What is Self-Medication?

Self-medication involves the selection and use by consumers of medicines legally available without a prescription, both in the treatment of self-recognised acute symptoms and as part of the management of chronic recurring conditions. Self-medication is an important and almost universal healthcare activity, and it is now widely accepted that responsible self-medication and self-care more widely are beneficial for consumers and health systems.¹

ASMI VISION:

Better health through responsible self-care

ASMI MISSION:

ASMI - the voice of the consumer self-care products industry, driving a credible and expanding evidence-based self-medication market to generate cost-effective health solutions and improved public health outcomes.

ASMI VALUES:

• Drivers of change through member contribution and industry interaction.
• Best practice in governance and service.
• Committed to representation by consumers, relevant industry sectors and health care professionals.
• Consistent in policy and action.
• A learning organization committed to competency development.

¹ Excerpt from a speech entitled “New medicines for self-medication—opportunities and challenges for pharmacy” by Dr David E. Webber, Director General, World Self-Medication Industry.
Representing companies involved in the manufacture and distribution of non-prescription consumer healthcare products and related businesses, ASMI is the peak industry body for the Australian self-care industry. Consumer healthcare products range from complementary medicines to over-the-counter medicines. Over 75% of ASMI members have at least one complementary product in their portfolio. More than 25% of ASMI members have product portfolios that are either solely complementary or dominated by complementary products. Also represented by ASMI are companies providing manufacturers with services, such as advertising, public relations, regulatory consultancy, legal advice and industry statistics.

The mission of ASMI is to promote better health through responsible self-care. This means ensuring that safe and effective self-care products are readily available to all Australians at a reasonable cost. ASMI works to encourage responsible use by consumers and an increasing role for cost-effective self-medication products as part of the overall Australian health strategy.

ASMI provides an authoritative voice for the consumer healthcare products industry as the acknowledged point of consultation for Government, regulators, consumer organisations, professional organisations and other stakeholders. ASMI also provides the industry with the latest domestic and international developments influencing the self-care industry in technical, regulatory, commercial, social and legal arenas.

As a member of the World Self-Medication Industry (WSMI), a non-government organisation with official links to the World Health Organization and the United Nations, ASMI helps to promote the worldwide recognition of the role of non-prescription and complementary medicines in health care. This is an expanding role as self-care medicines go beyond their traditionally acknowledged role in treating the symptoms of self-limiting ailments. Around the world there is an increasing acceptance of the important role self-care can play in the prevention and treatment of previously diagnosed chronic conditions by increasing access and providing effective cost-containment.
Members of the Australian Self-Medication Industry

**Honorary Life Members**
Mr K. Darke  
Mr A. D. Glover  
Dr W. A. Morgan  
Mr D. C. Murphy  
Dr J. Pentecost  
Mr D. Stephens  
Mr C. J. Tucker  
Mr A. J. Wardell  
Mr W. J. Wilkinson AM

**Ordinary Members**
3M Health Care Pty Ltd  
Allergan Australia Pty Ltd  
Arkopharma Australia  
Aspen Pharmacare  
Australian Pharmaceutical Industries  
Bayer Healthcare Consumer Care  
Biological Therapies Pty Ltd  
Boehringer Ingelheim Pty Ltd  
C B Fleet Co (Australia) Pty Ltd  
Cardinal Health  
Church & Dwight Australia Pty Ltd  
Combe International Ltd  
Ego Pharmaceuticals Pty Ltd  
Evidence Based Herbas Pty Ltd  
Flordis Pty Ltd  
Galderma Australia  
GiaxoSmithKline Consumer Healthcare  
H W Woods Pty Ltd  
Johnson & Johnson Pacific  
Living Naturally  
Mentholatum Australasia Pty Ltd  
Merck Sharp & Dohme (Aust) Pty Ltd  
Nestle Australia Ltd  
Novartis Consumer Health Australasia Pty Ltd  
Pfizer Pty Ltd  
Procter & Gamble Australia Pty Ltd  
Reckitt Benckiser  
Roche Products Pty Ltd  
Sanofi-aventis Australia/New Zealand  
Schering-Plough  
Smith & Nephew Pty Ltd  
Stiefel Laboratories Pty Ltd  
Symbion Consumer  
Wyeth Pty Ltd

**Associate Members**
ACNielsen  
Agilent Technologies Australia Pty Ltd  
Anthea Steans Consulting Pty Ltd  
AZPA International  
Clare Martin & Associates  
Clayton Utz  
Contract Pharmaceutical Services of Australia Pty Ltd  
Cormack Packaging Pty Ltd  
Crossmark  
Curtis Jones & Brown Advertising Pty Ltd  
DFC Thompson Australia Pty Ltd  
Engel, Hellyer & Partners Pty Ltd  
Euro RSCG Life  
Freehills  
Grey Healthcare Group  
Hahn Healthcare Recruitment Pty Ltd  
H&T  
IMS Australia Pty Ltd  
Kendle Pty Ltd  
Labmark Pty Ltd  
Lipa Pharmaceuticals Remedies Pty Ltd  
National Pharmacies  
Pathway International  
Palin Communications  
Oz Pharma Contracting & Consulting  
Regulatory Concepts Pty Ltd  
Singleton Ogilvy & Mather  
Sue Akeroyd & Associates  
Technical Consultancy Services Pty Ltd  
Ursa Communications
ASMI Committee of Management, Executive Subcommittee and Secretariat

Committee of Management

David Armstrong, Reckitt Benckiser (until Feb ‘06)
Robert Barnes, Symbion Consumer Products
Peter Cameron, Sanofi-aventis Australia/New Zealand (from Feb. ‘06)
Ralf Dahmen, Galderma Australia
Kevin Darke, GlaxoSmithKline Consumer Healthcare (until Apr. ‘06)
Lindsay Forrest, Reckitt Benckiser (from Mar. ’06), previously Boots Healthcare
Sue Hogan, Pfizer Pty Ltd
Ronda Jacobs, Cardinal Health
James Jones, Schering-Plough (from Feb. ‘06)
Peter Miles, Sanofi-aventis Australia/New Zealand (until Dec. ‘05)
David Murphy, Combe International
Trevor Norman, Mentholatum
Mark Sargent, Bayer Healthcare Consumer Care
John Sayer, GlaxoSmithKline Consumer Healthcare (from Apr. ‘06)
Nick Williams, Schering-Plough (until Dec. ‘05)

ASMI Secretariat

Chris Arblaster, Marketing & Development Director
Jonathan Breach, Regulatory Manager
Catherine Brunskill, Advertising Services Manager
Katherine Page, Office Administrator/Research Asst.
Peter Cranston, Technical Manager
Mary Emanuel, QUM Project Manager
Monica Johnstone, Member Services Manager
Christian Cuneo, Information Coordinator
Deon Schoombie, Scientific Director
Juliet Seifert, Executive Director
Lesley Speechley, Executive Assistant/Office Manager

Executive Subcommittee

ASMI President: Ralf Dahmen
Immediate Past President: Kevin Darke
Vice President/Secretary: David Murphy
Vice President/Treasurer: Trevor Norman
Chair, Marketing & Ethics Subcommittee: Sue Hogan
President’s Message

Our Industry and its market environment never cease to produce opportunities and challenges. I will here detail for you those key initiatives ASMI has pursued across the most relevant issues collectively facing our businesses.

It is important to appreciate the tremendous efforts made on our behalf by the Secretariat led by Juliet Seifert, particularly in the political context. Often the means to affect change that affects business’ bottom line begins with discussions across the political arena. For instance, before we can secure better protection for innovation and research, we have to sell in the ideas of data protection and a measure of market exclusivity. ASMI has blazed this trail and is now addressing the required legal framework. Similarly, quicker time to market is achieved by ensuring we get the best initial outcome in the design of the new Trans-Tasman system. For this reason, we have emphasised involvement at the front end of legislative design to ensure that our voice on behalf of all members is heard. This occurs not only locally but also internationally via the World Self-Medication Industry because there we help to shape the regional and global direction that allows us to achieve optimal export and import as well as establishing global trends that are congenial to our local circumstances.

