AUSTRALIAN SELF-MEDICATION INDUSTRY

BETTER HEALTH THROUGH RESPONSIBLE SELF-MEDICATION

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BETTER HEALTH THROUGH RESPONSIBLE SELF-MEDICATION

ANNUAL REPORT 2001-2002

contents

MISSION VISION

MISSION:

Better health through responsible self-medication

VISION:

ASMI - the voice of the non-prescription consumer healthcare products industry, contributing to the improvement of public health standards, locally, regionally and internationally, by driving a credible and expanding self-medication market andgenerating cost-effective health solutions.

Vision Statement for the Australian Self-Medication Industry

The Australian Self-Medication Industry strives to assist its members to provide cost-effective, safe, credible, efficacious products both to Australians and for export in order to contribute to the improvement of public health.

To this end, the core purpose of the Australian Self-Medication Industry is to represent its members to governments and other stakeholders in order to ensure that self-medication products are held as credible and integral in the overall Australian health system. ASMI seeks:

- opportunities to expand the self-medication market through improving access and streamlining regulatory processes;
- to provide incentives for companies to invest in further research and development of self-medication products;
- to ensure that by taking a responsible approach to the marketing of self-medication products its members are not disadvantaged in the market-place;
- to ensure its members are kept informed in a timely way of developments that will have an impact on their businesses;
- to improve consumer knowledge and recognition of self-medication products;
- to maintain its status as the peak body representing the non-prescription medicines sector of the industry; and
- to provide benefits to its members that member companies could not achieve on their own.

The success of ASMI will be measured by its ability to influence governments and other stakeholders to deliver an improved operating environment for its members that in turn delivers improvements to public health and by the widespread recognition by government and other stakeholders of the role of ASMI in achieving these outcomes.

> *"The success of **ASMI** will be measured by its ability to influence governments and other stakeholders.."*

Members & Honorary

Life Members (2001-2002)

Ordinary Members

3M Health Care Pty Ltd
Allergan Australia Pty Ltd
AstraZeneca
Aventis Pharma
Bayer Australia Ltd
Biovital Pty Ltd
Boehringer Ingelheim Pty Ltd
Boots Healthcare Australia Pty Ltd
C B Fleet Co (Australia) Pty Ltd
Carter Products Australia
Combe International Ltd
Ego Pharmaceuticals Pty Ltd
Mayne Health Consumer Products
Galderma Australia
GlaxoSmithKline Consumer Healthcare
H W Woods Pty Ltd
Janssen-Cilag Pty Ltd
Mentholatum Australasia Pty Ltd
Merck Sharp & Dohme (Aust) Pty Ltd
Novartis Consumer Health Australasia Pty Ltd
Pfizer Pty Ltd
Pharmacia Australia Pty Ltd
R P Scherer Holdings Pty Ltd
Reckitt Benckiser
Roche Products Pty Ltd
Smith & Nephew Pty Ltd
Stiefel Laboratories Pty Ltd
Taisho Australia Pty Ltd
Whitehall Laboratories Pty Ltd

Associate Members

Bates Healthworld Pty Ltd
Cellegy Australia 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
Grey Healthcare Group
Hahn Healthcare Recruitment Pty Ltd
Hammond & Thackeray Pty Ltd
IMS Australia Pty Ltd
Lipa Pharmaceuticals
McCann Healthcare
Medi Kwik Pty Ltd
Nature's Herbals
Pharmaceutical Professionals
PharmAction Holdings Pty Ltd
Reader's Digest Australia Pty Ltd
Regulatory Concepts Pty Ltd
Robert Forbes & Associates
Singleton Ogilvy & Mather
Sudler & Hennessey
Sue Akeroyd & Associates
Technical Consultancy Services Pty Ltd
Zero.com

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

Committee of Management

(2001-2002)

From left to right, back row:
• Trevor Juniper, Pharmacia Australia Pty Ltd • Geoff Bolland, R P Scherer Pty Ltd • Ralf Dahmen, Boehringer Ingelheim Pty Ltd • David Armstrong, Reckitt Benckiser • John Gurney, Mentholatum Australasia Pty Ltd • Mark Bowden, Pfizer Pty Ltd

From left to right, front row:
• Steven Mann, Mayne Health Consumer Products • Elizabeth Treble, Aventis Pharma • David Murphy, Combe International Ltd • Kevin Darke, GlaxoSmithKline Consumer Healthcare • Sue Williams, Boots Healthcare Australia Pty Ltd (not pictured)

ASMI Secretariat

(2001-2002)

From left to right, back row:
• Duncan Cannon, Office Assistant • Monica Johnstone, Member Services Manager • Jonathan Breach, Regulatory & Technical Manager • Lesley Speechley, Executive Assistant/ Office Manager (from Dec. 2001) • Chris Arblaster, Marketing & Development Director

Front row:
• Alexandra Macvean, Information Support Coordinator • Mary Emanuel, QUM Manager • Juliet Seifert, Executive Director • Sonia Goldner, Advertising Services Manager (from Dec. 2001) • Ruby Ragonese, Regulatory & Technical Manager

Not pictured:
• Tracey Shenton, Bookkeeper (until April 2002) • Georgina Woodbury, Bookkeeper (from April 2002) • Robyn Kirkness, Receptionist • Zephanie Jordan, Scientific Director (until May 2002) • Lucy Castro, Executive Assistant/ Office Manager (until Dec. 2001) • Montse Pena, Advertising Services Manager (until Dec. 2001)

Office Holders

President,
Kevin Darke

Vice-President/Treasurer,
David Murphy

Vice-President /Secretary,
Sue Williams

President-Elect,
Trevor Juniper

President's Message

It is my pleasure to report to you on the 2001/2002 year of your Industry Association.

