Review of the advertising arrangements for all therapeutic goods was initiated at the beginning of last year by the Parliamentary Secretary, The Hon. Senator Tambling, MP. There was general agreement that there should be de-regulation without any compromise to public health and safety, and a 'clean sheet' approach to the development of a new principle-based Therapeutic Goods

Advertising Code (TGAC), which should reflect current social values. The concept of a 'level playing field' across all sectors of industry was endorsed. It was agreed that in the new environment there should be transparency and that there would be a need for the application of appropriate sanctions with 'timeliness and teeth'.

Our two most important achievements through this review are first, a responsible approach to claim expansion that will be sustainable and second, a level playing field for all products. The Code is also consistent with other medicines programs such as the Quality Use of Medicines. By applying our principles across the board and upholding wider principles of exemplary trade practices, we have upheld the roles of self- and co-regulation.

*Galbally Review*

At the beginning of what would come to be known as the Galbally Review, we asked Rhonda Galbally to speak to our members in Melbourne about the opportunities presented by this Review. It was clear that the Review was an opportunity to promote

- our position on national uniformity,
- the separation of controls for medicines from those for other chemicals and poisons, and
- the simplification of scheduling processes and controls for medicines.

In all three of these areas, we have seen our goals reflected in the thinking of the Review and in the Options Paper. Along the way, we were able to allay fears that Industry would make a submission advocating the immediate dismantling of the current non-prescription schedules.

*Managing in a Crisis*

We were able to clear up other misconceptions about Industry this year. After the first paracetamol extortion threat, there was a call from some quarters to introduce tamper evident packaging (TEP). As ASMI members know, our Association has had regularly updated guidelines and audits for almost twenty years with very high levels of compliance.

As the extortion threat tentacles spread to a second company, the benefit of our TEP program and our long-standing Crisis Management Guidelines became clear. TGA's National Manager lauded the company and ASMI for demonstrating "best practice" despite the terrible circumstance.

Quite naturally, companies throughout our industry examined their own readiness. Many called the Secretariat for additional copies of our Guidelines. Next, meetings were called. TGA requested that we provide our Guidelines to other Industry associations. Soon our long-standing work became the template for a whole-of-industry approach to tamper evidence and crisis management.

## Setting the record straight

When some examples of ill-informed press continued to imply that Industry had been caught without tamper evident features in place, we published articles to address this error. Such misinformation did no service to our members who had for almost twenty years been implementing tamper evident features and statements on thousands of different products at their own cost under a system of pure self-regulation. We clarified that while no feature is "tamper proof", we continued to look at improvements in tamper evidence.

And yet some still expect our industry to succumb to "marketplace temptation". They would find our ACCC authorised Code of Practice, TEP Guidelines, and other self-inflicted curbs to be perplexing if not anathema. The reality of the situation is that making a quick dollar has never been in the long-term interest of the Industry. To join an Industry Association is to admit to a common and long term interest in what is good not only for one's own company but also for Industry viability in the long term.

## The playing field

Measures of the soundness of this approach are easy to come by. The International Organisation for Standardisation talks about an "equal global playing field which in turn leads to peace and prosperity between nations."

To get it wrong has serious consequences, of course. Protesters have been de rigeur at meetings of the World Trade Organisation because there is

# By Any Other Name (cont.)

In an opinion piece for the Daily Telegraph, Miranda Devine paraphrases American Theologian and biographer of the Pope, George Weigel:

Democracy and the markets are not just machines that run by themselves.

"It takes a certain kind of people to make them work, [people] possessed of certain virtues" and certain habits of mind.

For instance, [Weigel] says, only people "habituated to self-discipline" can be serious investors or entrepreneurs. They have to know how to work cooperatively with others, have willingness to defer gratification, be honest and have respect for others.