Success in the political arena is in part an exercise in media relations. This year we have significantly heightened the visibility of our views regarding many issues in the trade and popular press. Not restricted to our presence in print, our increased profile is also clear on expert panels and committees where our experience and expertise is sought after.

Speaking of experience, this year as a means of upholding the link to our Association’s corporate memory the ASMI Advisory Panel was instituted. Inviting past Presidents and others with a broad perspective built on many years of industry experience, ASMI has assembled a panel to brainstorm, reflect and input into those issues and ideas that guide our strategic direction. By tapping into this considerable resource for ASMI, we offset the effects of turnover within current industry leadership, mergers and the all too human tendency to get caught up in the current quarter.

Many of our activities these last 12 months progressed the Self-Care strategic objective declared at the 2005 AGM and Conference. We made the case for the importance of self-care from a health economic perspective and government announced an initial research grant to support our work. In the days and months after, on radio, in newspapers and the trade press, the role of our industry in self-care was extolled. The ASMI Self-Care document was widely distributed and requests for additional copies were received from many interested parties. Clearly, we struck a nerve at a moment in the history of Australian healthcare when everything from sustainability of current systems to self-management of chronic conditions is on the public agenda. Our focus continues to be the national health priority areas so that our role in key health outcomes is acknowledged and maximised.

We have as a large part of this effort continued to input into the Trans-Tasman model as it progresses. Delays have been frustrating for industry, but we must see them as opportunities to get it right.

We have also been engaged in practical help to industry to get it right in the manufacturing area. Several seminars in GMP featuring TGA auditors have been held. And even more impressively, a rigorous course to qualify authorised persons has been designed, written and run—and will this year see its first graduates—through the collaborative efforts of ASMI, the University of NSW and the Advanced Manufacturing Centre. Through ASMI’s perseverance, we have a course in place that will improve industry, develop its people and ensure quality.
This year not only did ASMI lobby hard and win a successful outcome in the area of patent certification for listables and specified registrables through briefings with key government departments, but we will also be commencing a formal review of research for select complementary medicines in order for government to provide evidence-based clinical advice to health professionals.

And all the action is not just in the regulatory and technical areas. This year The Missing Link Project is up and running. The data it provides plugs a hole in our knowledge about how product is being handled on the shelf. Simply put, industry knows more about product movement through the supply chain than it did a year ago. We can look forward to additional development of our human resources through the representative induction course now being designed. These projects are not only great for industry, but help to build our relationship with stakeholders such as pharmacy, consumers and government as well.

There are many more highlights so I direct your attention to the section of this report titled Achievements which details our efforts from meetings with grocery chains and Ministers to information provision and submissions to consultations. All this myriad activity actually reflects our strategic focus.

It is our challenge to select and direct our focus to those issues that will make the biggest difference and secure a sustainable future for our industry as a whole.

Behind every achievement is not only a hard working Secretariat and Committee of Management, but also the expertise and commitment of our member subcommittees. For many years ASMI has enjoyed the participation of a wide cross-section of the membership in our activities. This is set to continue with the successful start of a new group on contract manufacturing.

It has been a privilege to serve industry as your President, and I look forward to a watershed year for our industry.

Best regards,

Ralf Dahmen
ASMI President
ASMI Awards

2005 ASMI Award for Excellence

The ASMI Award for Excellence was made to Alan and Jane Oppenheim who are Managing Director and Scientific Director respectively of Ego Pharmaceuticals.

Since joining the then PAA in 1989, Alan has missed only one of this Association’s AGMs. He served on the then PAA Technical Committee (1990-1993 inclusive) and became the PAA’s representative member on the committee responsible for the Australian Standard for Sunscreens (1990-1993).

Jane is ASMI’s representative on the Standards Australia Sunscreen Committee and has chaired the ASMI Sunscreen Team since 1994. She has also served on the Regulatory & Technical Subcommittee. In 2000, Jane was the MC and Chair for the sunscreen workshop on UVA-testing which was held in conjunction with the WSMI Asia Pacific Regional Conference.

With a philosophy built on “Can we do that better?”, they have helped turn a family niche small business into one of the 100 fastest growing companies in Australia with 100 employees and a $30 million turnover—over $4M of that in exports. In fact, export is up this year by 30% and a $6M investment has been made in capital works—including an extra 2.5 acres.

Never resting on their laurel sulfates, this company continues to invest in R&D and now produces over 70 skin and health care products in its state of the art facilities.

Alan once described his participation in ASMI thus: “I take a personal interest in the industry especially in excessive, remarkable or unconscionable therapeutic claims by pharma, cosmetic and food products even if (especially if) they have no commercial affect on Ego. This probably increases the workload of ASMI staff.”

It is not easy to separate a description of their contributions together and individually from that of their company—in large part because they have not made a great deal of separation between life and work. An overflowing passion for bringing a scientific approach to the treatment and prevention of skin diseases has fuelled their lives and the Association has also benefited. As Alan once put it, “joining the association meant commitment.”

Whether asking a penetrating question or providing leadership in product areas such as sunscreens or serving on a complaint resolution panel or providing insightful responses to consultation drafts or serving on subcommittees, they have shown the same sort of service to industry as a whole that they have to their own enterprise. Doing things well is a way of life for them.

They have modelled how to do it well for the rest of industry too. Supporting dermatological research organisations and making it possible for Kids Tennis Foundation to go Australia-wide, this dynamic team has an infectious drive to bring out potential whether it is in their own products, the community, or this association. No wonder Ego won the Victorian Business Award from 60,000 entrants.

They are the proud inheritors of a business that it 2003 celebrated its 50th anniversary and has grown from making products for the direct use of his grandfather’s dermatological practice to exporting to New Zealand, Hong Kong, Singapore, Malaysia, Fiji, Papua New Guinea, Cyprus, Malta, Jordan, Bahrain, United Arab Emirates, Saudi Arabia, Yemen, Taiwan, Vanuatu, Solomons, Western Samoa and the United Kingdom.
2005 ASMI Marketing Awards

ASMI honours marketers’ excellence in new product introductions and promotional programs through its ASMI Awards. Winning entries serve as a model for members and non-members and establish a standard of excellence to improve the industry’s performance.

The four awards were judged by an Expert Judging Panel made up of independent experts experienced in the disciplines involved and knowledgeable about the consumer healthcare market. The ASMI Awards were presented at the ASMI Annual Conference Banquet at the Australian Technology Park, Sydney on 21 September.

ASMI is delighted to congratulate the ASMI Marketing Award Winners for 2005:

Best Switch
Diflucan One by Pfizer
Consumer Healthcare

Best New Product Introduction
Lamisil Spray by Novartis
Consumer Health

Best Promotion of an Existing Product – OTC category
NicabateCQ Lozenge by GlaxoSmithKline Consumer Healthcare

Best Promotion of an Existing Product – Complementary category
Joint winners
Nature’s Own by Mayne
Consumer Products (now Symbion Consumer)
Ostelin by Boots Healthcare

These companies can be rightly proud of their achievement in a growing and competitive field of applicants in this the third year of the ASMI Marketing Awards.
Achievements toward the Strategic Objectives of ASMI

STRATEGIC OBJECTIVE 1: MAXIMISE ACCESS TO MARKET

Contribute to global regulatory harmonisation through the creation of a single market for consumer self-care products in Australia and New Zealand.

Goal 1.1: Work with regulatory authorities to produce a single Trans-Tasman regulatory system benchmarked to international regulatory best practice that delivers maximum efficiency to industry and responsible access to the widest range of products to consumers.

ASMI continued to represent the interests of members in the regulatory arrangements for the joint Australia/New Zealand Therapeutic Products Authority (ANZTPA). As part of a consultation process we responded to a wide range of discussion documents and consultation papers.

ASMI continually monitors international regulatory developments to initiate, where appropriate, the adoption of best-practice approaches by the regulator.