At our annual conference last September, ASMI looked at how much the market environment can change in only a few years. Everyone involved was, of course, painfully aware that the global environment can change between 8:00 and 9:00 on a sunny New York morning.

In the aftermath of those events, it seems hackneyed to say that the only constant is change. What we learned in the last year was just how fast and how profound that change can be.

Such a momentous year reminds us of our interconnection, our need for allies, and the danger of allowing even the most seemingly intractable relationship problems to fester. Prudence and partnership are possibly more important than ever.

If asked to characterise this year, I would say it was a year in which we strengthened the Association. Part of our added vitality came in the form of new memberships.

We welcomed AstraZeneca, Lipa Pharmaceuticals, Clare Martin & Associates, Freehills, Robert Forbes & Associates and Zero.Com.

ASMI was also reinforced by building on our offerings in the marketing area, strengthening the ASMI "brand", restructuring our Secretariat to optimise relevant coverage, increasing the reach and depth of our publications and website, exercising our self-regulatory muscles to create a more level playing field in the area of promotions, charging our Marketing and Ethics Subcommittee with taking a hard look at our Code of Practice to ensure maximum competitiveness with non-members without compromising our principles, and demonstrating industry leadership in regulatory matters.

As the section of this report entitled Achievement Highlights goes into ASMI's "wins" in depth, I'll just touch on a few examples here:

- Created and filled a key new Secretariat position—Marketing & Development Director Chris Arblaster.

> *"Prudence and partnership are possibly more important than ever."*

- Restructured the Secretariat to meet member needs by optimising information flow and providing resources in keeping with the Strategic Plan.
- Provided strong advocacy for the adoption of a new harmonised Code of GMP, which increases our competitiveness in international trade. TGA entrusted ASMI with the whole-of-industry coordination of training seminars on this new Code.
- Established the Promotional Monitoring Panel, providing guidance on "below the line" promotional material.
- Raised the bar still higher for our publications and website—not with monetary outlays, but rather the initiative of the Secretariat staffers.
- Earned great coverage of our events and achievements in international publications such as OTC Bulletin and OTC Business News and in local trade publications.

In my final year as ASMI President, I'm happy to report that our efforts are focussed, appropriately resourced, and strategically strong. Fiscally sound and flexible, the Secretariat is well poised for current and future challenges. Achieving a level playing field in all areas of industry endeavour, including the thorny debate around housebrands, is certainly one of our major challenges and has been selected as the theme of our AGM and Conference 2002.

I will no doubt get an opportunity to repeat the following remarks elsewhere, but in closing, I'd like to thank the membership for allowing me to represent you for these last five years as President of ASMI and to thank Juliet and her team for their tremendous support and loyalty. We are indeed fortunate to have such a talented group representing our collective interests. I am confident that the membership will also throw its support behind our President-Elect, Trevor Juniper in September.

Kevin Darke, ASMI President

Achievement Highlights

(arranged by Strategic Objective)