He says we have been living off the moral capital of the past. The dominant Western culture of secular "utilitarianism…is self-cannibalising".

not a high degree of faith that faceless corporations will look out for the 'little guy'. As Kofi Annan, United Nations Secretary-General put it:

…even where the global market does reach, it is not yet underpinned, as national markets are, by rules based on shared social objectives. In the absence of such rules, globalisation makes many people feel they are at the mercy of unpredictable forces. (General Assembly, April 2000)

We are fortunate enough in this Industry to make a special kind of product. We long ago learned that we had to think about its effects in the right and wrong hands, its packaging, its proper disposal, its safety and its efficacy, the information that comes with it, how it is advertised and to whom. We included consumer groups in our discussion because we understood the necessity and value of their input. How far ahead we are of many industries without codes or which have not chosen a path of self-restraint with full knowledge of its advisability!

Our world body (WSMI) has put principles in writing to foster shared social and economic objectives in health through shared approaches to regulation. ASMI contributed to their drafting and has participated in conversations with developing nations in our region. Our upcoming Conference will provide a platform for sharing our best approaches to challenges we jointly face.

**Smelling like a rose?**

In the area of health, there will always be a balancing act to perform – to balance cost and cure, evidence and claim, safety and efficacy, information and promotion, control and choice. To be able to balance, you must know your centre of gravity. Every so often, even a balanced Industry must check to make sure that the centre has not shifted, that the balance has not been thrown off.

This has been a year for examination of our core values and the balance we derive from them. We made sure that our plan was in line with our members' needs, expectations and plans for growth. We endeavoured to ensure that our strategies fit their objectives. We made sure that we were called by a name that is in balance with who we are. We ensured that our actions spoke of this balance to others.

To remind us of the principles of partnership, transparency and openness, we can look to our new logo. It is built of arms linked to one another and to paths of reason. It is a flexible, organic form with a strong central core, balanced but not rigid, Australian by design but not parochial.

***So, what is in a name? If it resonates properly, a name is a shorthand for who we are, what we represent, what we stand for, where we are going.***

# ASMI Secretariat

Front Row:

Juliet Seifert,
*Executive Director*

Montse Peña,
*Advertising Services Adviser*

Back Row:

Judith Brimer,
*Project Officer*

Mary Emanuel,
*Regulatory & Technical Manager*

Zephanie Jordan,
*Scientific Director (2000)*

Monica Johnstone,
*Member Services Manager*

Wendy Long,
*Office Manager/Executive Assistant*

Deon Schoombie,
*Advertising Services Manager*

Michelle Johnston,
*Office Assistant*

Not Pictured:
Robyn Kirkness,
*Reception (P/T)*

Bronwyn Capanna,
*Scientific Director (1999)*

Michele Tychsen,
*Regulatory & Technical Manager – Complementary (2000)*

# Our Achievements 1999-2000

For better and worse, this is a year Industry will not soon forget.

On the one hand, sales and 'switch' were up; on the other, our sector was challenged with extortion attempts and extensive recalls.

Despite the challenges, in the final analysis this year will be remembered by the Association for the history we created together. This was the year of Y2K and GST preparations. It was also the year that the Member Survey showed a remarkable solidarity with our strategic objectives and strong backing for taking the step of changing our name. On 8 June, in a unanimous vote, we became the Australian Self-Medication Industry.

We listened to the membership and added resources in the area of complementary medicines. We also updated our approach to information provision, adding a website and improving publications.

We embarked on a new Therapeutic Goods Advertising Code. Throughout the development period, the Association staunchly advocated a "blank sheet" approach to the new Code to ensure a more level playing field and expanded claims where appropriate. The new advertising controls now in place reflect our success.

This was again a year of major reviews, in particular the National Review of Drugs, Poisons and Controlled Substances Legislation (Galbally Review). We were also active in the review of TGA fees and charges, ensuring that Industry did not end up with a doubling of fees on the move from 50% cost recovery to full cost recovery by the TGA.

In the wake of the paracetamol recalls, both our Crisis Management Guidelines and our Tamper Evident Packaging Guidelines were held up as best practice to Industry. These guidelines are now the basis of a whole-of-industry approach to managing any such event in the future.

In short, it was a productive year. As the detail by strategic objective below shows, ASMI accomplished a great deal to improve the future of our Industry in Australia and beyond its shores.

