Annual Report

2002-2003




Australian Self-Medication Industry

BETTER HEALTH THROUGH RESPONSIBLE SELF-MEDICATION

ASMI is the voice of the Australian consumer healthcare products industry including both Over-The-Counter and Complementary Medicines.

Front Cover Inset Photograph
4th Picture from left:
Hawthorn Berries - supplied by Nick Burgess

VISION:

Better health through responsible self-medication

MISSION:

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

ASMI Members as at 30 June 2003

Ordinary Members

3M Health Care Pty Ltd
Allergan Australia Pty Ltd
Australian Pharmaceutical Industries
Aventis Pharma
Bayer Australia Ltd
Blackmores Ltd
Boehringer Ingelheim Pty Ltd
Boots Healthcare Australia Pty Ltd
C B Fleet Co (Australia) Pty Ltd
Cardinal Health
Carter Products Australia
Combe International Ltd
Ego Pharmaceuticals Pty Ltd
Eucanol Sales Pty Ltd
Galderma Australia
GlaxoSmithKline Consumer Healthcare
H W Woods Pty Ltd
Herron Pharmaceuticals
ICN Pharmaceuticals Australasia Pty Ltd
Janssen-Cilag Pty Ltd
Johnson & Johnson Pacific
Mayne Health Consumer Products
Mentholatum Australasia Pty Ltd
Merck Sharp & Dohme (Aust) Pty Ltd
Novartis Consumer Health Australasia Pty Ltd
Pfizer Pty Ltd
Reckitt Benckiser
Roche Products Pty Ltd
Schering-Plough Pty Ltd
Smith & Nephew Pty Ltd
Stiefel Laboratories Pty Ltd
Wyeth Pty Ltd

Associate Members

ACI Plastics Packaging Pty Ltd
Clare Martin & Associates
Contract Pharmaceutical Services of Australia Pty Ltd
Cormack Packaging Pty Ltd
Curtis Jones & Brown Advertising Pty Ltd
Engel, Hellyer & Partners Pty Ltd
Freehills
Gallandeer Ridge Pty Ltd
Grey Healthcare Group
Hahn Healthcare Recruitment Pty Ltd
Hammond & Thackeray Pty Ltd
IMS Australia Pty Ltd
Lancom Technology
La Rosa Langley Pty Ltd
Lipa Pharmaceuticals
McCann Erickson Advertising
Medi Kwik Pty Ltd
Porter Novelli
Oz Pharma Contracting & Consulting
PharmAction Holdings Pty Ltd
Reader's Digest Australia Pty Ltd
Regulatory Concepts Pty Ltd
Singleton Ogilvy & Mather
Sudler & Hennessey
Sue Akeroyd & Associates
Technical Consultancy Services Pty Ltd

Honorary Life Members

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

ASMI Committee of Management

Officers

1. *ASMI President*
   Trevor Juniper, Sept. 2002 – April 2003
2. *ASMI President*
   Kevin Darke, from May 2003
3. *Vice President/Secretary*
   Sue Williams
4. *Vice President/Treasurer*
   John Gurney

Back Row L-R: John Gurney, Mark Bowden, Ralf Dahmen, Denis Dikschei. Front Row L-R: Kevin Darke, Sue Williams, David Murphy, Ronda Jacobs.

Committee of Management 2002–2003

David Armstrong, Reckitt Benckiser

Geoff Bolland (until March 2003)/Ronda Jacobs (from April 2003), Cardinal Health

Mark Bowden, Pfizer Pty Ltd

Ralf Dahmen, Boehringer Ingelheim Pty Ltd

Kevin Darke, GlaxoSmithKline Consumer Healthcare

Denis Dikschei, CB Fleet (Australia) Pty Ltd

John Gurney, Mentholatum Australasia Pty Ltd

Trevor Juniper, Pharmacia (until April 2003)

Steven Mann, Mayne Health Consumer Products

David Murphy, Combe International

Elizabeth Treble (until April 2003)/ Leah Goodman (from April 2003), Aventis Pharma

Sue Williams, Boots Healthcare Australia Pty Ltd

Back Row L-R: Mary Emanuel, Alexandra Macvean, John Moursounidis, Duncan Cannon, Chris Arblaster, Monica Johnstone, Jonathan Breach. Front Row L-R: Peter Cranston, Susan Parker, Juliet Seifert, Lesley Speechley.

ASMI Secretariat

Chris Arblaster, Marketing & Development Director

Jonathan Breach, Regulatory & Technical Manager

Duncan Cannon, Administrative Assistant

Peter Cranston (from May 2003), Regulatory & Technical Manager

Mary Emanuel, QUM Manager

Monica Johnstone, Member Services Manager

Robyn Kirkness, Reception

Alexandra Macvean, Information Support Coordinator

John Moursounidis, Advertising Services Manager

Susan Parker, Scientific Director

Ruby Ragonese (until April 2003), Regulatory & Technical Manager

Juliet Seifert, Executive Director

Lesley Speechley, Executive Assistant/Office Manager

President's Message

It is my pleasure to report that ASMI continues to grow with 75% of the consumer healthcare product industry working together under our banner. We have access to and credibility with government, regulators and the policy and opinion leaders who are the key to our market environment.

In the last few years we have seen the effects of two crises: one affected a particular substance and the other, by implication and media hurricane, an entire market sector. In both cases ASMI acted quickly, decisively and appropriately.

The recent recall crisis was a salutary reminder to us about the consequences of non-compliance and a great example of our ability to provide useful resources and be a positive influence. Juliet Seifert was widely interviewed and quoted as the balanced industry voice. It came as no surprise to many industry watchers that she was named to the Expert Committee on Complementary Medicines in the Health System.

This crisis demonstrated the capabilities of the ASMI team. It also reflected well on our strategic approach and long-term view as an association. Our tradition of rigorous advocacy, pro-active self-regulation and sustained strategic alliances in a non-adversarial way, particularly with Government and regulators, has positioned us to be key influencers of policy and has won for us recognition as drivers of change.

Additionally, ASMI understands the primacy of the consumer. Maintaining consumer safety and confidence ensures the long-term credibility of industry and its products.

This year we've increased our offerings in the marketing area yet again. A new Sales Directors Forum has been formed, and Marketing & Development Director, Chris Arblaster has been very active in extending the scope of commercially oriented issues and services as well as targeting prospective new members. May I take this opportunity to welcome new Ordinary Members who joined in the last year: API, Blackmores, Eucanol, ICN, Johnson & Johnson and Schering-Plough. New Associate Members were ACI Plastics Packaging, Gallandeer Ridge, La Rosa Langley, Oz Pharma, and Porter Novelli. In particular, a special welcome to the new complementary medicine members.