Maximise Freedom of Access

- Pseudoephedrine Subcommittee formed. ASMI has taken the leadership role involving members and non-members in developing an Industry Code of Conduct for the sale, supply and promotion of pseudoephedrine-containing products.
- Final report from the National Review of Drugs, Poisons and Controlled Substances Legislation (Galbally) largely reflects ASMI position in key areas such as achieving national uniformity, medicines focus through splitting the NDPSC and refining scheduling processes.
- Final report on the Productivity Commission Review into Cost Recovery Arrangements largely reflects ASMI position that 100% cost recovery is excessive. Public activities should be government funded and industry charged on a fee for service basis.
- Achieved provision of evaluation reports from the Office of Complementary Medicines to sponsors for matters being considered by the Complementary Medicines Evaluation Committee (CMEC).
- ASMI pro-active in improving transparency within the mapping of CMEC processes and establishing approximate timeframes.
- Ruby Ragonese (ASMI) appointed as a member to the Therapeutic Goods Committee (TGC) Subcommittee on Manufacturing Principles. ASMI provided strong advocacy for the adoption of the internationally aligned Pharmaceutical Inspection Co-operation Scheme (PIC/S) Code of GMP as the Manufacturing Principle in Australia. ASMI is taking a leading role in education and facilitation of implementation during 2002 and 2003.
- ASMI led the whole-of-industry consultation process on the Therapeutic Goods Administration (TGA) approach to the minimisation of transmission of TSEs from low risk materials. Achieved reconsideration of approach in line with international status.
- ASMI asked to Chair subcommittee to examine options for incorporating Tamper Evident Packaging (TEP) Guidelines in legislation.
- Achieved review of warning statements required in advertising of analgesic products to ensure consistency with regulatory requirements.
- ASMI active in refuting proposal to introduce unique age-based directions for use on complementary medicines, thereby preventing inconsistency with OTC medicines.
- ASMI key in developing export policy and identifying opportunities for legislative change to facilitate exports of medicines from Australia.
- Major reformatting of ASMI Code of Practice. The Code was reformatted in order to make it easier to use, understand and locate the specific provisions for advertising/promoting of non-prescription consumer healthcare products. Explanatory notes have been inserted near the relevant sections.
- Active in preventing certain herbs from being banned by the National Drugs and Poisons Schedule Committee (NDPSC) because of perceived risk of contamination with aristolochic acid – ensuring consistency with TGA and FDA positions.
- After 4 years of deliberation by the Therapeutic Goods Committee, Therapeutic Goods Order (TGO) 69 – General requirements for labels for medicines, was finally published, and is to be phased in over a period of time to replace TGO 48. The new TGO offers many changes that are more straightforward and easier to apply.
- ASMI has actively supported the development of the Trans-Tasman Single Regulatory Agency – participating in working groups on advertising, export medicines and transition arrangements.
- Submissions made on behalf of our sector were numerous, including representations on these important subjects:
  - GMP Audit and Licensing Section Review
  - Introduction of dissolution standards for folic acid tablets
  - Child-resistant packaging TGO 20 & 33
  - BP 2002 – amendment 1
  - Ethanol Standard TGO 29
  - Health claims on foods
  - Medical Purpose foods
  - Caffeine containing products / foods
  - Compositional guidelines for complementary medicines
  - NDPSC pre and post meeting gazette notices
  - NZ Medicines Classification Committee agenda items
  - Family packs guideline in the Australian Guidelines for the Registration of Drugs, Vol. 2 (AGRD2)
- Framework for new Australian Guidelines for Complementary Medicines (AGCM) agreed upon with ASMI position on alignment with AGRD2/AGRM being adopted. Specific work undertaken on a document entitled "Quantifying by Input Guidelines" that will set clear criteria as to the acceptability of these methods for sponsors.
- Worked to achieve consistent communication about the withdrawal of phenylpropanolamine and counteract misinformation in the media.
- Supported increased acceptable daily dose for iron supplements consistent with other major markets.
- ASMI fully endorsed the replacement of the NDPSC Record of Reasons with extracted ratified minutes in order to reduce duplication within the NDPSC Secretariat and provide more information for the basis of scheduling decisions.
- Juliet Seifert (ASMI), in 2002, returned to the Chair of the Therapeutic Goods Advertising Code Council (TGACC).
- Proposals made to TGACC to permit reference to prevention of skin cancer in advertising of sunscreen products.

Sustain a Supportive Service Environment

- Cost effective major enhancements to the ASMI website including cosmetic and navigational improvements and significant new features (such as newsletter indices, privacy policy, Quality Use of Medicines (QUM) section, Calendar, Acronym portal, Honorary Life Members, Consultants list). A web-based trial of member surveying showed promise, and trial of web-based provision of meeting papers suggested future directions. Restructuring of the Regulatory & Technical section improved usability and access by members to a wider array of materials.
- Two-day conference in Canberra succeeded in raising issues key to industry's future. Features included a banquet and a marketing seminar held concurrently with the AGM. Despite September 11 and Ansett's troubles, our mid-September conference was well attended by members and stakeholders.
- ASMI Secretariat restructured in line with member needs and future directions:
  - Marketing & Development Director appointed – Chris Arblaster
  - QUM Manager position created – Mary Emanuel
  - Information Support Coordinator appointed – Alexandra Macvean

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- Redevelopment of the ASMI newsletters in line with member needs in areas such as commercial /marketing news.
- Development of a compliant ASMI Privacy Policy prior to the legal deadline and aid given to those members seeking a similar policy document.
- Cost-neutral upgrades to broadband Internet connection and of phone system including new services such as voice-mail and direct line numbers.
- Advertising Seminar held in Melbourne.
- Capacity turnout for free breakfast seminar on broadband and IT security.
- Coordination of evidence-based medicine training, "Where's the Evidence?" with on-going discounts negotiated for ASMI members.
- Successful ASMI Induction day held in May with 38 participants from 11 Member Companies.
- David Stephens was awarded Honorary Lifetime Membership of the Association.
- Dinner held for Melbourne members with the Secretariat, Committee of Management and guests from key stakeholder groups in healthcare.
- Members surveyed and feedback reflected in the Strategic Plan and topics for debate at the annual conference.