### Maximise Freedom of Access

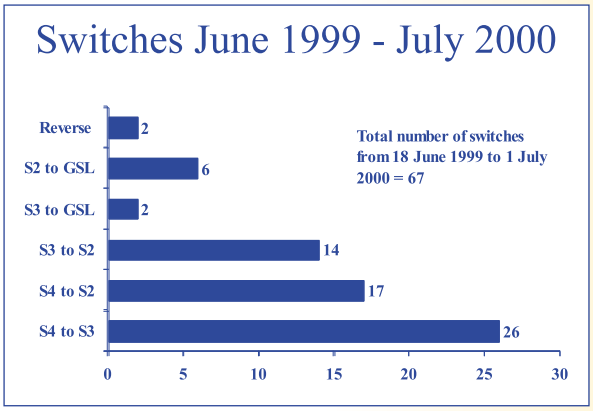
This objective sets out to establish and maintain a harmonised system of product access, which provides consumers with equal and appropriate availability to non-prescription consumer healthcare products.

In order to achieve this, we have continued to work in the areas of advertising reform, streamlining of regulatory processes and tax reform.

- Face-to-face meetings have strengthened our relationships with the TGA, especially with the OTC Medicines Evaluation Section, the Office of Complementary Medicines, the Australian Register of Therapeutic Goods and Information Technology sections; we have also been active participants in the TGA-Industry Consultative Committee (TICC).
- The ASMI Technical Special Team co-ordinated a liaison meeting with the TGA evaluators from both the OTC Medicines Evaluation Section and the Office of Complementary Medicines at the Warner Lambert manufacturing site in Caringbah.
- The Reg & Tech Core Group and Special Teams responded to the revised draft Australian Guidelines for the Registration of Medicines Volume 2, providing pro-active development of guidelines for sponsors of rescheduled products, reporting of adverse reactions, guidelines for ibuprofen and naproxen products, moratorium on application of draft policy and the application of new policy to existing products.
- We were successful in negotiating to provide sponsor access to evaluation reports prior to applications going to the Medicines Evaluation Committee for consideration.
- The TGA labelling project discussion paper proposed adoption of performance-based labelling principles into labelling regulation, and centralising of input for labelling requirements. This was in response to our initial proposals to the project.
- We outlined proposals for the conduct of the

review of grandfathered products. We are considered key players to be consulted as issues around grandfathered products arise.

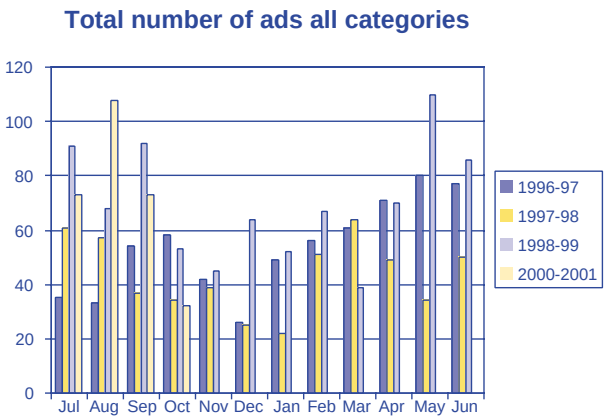
- Our involvement in the redevelopment of ELF has continued and an agreed model has been signed off. The new system features increased levels of self-assessment, simplified requirements and increased compliance.
- We continue to work toward increased and clarified product categories that are exempt from GST with the goal of all therapeutic products being GST-free.
- Our involvement in the reform of export regulation has resulted in a commitment to an implementation plan following on from the Review of Export Arrangements. Implementation is set for 2001. An interim electronic system and other improvements have been agreed for implementation during 2000.
- Our continued representations have resulted in a proposal to increase GMP clearance fees being retracted.
- The trans-Tasman harmonisation of scheduling project is 80% complete with our "top 20" list being dealt with as a priority.
- The Association developed a comprehensive submission, based on competition principles, to the National Review of Drugs, Poisons and Controlled Substances Legislation. Our submission has been used in outlining proposed models during negotiations with the States and Territories and most of our proposals were present in the resultant Options Paper.
- We have continued to develop our expertise in complementary medicines and are considered a key player in negotiations on matters in the complementary medicines area.
- The Association worked on a steering group to produce the TGA information kit, which acts as a plain English guide to the TGA and its processes.
- Zephanie Jordan, ASMI's Scientific Director, was invited to become a member of the Medicines Evaluation Committee and the NSW Poisons Advisory Committee. She has also taken up the role of ASMI representative on the Complaints