We've seen commendable growth leading to large conference and induction turn outs and even higher subcommittee participation levels. Our representation continues to increase in every area from small Australian-owned companies to large multi-nationals. We've also seen the increasing trend among our members to have interests in both OTC and complementary medicines as well as in multiple distribution channels.

To support this growth, the ASMI team has become increasingly skilled in electronic provision of services while actually spending more time than ever face-to-face with the membership. New member services have been added such as the provision of a great strategic trend document – authored by the Secretariat team, which is available for members on the website.

In the scientific, technical and regulatory arena it has been a very busy year for Scientific Director, Susan Parker, the STAR team and our committees as they participate in the process of improving the code of GMP, and other complex regulatory issues.

Our achievements against our strategic plan are many. I urge you to read about these in the section of this Annual Report headed Achievement Highlights.

On behalf of your Committee of Management and the ASMI Secretariat, I wish all our partners a prosperous new financial year.

Sincerely,

Kevin Darke, ASMI President

Achievement Highlights

Each year ASMI reports on its achievements toward the objectives stated in the ASMI Strategic Plan. The 2002-2003 membership year was remarkably eventful with not only the largest recall in Australian history, but also major work undertaken to establish trans-Tasman advertising arrangements and a new regulatory agency to cover Australia and New Zealand. Long-term proactive involvement by ASMI in areas such as GMP, crisis management, harmonisation and the self-regulation of advertising came to abundant fruition this year.

This list of our achievements, arranged by strategic objective, highlights ASMI's accomplishments and is not meant to be exhaustive.

1. Maximize Freedom of Access

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

Industry Advertising Codes and the promotional environment

- *Significant changes have been proposed to the ASMI Code of Practice to modernise various clauses.*
- *A major submission was made to the Review of Advertising Therapeutic Goods in Australia and New Zealand.*
- *ASMI supported changes to the Therapeutic Goods Advertising Code (TGAC) to remove the prohibition regarding sampling advertising.*

Improvements to the regulatory environment

- *ASMI Executive Director Juliet Seifert and two ASMI members were named to the Expert Committee on Complementary Medicines in the Health System (ECCMHS) by the Parliamentary Secretary to the Minister for Health & Ageing.*
- *The revision of the Australian Guidelines for the Registration of Drugs, Vol 2 (AGRD2) proceeded as planned, with the new publication Australian Regulatory Guidelines for OTC Medicines (ARGOM) launched on 1 July 2003.*
- *The AGRD2 chapters on Labelling, Product Information (PI) and (CMI) have been revised. These topics as well as information on, for example, brand naming, endorsements, and pregnancy warning statements are included in a new ARGOM chapter titled 'Presentation'.*
- *The 'Paediatric products' guideline of the Policy Guidelines in Supplement 1 to the Australian Guidelines for the Registration of Drugs, Vol 2 (AGRD2) has also been revised to take account of ASMI's comments and has been included in ARGOM.*
- *The first chapters of the Australian Regulatory Guidelines for Complementary Medicines (ARGCM) were released for consultation.*
- *A formal consultation document on the trans-Tasman joint agency was issued in June 2002, seeking comment on proposals by New Zealand and Australian officials. The document provided information on the establishment and governance of the agency, and the regulatory framework that would apply to medicines, medical devices and complementary healthcare products. ASMI compiled a comprehensive response to the proposals.*
- *The ASMI Code of Conduct – Helping Prevent the Diversion of Pseudoephedrine-Containing Non-Prescription Medicines has been granted interim authorisation by the ACCC. All current and future manufacturers and/or sponsors of pseudoephedrine-containing products are covered by the authorisation. The Code covers procedures for sales monitoring, record keeping, company liaison, notification of suspicious orders or enquiries, promotional activities, promulgation of a "responsible conduct" message and security.*
- *ASMI provided input on the draft report of the National Competition Principles Review of the Commerce (Trade Descriptions) Act 1905 and the Commerce (Imports) Regulations 1940.*
- *An update of the Review of Non-Prescription Analgesics, first published in 1998 was conducted during the second half of 2002. TGA met with the ASMI Analgesics Team to discuss the terms of reference of the Review Update. ASMI ensured that our members' views were considered. The final version of the Review Update has now been released and many of ASMI's comments were incorporated.*
- *Following the acceptance of ASMI's proposal for USP mineral limits to be adopted by the TGA, the Therapeutic Goods Order No.56 General standard for tablets, pills and capsules is to be reviewed in its entirety.*
- *A number of submissions have been made by ASMI throughout the past 12 months over various aspects of the food/medicines interface, e.g. food-type dietary supplements, formulated beverages (addition of vitamins and minerals), fortification of foods with calcium, foods for special medical purposes.*
- *Following publication of the Transmissible Spongiform Encephalopathy (TSE) Guidelines, an industry/TGA workshop was held where case studies were used to uncover issues and concerns regarding the interpretation of, and compliance with the guidance document. One outcome of the workshop was that the TGA and industry jointly develop a questionnaire with the aim of including it in the TGA guidelines.*
- *The first seminar in Australia on the new Code of Good Manufacturing Practice (GMP), was jointly organised by ASMI, Medicines Australia and the NSW RACI Pharmaceutical Sciences Group, and held on the date of gazettal, 28 August 2002.*
- *ASMI had input into the Corcoran Review of the TGA Good Manufacturing Practice Audit & Licensing (GMPAL) Section.*

- *A working party has been established to pursue avenues for obtaining market/data exclusivity for non-prescription medicines. This is a high priority for ASMI in the coming year.*
- *ASMI and Medicines Australia met with the Department of Health and Ageing to discuss ongoing industry concerns over the central medicines database project including ownership of data and liability in the event of incorrect data resulting in an adverse event.*
- *Jonathan Breach, Regulatory & Technical Manager for Complementary Medicines, has been appointed as a member of the Kava Expert Group, which has been formed to review the data on Kava, following the voluntary Kava recall initiated in 2002.*
- *ASMI submitted detailed comment on a NSW Parliamentary Committee for Children and Young People inquiry into the use of prescription drugs and over-the-counter medications by children and young people, including efficacy and effectiveness.*

Tamper Evident Packing (TEP)

- *As part of a subcommittee of the Industry Government Crisis Management Committee, ASMI has been involved in developing a revised Code of Practice for TEP and agreeing the most appropriate method by which the Code will be enforced.*
- *ASMI was also involved in a TEP Working Party developing a brochure that will provide consumers with information on tamper evident packaging, as well as general information on using medicines safely and effectively.*

2. Sustain a Supportive Service Environment

Ensure optimal communication within the Secretariat, between the Association and its members and between the Association and all relevant stakeholders. Develop ASMI as a primary information resource for industry.