ASMI is responding to member needs in the technical and GMP arena and facilitating the development and implementation of industry wide solutions:

- An ASMI member audit register has been implemented to monitor Therapeutic Goods Administration (TGA) audit activities for consistency and uniformity.
- The Postgraduate Certificate in GMP Program at University of New South Wales (UNSW) is up and running. The first group of students will qualify in mid 2006. The program has been well received by industry and is also attracting international participation.
- ASMI collaborated with Advanced Manufacturing Centre (AMC) to establish “Third Party Quality Guidelines”, and “Reduced Testing Guidelines” both with the involvement of TGA.
- Member training needs are also addressed on an ongoing basis. ASMI presents annual workshops and the next will be held in June 2006 on computer validation. In-house training is also conducted at the request of member companies.
- There are many major issues peculiar to contract manufacturers. ASMI is collaborating with AMC and other industry stakeholders to explore the establishment of a contract manufacturing group to deal with the needs of this sector.

ASMI fosters open communication with the regulator and other stakeholders. We participate in a wide range of forums in the development, implementation and promotion of uniform regulatory standards.

ASMI monitors and addresses interface issues between therapeutic goods legislation and other federal and State and Territory jurisdictional legislation that may impact on therapeutic goods.

Legislative underpinning for the Qualified Person has been identified as a priority by the TGA. ASMI will participate in the development of a regulatory model to provide legislative underpinning for the Qualified Person, including accreditation, tertiary education and training.

ASMI is a member of the Word Self-Medication Industry (WSMI) and contributes to the development of key WSMI and partner organisation documents and initiatives.

ASMI also influences the planning and implementation of WSMI regional meetings and conferences, including forums for regulators.

Goal 1.2: Pursue minimum effective regulation of consumer self-care products in line with quality, safety and efficacy principles and consistent with ensuring consumer confidence in the market.

ASMI advocates the adoption of an evidence-based approach to total product presentation.

- ASMI developed a position paper on brand extensions (umbrella branding) which underlines the principles that should underpin regulatory requirements, i.e. consumer focused (evidence-based) labelling and QUM (Quality Use of Medicines). ASMI promotes the adoption of a single guideline.
• ASMI regularly organises Consumer Focused Labelling (CFL) workshops to promote industry-wide adoption of these principles.

To optimise the management of ingredient and category-specific issues, ensuring appropriate levels of consumer access to products and substances, ASMI monitors an extensive range of substances as well as therapeutic and product categories. In addition to our regular comments to the National Drugs and Poisons Schedule Committee (NDPSC), we ensure that ASMI’s point of view is taken into consideration through various committees and forums.

Goal 1.3: Negotiate an appropriate level of cost recovery with responsible, transparent and accountable administration thereof.

ASMI continuously pursues improved efficiencies, greater accountability, transparency and improved reporting by the TGA to industry through the Therapeutic Goods Administration Industry Consultative Committee (TICC).

• The Australian National Audit Office (ANAO) Report released at the end of 2004 triggered wide-ranging reforms in the TGA. ASMI remains closely involved with the TGA to ensure that all the recommendations in the report are implemented.
• The TGA reviewed its Service Charter with ASMI input.
• ASMI and other industry stakeholders provided early input into a new cost recovery model under ANZTPA. ASMI hosted a consultation meeting with TGA, Medsafe and industry to discuss the principles on which the fees and charges structures will be modelled. ASMI also responded to a proposal to increase fees and charges for 2006/07 and engaged in further discussions at TICC.

Goal 1.4: Drive market innovation through establishment of appropriate incentives for new product development and switch.

ASMI is participating with the regulator to implement intellectual property provisions under ANZTPA. We continue to lobby and have achieved in-principle support for our position.

ASMI advocates principles-based, flexible legislation and policies to deliver greater efficiency and opportunity for rescheduling, resulting in increased consumer access to our products and improved market opportunities for our members.

• We developed a position paper in response to the recommendation of the Galbally Report for a single pharmacy schedule.
• ASMI is pursuing significant reforms in the current scheduling system. We provided comment on the proposed scheduling model under ANZTPA and will be pursuing further reforms in 2006 – abolition of Appendix H, de-linking advertising decisions from scheduling decisions and gaining advertising for all non-prescription medicines.

Goal 1.5: Ensure a level playing field by influencing the regulatory environment at the interfaces.

ASMI remains engaged in all consultations and policy development with agencies responsible for interface areas, i.e. FRSC, FSANZ and NICNAS.

• Major reviews of the regulation of foods are underway, particularly in the area of health claims in foods and the fortification of foods with vitamins, minerals and biologically active substances. ASMI has influenced these processes through our membership on the Standard Development Advisory Committee and through submissions.
• Following the adoption of the recommendations in the Newgreen Report, major reforms in the regulation of cosmetics are being implemented. ASMI is a member of the Implementation Group, which is responsible for oversight of this process.

Goal 1.6: Expand the scope of responsible advertising to consumers.

ASMI is advocating a system whereby all companies are bound by a co- and self-regulatory code of practice.

• Through our intimate involvement in the Interim Advertising Council (IAC) process to develop an advertising system under ANZTPA, the majority of ASMI’s proposals have been accepted. ASMI will be part of the Implementation Steering Group for the new system.
ASMI is committed to ensure that there are equitable schemes of advertising and promotional control in the therapeutic products, food and cosmetic industries where health claims are used in promotion.

Having reviewed its position on the advertising of S3 substances, ASMI is now advocating that the advertising of all non-prescription medicines and the regulation of advertising be managed through the Therapeutic Goods Advertising Code Council and the Therapeutic Goods Advertising Code rather than through the scheduling process.

Goal 1.7: Implement the IAC recommendations for a cost-effective and efficient centralised approval, complaints, monitoring and evaluation system for all products making health claims.

ASMI is committed to the proposal for a centralised advertising function for all healthcare products which may be legally advertised.

ASMI has gained the in-principle agreement of the TGA on a model which will be further negotiated via the IAC Implementation Steering Group.

Goal 1.8: Develop and maintain industry-wide contingency management protocols to manage events such as product tampering and other disasters that affect consumer self-care product industry sectors.

ASMI is a member of the Health Infrastructure Assurance Advisory Group (HIAAG) and the Pharmaceutical Industry Forum under the Department of Health and Ageing. The groups coordinate and advocate the implementation of business continuity planning protocols in the event of national crises, such as an influenza pandemic or terrorist attack.

ASMI is responsible for the maintenance of the existing Crisis Management Protocols and will ensure the adoption of these guidelines as well as the Tamper Evident Packaging Code under ANZTPA.

STRATEGIC OBJECTIVE 2: CHAMPION SELF-CARE—THE FOUNDATION FOR A HEALTHY AUSTRALIA

Develop an integrated approach to the role of consumer self-care products in enhancing and restoring health, preventing disease and limiting illness.

Goal 2.1: Gather and promote appropriate research-based evidence which builds the case for self-care.

- A self-care policy document entitled “Self-Care in Australia” was completed, widely distributed and made available on the ASMI website in October 2005.
- ASMI secured Government funding for research in self-care. Parliamentary Secretary, Christopher Pyne MP announced $65,000 in research funding at the ASMI 2005 Conference, and ASMI contributed an additional $25,000. With a researcher identified and the proposal accepted by the Department of Health and Ageing, the research is expected to take place later this year.
- ASMI has been building relationships with research stakeholders through meetings with National Health and Medical Research Council (NHMRC), academics, the National Prescribing Service (NPS), the Omega-3 Centre, and the Department of Health and Ageing.
- ASMI has collected systematic reviews of non-prescription healthcare products in National Health Priority Areas (NHPA). ASMI commissioned a strategic review of research with recommendations on opportunities for further research in NHPA with regard to member products/ingredients.
- A self-care section has been added to the ASMI website.

Goal 2.2: Gain increased understanding and support by healthcare professionals of responsible self-medication.