Resolution Panel administered by the Therapeutic Goods Advertising Code Council.

- The Association publicised, domestically and internationally, issues and record progress in switch.
- The Association was involved in all facets of the development and launch this year of the revised Therapeutic Goods Advertising Code (TGAC).
- Accompanying regulatory amendments to the TGAC were negotiated and gazetted achieving:

- separation between regulatory and advertising issues,
- significantly improved opportunities for expansion of advertising claims, and
- significant progress towards a level playing field.




Data collected during the last five financial year periods has shown a progressive increase in the number of advertisements approved by the Advertising Services Office. 523 advertisements were approved in the 1996-997 financial year and this figure increased to 770 in the 1999-2000. The graph above suggests that May through to September is the busiest time in the Advertising Services Offices.

# Our Achievements (cont.)

- ASMI was a member of the TGACC Communication Team and participated in the planning of a nationwide education drive.

- launch of the new TGAC,

- production and distribution of a consumer leaflet,

- development of the TGACC website,

- national roadshow – Sydney, Brisbane, Melbourne, Adelaide and Perth.

- A renewed ASMI Membership Advertising Education Program was launched. This program has been expanded and will continue throughout the next financial year.

**Sustain a Supportive Service Environment**

- The Membership was surveyed by The Leading Edge. The results were the basis of changes in publications and services to better suit members' needs. The results were also used to fine tune the strategic objectives of the Association.

- Phase One of the Website **(www.pmaa.com.au)** was launched in January 2000. Additions have been made throughout the year, including an immediate adjustment after the vote for changing the Association's name **(www.asmi.com.au)**. Plans were made for Phase Two, which will include password protected, members-only areas of the site.

- Data held by the Secretariat was enhanced this year. Sales data on a category level was obtained from AZTEC for the website.

- The Association upgraded its Membership Database.

- We created GST compliant processes for member subscriptions and developed compliant internal systems for accounting.

- New levels of staffing have been achieved to provide additional resources in complementary medicines and administration. This year also saw the appointment and training of the Advertising Services Adviser with expertise in Complementary Medicines.

- Free breakfast seminars on the Internet ("Java & Cookies") were trialed.

- The PMAA Newsletter was retired, and ASMI's One Voice was launched as the primary vehicle for disseminating general industry information to members on a fortnightly basis. Electronic provision of One Voice was implemented with the first issue.

- The Reg & Tech Update has been redesigned and renamed "R&T Express". It provides shorter information items on a wider range of issues and is also available electronically. Attachments are also provided electronically via the website where possible.

- Advertising Services achieved improved approval turn-around times.

- Advertising Services also implemented a new fee structure for approvals.

- In-principle agreement was reached for the development of a single advertising approval database with links to the TGA.

**Achieve a Whole-of-Industry Approach to the Quality Use of Medicines**

This objective seeks to promote the quality use of medicines to all relevant stakeholders to secure commitment to performance-based approaches to regulation.

- For the first time, the revised Australian National Medicines Policy made direct reference to our sector – including complementary medicines – after extensive involvement by ASMI in the drafting process.