Achievements in the provision of services

- *In a 48 hour period, the membership provided a list of products unaffected by the Pan recall which the Secretariat made available to the public on the ASMI website. Hits to the ASMI website immediately jumped to 30 times normal.*
- *New features were added to the ASMI website including a strategic planning aid entitled Trendscan. This new resource covered Australian and international trends in key areas such as the regulation of OTC and complementary medicines, IT, trans-Tasman harmonisation, consumers, GMP and illicit diversion.*
- *Members of ASMI were surveyed in areas such as export interest, e-mail capabilities, and specialised regulatory matters.*
- *Eleven member companies were represented at the first Sales Directors Forum conducted by ASMI.*
- *Seven successful ASMI Induction days were held with three conducted "in-house" and one in Melbourne.*
- *A dinner was held for Melbourne members with the Secretariat, Committee of Management and stakeholder guests.*
- *ASMI held a successful one-day conference in Sydney with over 190 delegates confronting the topic of "a level playing field". Features included a banquet, the inaugural ASMI Excellence Award and a well attended AGM.*
- *A scheduling database has been created which will, when input is complete, allow ASMI members to request reports on information now currently available only in the hardcopy publication, SUSDP.*
- *Through increased data harvesting and data reporting enhancements, ASMI was able to provide more precisely tailored information to its membership throughout 2002-2003 and especially during the period of the recall.*
- *Advertising Services Manager, John Moursounidis (with Judith Brimer of the Therapeutic Goods Advertising Code Council) provided training in advertising approvals and the ASMI Code of Practice. This training was held in Sydney, Melbourne, and Brisbane.*
- *A first-ever specific Industry Survey for the whole consumer healthcare product sector was developed for launch in June 2003. The survey will provide data on sales, marketing and regulatory structures and benchmarks for the non-prescription sector.*

Maximising the capabilities of the ASMI Secretariat

- *Working closely with the Executive Subcommittee and Committee of Management, Juliet Seifert has built a Secretariat team of a calibre to exceed member expectations and deliver the objectives of the Strategic Plan.*
- *ASMI Secretariat undertook cross-training in several functions and received training in relevant areas such as e-marketing, media, persuasive presenting, and project management.*

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

Promote the Quality Use of Medicines to members and all other relevant stakeholders to secure commitment to performance-based approaches to regulation and communication, e.g. information provision.

Performance-based labelling

- *Following provision of initial comment and support for the TGA consultation report Review of the Labelling Requirements for Medicines: Consumer focused labelling – A Way Forward?, the ASMI Labelling & Consumer Information Team met with TGA and Communications Reasearch Institute of Australia representatives to discuss several issues including the recommendations, and ASMI's proposed initiative to develop an Industry Code of Practice.*
- *The ASMI Working Group of the Labelling and Consumer Information Team, in consultation with the TGA and the Communications Research Institute of Australia (CRIA), drafted a broad outline for an Industry Code of Practice for performance-based labelling. This was based in part on the experience gained from the development and application of the CMI Usability Guidelines.*
- *ASMI participated in the TGA Stakeholder Consultation meeting to review the draft Industry Code of Practice. The Code was endorsed by all stakeholders at the meeting.*
- *ASMI is involved in the TGA Non-prescription Medicines Label Review Steering Committee and its two subcommittees (Label Legislation Subcommittee and the Industry Code of Practice Subcommittee).*
- *ASMI is now running the Industry Code of Practice Subcommittee on behalf of the TGA. The Industry Code of Practice Subcommittee is in the process of developing an Executive Summary, which will explain the principles of performance-based labelling and how it is achieved. This document will be freely available. The Code of Practice or 'how to' manual will contain the detail of writing and designing labels to achieve performance-based labelling, and will be available for purchase. It is also anticipated that CRIA will organise and run a labelling certificate course, at which participants will receive a copy of the Code of Practice.*

Representation on key external committees and at key events

- *ASMI continued to have representation on MEC, with Mary Emanuel joining MEC as the expert with relevant experience in regulatory affairs.*
- *Juliet Seifert, Susan Parker and Mary Emanuel were invited to participate in the National Prescribing Service (NPS) Planning Day in January 2003.*
- *Susan Parker and Mary Emanuel are members of the NPS - Pharmaceutical Industry Project Group. The purpose of this Group is to identify areas of collaboration between NPS and the pharmaceutical industry that contribute to Quality Use of Medicines (QUM) by increasing networks, sharing and disseminating knowledge, further educating GPs and pharmacists on therapeutics and raising consumer awareness of the use of medicines.*
- *Susan Parker is a member of the NPS Communication Working Group, which reviews the content of the NPS News.*
- *Susan Parker and Mary Emanuel participated in an NPS stakeholder workshop that was reviewing and providing comment on the draft QUM Training Module.*
- *Mary Emanuel was the industry representative on the Consumer Medicine Information (CMI) Content/Quality Assurance Reference Group (QARG) until September 2002, at which time she took on the position as Project Officer to the Reference Group. Susan Parker was subsequently selected as the industry representative. In addition to monitoring CMIs, newly formed Consistency Working Groups are in the process of drafting new core CMIs, including one for intranasal corticosteroids. The QARG Project Officer position also entails participation in the CMI Electronic Distribution Working Group (EDWG).*
- *Mary Emanuel participated in a Pharmacy Guild of Australia workshop on developing a system dynamics model of medicines use in the Australian health system.*
- *Susan Parker was re-elected as a PSA (NSW) Councillor in April 2003 for another two-year term. Susan was also awarded lifetime membership of ARCS in June 2003.*

ASMI represents Industry on many expert committees, external advisory committees and to various inquiries, including:

- *Expert Committee on Complementary Medicine in the Health System (ECCMHS)*
- *Medicines Evaluation Committee (MEC)*
- *Australian Council for Safety and Quality in Healthcare Medication Safety Taskforce*
- *Alternate on National Drugs and Poisons Schedule Committee (NDPSC)*
- *Australian Pharmaceutical Advisory Council (APAC)*
- *APAC Subcommittee on the Misuse of Medicines*
- *Interim Advertising Council (IAC)*
- *NSW Poisons Advisory Committee (NSW PAC)*
- *Therapeutic Goods Committee (including its Labelling, GMP & CRP Subcommittees)*
- *Australian Standards Subcommittees for Sunscreens and CRCs*
- *Medicines Partnership of Australia (MPA)*
- *National Prescribing Service (NPS)*
- *CMI Quality Assurance Reference Group (QARG)*
- *Therapeutic Goods Administration Industry Consultative Committee (TICC)*
- *Industry Government Crisis Management Committee*
- *Australian Regulatory Guidelines for Complementary Medicines Working Group*
- *Medicines Coding Council of Australia*
- *Kava Expert Group*
- *Therapeutic Goods Advertising Code Council (TGACC)*
- *Complaints Resolution Panel for the TGAC*
- *PHARM Communication Subcommittee*
- *PHARM Industry Working Group*
- *Australian Institute of Pharmacy Management Board (AIPM)*
- *Board of the World Self-Medication Industry and its subcommittees*

Inquiries and reviews on:

- *GMPALS*
- *Medications & Children*
- *National Competition Principles Review*
- *TSE*
- *Trans-Tasman regulatory agency*
- *Food type dietary supplements*
- *Calcium fortification*
- *Formulated beverages*

Furthering QUM in areas relevant to consumer healthcare products

- *The Association is working with the Pharmaceutical Society of Australia (PSA) on ways of increasing industry knowledge of, and pharmacy use of the PSA S2/S3 professional standard protocols.*
- *ASMI met with Pharmacy Guild of Australia and Pharmaceutical Society of Australia representatives to discuss the TGA Labelling Project and explain the concept of performance-based labelling and its benefits to all medicine users.*
- *The QUM and CMI sections of the ASMI website have been expanded.*
- *ASMI regularly sends scheduling updates to our European sister organisation, AESGP, for inclusion in the World Self-Medication Industry (WSMI) worldwide scheduling classification of non-prescription ingredients.*

4. Broaden the Relevance & Influence of the Association

Secure the Association's future as the peak body representing the entire spectrum of the self-medication industry.

- *ASMI welcomed new members to the Association in 2002-2003: ICN Pharmaceuticals, Johnson & Johnson Pacific, Blackmores, Herron Pharmaceuticals, Australian Pharmaceutical Industries, Schering-Plough, Eucanol, ACI Plastics Packaging, Gallandeer Ridge, La Rosa Langley, Oz Pharma Consulting, and Porter Novelli.*
- *A new e-mail newsletter for non-members was commenced in November 2002 and is now published every three weeks.*
- *ASMI has achieved good integration and articulation between government and peak bodies in health.*
- *ASMI has built a constructive relationship with the Parliamentary Secretary to the Minister for Health and Ageing and other key government officials and relevant representatives of the other parties.*
- *Through her seat on the Australian Pharmaceutical Advisory Council (APAC) which advises the Minister, Juliet Seifert has been directly involved in APAC strategic planning and its working party on National Medicine Policy indicators.*
- *In addition to ongoing relationships with the Pharmaceutical Society of Australia, the Pharmacy Guild of Australia, the Australian Institute of Pharmacy Management, the Medicines Partnership of Australia, and the National Prescribing Service, ASMI has instigated information sharing with several other stakeholder organisations including the National Herbalists Association of Australia, Australian Natural Therapists Association, Australian Traditional Medicine Society and Federation of Natural and Traditional Therapists.*
- *Juliet Seifert participated in the governance structure of our world body, the World Self-Medication Industry (WSMI), including in its strategic planning processes. This work has important flow on effects for Australian industry in areas such as international harmonisation, export, trend spotting, and statements supporting the role of self-medication from health professional world bodies.*
- *ASMI was a frequent contact for the broadcast and print media on issues involving paracetamol, pseudoephedrine, kava, the regulatory system and the Pan recall. During the recall, key ASMI staff members were widely consulted by media for a balanced view.*
- *ASMI's voice was heard at several important conferences as well as in articles placed in industry publications such as OTC Bulletin, Journal of Complementary Medicine, and Pharmaceutical International.*
- *An ASMI leaflet was included in the Journal of Complementary Medicine (circulation 22,000) directing health professionals and other subscribers to the ASMI website list of member products unaffected by the recall.*
- *Juliet Seifert served on the planning committee for the World Self-Medication Industry 14th General Assembly and 5th Asia Pacific Regional Conference. Juliet Seifert and Monica Johnstone served as the Secretariat to the associated Regional Regulators' Forum in November 2002. This important meeting resulted in The Tokyo Declaration which followed closely on the achievements of The Sydney Declaration of 2000.*
- *Juliet Seifert was chair of the Therapeutic Goods Advertising Code Council (TGACC), on a rotating basis, and ASMI played a key advocacy role for industry in the continuing development of advertising codes.*
- *ASMI has a seat as an industry representative on the Interim Advertising Council (IAC), which has been set up to design the system of trans-Tasman advertising controls including advertising clearance, complaints, appeals and administration mechanisms for the proposed trans-Tasman regulatory agency.*
- *Advertising Services Manager, John Moursounidis is an observer on TGACC and alternate on the Interim Advertising Council (IAC).*
- *Advertising Services is continually in contact with TGA Advertising Unit to keep ahead of pending changes to legislation, to seek clarification and explanation of changes and to actively lobby and provide an ASMI position on advertising policy/legislative issues.*

ASMI Excellence Award

Anthea Steans, Boots Healthcare, may have been the only person at the ASMI Conference Banquet surprised by her selection as the inaugural winner of the ASMI Excellence Award.

The Committee of Management and Secretariat created the criteria for this new award. ASMI looks for efforts on behalf of ASMI that lead to the delivery of outcomes for the whole-of-industry. The agreed criteria for the award are as follows:

- *Membership in ASMI*
- *Special service to ASMI and/or the whole of industry*
- *Service exceeding satisfactory participation on a subcommittee under normal circumstances*
- *Agreement of the ASMI Secretariat and the Committee of Management (and Subcommittee Chair where appropriate)*
- *Both productive long service and promising work by those new to the ASMI committee structure may be recognised.*

The ASMI Excellence trophy is a reminder of our commitment to a unified voice. The plaque on this beautiful didgeridoo reads "ASMI Excellence Award in recognition of service to the Australian Self-Medication Industry".