- To enhance ASMI’s network of supporters of self-care among health professionals and consumer groups, ASMI invited conference speakers to initiate newsletter articles and publish reciprocal notices of events.
- Using existing networks and events, ASMI is promoting self-care agenda to all relevant stakeholders. For instance, Juliet Seifert presented to the Pharmaceutical Society of Australia (PSA) council on ASMI’s self-care agenda and our self-care position paper was presented to the Australian...
Pharmaceutical Advisory Council (APAC) and to Chairs of PHARM and National Prescribing Service.

**Goal 2.3: Secure government support for the strategic importance of self-care.**

- To aid in the review of existing data on self-care health economics which measures the impact of responsible self-medication on the Australian healthcare system, ASMI compiled a regularly updated electronic database.
- ASMI worked with NPS on development of their proposed consumer-based research, monitored research by academics such as Prof Charlie Xue, Prof Alastair MacLennan and Prof Stephen Myers. Alliances for research and information provision have been established with the Arthritis Foundation, Arthritis NSW, the Heart Foundation, and the National Prescribing Service.

**Goal 2.4: Ensure the Pharmaceutical Benefits Scheme (PBS), taxation, private and public health insurance schemes are all structured to acknowledge and promote self-care.**

- Submissions and representations were made to Pharmaceutical Industry Working Group (PIWG) PBS subgroup and the Department of Industry and Treasury, illustrating savings that could be made to the PBS and the healthcare system by removal of GST from unscheduled products.
- In order to remove the impact of scheduling on PBS reimbursement and ensure self-care products are not disadvantaged by any changes to the PBS, ASMI is represented on all groups involved in PBS effectiveness and long-term affordability. ASMI is an active participant in the PIWG PBS Working Group and was invited to a special meeting with the Minister to discuss improved effectiveness and the long-term affordability of the PBS.

**Goal 2.5: Ensure the application of Quality Use of Medicines principles in the self-care arena.**

- The ASMI Marketing Award scheme stresses quality use of medicines (QUM). This year ASMI added an Award for Best Promotion of an Existing Complementary Product.
- ASMI encourages member participation in other award schemes promoting QUM. For the National Medicine Symposium (NMS) 2006, ASMI began promotion early and encouraged members to submit applications for QUM awards. ASMI collaborated with other industry stakeholders to develop a poster for presentation at the NMS aiming to increase understanding of QUM principles throughout the product development process (see pages 12-13).
- ASMI is represented on relevant QUM committees and provides information on QUM activities to members. These include APAC and its Working Parties, the NPS Medicines Industry Liaison Group, and the APF 20 Editorial Committee. ASMI has also held discussions with PHARM on possible research activities.
- Mary Emanuel of ASMI is the QARG Project Officer (government funded). The Quality Assurance Reference Group (QARG) assesses quality of Consumer Medicine Information (CMI), CMI content, develops core CMIs and provides training on writing and testing CMIs. It also oversees review of the CMI Usability Guidelines and the CMI Vocabulary List.
- This year, core CMIs for Pseudoephedrine and other ingredients with which it is combined were completed and added to the QUM section of the ASMI website.

**STRATEGIC OBJECTIVE 3: DELIVER A PROACTIVE AND SUPPORTIVE MEMBER SERVICE ENVIRONMENT**

Develop ASMI as an essential resource for the integrated self-care products industry and its stakeholders.

**Goal 3.1: Regularly ensure all projects reflect the integrated nature of the marketplace and member needs and expectations.**

- As part of our commitment to tailoring activities to members’ needs and market realities, ASMI representatives visit each member in order to receive direct input into key issues affecting business and to check progress of member services provision. This year, 60% of Ordinary Member companies were visited, 25% of Associate Members, and...

...continued on page 14 >>
To help illustrate this, a working group of the NPS Medicines Industry Liaison Working Group (Mary Emanuel – ASMI, Jude Tasker – Pfizer Australia and a member of Medicines Australia, and Robert Rona and Greg Pearce – both from Alphapharm, a member of the GMA) developed this poster. It charts each step of the pathway for prescription, OTC and complementary medicines and includes examples of QUM activities. The chart also demonstrates which step of QUM is relevant at each stage of the development process.

The chart can be used as a stand-alone document or as part of a broader QUM education program.
many others were contacted by phone and face-to-face through their subcommittee participation.

- ASMI continues to enhance its membership database for targeted service provision.
- Member Surveys confirmed the relevance of existing services and indicated areas of need and the feasibility of proposed new services. These included a Website Survey and spot surveys on issues such as IT compatibility.
- ASMI’s Membership Services Subcommittee has an ongoing focus on member services ranging from new on-line services and provision of marketing data to the organisation of the annual ASMI AGM and Conference in line with the objectives of the Strategic Plan.

**Goal 3.2: Expand membership coverage by promoting relevant current services and identifying any additional needs.**

- To continually increase ASMI’s ability to target appropriate new members involved in all relevant categories, the Secretariat investigates websites and other information sources. Enhancements to the ASMI database improved specialised targeting of member services and non-member awareness.
- ASMI continues to develop relationships with pharmacy banner groups and chains. This year visits were paid to Amcal, Guardian, Chemmart, Terry White, Priceline, Soul Pattinson, and MyChemist.

**Goal 3.3: Ensure availability and relevance of information for members to assist them to take advantage of opportunities for growth and to pre-empt and/or manage possible threats.**

- ASMI this year optimised our publications in formats amenable to electronic dissemination. Publications include **ASMI Voice** (including STAR & RE:Claim), **SMS**, **Annual Report**, **For the Record**, Conference Registration brochure, Conference Program, **Trendscan 2006**, a brochure launching the new Manufacturing Award, an updated version of **Self-Care in Australia** and other publications. These publications are distributed to an ever-growing subscription list.
- The Secretariat continues to develop and improve ways of communicating timely and useful knowledge to all levels of the membership through its website. ASMI has achieved many number one hits in search engines such as Google on a wide range of topics and for companies on its Services Directory. New features recently added include additional navigation, major updates to QUM and Advertising sections, a new complementary medicine section, a Committee of Management page, a dynamic Strategic Plan section accessible to members, new industry data and much more. ASMI now routinely receives media inquiries, expressions of interest in membership, requests for links from related sites and other useful contacts via the website.
- The ASMI Conference 2005 provided a forum for stakeholder debate on key issues and for updating members on Association activities and achievements. The launch of the strategic self-care initiative provided a theme and focus for the day which was attended by over 250 participants. The 2005 Conference exceeded its sponsorship target with many returning sponsors. The 2006 conference will build on the self-care theme, this time with a focus on how the consumer and the commercial considerations of industry are well served by self-care.
- ASMI provided members with regular induction programs on the Association and the operation of the ASMI Code of Practice.
- Members have also been provided with training on specific regulatory, technical and advertising issues as required. These include the Complementary Medicine Technical Conference in August 2006 held in Wellington NZ, the GMP workshop on Computer Validation by ASMI and TGA, and Labelling Workshops.
- Members requesting regulatory information about the region find a wealth of material available through ASMI’s links with WSMI and the regional Regulators’ Forum.
Goal 3.4: Increase ASMI income from non-fee initiatives and activities to reduce dependence on fee income by 25%.

- This year, ASMI developed and implemented “The Missing Link” pharmacy in-store audit service. A significant number of members committed to the project. Data collection commenced early in 2006.
- In conjunction with Travel Business Services, “ASMI Travel and Event Management” has entered a trial period.
- ASMI continues to investigate and implement other income generating activities, such as licensing activities, the on-line Services Directory now in its third year and regular newsletter ads.

Goal 3.5: Provide opportunities for leadership development and esprit de corp within the membership to promote whole of industry perspectives.

- ASMI held functions to honour the achievement of our members such as the Melbourne dinner, the ASMI Awards Banquet and the Committee of Management/Subcommittees’ end-of-year reception.
- A Manufacturing Excellence Award was launched this year. It will acknowledge efforts to improve manufacturing innovation and best practice.

STRATEGIC OBJECTIVE 4: BROADEN THE RELEVANCE AND INFLUENCE OF THE ASSOCIATION

Secure the Association’s future as the peak body representing an integrated self-medication industry.