Achieve A Whole-of-Industry Approach to the Quality Use of Medicine

- ASMI is a member of the Australian Council for Safety and Quality in Healthcare committee. ASMI also participated in a Medication Safety Workshop, the outcome of which was to establish a Medication Safety Taskforce to develop and drive national initiatives for action to improve medication safety in Australia.
- ASMI participated in the National Prescribing Service (NPS) Planning Day, and is an integral member of the NPS/Industry Working Group that was established as an outcome of the Planning Day.
- Quality Use of Medicine (QUM) section added to the ASMI website including links to the National Medicines Policy and provision of all core Consumer Medicine Information (CMI) documents. QUM articles are now regularly included in One Voice and STAR newsletters.
- Juliet Seifert and Mary Emanuel represented ASMI on the Organising Committee for the National Medicines Symposium. This helped ensure that non-prescription medicine issues were included on the Symposium's program.
- Juliet Seifert, and subsequently Mary Emanuel, represented ASMI on the S2/S3 Pharmacy Professional Standards Implementation Project Advisory Committee. This project aimed to ensure that pharmacists provide consumers with appropriate information to ensure that S2 and S3 medicines are used appropriately and safely.
- Mary Emanuel represented the Association on the Consumer Medicine Information (CMI) Quality Assurance Reference Group (QARG). This group monitors the quality of the information being provided to consumers in CMIs.
- ASMI participated in the meeting on Future Directions of the Drug Utilisation Subcommittee (DUSC). The meeting considered how DUSC could most effectively contribute to the National Medicines Policy, and in particular QUM, in the next few years and whether it was possible at this stage to collect utilisation data on non-prescription medicines.
- The Secretariat provided comments to the National Medicines Policy Section of the Department of Health and Ageing on the proposal to establish a QUM Consumer Education Organisation.
- ASMI was represented during the Medicines Coding Council of Australia (MCCA) Medicines Database Project which is intended to improve data integrity throughout supply chain.
- Identified main national centres of Complementary Medicine research that provide resources and potential opportunities for member companies.
- ASMI participated in the major revision to the "Glossary of Permissible Representations" in the Therapeutic Goods Advertising Code.
- Juliet Seifert was part of a working group to develop a QUM Strategy and Operational Plan, specifying the role of all the partner stakeholders.

Broaden the Relevance and Influence of the Association

- ASMI welcomed new members to the Association: AstraZeneca, Lipa Pharmaceuticals, Clare Martin & Associates, Robert Forbes & Associates, Zero.Com, Freehills.
- Secretariat restructured with the appointment of a Marketing and Development Director to focus on increasing ASMI membership, meeting current members' needs and increasing non-fee income.
- ASMI continued its broad representation of industry on these bodies: Medicines Evaluation Committee, Australian Pharmaceutical Advisory Council (APAC), NSW Poisons Advisory Committee, Joint Herbal Task Force, Therapeutic Goods Committee (including its Labelling, GMP & CRP Subcommittees), Australian Standards Subcommittees for Sunscreens and CRCs, TGA's Strategic Information Management Environment (SIME), CMI Content Quality Assurance Reference Group (QARG), Complaints Resolution Panel for the TGAC, Therapeutic Goods Administration Industry Consultative Committee (TICC), Industry Government Crisis Management Committee, Therapeutic Goods Advertising Code Council, PHARM Industry Working Group, Australian Institute of Pharmacy Management Board, alternate industry position on National Drugs and Poisons Schedule Committee (NDPSC).
- In addition to Australian stakeholders and ASMI members, the 2001 ASMI Conference was attended by delegates from the Proprietary Association of Japan, the Non-Prescription Medicines Association (NZ), and Medsafe.
- The TGA Report on the Review of Labelling that has just been released reflects the performance-based principles that were initially proposed and consistently supported by ASMI.
- Executive Director, Juliet Seifert was invited to speak to industry conferences on self-regulation in New Zealand and Mexico as well as presenting to AIC in Sydney.
- ASMI contributed articles to publications at home and abroad as part of our commitment to harmonisation in general and the progression of members' interests.
- ASMI was the point of contact for trade and fact-finding delegations form China and Japan.
- Two projects initiated which will increase non-fee income—Corporate Reputation research in Pharmacy and Brand Relevance research.
- Participated in the review of strategic direction of the World Self-Medication Industry (WSMI), our world body. Helped WSMI develop its current operating plan.
- Juliet Seifert was involved in the planning of the 1st Latin American Regional Meeting of WSMI. She gave a joint presentation with Graham Peachey of TGA and participated in the regional Regulators' Forum attached to that meeting.
- Involved in the planning of the 14th General Assembly of WSMI and the 5th Asia Pacific Regional Conference, and its Regulators' Forum, to be held in Tokyo in November 2002.
- Seat on the WSMI Board and participation in WSMI Subcommittees.
- Active participation on the Medicines Labelling Group, an international initiative to achieve performance-based labelling.

In Sickness and in Health
– *the Trans-Tasman Joint Agency*

You are cordially invited to the wedding of Ozzie and Zeala to take place some time in 2004. While some have argued that they already fulfil the definition of a de facto couple, others point out that they do hang on to separate residences (next door to one another) and have yet to make the full commitment a marriage entails. Many relatives are hopeful and say that this will be best for their kids, while a few friends are not entirely convinced that this is a marriage made in heaven. True love? Marriage of convenience? Will it last?