Anthea is to be commended for ten years of continuous service on two ASMI subcommittees.

Cited as a tremendous industry statesperson, and earning respect from TGA and other industry stakeholders which increased the Association's lobbying capacity, Anthea has always constructively pushed and challenged the TGA to justify its position and to examine its boundaries. Anthea was instrumental in achieving the scheduling reforms associated with the trans-Tasman harmonisation process.

Anthea made a vital contribution to enabling our products to be assessed by MEC (the Medicines Evaluation Committee) rather than ADEC—in other words, gaining for Industry a process suited to our sector rather than one designed for the prescription industry.

Anthea has guided industry strategy in the regulatory arena. There is no doubt that many of the recommendations from the Galbally Review were derived from ASMI's submissions to the National Review of Drugs Poisons and Controlled Substances Legislation and that she was integral in setting the ASMI agenda for this review. Anthea served on both industry and government committees and has supported the education and development of professionals within the industry.

Anthea has been the President of ARCS. As nominated by the Association (then PMAA), she was given a Ministerial Appointment to the Therapeutic Goods Committee (TGC). She has been working in clinical research, regulatory affairs and scientific affairs for Boots for 15 years, and now serves as Director of Scientific Affairs.

In the Balance

Nothing can be more absurd than the practice that prevails in our country of men and women not following the same pursuits with all their strengths and with one mind, for thus, the state instead of being whole is reduced to half.
Plato, The Laws

A man may be a tough, concentrated, successful money-maker and never contribute to his country anything more than a horrible example. A manager may be tough and practical, squeezing out, while the going is good, the last ounce of profit and dividend, and may leave behind him an exhausted industry and a legacy of industrial hatred. A tough manager may never look outside his own factory walls or be conscious of his partnership in a wider world.
Sir Robert Menzies (1894–1978)

It was noted in a speech by John F Kennedy in 1959, and since and perhaps before, that when written in Chinese, the word for crisis is composed of two characters. One represents danger and the other opportunity. This dual nature has led many to wax philosophical in the aftermath, sifting for lessons and silver linings the way bushfire victims sift through ashes for spared valuables. After the heat has dissipated, it is only natural to try to rebuild in such a way that our structures are better, safer, smarter than before.

This phoenix-like opportunity for regrowth has traditionally been seen as a kind of purification. It can become a rededication to the best of what remains or it can signal the emergence of a new order.

This emergence is well described by Thomas Kuhn's seminal work The Structure of Scientific Revolutions. In it he argues that the awareness and acknowledgment that a crisis exists loosens theoretical stereotypes and provides the incremental data necessary for a fundamental paradigm shift[1]. The shift is occasioned by the discovery of an anomaly, by a crisis which calls the unexamined into question—but it does not instantly convert everyone to a new unified position. That takes additional time, practical demonstration and dedicated action.

Though crises seem to be the defining moments, the watershed events and the turning points, they may actually serve to unseat tired models making way for new ones that were already emerging well in advance of any crisis. As Aldous Huxley (1894–1963) put it, "The amelioration of the world cannot be achieved by sacrifices in moments of crisis; it depends on the efforts made and constantly repeated during the humdrum, uninspiring periods, which separate one crisis from another, and of which normal lives mainly consist."

As we sift through the ashes of the Pan recall and learn its lessons, we must cast our minds back much further than the 28th of April 2003. We must remember that in the humdrum period after the Tylenol recall in the USA, now more than two decades ago, the Association put in place self-regulatory tamper evident packaging guidelines and audited our membership until another crisis convinced the last of the sceptical that our guidelines should be the basis of a whole-of-industry approach to consumer protection. Similarly, the Association created Crisis Management Guidelines and kept them updated year after year until they too became an industry standard.

As a case in point, earlier this year, ASMI became involved in work on GMP standards with the Therapeutic Goods Administration (TGA). In this case, prescience had less to do with this pro-activity than adherence to principles. It is said that "One of the tests of leadership is the ability to recognize a problem before it becomes an emergency."[2] While mere commercial short-term advantage might seem to be served by avoiding any clearly defined GMP standards, the long- term interest of the industry is surely bonded to consumer protection. The important balance is struck through direct industry participation in the process by which GMP is clarified and codified. Consumer confidence, advantageous export opportunities, and our sector's role in the Australian healthcare system are in the balance.

So whether we decided from the embers of the Pan recall that it was an expurgation waiting to happen, a business catastrophe for the unprepared, or a firm reminder to keep up the discipline as consumers have a right to expect (or all of these in different measures), the largest recall in Australia's history was a test, the results of which are just now coming in.

[1] *Kuhn's work is given a very helpful summary by Professor Frank Pajares of Emory University on http://www.emory.edu/EDUCATION/mfp/Kuhn.html.*
[2] *Attributed to Albert Glasgow.*

Exactly what was being tested is subject to much discussion especially in the period immediately following the initial recall. Early media coverage would have suggested that TGA was a worthy subject of scrutiny for reasons as varied as having moved too fast or too slow and having done too little or not enough. Various health stakeholders and even a Premier offered up the efficacy of all complementary medicines for sceptical examination. Prominent pioneers of complementary medicines argued that the focus of attention should be the OTC product which was first recalled. In retrospect, it is understandable that there was more heat than light in these allegations.

It has been said that a crisis unmasks everyone.

ASMI's response should also be the subject of review. In a nutshell, the Association did what it does best. ASMI contacted every Member as well as our key strategic partners at the TGA, in Government and in our worldwide network. The Secretariat began the process of providing reliable information for consumers, journalists and our other health partners. This took the expected forms of media interviews and media releases, but also the positive, proactive step of providing on the ASMI website within 48 hours the enormous list of ASMI member products unaffected by the recall. ASMI provided consultation to those companies which did have recalled products. And ASMI provided regular updates to the membership as well as in-depth briefings to parliamentarians and leading consumer advocates.

At the same time, the ASMI Secretariat kept our original commitments to provide Industry's perspective at scheduled meetings, produced our newsletters on the appointed days, recruited new members to the Association, progressed the projects in the Strategic Plan and generally went about the ordinary tasks of which Huxley would say ordinary Association lives consist.