Goal 4.1: Maintain and increase the representation of companies dealing primarily with complementary medicines so that ASMI represents 85% of the complementary market.

- This year ASMI recruited new Ordinary Members EB Herbals, and Arkopharma. New Associates Member recruits are: AZPA, Kendle, National Pharmacies, Euro RSCG Life, and Agilent Technologies.
- Development of potential membership is on-going through data mining and provision of a non-member newsletter to expand ASMI’s distribution in this area.
- ASMI assisted members not currently in the complementary medicines category to expand their business into the category.

Goal 4.2: Influence through participation in key processes and with key stakeholder groups to increase opportunities and minimise threats.

- The ASMI Secretariat maintains existing representation on key committees and seeks representation on new relevant committees.
- ASMI presented its positions to key stakeholders such as Pharmacy Guild, Government, grocery retailers and others through many channels, such as representations made to the Pharmacy Guild, the Pharmaceutical Society, the Medicines Partnership, the National Prescribing Service, the National Pharmaceutical Services Association, the Australian Food and Grocery Council, the Department of Health and Ageing, Treasury, the Parliamentary Secretary and Health Minister. ASMI also met with organisations such as the Heart Foundation, attended meetings on illicit manufacture, and supported the Princeton Ball.
- Very wide distribution was made of the ASMI Annual Report and Self-Care in Australia. Key stakeholders were invited as conference speakers and guests, meetings were held with pharmacy banner groups and chains, and correspondence with stakeholders was conducted to renew contact and provide the voice of our industry to our key partners.
- Each year ASMI provides speakers for and attends many events, such as the NPS Summit - Informing Judgements about Medicines; ARCS, “Patient-Centred Healthcare”; “QUM of Cardiovascular Medicines”; the conferences of our sister associations and world body; 9th National Chemical Diversion meeting, National Herbalists Association of Australia Seminar Series; the Health Minister’s opening of the Contract Pharmaceutical Services of Australia (CPSA) facility; Pharmacy 2005; PSA New Graduate Update: APP 2006 and PSA’s Self-Care meeting.
- ASMI actively fosters a network of relationships with key stakeholder organisations. Complementary healthcare practitioners and researchers,
for instance, were accessed through interactions with the National Herbalists Association of Australia, Australian Natural Therapists Association, Australian Traditional Medicine Society and Federation of Natural and Traditional Therapists on issues of scheduling, adverse event reporting and substance specific issues. ASMI also had involvement in the Natural Health Care Alliance (NHCA), Federation of Natural and Traditional Therapists (FNTT) Quality Standards Committee, Australian Centre for Complementary Medicine Education and Research (ACCMER), University of Western Sydney ComplMED and RMIT (Melbourne).

• ASMI maintains active participation with the distribution channels through activities such as participation in S2/S3 meetings held by the Pharmacy Practice Foundation, meeting with Coles Myer executives, involving pharmacy and consumer advocates in our conference, meetings with NPSA, providing promotion for Women in Pharmacy seminars, Department of Industry meetings, and hosting the new Contract Manufacturing Group.

Goal 4.3: Develop, implement and manage an active media and communication strategy.

This year, ASMI established a dedicated media facility to promote ASMI as the respected voice on all issues relevant to our sector. The Secretariat “skilled up” in a PR workshop, and a cost effective media plan was developed. The media contacts on the ASMI database were increased and used to spread the word on a number of issues throughout the year such as the launch of self-care, the role of complementary medicine, pseudoephedrine, compliance, Nicotine Replacement Therapy, the government’s health reforms, Echinacea, the ASMI/ NZSMI alliance, TGA Fees and Charges and other topics. ASMI took a full page ad in an Austrade publication used internationally to support our sector.

The focus remained on the use of cost-effective media opportunities. These included:

• coverage in the 
  *Pharmaceutical Journal (UK)*;
• monthly columns in 
  *PharmainFocus* and *i2P*;
• interviews for newspapers and journals (e.g. *British Medical Journal, Sydney Morning Herald*);
• articles in the *Journal of Complementary Medicine* and Jonathan Breach’s regular column in the *Australian Journal of Pharmacy*;
• the promotion of the ASMI conference in *OTC Bulletin, CHF Bulletin, Robert Forbes Newsletter, and PharmainFocus*;
• Advertising Services Manager, Cath Brunskill was invited to provide an article on co-regulatory advertising controls for therapeutic products by the journal of Victoria’s Health Issues Centre.

Goal 4.4: Through WSMI participation, gain support for initiatives that can assist in driving ASMI objectives.

• ASMI promotes WSMI collaborative statements to government, medical and pharmacy organisations. This promotion is carried out locally through our relationships here. This year, ASMI representatives attended the Annual General Meetings of Consumers’ Health Forum and the National Prescribing Service, the Guild Pharmacy Dinner, and held regular meetings with industry bodies ranging from devices to generics, and actively participated in the Medicines Partnership of Australia.

Goal 4.5: Establish a single Trans-Tasman industry association for the integrated self-care products industry to reflect the marketplace and optimise efficiencies.

• ASMI celebrated an alliance with NZSMI this year which was announced at the 2005 Annual General Meeting. Both industry bodies now hold regular meetings of their executive committees.
• ASMI assisted NZSMI in creating and launching its first website ([www.nzsmi.org.nz](http://www.nzsmi.org.nz)).
• ASMI’s scientific, regulatory and technical information is shared with NZSMI.
• In 2005 and 2006, ASMI’s Strategic Planning was carried out with the involvement of the NZSMI Executive.
• The Marketing & Ethics Subcommittee has developed and shared with NZSMI a document on the difference between the existing ASMI and NZSMI codes.
STRATEGIC OBJECTIVE 5: IMPLEMENT BEST PRACTICE IN ASSOCIATION MANAGEMENT

Ensure the optimal management of the association in key functional areas.

Goal 5.1: Ensure quality governance by Committee of Management.

- ASMI scrupulously performs all duties specified in the ASMI Rules, including the election of officers and activities associated with ensuring the proper conduct of the Annual General Meeting (AGM).
- This year, ASMI plans a new look AGM designed to increase the dynamism of this important meeting. Two external speakers will provide key updates on the progress toward the new joint regulatory arrangements.
- All ASMI subcommittees have good industry representation.
- Annually, a review of the Code of Practice, Privacy Policy, Rules and other major documents is undertaken. This year the complaints process has undergone an independent review.

Goal 5.2: Maintain optimal financial management.

- ASMI maintains appropriate insurance, tax, confidentiality documents as well as appropriate financial records for provision to the ASMI treasurer and annual audit.
- ASMI fulfills its legal obligations to the Australian Tax Office (ATO), Fair Trading, and TGA.

Goal 5.3: Optimise the strategic planning process

- ASMI provides Grant Reports to TGA and the Department of Health and Ageing on the Advertising and QARG Grants.
- To optimise asset management, ASMI maintains quarterly reviews of depreciation, interest bearing deposits, term deposits and investment decisions.

Goal 5.4: Maximise the value of the human resources of ASMI.

- Cost effective means for the Secretariat’s training and development are routinely sought and implemented. This year, electronic communication, media training, Occupational Health & Safety training and presentation skills were upgraded. ASMI’s Jonathan Breach also completed his Graduate Diploma in Herbal Medicine.

Goal 5.5: Promote team integration.

- To foster esprit de corp at the ASMI Secretariat, special milestones were observed (such as long service), staff lapel badges presented and regular staff meetings held.
- As part of ASMI’s strategy to contain the cost and increase the speed of communications, improved and streamlined computer use by the Secretariat is supported.

Goal 5.6: Maintain and establish internal crisis management procedures

- This year, a disaster plan for the ASMI Secretariat was composed. The plan covers disaster recovery from scenarios such as fire, quarantine, transit disruption and other disasters. In the event of a disaster, ASMI’s key tasks are given priority and systems put in place to minimise disruption.
Single Market, Singular Opportunity

Like you, I want to see a risk-based system of regulation that is based on a globally harmonised approach. We all want to see a level playing field that keeps the cowboys out, but at the same time is adaptable and responsive to the regulatory challenges created by innovations at the cutting edge of technology. That is what I expect to see delivered through the joint regulatory scheme with Australia.