It is hard to judge a marriage from its outset. Many questionable pairs have stood time's test while "perfect couples" have split before the wedding is fully paid off. The going wisdom is that those willing to work at the relationship have the best chance—and it is best to agree up front on the big issues like money, disciplining the children and the division of household duties, all while keeping a sense of humour.

The Proposal

When the Trans-Tasman Mutual Recognition Arrangement (TTMRA) was proposed in 1998, the reaction of both the prescription and non-prescription sectors in both countries was to request more time to consider the proposal. While the idea of harmonising arrangements between Australia and New Zealand was on the agenda of all concerned, it was also recognised that such things should not be entered into lightly in the area of health.

At the time, the differences seemed very great. New Zealand had direct-to-consumer advertising of prescription medicines, Australia did not. The two countries maintained two separate systems of advertising controls. The regimes for overseeing complementary medicines varied a great deal. Both sides, and this concern was vociferously argued by pharmacy in Australia, feared an approach that might smack of "least common denominator" thinking. Scheduling differences were significant and indicated different philosophies on certain ingredients. These differences dictated considerable labelling variances as well. The consumer health lobby in Australia was already of long standing and highly represented in many processes, while the consumer voice was just emerging in New Zealand. Both regulatory agencies had to consider issues of sovereignty and public health priorities—which are never identical in any two jurisdictions.

The TTMRA seemed to thrust together a rather unlikely pair. It could be said that the proposal came before courting had taken place.

Gone A' Courtin'

Though many differences remain, the parties have become more accustomed to the idea of some sort of eventual relationship.

Thousands of hours of work have taken place to address the majority of scheduling differences. Many meetings occurred under the auspices of a variety of chaperones including both industry bodies and the World Self-Medication Industry (WSMI), both regulatory bodies, the Therapeutic Goods Advertising Code Council and many others.

ASMI has participated as a vigilant godparent looking out for the interests of Australian Industry, responsible self-medication and the eventual union. In this process ASMI has been joined by industry's New Zealand godparent, the New Zealand Self-Medication Industry (NZSMI)

The Pre-Nuptial Agreement

A task force was set up to explore an optimal arrangement drawing on resources from the best of the Australian and New Zealand as well as the gifts of the rest of the world. This highly consultative process has included presentations to government, regional regulators, industry, health professionals and consumers. For many, the embodiment of the process has been the wedding planners, the jocular and candid partnership of Graham Peachey (TGA) and Stewart Jessamine (Medsafe) who together at the podium model the synergy the proposed joint regulatory agency is designed to attain.

The stakes are becoming more clear. Australia and New Zealand are engaged in an experiment with wide-ranging implications for both markets, the region and international harmonisation efforts more generally.

Currently, more separates Australian and New Zealand markets than just the Tasman Sea. But our differences are subject to discussion and potentially could change under the proposal now open for consultation.

The Trans-Tasman Therapeutic Goods Agency Project involves New Zealand and Australia giving consideration to establishing a Joint Agency to regulate therapeutic goods in both countries.

The goal of the project is to create a new agency that will replace the Therapeutic Goods Administration (TGA) in Australia and Medsafe in New Zealand. New legislation for both countries would set out what controls would apply to what therapeutic goods.

Industry Associations in both countries enjoy productive relationships with their respective regulatory agencies and are among the key consultation partners. The Australian Self-Medication Industry and NZSMI have been actively consulted since the initial stages of the proposal. As consultation partners, Industry has been in a position to urge the adoption of principles important to us, such as:

- stakeholder representation in determining strategic direction, including Industry representation on the Agency's Board;
- stakeholder consultation from the emergence of an issue through its resolution;
- clear separation of roles and powers between the Agency and the health policies of Australia and New Zealand, in practice as well as in law;
- a regulatory culture based on Council of Australian Governments (CoAG) and New Zealand Guidelines, with a minimum level of regulation necessary to fulfil legitimate public safety objectives; and
- a review of the current export licensing system, which industry sees as a barrier to exports.

In turn, Industry accepts that there will be some cost recovery from Industry so long as it is limited to those costs incurred in fulfilling the Agency's regulatory function—not its public interest obligations such as surveillance, ministerial briefings and international obligations.

Whenever sovereignty is at stake or a particular sector sees the possibility of losing some positive element in the current system, there is of course anxiety. Many ongoing concerns over the Joint Agency are now actively being addressed by appropriate health stakeholders including ASMI.

Drawing on the best features of the New Zealand, Australian and international approaches, the proposed Joint Agency is an enormous opportunity to take advantage

> *"If plans continue to stay on track, a* ***Joint Agency*** *could be a reality in 2004..."*

of our combined markets while paving the way for future harmonisation efforts beyond Australia and New Zealand. A treaty would set out broad enduring principles for the Agency. As the consultation paper describes, "The Agency would regulate therapeutic products using a risk-management approach, in which the degree of regulatory control would be proportional to the risk associated with the use of the product." ASMI has recommended exact definition of this risk-based approach, urging that the approach be based on

- risk-based assessment (rather than risk-adverse),
- transparent processes, and
- access to appeals processes which are independent of Ministers and Agencies.