These ordinary activities, planned in accordance with operating principles of transparency, accountability, timeliness, efficiency, and financial stability, undergird the consultative approach of the Association. They are apparent in the relationships between the Committee of Management and the Secretariat and with those outside of the Association. They are ASMI's modus operandi for the simple reasons that they work, they keep the focus on the long-term viability of the Industry and they support the consumer.

An Association may support companies, but it is not itself a company in the usual sense. ASMI delivers a message beyond competitive, commercial self-interest by balancing commercial realities with consumer advantage. What Industry leadership really means—adding value to product, processes and relationships—may not be flashy in times of crisis. What counts are preparation, consultation, and unrelenting attention to those principles which make partnership possible.

There is an Arab proverb that says, "He who dines alone, chokes alone." This sentiment speaks to the danger aspect of a crisis. While this cannot be underestimated, nor should it be the sole focus. To do so is to miss the opportunities taking place simultaneously with a crisis or even those which are a result of it.

Tempered by the fires of crises long past and more recent, with considerable collective memory and a long range view, the Association can find opportunities in existing projects such as the on-going work on trans-Tasman regulatory and advertising arrangements and the Association's efforts to obtain a measure of data and market exclusivity. In fact, the outcomes will be strengthened by the lessons of this and other crises. Processes will be better, the need for certain safeguards more clearly understood and the importance of our interconnections increasingly recognised. While this cannot guarantee the end of crises, it will ensure that crises are not the end of Industry.

"It has been said that a crisis unmasks everyone."

Outcomes of Complaints lodged under ASMI Code of Practice 2002–2003

Appeal Lodged regarding a complaint determined in 2001–2002:
Ego Pharmaceuticals against the determination.

Outcome: *In respect of the Panel finding regarding the use of AUST R number breached clause 5.1.3 of the ASMI Code of Practice, the Arbiter found that the Panel was incorrect. The Arbiter agreed with other aspects of the Panels determination regarding whether the advertisement made therapeutic claims.*

Lodged Complaint: *Pharmacia Consumer Healthcare*

Against: *GlaxoSmithKline Consumer Healthcare*

Complaint: *Advertisement for Nicabate CQ Clear directed to healthcare professionals.*

Alleged Breaches:
1. *The claim "24h-hour control" is misleading and breaches clause 5.2 of ASMI Code of Practice.*
2. *The advertisement is a repeat breach of clause 5.1.3 and 5.2 of ASMI Code of Practice as the reference does not substantiate the claim and that a similar claim is made within 24 months of a previous breach.*
3. *The context of the advertisement is entirely comparative and this would infer that Nicorette patch has a worse safety profile than Nicabate CQ patch.*
4. *The reference cited does not support the claim "…further increase their chances of quitting…".*

Outcomes:
1. *Complaint dismissed as the statement is unlikely to mislead reasonable healthcare professionals.*
2. *Complaint upheld as there is no adequate scientific evidence to support it and that it is a repeat breach as defined in the ASMI Code.*
3. *Complaint dismissed, as reasonable healthcare professionals would not understand it to be a comparative claim.*
4. *Complaint upheld, as the advertisement is misleading in suggesting the reference supports the claim in breach of clause 5.1.3 of ASMI Code.*

Appeal Lodged: *GlaxoSmithKline against the decision of the Panel regarding claim 2. The arbiter found the Panel's decision justified and agreed with the sanctions imposed.*

Lodged complaint: *Pharmacia Consumer Healthcare*

Against: *GlaxoSmithKline Consumer Healthcare*

Complaint: *Advertisement and promotional material for Nicabate CQ Lozenges directed to healthcare professionals.*

Alleged Breaches:
1.1 *The statement "Which form of NRT should you recommend to your customers?" is a misleading comparison.*
1.2 *Segmentation of quitting population into "Shield" and "Sword" quitters is not supported by scientific literature.*
1.3 *Lack of substantiation for the statements regarding "Shield" and "Sword" quitters and that the statements are likely to mislead.*
2. *Lack of substantiation for the claim regarding the important indicator of time to first cigarette.*
3. *Clauses 5.1.3 and 5.1.3 of ASMI Code of Practice—misleading claim with the inference that chances of quitting are tripled.*
4. *The claim "Delivers more nicotine than gum" is misleading and unbalanced.*
5. *The claim "Lozenge use is also simple with no special techniques involved-…" is misleading.*
6. *Clause 5.5.1 of ASMI Code of Practice—minimum requirements of advertising of Pharmacist Only Medicines S3 to healthcare professionals.*
7. *The claim "highly dependent smokers likely to smoke within 30 minutes of waking should begin with 4mg lozenge, which is clinically proven to triple these smokers' chances of quitting" is misleading and unsubstantiated.*

Outcomes:
1.1 *Complaint dismissed as frivolous and vexatious.*
1.2 *Complaint dismissed as frivolous and vexatious.*
1.3 *Complaint dismissed.*
2. *Complaint dismissed as frivolous and vexatious.*
3. *One component of the complaint was upheld and three aspects were dismissed.*
4. *Complaint dismissed.*
5. *Complaint dismissed as vexatious.*
6. *Complaint upheld.*
7. *Complaint dismissed.*

Appeal Lodged: *Pharmacia against the decision of the Panel regarding claims 3 and 4. The arbiter found the Panel's decision justified in relation to claim 3 and upheld the appeal in regard to claim 4.*

Lodged complaint: *Roche Consumer Healthcare*

Against: *GlaxoSmithKline Consumer Healthcare*

Complaint: *Promotional items for Panadol directed to consumers*

Alleged Breaches: *Shelf tickets "Special" and "Temporary Price Cut" breach Clause 6.2 of ASMI Code of Practice.*

Outcomes: *The Panel concluded that the promotion did not fail the test in paragraph 1 of section 6.2 of the Code and that there was no breach.*

Lodged complaint: *Boots Healthcare*

Against: *GlaxoSmithKline Consumer Healthcare*

Complaint: *Advertisement and training materials for Panadol directed to healthcare professionals.*

Alleged Breaches:

1. *Clauses 5.1.3 and 5.2 of ASMI Code of Practice – false and misleading statements; "New evidence is emerging which shows that there may be important cardiovascular risks associated with the use of some non-steroidal anti-inflammatory drugs" and "A recent study has demonstrated that OTC doses of ibuprofen can antagonise the antiplatelet action of aspirin, limiting its cardioprotective effect".*
2. *Clause 5.1.3 of ASMI Code of Practice – claims various aspects of the training manual are misleading and unbalanced.*
3. *Clauses 5.1.3 and 5.2 of ASMI Code of Practice – regarding various statements in an advertisement titled "Panadol–a pain reliever you can stomach" and in training material on gastrointestinal risks associated with analgesic use.*

Outcomes:

1. *No breach found as the claims are not misleading and unbalanced and the references adequately support the advertised claims.*
2. *One breach was found from the seven aspects of this complaint.*
3. *One breach was found from the three aspects of this complaint.*

Lodged complaint: *Pfizer Consumer Healthcare*

Against: *Aventis Pharma*

Complaint: *Advertisements and promotional material for Telfast directed to healthcare professionals and consumers.*

Alleged Breaches:
Misleading claims that Telfast is the only anti-histamine available in a "higher", "stronger" or "extra strength" dose.