—The Hon. Annette King, then the Health Minister, New Zealand (2004 speech to MIANZ Annual Conference: The benefits of a Trans-Tasman Therapeutic Products Joint Agency)

With the establishment next year of a joint agency to regulate medicines and therapeutic products in both Australia and New Zealand, any proposed implementation action that will bring change to the Australian regulatory environment will require consultation with all affected stakeholders in both countries.

—The Hon. Christopher Pyne, Parliamentary Secretary to the Australian Minister for Health & Ageing

Recently in a university ethics course, students were confronted with a dilemma designed to produce lively argument about the relationship between choice and responsibility. At the top of a hill, the scenario poses, is a tram. The brakes on this tram have failed, and it is up to you to decide either to allow the tram to proceed on its current track where it will surely strike twenty people or to throw the switch thereby diverting the tram onto an alternate track where it will strike three people.

The students, predictably, argued for a range of positions. Some said that taking no action exempted them from any responsibility for the twenty on the main track; the outcome was the fault of gravity or it was the responsibility of the twenty to watch out for themselves. Other students saw taking action as heroic and argued that the right course was to throw the switch to minimise the destruction, though few were comfortable with the responsibility for the three lives at risk from their action. A few students defied the scenario, unhappy with either horn of the dilemma and insisted they would invent a third “choice” by shouting, “Get off the track” in the hope of saving everyone.

Much the same argument takes place in the economic realm. There is a “steady as she goes” contingent who trust market forces to produce a result that is up to the individual company to assess and make appropriate provisions. Others feel a hand on the lever can direct the market in such a way that fewer are run over in the process. Still others opt for no action other than vociferous warnings to the unwary.

It is a rare student, who taking responsibility for the outcome, proclaims that he or she would have redesigned the tram.

Our industry finds itself at one of those rare times when the tram is being redesigned. There are many voices surrounding this redesign. Some say that despite the Trans-Tasman Mutual Recognition Arrangement, we should not take any action, that Australia and New Zealand should keep their separate and increasingly expensive systems because to do otherwise would be too onerous for some segment of the market. Others say that only a minor change of direction is needed and that this way fewer will be disadvantaged. Still others shout from their media releases that only running away from the proposed Australia New Zealand Therapeutic Products Authority will save those in its path from certain ruin.

In spite of these other voices, we must take responsibility for outcomes and engage the redesign process. If we do, there is much to gain; if we do not,
there is much to lose. We might even lose the best chance in our generation of a single market.

Why should we care?

Those who spend considerable time thinking about the global context in which our industry finds itself note a “rising tide of pharmaceutical nationalism”\(^2\). Overzealous protection of local industry ultimately cuts supplies of key medicines to the consumer and fails in its intention to support the development of local players because it does not recognise the benefits of competition. While trying to protect local industry from multinational Goliaths, the beneficial elements of competition—such as innovation and improved quality—fail to mature. Who indeed does David become if he never picks up the stone?

Smaller markets are rightly concerned with their place in an increasingly globalised environment. But we do have a strategic advantage given that many of the effects of international trends, like the giants they are, can be spotted on the horizon before they reach our shores. This requires a measure of vigilance or we can find ourselves battling last year’s giants. The fact is that protectionist backlash against globalisation is already being called “outdated” by industry pundits in the larger markets such as Europe as we can see from a recent speech by Dr Hubertus Cranz of the AESGP. Cranz associates this backlash with unnecessary costs and market barriers that must be removed if innovation is to be fostered. Cranz argues that a consistent legal and regulatory framework is key to both innovation and adequate market access.\(^3\)

The Europeans are telling us that the counter-revolution is already passé, international consolidation is marching forward and an increasingly lively debate on health has been engaged by governments, health practitioners, consumers, industry and the media. Both market changes and the debate have moved on to such an extent that the status quo is now a moving target. It is therefore incumbent upon all the stakeholders to address what the Business Council of Australia has described as “conflicting, overlapping and inconsistent regulation as one of the key drivers of high compliance costs.”\(^4\)

In short, industry needs to be smart, nimble and part of the solution to the pressing healthcare challenges facing consumers and the governments which help to pay for those solutions. The characteristics of a trans-Tasman market support this type of flexible and vital industry. A single market supports both best practice regulation that is vital to industry participating optimally in health and industry competition that fuels innovation and quality.

This has always been the plan. The objectives of the mutual recognition agreement are to:

- lower costs to business and improved competitiveness by allowing manufacture to a single standard;
- provide greater choice for consumers;
- engender greater cooperation between regulatory authorities; and
- instil greater discipline in regulators contemplating the introduction of new standards, regulations and occupation registration requirements.\(^5\)

The plan seems to be working. According to the 2003 Review of the Trans-Tasman Mutual Recognition Arrangement:

Overall, the Productivity Commission found that both the Trans-Tasman Arrangement and the Australian Agreement are achieving their trade facilitation objectives and continue to deliver significant benefits to manufacturers, service providers and consumers. The Trans-Tasman Arrangement in particular continues to deliver on the Australian and New Zealand governments’ strategic objective of creating a seamless trans-Tasman market and remains a key driver of trans-Tasman economic integration and policy co-ordination.\(^6\)

Though a few may be nostalgic for small parochial markets and protectionism, they cannot deliver the lower costs, greater choice and better regulation—and are not sustainable nor are they in the best interest of the consumer.

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\(^1\) Hubertus Cranz, AESGP Conference, Athens, 13 March, 2006.

—Ivan Turgenev
By removing the physical, regulatory and fiscal barriers between Australian and New Zealand’s markets, growth is fuelled, economies of scale become more readily available and industry benefits from lower costs by making a single application to enter the market and through the production of a single pack. Increased profitability promotes a viable industry that can innovate and provide consumer choice.

What is in the interest of the consumer, government and industry, and made more possible by an optimised regulatory scheme, is wider access.

Wider access to treatment has been proven beneficial, according to the European President of GlaxoSmithKline, Manfred Scheske, and is well demonstrated in public health outcomes in cases such as tobacco dependency. Other health priority areas such as obesity have also seen the benefit of wider access as shown by the first year results after Orlistat was switched in the Australian market.

To achieve the benefits of a single market, in addition to best practice regulation, we need to work toward what might be termed best practice buy-in. This will include harmonisation across the States and Territories of Australia so that regulation is seamlessly harmonised except in those rare situations where, due to particular local circumstance, exceptions are made on public health and safety grounds. In the same way that we now see the benefits of every State and Territory using the same gauge railway, we must foster better understanding in the various jurisdictions for the benefit of a single market.

Whether the new market is more like a Bullet Train or Puffing Billy is largely a matter of how well all of the stakeholders work in partnership over the next eighteen months. At such times the track already laid is tested as is the nerve of the participants.

Perhaps it is useful to remember the golden spike that was ceremonially driven to join the two parts of the Trans-Continental Railway in Utah in 1896. The ceremony was two days late due to bad weather and a union dispute, and the process took six years from groundbreaking to the famous joining. On one facet of the spike was engraved: “May God continue the unity of our Country, as the Railroad unites the two great Oceans of the world.”

Our process has also endured delays and taken at least as many years to span the Tasman. Great enterprises involving unity are prone to such challenges. In hindsight, the benefits are impossible to ignore.

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7 Manfred Scheske, 7 June 2006 speech at Athens AESGP Conference.
Outcomes of Complaints Lodged under the ASMI Code of Practice

**Complaint 01/05**

**Appeal Lodged:** Pfizer disagrees that the advertisements contained false or misleading representations.

**Outcomes:** The Arbiter accepted some aspects of the appeal and modified the sanctions.

**Complaint 02/05**

**Appeal Lodged:** Pfizer appealed the finding of the Panel that dismissed Pfizer’s complaints concerning advertisements by Schering-Plough promoting Claramax.

**Outcomes:** The Arbiter accepted the appeal and found the claims were a moderate breach of clause 5.3.1. Schering-Plough was ordered to issue a corrective statement.