- Our involvement in the development of the Guidelines for the Levels and Kinds of Evidence to Support Claims for Therapeutic Goods has resulted in the adoption of a set of requirements for the evidence to be held in support of claims for complementary and listable products. This is a big step forward to achieving a level playing field for listable and complementary products.
- Deon Schoombie, Advertising Services Manager, is a member of the Advisory Group established to provide guidance to sponsors and the TGA on the implementation of the Guidelines.
- We were instrumental in managing extortion crises at an Industry level, and our Crisis Management Guidelines and Tamper Evident Packaging Guidelines have been held up as examples of best practice. All interested parties have subsequently undertaken to review both guidelines with a view to achieving application to the whole of industry.
- ASMI has been instrumental in negotiations with the TGA on label requirements for guarana and St John's Wort to achieve an outcome that serves to inform consumers and which can be implemented by Industry.

**Broaden the Relevance and Influence of the Association**

This objective is designed to secure the Association's future as the peak body representing the entire spectrum of the self-medication industry in Australia.

- The Association developed, tested and ultimately agreed on a new, more appropriate name for the Association. The membership unanimously endorsed the change of name to the Australian Self-Medication Industry at a Special General Meeting on 8 June 2000.

  Our up-to-date new name reflects the expanding role of complementary medicines in our sector as well as alignment with our world body (World Self-Medication Industry). The National Manager of the TGA, Terry Slater, welcomed the name change in an address to our membership.
- With the help of noted artist, Tracey Bostock, the visual identity for the new name was developed. All necessary administrative changes were initiated immediately after the unanimous vote. New publication designs were implemented.
- As part of the promotion of our new identity, ASMI contacted all of its stakeholders to announce the new identity and renew contact.
- The Association maintained representation on key external committees.
- This year we gained representation on the TGA Strategic Information Management Environment (SIME) special interest groups.
- We grasped opportunities to promote ASMI issues to stakeholder audiences by giving presentations to several groups domestically and internationally.
- ASMI for the first time contributed to the AESGP (European association) publications on international regulatory systems and classification of substances comparisons.
- ASMI contributed to the UK publication called the Health Supplements Handbook, which outlines regulatory systems for complementary medicines.

# Our Executive Director from the Lookout's Post

So that the Industry may get on with what it does best, an Industry Association must often play the role of the lookout perched in the crow's nest. It is our job to scan the horizon for shoals or new worlds, for challenges or opportunities along the course of our mutually chosen strategic direction.

In this role, it falls to the Association to pose to the membership--and indeed, other stakeholders as well--the threshold questions as we enter new waters.

What are the threshold questions now that industry has entered a period of maturity marked by expansion through consolidation, global markets for both the multinational and Australian owned manufacturers, a trend toward transglobal corporate structures and a trend toward deregulation?

We find these probing questions everywhere. For instance, sometimes an examination of our jokes reveals our deeper concerns. At the close of a Committee of Management meeting recently, a member quipped that in a couple of years, the Committee of Management would be down to one very large member called R----. While this will never be the case literally, the mergers this year of six member companies into three has naturally been felt.

So one of the threshold questions must be, "How will we cope with rationalisation while still delivering safe, quality, efficacious products?" What will the best practice models be for streamlining their delivery?

The Industry body can reflect the trends in Industry and deliver some of the answers to these questions. Through conferences and publications, we can communicate the best models from around the world. Through our direct contact with Government and regulators, we can help create an environment for Industry capable of withstanding change, responding to new demands and fulfiling newly earned responsibility for self- and co-regulation.

Also, we must ask a similar threshold question of regulators: in five years, how many regulatory agencies will there be in this region or even in the world? Regulatory systems must also be best practice to become influential regional and global models. This in turn is vital to Industry sustaining viable local markets and developing new export markets.

In short, our aspiration to be Industry's "one voice" speaks to not just internal unity but also our effectiveness externally. This is the reason we strove so hard to get the full scope of self-medication recognised in Australia's National Medicines Policy. Its concerns are ours, its course and ours have much in common:

- access to affordable products created in an appropriate environment to maintain quality standards for safety and efficacy;
- quality use of medicines through means such as better communication, appropriate information, tamper evidence, technological improvements;
- recognition of complementary medicines as part of the Policy for the first time, creating a foothold for enlightened views on prevention and well being;
- viability of our Industry, and indeed its flourishing at both ends of the spectrum—both through switch and through expansion of our understanding of the contribution of traditional medicines.