Outcomes:
No breach was found as Zyrtec is not available in a 20mg dose and the difference in colour and size of representation for Telfast and Zyrtec did not convey clinical difference.

Appeal Lodged:
Pfizer appealed against the decision of the Panel regarding the statement that Telfast is the only antihistamine available in a "higher", "stronger" or "extra strength" dose. The arbiter found the Panel's decision justified.

Lodged complaint: *Consumer*

Against: *Pfizer Consumer Healthcare*

Complaint: *Promotional item for Ponstan directed to consumers*

Alleged Breaches: *Clause 6.2 of the ASMI Code of Practice is breached by offering a free gift inducing purchase for a product that may not be needed.*

Outcomes: *The Panel, on balance, was not satisfied that the promotion is likely to induce purchase in contravention of section 6.2 and thus dismissed the case.*

Lodged complaint: *Pfizer Consumer Healthcare*

Against: *Aventis Pharma*

Complaint: *Advertisement for Telfast directed to healthcare professionals.*

Alleged Breaches: *Clauses 5.1.3 and 5.2 of the ASMI Code – inaccurate and misleading statements regarding the benefits of Telfast 180mg dose over the 120mg dose and other hayfever products.*

Outcomes: *The Panel upheld the complaint, as there was no statistically significant clinical data to support the claim that 180 mg Telfast is more effective than 120 mg Telfast, Claratyne and other hayfever products on the market.*

Lodged complaint: *Aventis Pharma*

Against: *Schering-Plough*

Complaint: *Advertisements directed to healthcare professionals and consumers*

Alleged Breaches:

1. *Clauses 4.1, 5.1.3 and 5.2 of ASMI Code – misrepresentation of Telfast indications by use of the statements "some antihistamines like Telfast, are not indicated for perennial allergic rhinitis and are therefore not approved for use in persistent allergies", "Claratyne is also indicated for more allergy conditions than any other non-sedating antihistamine" and "Claratyne is the only non-sedating antihistamine indicated for the relief of seasonal allergic rhinitis. Perennial allergic rhinitis and chronic urticaria. Telfast is not indicated for perennial allergic rhinitis therefore is not approved for use in persistent allergies".*
2. *Clauses 4.1, 5.1.3 and 5.2 of ASMI Code and clauses 4.1.1(b), 4.1.2(c), 4.1.2(d) and 4.3 of TGAC – various*

Outcomes of Promotional Monitoring Panel Meetings 2002/2003

This summarises the outcomes of the ASMI Promotional Monitoring Panel meetings for the year ending 30 June 2003. 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 three 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:

- *smoking cessation,*
- *complementary healthcare products,*
- *antiseptics and disinfectants,*
- *pain relief,*
- *weight loss and*
- *miscellaneous (ear drops, eye drops, oral care).*

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 157 items were reviewed, of which 57 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

statements concerning the interaction of fruit juices and Telfast and Claratyne.
3. *Clauses 4.1, 5.1.3 and 5.2 of ASMI Code – "Claratyne has no known food interactions" is inaccurate.*

Outcomes:
1. *The Panel found that the statements were misleading and breached clauses 5.1.3 and 5.2.*
2. *The Panel found that the statements were misleading and breached clauses 5.1.3 and 5.2 of the ASMI Code of Practice and clauses 4.1.1(b), 4.1.2(c), 4.1.2(d) and 4.3 of TGAC and hence clause 4.3 of ASMI Code.*
3. *The Panel found the statement to be unbalanced and misleading.*

Appeal Lodged:
Schering-Plough appealed regarding some of the statements in the retraction letter required by the Panel. At the hearing of the appeal, the parties agreed upon the form of the statements that were the subject of the appeal. The Arbiter agreed that the form of the revised statements was consistent with the determination of the Panel.

Lodged complaint: *GlaxoSmithKline Consumer Healthcare*

Against: *Pharmacia Consumer Healthcare*

Complaint: *Advertisement for Nicorette patches directed to healthcare professionals.*

Alleged Breaches:
1. *Clauses 5.1.3 and 5.2 of ASMI Code of Practice – misleading representation regarding the importance of sleep disturbances whilst on nicotine replacement therapy.*
2. *Various misleading statements regarding relapse and nicotine delivery claims.*

Outcomes:
1. *No breach found as Pharmacia has not misled by omission nor does the advertisement imply Nicorette 16 hour patches are safer then 24-hour patches.*
2. *One minor breach of clause 5.1.3 was found regarding the use of study data from heavy smokers in support of a claim in relation to Australian smokers.*

Lodged complaint: *Aventis Pharma*

Against: *Pfizer Consumer Healthcare*

Complaint: *Advertisements and promotional material for Zyrtec directed to consumers and healthcare professionals.*

Alleged Breaches:
1. *Clauses 5.1.3 and 5.1.4 of ASMI Code of Practice and 4.1.2(a) of TGAC regarding various statements relating to onset of activity.*
2. *The statement "It delivered twice as many satisfied patients" is a hanging comparison which is misleading by omitting the reference to Claratyne.*
3. *Clauses 5.1.3 and 5.1.4 of ASMI Code of Practice – the statement "Its antihistaminic activity has also been shown to be longer lasting and more consistent than the highest strength of Telfast" does not reflect the overall body of evidence.*
4. *Clauses 5.4 of ASMI Code of Practice and 4.1.2 and 4.3 of TGAC regarding the comparative table in the Zyrtec consumer leaflet.*

Outcomes:
1. *The Panel found that the statements were misleading and breached clauses 5.1.3 and 5.1.4 of ASMI Code of Practice.*
2. *This aspect of the complaint was dismissed.*
3. *The Panel found this claim to breach 5.1.4 of ASMI Code of Practice.*
4. *This aspect of the complaint was dismissed.*

and so it should not be concluded that the overall level of non-compliance is high when, if fact, almost all sponsors had fully compliant promotional material.