**Complaint 03/05**

**Complainant:** GlaxoSmithKline Consumer Healthcare  
**Against:** Wyeth Consumer Healthcare  
**Complaint:** Advertisement for Advil directed to pharmacists.

**Alleged breaches:**

1. Clauses 5.1.4 – failed to provide sufficient information to substantiate the claim “one Advil Liquid Capsule provides stronger, better relief than two paracetamol tablets in the relief of mild to moderate pain” and hindrance of the supply of information constitutes unfair conduct in breach of clause 4.1.
2. Clause 5.1.3 – the above claim is not supported by the information and is misleading.

**Outcomes:**

1. The claim is unsubstantiated and is a moderate breach of clause 5.1.4. The alleged breach of clause 4.1 was dismissed.
2. This aspect of the complaint was upheld and is a moderate breach of clause 5.1.3.

**Sanctions:**

Wyeth was ordered to:
- discontinue citing an unpublished reference that it is unwilling or unable to provide without delay upon request,
- discontinue the practice of failing to provide a full copy of any unpublished cited reference without delay upon request,
- discontinue describing a published paper as “data on file”;
- cease publication in any media of the offending claims, and
- publish a corrective advertisement.

**Complaint 04/05**

**Complainant:** Pfizer Consumer Healthcare  
**Against:** Aspen Pharmacare  
**Complaint:** Murine “Solutions for Eyes” leaflet directed to consumers.

**Alleged breaches:**

1. The statement “redness of eyes due to excess alcohol and partying” breaches clauses 3.2.4 and 5.1.3 of ASMI Code of Practice and clauses 4.1.2 (c) and (f) of the TGAC.
2. The statements “Brightens better”, “Clear Eyes brightens eyes better than Visine” and “Naphazoline Clear Eyes – Clinically proven to have significantly more whitening than tetrahydrozoline” breach clauses 3.2.3 and 5.1.3 of the ASMI Code of Practice and clauses 4.1.2 (c) and (f) and clause 4.3 of the TGAC.
3. The visual depiction of two eyeballs is false and misleading breaching 5.2.2 of the ASMI Code of Practice and 4.3 of the TGAC.
4. The statement “Clear Eyes works in 5 minutes & lasts up to 8 hours. So even after a big night out you look bright-eyed all day” encourages inappropriate use for a vasoconstrictor eye preparation, in breach of clause 4.1.2(f) of the TGAC and clause 3.2.4 of the ASMI Code of Practice.

**Outcomes:**

1. This aspect of the complaint was not justified.
2. The claims were found to be misleading and in breach of clause 5.1.3 of the ASMI Code of Conduct and paragraphs 4.1.2(c) and (f) and clause 4.3 of the TGAC. Likewise the statement “Brightens better”. This aspect of the complaint is upheld as a moderate breach.
3. The Panel find the comparison to be unbalanced and misleading, in breach of clause 4.3 of the TGAC. This aspect of the complaint is upheld as a moderate breach.
4. This aspect of the complaint was dismissed.

**Sanctions:**

a. to discontinue the practice of publishing and distributing the leaflet;
b. to cease publication in any media (until they can be supported) of the representations in relation to Murine Clear Eyes;
c. to cease publication in any media (until it can be supported) of the visual depiction of two eyeballs, one “white” after using Murine Clear Eyes and the other reddened after using Visine;
d. to cease publication in any media (until it can be supported) of the unqualified representation in relation to Murine Sore Eyes: “relieves puffiness”;
e. to use its best endeavours, by way of fax, email or personal visit to pharmacies and other recipients to which the leaflet may have been distributed, to retrieve and destroy all copies of the leaflet that may remain available to consumers and to report to ASMI upon those endeavours; and
f. as Pfizer made no attempt to resolve the matter by informal channels prior to sending Aspen its formal complaint, the costs of the Panel were equally shared.
Appeal Lodged: Pfizer was concerned that the Panel’s determination sets a precedent which makes it mandatory for members to attempt to informally resolve matters prior to bringing formal complaints.

Outcomes: The Arbiter upheld the panel’s decision and ordered Pfizer to pay the costs of the appeal.

Complaint 05/05
Complainant: Pfizer Consumer Healthcare
Against: GlaxoSmithKline Consumer Healthcare
Complaint: Print and radio advertising and promotional leaflet for Nicabate CQ directed to consumers.
Alleged breaches: Clauses 5.1.3 and 5.2 of the ASMI Code of Practice and 4.1.1(a), (b) and (c) and 4.2 and 4.3 of TGAC
Outcomes: The Panel finds both radio advertisements inaccurately and misleadingly represent to those members of the radio audience that the Nicabate 24-hour patch is more effective in achieving quitting than the Nicorette 16-hour patch thus breaching the clauses mentioned above. One advertisement was found to be a moderate breach. The other was a severe breach.
The other aspects of the complaint were dismissed.
Sanctions: The Panel required GSK to:
   a. cease publication of the radio advertisements,
   b. to cease publication forthwith in any media of the representations contained in the radio advertisements,
   c. in relation to the moderate breaches a fine of $10,000, and
   d. in relation to the severe breaches a fine of $30,000.

Appeal Lodged:
   1. Pfizer appealed against the rejection of the complaints brought against print advertisements and the leaflet.
   2. GSK challenged the severity of the fines.
Outcomes: The arbiter dismissed all aspects of Pfizer’s appeal. The arbiter downgraded the severe breach to moderate and reduced the size of the fine to $10,000.

Complaint 06/05
Complainant: Schering-Plough
Against: Wyeth Consumer Healthcare
Complaint: Advertisements directed towards pharmacy assistants and buyers which were offering discounts and gifts for volume purchases.
Alleged breaches: The advertisement breaches clause 4(3) of the TGAC and clause 4.1 of the ASMI Code of Practice.
Outcomes: The Panel dismissed all aspects of the complaint.
Sanctions: The Panel ordered Pfizer to:
   1. For the detail aid:
      i. use its best endeavours as soon as possible to retrieve all copies of the detail aid;
      ii. discontinue (until it can be supported) the practice of using the offending representations;
      iii. cease publication in any media (until they can be supported) of the representations;
      iv. send to all pharmacies to which the detail aid was distributed a corrective letter;
      v. publish a retraction;
      vi. for the repeat breach concerning the efficacy claim, to pay a fine of $50,000; and
      vii. for the repeat breach concerning the drowsiness claim, to pay a fine of $30,000.
2. Journal advertisements 1 and 2:
   a. discontinue (until it can be supported) the practice of using the offending representations,
   b. cease publication in any media (until they can be supported) of the representations.
3. Journal advertisement 3:
   a. discontinue (until it can be supported) the practice of using the offending representations;
   b. cease publication in any media (until they can be supported) of the representations;
   c. publish a retraction; and
   d. for the repeat breach concerning the drowsiness claim, to pay a fine of $30,000. This fine was suspended.

Appeal Lodged: Pfizer appealed certain findings made by the Panel and sought amendments to certain undertakings and retractions required by the Panel. It also disputed the size of the fines. Schering-Plough cross-appealed the dismissal of the complaint concerning certain aspects of the journal advertisements. It also sought imposition of increased fines and raised certain issues in relation to the publication of the retractions.

Outcomes:

Outcomes of Promotional Monitoring Panel Meetings

This summarises the outcomes of the ASMI Promotional Monitoring Panel meetings for the year ending 30 June 2006. The aims of the process are to demonstrate the effectiveness of self-regulation, encourage compliance with the ASMI Code of Practice and to improve compliance rates in the future. The Promotional Monitoring Panel is independent of the ASMI Complaint Panel and does not have the power to impose sanctions for Code breaches.

The Promotional Monitoring Panel met four times to review “below-the-line” advertising materials for compliance with the Therapeutic Goods Advertising Code (TGAC) and the ASMI Code of Practice. Promotional materials in the following therapeutic categories were selected for review:

- Cough/Cold,
- Gastrointestinal,
- Urinary,
- Oral Care,
- Weight loss, and
- Dermatologicals,

As a pilot, one meeting was devoted to media releases for all categories.