Self-medication has always been about getting the balance right between commercial realities and health outcomes. The balance must always result in public benefit. This is as basic as balancing the winds and the currents to stay on course. An eternal threshold question is: What does the consumer want and need? How is that changing over time? Can our industry deliver on that need in a way that is safe and efficacious as well as socially responsible? How do we resolve the tensions between sustaining a viable Industry and meeting consumer expectations?

To belabour my metaphor, one cannot balance a ship from the crow's nest. The best the lookout can do is shout advanced notice of the squalls, suggest steerage and be willing to climb out on a yardarm to untangle the rigging when necessary. It is up to the whole crew to bring the ship of Industry back on course and to maintain smooth sailing.

Some pirates, as we learned this year from the extortion cases, will come upon us without warning, but we withstand these assaults together. We found that we can count on our preparedness to manage the crisis, our partners (in TGA, regulators in the States and Territories, professional organisations, and law enforcement agencies) to help us, and our own principles to respond in ways both responsible and humane. We learned that while this is no guarantee of zero harm, that renewed vigilance and expansion of our learnings even to non-members is the way forward.

What do we see on the horizon? Many opportunities to be leaders in Industry responsibility, to be partners in regulatory improvement, to be understood as real partners in health and to be on the forefront of expanding markets. If we steer a course in this direction, others will want to join our fleet.

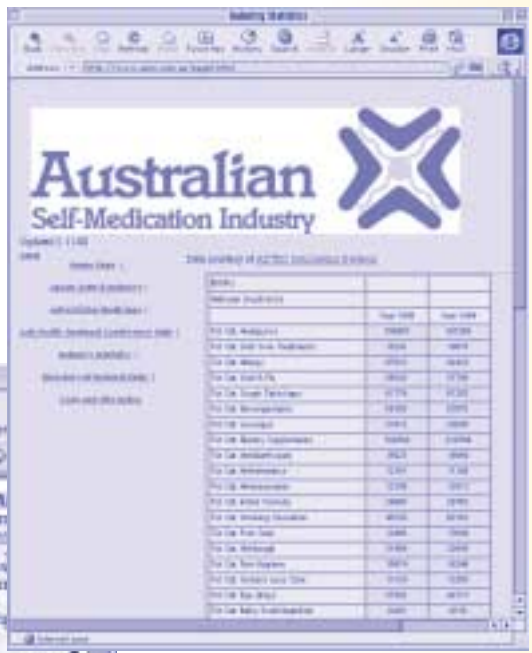
Juliet Seifert
ASMI Executive Director

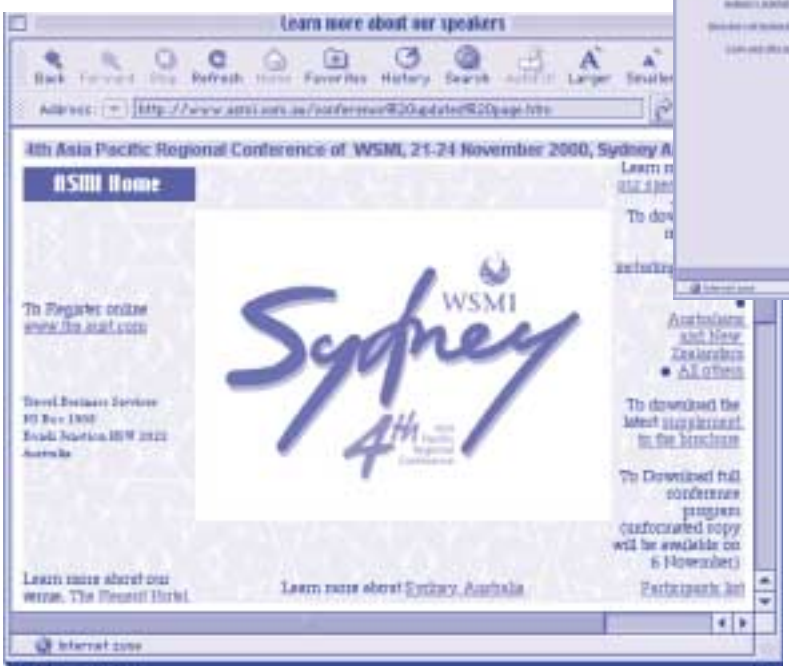
# Our Website

This year, the writing was on the wall – it was time to start writing for the web.