ASMI has promoted an approach based on scientific principles that is protected from political whim. This includes a concern over "opt-out" provisions, which ASMI argues should be severely limited to only the most extraordinary of situations. We promote this approach with full knowledge that it necessitates addressing the challenges usually relegated to the "too hard" basket. Just as steel is strengthened in the forge, so too will our partnership be strengthened by finding common ground in relation to our differences.

While the consultation document provides the proposed outlines of the establishment and governance of the Agency, and the regulatory framework that would apply to medicines, including complementary healthcare products and medical devices, it comes to no final position in two important areas of policy—the scheduling process and advertising. Separate reviews are addressing these areas, with ASMI active in both.

Wedding Bells

If plans continue to stay on track, a Joint Agency could be a reality in 2004, marking unprecedented cooperation leading to real gains for Industry as these markets merge. Due to extensive consultation, when the question is posed, "Is there any reason that this pair should not be joined in matrimony?", the ensuing hush will be the sign that the significant objections have been addressed.

The tears at weddings are a sign of the high emotion surrounding human enterprises of this sort. Anxiety, temporary cold feet, fussiness about details, and pressing deadlines are all to be expected. Some nervousness about the in-laws is natural— at the reception, the Kiwis are unlikely to teach us how to do the Haka. But focussing on the advantages usually helps to give us the fortitude to endure the process of the wedding and even manage to enjoy it a bit.

It has become more common in recent years for marriage celebrants to entreat the assembled guests to support the vows made and to take some responsibility as a community for keeping the knot strongly tied. As health stakeholders, the success of a Joint Agency will not rest with the regulators alone.

Happily Ever After?

How will Ozzie and Zeala look to one another at their Tin Anniversary? If they continue to work at the relationship and their brood prospers, everyone will wonder what all the initial fuss was about.

Perhaps we will be able to forgive them a bit of middle-age spread if they are not quite as lean and lithe as they had at first intended to stay. Perhaps they will forgive Industry the anniversary gift of a gym membership should that happen.

In short, the process of working together will continue. We will enjoy the benefits of an extended family. If we achieve a happy family, we will be an example to our region and the world.

Executive Director's *Message*

A recent article detailed the rather simple solution to diarrhoea that could save the lives of up to one million children a year—hand washing. Despite health campaigns and various attempts to improve the dreadful statistics, washing rates remained low—until a partnership approach was taken:

> Bringing together all those concerned with encouraging hand-washing turned out to be a revelation. The private-sector soap companies and the government officials and health workers found it hard to understand each other at first. The ponderous bureaucracy of officialdom dismayed the soap companies. The bureaucrats misjudged the difficulty of getting rival companies to work together.
>
> —"How to save 1m children a year", The Economist 6 July 2002

Our revelation took place a few years ago, and we've been spreading the word, with our partners, ever since.

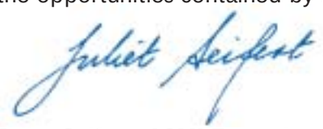
It is not easy to take a mindset used to seeking out conflict-of-interest to begin seeking confluence of interest, but it is a worthy project. We must loosen our hold on ideas such as "compromise" (where both parties are completely discrete and both a bit disappointed) and "win-win" (where both parties see the world in a strictly competitive paradigm and are suspicious that one of the "wins" is actually a disguised loss) in order to achieve outcomes that are truly the product of a joint agenda.

This is, admittedly, a very hard thing to imagine at the level of companies—short of a merger, separate balance sheets must be maintained. But at the level of government, industry associations, consumer groups and professional bodies some very productive blurring of traditional boundaries and sharing of resource can occur.

It is especially important that we partner effectively in matters of health. When the problems we tackle are characterised by communication issues—streamlining processes, lowering the incidents of adverse events, enhancing the performance of health information, creating better market environments, maximising access in a responsible fashion—we are unlikely to make lasting headway by employing tactics that are combative.

The old adage goes, "In business, it's not what you know but who you know." Perhaps the new adage should be that it is who you know and what you do with that knowledge. Alliance is not blind allegiance. ASMI has a strong sense of self, of mission and strategic objectives. Defining ourselves through these positive values allows us to represent an Industry with wide interests in a continuous spectrum from prevention through relief and even to cure, from mild and temporary symptoms to chronic and recurrent conditions, from recommended to self-selected medicines. We are an important health stakeholder, and this is increasingly acknowledged. This has been achieved by an active and astute membership working in a sound structure supported by a highly skilled and focussed Secretariat.

As we look forward, the sort of challenges we will face immediately and in the long term are well served by the structure we've built. At ASMI, we look forward to working with the membership and our partners to meet those challenges and make the most of the opportunities contained by them.



Juliet Seifert, ASMI Executive Director

Outcomes of **Complaints** lodged under *ASMI Code of Practice 2001/2002*

Lodged complaint: Roche Consumer Health

Against: GlaxoSmithKline Consumer Healthcare

Complaint: Advertisement for Panadol directed to pharmacists.