Member companies were generally very positive and active in delivering materials to the Panel and were also very keen to provide Panel participants (non-competing) to adjudicate. A total of 432 items were reviewed, of which 138 were found to contain one or more possible breaches of the ASMI Code of Practice or the TGAC. However, it should be noted that many of the breaches were repeats by the same company within a campaign and so it should not be concluded that the overall level of non-compliance is high when, in fact, almost all sponsors have fully compliant promotional material.

Compliance with the TGAC was generally of a high standard. Non-compliance issues included the following:

- 72% was for lack of mandatory statements or statements that were not prominently displayed (20%), in breach of Clause 6.2 (“Always read the label”; “Use only as directed”; “If symptoms persist consult your healthcare professional”).
- 1% implying that products are safe in breach of Clause 4.1.2(i).
- 12% not declaring any valuable consideration for healthcare professional in breach of clause 4.6(b).
- 4% making misleading statements in breach of Clause 4.2(c).
- 2% encouraging inappropriate purchase in breach of Clause 4.2(f).
- 1% providing a 100% guarantee in breach of Clause 4.2(h) & (g).
- 2% not making correct and balanced statements in breach of Clause 4.1(b).
- 1% making government endorsement in breach of Clause 4.5.

Compliance with the ASMI Code of Practice was also good. Non-compliance issues related to lack of compliance with TGAC, in breach of Clause 4.3.1 mainly related to missing mandatory statements.
Executive Director’s Message

In 2006 it is hard to imagine a newspaper devoid of headlines about responses to terrorism, the challenges to our infrastructure, water management, and the ramifications of our expanding waistlines. These issues are both signs of the time and symptoms of the increasing complexity that makes forecasting difficult, solutions elusive and the assignment of blame almost irresistible.

Our industry is subject to the vicissitudes of these times so our members and stakeholders can rightly ask of ASMI what it is we are doing to respond to the increasing rate of change in our businesses and our markets and how we assist industry to be part of the solution to the challenges facing us.

This year we assessed the need to focus resource not only as we have in the past on matters of regulatory and technical complexity, member services and timely provision of information, but also on the larger and more far-reaching strategic “big picture”. First ASMI established an advisory group to tap the expertise of industry leaders of long standing and of those specialists in areas such as consumer advocacy, government relations and trade practices who could consider the possible shape of our industry without the strictures of emersion in the day-to-day detail. The outcomes of the discussions of this group were fed into the considerations of our elected Committee of Management and especially the strategic planning process. More recently we have also established a high level Trans-Tasman Issues Group to provide particular guidance during the period of consultation on issues which are just as vital as they are labyrinthine. The work of this group will be regularly communicated to our members and other relevant audiences to assist industry to make the best possible transition into new arrangements.

The self-care initiatives that we launched last year are also part of our strategy to optimise the contribution of our industry to Australia’s health and ensure that our contribution is recognised. We didn’t invent the notion of self-care but we have been able to establish the role our industry can play in supporting consumers’ participation in their own care.

Over the last year we have seen just how timely our work in self-care has been. Real debate is taking place on every imaginable front from whether to allow lamingtons at the school sausage sizzle to the serious question of the direction of multi-billion dollar corporate philanthropy.

On the first day of the new fiscal year The Economist ran a piece contemplating the enormous donation to the Gates Foundation made by Warren Buffet. Entitled “How to spend it”, the article suggests that “The question is, how to spend it wisely. In particular, there is the ticklish issue of how much to disburse on preventing and treating, and how much to reserve for research into better ways of doing things in the future.”

While these funds are earmarked for the developing world rather than a market such as ours, the questions remain much the same: where to best focus our efforts and our funds, how to measure our results in areas that impact on disease and the effectiveness of prevention.

Wasn’t it Dostoyevsky who asked, “What then must we do?” We saw some of our answers this year. They were varied. ASMI Associate Members Cardinal and CPSA teamed up to manufacture and donate high dose Vitamin A to protect the eyesight of children in Niger. ASMI has undertaken a research project to provide evidence of how complementary medicines can contribute to health outcomes. Access in Australia to nicotine replacement therapy continued to grow. Industry worked with police and government to limit illegal diversion of ingredients into street drugs. The quality of manufacturing was supported by the successful completion of the GMP course by its foundation students. ASMI’s Missing Link project provided industry with better data on which to conduct its business. Whether it was through generosity, maximised access, diligence, education or information, the industry moved ahead and made a greater contribution to health and the long term viability of the industry. ASMI is proud to have played a part.

The future is just as likely to require a complex interplay of prevention and intervention. Our industry exists at that exciting nexus and ASMI will be there to facilitate an environment in which our sector will play an increasingly significant and vital role.

Juliet Seifert, Executive Director, ASMI
Keeping an Eye on the Harmonisation Ball

While Australian and New Zealand-based companies are greatly focused on the proposed Australian New Zealand Therapeutic Products Authority (ANZTPA), those with a focus on regional developments and export potential should keep at least one eye on what is happening in the wider Asia Pacific region.

In particular, the rapid pace of development of common technical and regulatory standards for pharmaceutical medicines amongst member states of the Association of South East Asian Nations (ASEAN) is accelerating, with many common principles agreed to and timelines for a regional roll out for a number of aspects established. With ongoing guidance from the World Health Organisation, the European Union, the United States, Australia and Japan, the development of sophisticated regulatory arrangements in the region has already placed a number of key ASEAN nations in a position of comparable market requirements.

Given that the socio-economic strength of individual nations varies, this will see a staged implementation of these standards. However, the fact remains that this region is fast moving towards establishing common regulatory requirements as a precursor to strengthening the region as an influential trading block. This provides both opportunity in terms of export and threat in terms of global competition.

One should, however, give heed to the importance of traditional medicines to consumers in these countries and the opportunity this presents for mature brands. Already many globally focused companies offer popular OTC brands within these countries, utilising herbal medicinal ingredients and extracts straight out of local traditional pharmacopoeia, offering a culturally familiar medicine under the livery of a global brand.

Currently the harmonisation of regulatory standards for traditional medicines across the Asian markets is proving to be a more problematic affair for ASEAN due to the breadth of regulatory approaches encompassing food, pharmaceutical and traditional medicinal principles. Formal processes to start driving harmonised approaches to the regulation of traditional medicinal products as part of the modern consumer self-care market are underway.

Companies with a long-term view to product development opportunities would do well to keep their eyes on the harmonisation ball amongst our neighbouring markets to ensure that other important opportunities are not overlooked.

Congratulations to the First Graduates of the Certificate in Good Manufacturing Practice Program

ASMI is delighted to announce the completion of the Graduate Certificate in Good Manufacturing Practice (GMP) by two students of its inaugural class. These graduates are Mark Rendulic of Sanofi-aventis Australia/New Zealand and Jannine Brookes of Bayer Healthcare Consumer Care.

This distance-learning program, culminating in a Graduate Certificate in Good Manufacturing Practice (GMP), offers its students the knowledge to understand and manage complex operational and logistical interactions common to the manufacture operations of medicines and medical devices. Students completing the program gain an understanding of global GMP management requirements. This course is designed for management personnel acting as Qualified Persons within the therapeutics goods industry. The course material encompasses all the diverse elements required to ensure that each batch of a medicinal or therapeutic good meets the quality requirements as stipulated by manufacturing and marketing licences and GMP. Stringent application of GMP requires people not only with experience from the therapeutic goods industry but also those who have a good understanding of the manufacturing, quality and regulatory principles underpinning the GMP management philosophy.

The program is supported by the Australian Self-Medication Industry, the Advanced Manufacturing Centre, the University of New South Wales, the Therapeutic Goods Administration, the Royal Australian Chemical Institute, Medicines Australia and the Medical Industry Association of Australia and has been introduced as a response to changes to the application of regulatory requirements in Australia and New Zealand.

For more information on this program, please see www.asmi.com.au/GMPCourse.htm.