ASMI members welcomed our modest initial site (www.pmaa.com.au) in January 2000 and, through the member survey, confirmed that they wanted the option of receiving more information from the Association via the website.


Following the name change, the ASMI Secretariat internally redeveloped the site in two stages (www.asmi.com.au). The second stage will provide password-protected member services on-line. Our low cost, fast and flexible website is providing information and services, while freeing up staff time and resources for vital projects to benefit the membership.



# Our Complaint Handling Process

**Outcomes of Complaints Lodged under the ASMI Code of Practice 1999/2000**

*Lodging complaint:* Hexal
*Against:* Glaxo Wellcome
*Complaint re:* Advertising and promotion of Zovirax to healthcare professionals
Alleged breaches: Clauses 5.2 and 5.5 of the ASMI Code of Practice—alleged inappropriate clinical comparisons drawn from animal studies and references to international data alleged to be misleading.

*Outcome:* Alleged breach in relation to animal studies was not upheld. Comparison to generic products was found to be in breach of clause 5.2 of the ASMI Code. The Complaints Panel required an undertaking to discontinue publication of the advertisement and a corrective statement to be addressed to all Australian pharmacists.

Lodging complaint: Faulding
*Against:* Schering-Plough
Complaint re: Sales piece for Claratyne distributed to Australian pharmacies
Alleged breaches: Clauses 5.1.3, 5.2. and 5.6 of the ASMI Code of Practice – a superlative claim alleged to be unqualified, certain claims alleged to be inconsistent with the PI, alleged misleading representation of a competitor product and alleged breach of prohibition on incentive program for Schedule 3 products.

*Outcome:* Representation of an unapproved indication found to be misleading and a severe breach of clause 5.1.3 of the ASMI Code. Three minor breaches of clause 5.1.3 were found in relation to comparative claims but the alleged breach of clause 5.2 was not upheld. Incentive program was not found to be in breach of clause 5.6 of the Code. For the severe breach, the Panel required an undertaking to discontinue the promotion of the unapproved indication, a retraction letter to be sent to Australian pharmacists and the payment of a fine of $5000. For the minor breaches the Panel required an undertaking to discontinue publication of the relevant parts of the advertisement.

*Lodging complaint:* Janssen-Cilag
*Against:* Bayer
*Complaint re:* Consumer promotion of Canesten anti-fungal products through bonus packs
Alleged breach: Moderate breaches of clause 6.2 of the ASMI Code of Practice – alleged that the promotion of a "Bonus – Limited Offer" and bundling of Canesten with other products would encourage consumers to purchase a product that might not be needed or in larger quantity than is sufficient to meet the needs of the purchaser.

*Outcome:* The Complaints Panel found two minor breaches of clause 6.2 and required an undertaking to cease distribution of the packets in similar form and to retrieve any remaining stock from wholesalers.

*Lodging complaint:* Pfizer
*Against:* Janssen-Cilag
*Complaint re:* Detail aid for Vermox directed to pharmacists
Alleged breach: Three claims made in a detail aid alleged to be misleading comparative advertising and therefore in breach of clause 5.2 of the ASMI Code.

*Outcome:* The Complaints Panel found moderate breaches of clauses 5.2 and 5.1.3 of the ASMI Code in relation to two of the claims alleged to be in breach but did not find a breach in relation to the third claim. The Panel required an undertaking to discontinue the advertisement, to retrieve any remaining detail aids from pharmacies and to issue a corrective statement by way of a letter in the form specified by the Panel to all pharmacists who received the detail aid.

# AUSTRALIAN SELF-MEDICATION INDUSTRY

BETTER HEALTH THROUGH RESPONSIBLE SELF–MEDICATION

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