Alleged breaches:

1. Clauses 5.1.3 and 5.2 of ASMI Code of Practice – failed to compare like with like; misleading dose comparison for OTC NSAIDs, including a bleeding ulcer and describing as 'disastrous' the risk of serious GI events with prescription NSAIDS.
2. Clause 5.2 of ASMI Code of Practice – misleading claim that Panadol had no increased risk of GI complications; no comparators were mentioned and the comparison could be interpreted as taking no medication.

Outcomes:

1. No breach found, as pharmacists should appreciate the difference between prescription and OTC products.
2. No breach found, as the accuracy of the statement was not challenged, only that no comparator was included; the subheading preceding the claim made it clear that Panadol was being compared to placebo.

Lodged complaint: Boots Healthcare Australia Pty Ltd

Against: Roche Consumer Health

Complaint: Advertisements and mailer for Aleve directed to consumers and pharmacists.

Alleged breaches:

1. Clause 5.1.3 of ASMI Code of Practice – unapproved indication, 'for use in the pain relief of hangovers'.
2. Clause 5.1.3 of ASMI Code of Practice – misleading dosage graph with the dosage instructions on the pack related to duration of action for each product; for Nurofen the duration was implied to be 4 hours, whereas the reference showed it to be 6 hours.
3. Misleading claim that 8-12 hours of pain relief could be obtained with a single tablet of Aleve, whereas the approved dosage was two tablets.
4. Clause 5.2 of ASMI Code of Practice – misleading claim, unsupported by reference, that 64% of pain occasions where a pain reliever was taken can last longer than 4 hours.
5. Misleading claim that effective relief within 20 minutes implied total relief.

Outcomes:

1. No breach found – the qualification 'self-inflicted pain' preceding 'hangover' made it clear that Aleve could only be used for relieving the headache or head pain of hangover, not the other symptoms.
2. Complaint upheld – the graph was found to be misleading as it implied that product dosage intervals were consistent with their duration of action, without providing any supporting scientific evidence.
3. No breach found - 'dose' was not considered synonymous with 'tablet', and a study comparing a single dose of Aleve with a single dose of ibuprofen showed that one tablet of Aleve can provide an analgesic effect for 12 hours.
4. Complaint upheld – the reference did not support the claim; survey respondents were not asked about taking pain relievers before responding on the duration of pain.
5. No breach found – the ordinary reader would not understand 'effective' pain relief to mean 'total' pain relief.

Lodged Complaint: Aventis Pharma Pty Ltd

Against: Schering-Plough Pty Ltd

Complaint: Advertising and promotion of Claratyne and Clarinase directed to pharmacy assistants and pharmacists.

Alleged breaches: Clauses 6.1.5 and 6.2 of ASMI Code of Practice – both the 'mystery shopper' reward promotion to pharmacy assistants and the 'Shoot for the Stars' incentive promotion to pharmacists were conditional on product purchase.

Outcomes: Complaint upheld for mystery shopper promotion – flyer was vague about when it was appropriate to recommend the products, and lacked details about when it was inappropriate, e.g. in infections and sinusitis, together with contraindications and interactions. The advertisement in Post Script also lacked the above information. No breach was found for the Shoot for the Stars promotion as it was based on acquiring stock rather than on product sales.

Appeal Lodged: Against decision of Panel regarding "Shoot for the Stars" promotion. The Arbiter found that the "Shoot for the Stars" promotion breached 6.2 of the Code.

Lodging complaint: Ego Pharmaceuticals Pty Ltd

Against: Galderma Australia Pty Ltd

Complaint: Advertising for Cetaphil directed to consumers.

Alleged breaches:
A mini-poster, three leaflets (for Cetaphil, eczema and acne) and a window display advertised for therapeutic use non-prescription consumer healthcare products that are not on the ARTG and that the advertised claims are misleading and otherwise in breach of the Code.

Outcomes: Complaint upheld for mini-poster – the depiction of eczema-affected skin and suggestion to seek the pharmacist's advice represented the products as alleviating disease. It was considered that the poster offered a sample, breaching Clause 4.3.1 of ASMI Code, but did not include a healthcare professional recommendation as alleged. It was not accepted as alleged that merely mentioning a disease implied that the product was therapeutic, nor that the pharmacist was an agent of Galderma. Complaint upheld for Cetaphil leaflet - therapeutic use implied, and recommendation by a healthcare professional was included. Complaint for window display and eczema leaflet upheld - similar reasons as above. No breach was found for the acne leaflet – found to be educational material, unlikely to represent the products as being for therapeutic use.

Lodged Complaint: Aventis Pharma Pty Ltd

Against: Schering-Plough Pty Ltd

Complaint: Advertisement for Claratyne directed to healthcare professionals and consumers.

Alleged breaches: Clauses 5.1.3 and 5.2 of ASMI Code of Practice – the claim that Claratyne was a better antihistamine than Telfast was not consistent with the body of evidence and was not fully supported by the reference.