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

- *Mandatory statements either absent or not prominently displayed, in breach of Clause 6.2 ("Always read the label"; "Use only as directed"; "If symptoms persist consult your healthcare professional").*
- *Absent analgesic warning statements ("Incorrect use could be harmful") in breach of Clause 7.1.2.*
- *Implication that analgesic use is safe in breach of Clause 7.1.3.*
- *Implication of healthcare professional endorsement in breach of Clause 4.4.1.*

Compliance with the ASMI Code of Practice was also good. Non-compliance issues included the following:

- *Lack of compliance with TGAC, in breach of Clause 4.3.1 mainly related to missing mandatory statements.*
- *S3 warnings not sufficiently direct in stating that a pharmacist's advice is required in breach of Clause 4.3.1.*
- *Not obtaining pre-approval when material was directed to consumers in addition to healthcare professionals in breach of Clause 5.4.1.*

The Closing Interface— the Future of Complementary Medicine

Complementary medicines are going to face the challenge of a growing international market for non-supplementary 'functional food' products making health claims.

In Australia many of these claims are currently the domain of Listable complementary medicines. Both Europe and the United States are finalising regulatory frameworks that will allow foods to make health claims over and above those involving nutrition content. Their frameworks will employ pre-market evaluation and a "levels of evidence" system conceptually similar to that which we currently use in Australia for complementary medicines. Food Safety Australia New Zealand (FSANZ) is also working towards the implementation of such a system, bringing the interface between foods and medicine much closer and begging the question, "how much room exists between the two for a true third category straddling this interface?"

Those watching overseas trends have noted the declining consumer confidence in US dietary supplements over seemingly endemic quality issues. It should therefore come as no surprise that there is now a proposal in the US to introduce specific Good Manufacturing Practice (GMP) standards for dietary supplements that are much closer to pharmaceutical GMP than food standard GMP.

Herbal medicines and herb/vitamin/mineral combination products across the European Union member states are also undergoing a status change. These products will be regarded as medicines rather than foods. The rest of the world is now playing "catch up" to regulatory principles for safety, quality and efficacy with which Australia has had the benefit of working for over a decade.

Are we then truly over-regulated or were we only ahead of our time?

The closing interface would indicate a need for complementary medicines to differentiate themselves from the future food market based on "health claims". That differentiation can deliver a positive growth area for complementary medicines if they are manufactured to the highest quality standards to allow their use in the holistic health management of serious and chronic conditions as well as in their established role in preventative medicine.

The challenge for this industry, and one ASMI is actively addressing, is obtaining provisions for data protection and market exclusivity for original research and innovation that give our local industry incentives for pushing the boundaries of complementary medicine in growth area such as arthritis, cardiovascular health and others designated as National Health Priorities.

Executive Director's Message

Recently I took a moment to look at the mission statements and websites of many of ASMI's member companies. Though widely varied, certain concepts recurred, in particular the desire to demonstrate leadership and make a lifelong commitment to the health of consumers. This seems to me a good trend.

I think it was Nicholas Johnson, a former US Federal Communications Commissioner and now law lecturer, who said that "It used to be that people needed products to survive. Now products need people to survive." This is quite true of our Industry. It took some time to come to the position where we recognised that while we fill healthcare needs, our focus must remain on the consumer. Our Industry's health depends on the consumer perhaps even more than their health depends on us.

As ASMI reviews its strategic plan, I ask myself the question, what projects can we undertake that will best help industry to make the most direct, most responsible connection with the consumer—both by means of improving access to product engaging in a quality-use-of-medicines approach as well as exercising our role as a policy influencer. This has led us to pioneer labelling improvements and CMI and to self-regulate in areas such as advertising; it has also led us to champion the inclusion of the consumer voice on important government and industry committees and in the design of Industry conferences, both locally and regionally and even internationally.

Consumer focus is also at the heart of how we define the organisation that is ASMI. We address ourselves to the full spectrum of products that are available without a prescription to the consumer. For us, there is no great dividing line between a switched OTC with a former life as a prescription treatment and an herbal preparation with its roots in traditional use. Both are consumer medicines. Increasingly, you may even find these ingredients combined in a single product or produced separately by the same company.

The ASMI team also demonstrates this breadth and blend. While we have specialists in complementary medicine, OTCs, technical aspects of manufacture, pharmacy, communication and other areas, we are committed to a view that is balanced. One hears about alternative medicine, but the real alternative is consumer choice—not the philosophy of the manufacturer.

In the coming year, ASMI will dedicate considerable resource to projects that improve regulatory and advertising systems in ways that help member companies meet their objectives and those we have as a united Industry to be leaders and create real consumer advantage. These projects include data/marketing exclusivity and trans-Tasman regulatory and advertising arrangements.

Data/market exclusivity would creative incentive for research in areas where it has been sorely lacking, particularly in complementary medicines but also in new indications for all non-prescription medicines. Better evidence and the best fit between claim and efficacy has always been in the consumer interest.

The new arrangements for Australia and New Zealand also deserve our considerable attention. We have a watershed opportunity that does not occur very often. In one move, our market will grow and we have a chance to get the regulatory and advertising arrangements fundamentally right, taking the best of both systems as well as the best of world best practice.

Along the way, we are building and strengthening important bridges—for instance, the ASMI Committee of Management has already held a meeting with the Executive Committee of our New Zealand counterpart, NZSMI. Consumers stand to benefit from a more modern, streamlined and effective system that is the same in its essentials for both countries.

I look forward to an exciting year in which we work with our partners to advance these and other projects. We have a great deal to assimilate since the recent challenges of the Pan recall, but we have the team to do that productively. The Association is well placed with an ever increasing membership committed to the principles that will ensure our viability as a health partner in the long term.

Juliet Seifert, Executive Director

Industry Survey

The ASMI Membership Services Subcommittee conducted the inaugural ASMI Industry Survey in order to provide information on the sales and marketing policies, structure and practices of companies that operate in the consumer healthcare products market. The survey will be conducted annually and the results will only be available to those companies that submit their own data for inclusion. The survey provides valuable strategic and practical information for use in marketing and sales plans.

AUSTRALIAN SELF-MEDICATION INDUSTRY

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