Outcomes: Complaint upheld – claim of superiority was not supported by all the available data; the reference and a second study showed that Claratyne and Telfast were equally effective in relieving the symptoms of seasonal allergic rhinitis over the period studied. The reference indicated that Claratyne had a faster onset of action, but the Telfast dose used in the trial was only half of the dose most commonly used in Australia.

Appeal lodged: Schering-Plough against the decision of the Panel. The Arbiter found the Panel's decision justified that the advertisement is misleading or likely to be misleading.

Lodged Complaint: Ego Pharmaceuticals Pty Ltd

Against: Galderma Australia Pty Ltd

Complaint: Advertisements for Cetaphil products directed to consumers.

Alleged breaches: The advertisement included misleading therapeutic indications for products not on the ARTG, and breached ASMI Code of Practice.

Outcomes: Complaint upheld – context of advertisement was considered likely to represent products as being for therapeutic use. It also included a healthcare professional recommendation, in breach of Clauses 4.4.1(c) of TGAC and 4.3.1 of ASMI Code of Practice. Given that the product was a cosmetic, this was considered misleading and unsubstantiated, and in breach of Clauses 5.1.3 and 5.1.4 of the ASMI Code of Practice. Additionally, serious skin diseases were mentioned in the advertisement, in breach of Clause 5.2 of the TGAC.

Lodged Complaint: Ego Pharmaceuticals Pty Ltd

Against: Galderma Australia Pty Ltd

Complaint: Advertisement for Cetaphil products directed to healthcare professionals.

Alleged breaches: The advertisement included misleading therapeutic indications for products not on the ARTG, with a pack shot showing an AUST R number, and breached the ASMI Code of Practice.

Outcomes: Complaint upheld for AUST R on pack shot – considered likely to impact on the perceptions of healthcare professionals. No breach was found for the other complaints – the statements did not amount to therapeutic claims.

Appeal Lodged: Ego against determination

Outcome: Pending

Lodged Complaint: Ego Pharmaceuticals Pty Ltd

Against: Galderma Australia Pty Ltd

Complaint: Advertisements for Cetaphil products directed to consumers.

Alleged breaches: The advertisements included misleading therapeutic indications for products not on the ARTG, and were similar or identical to material previously found to be in breach of ASMI Code of Practice.

Outcomes: No breach found – significant differences were found between these materials and the ones previously found to be in breach; the statements did not amount to claims for therapeutic use and the mere mention of a disease was not sufficient to imply a therapeutic claim.

Lodged Complaint: Ego Pharmaceuticals Pty Ltd

Against: Galderma Australia Pty Ltd

Complaint: Failure to comply with an earlier Panel determination concerning advertisements for Cetaphil products directed to consumers.

Alleged breaches: The advertisements included misleading therapeutic indications for products not on the ARTG, identical to materials previously found to be in breach of the ASMI Code of Practice.

Outcomes: The Panel did not find a failure to comply with the earlier determination – it was not demonstrated that the materials in breach had been distributed after the Panel's determination, and some of the materials were revised versions of the earlier ones.

Lodged Complaint: Pharmacia Consumer Healthcare

Against: GlaxoSmithKline Consumer Healthcare

Complaint: Advertisement and promotion for Nicabate CQ Clear directed to consumers.

Alleged breaches: Clause 6.1.5 of ASMI Code of Practice – the promotion "Win a car! Win Cash!" prize competition was conditional upon product purchase.

Outcomes: Complaint upheld – the competition was found to be in breach.

Outcomes of
Promotional Monitoring Panel
Meetings 2001/2002

This is the inaugural report of the Promotional Monitoring Panel. 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 Complaints 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. The following therapeutic categories were selected for review:

- smoking cessation
- cough/cold
- antimicrobial
- allergy
- sunscreen
- dermatological
- pain relief
- GI/urinary
- device

A total of 472 items were reviewed, of which 18.6% were found to contain one or more possible breaches of the ASMI Code of Practice or the TGAC.

Of the 18.6%, 27% of breaches involved lack of mandatory statements. Misleading comparisons accounted for 3.6% of breaches. Other breaches represented less than 2% each.

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

- Mandatory statements absent, in breach of Clause 6.2
- Mandatory statements not prominently displayed, in breach of Clause 6.2
- Misleading or inappropriate comparisons, in breach of Clauses 4.1.9(b), 4.1.2(c) and/or 4.2
- Researcher and sponsor not identified for study results, in breach of Clause 4.2
- Claims likely to lead to inappropriate use, in breach of Clause 4.1.2(f)
- Claims of product safety, in breach of Clause 4.1.2(i)
- Claim of 100% or almost 100% accuracy, in breach of Clause 4.1.2(g)

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
- Misleading comparisons, in breach of Clause 5.1.3
- Inappropriate comparisons, in breach of Clause 5.2
- Information unlikely to promote responsible medicine use, in breach of Clause 5.4
- Prize competition conditional upon product purchase, in breach of Clause 6.1.5
- S3 product information absent (contraindications, precautions, side-effects, company address), in breach of Clause 5.5.1
- S2 product information absent (active ingredients), in breach of Clause 5.4

> *"The Promotional Monitoring Panel met four times to review "below-the-line" advertising materials..."*